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# Obviousness Analysis: Role of the Judge Versus That of the Jury

Cesar Udave\*

## Introduction

The Constitution of the United States grants Congress the enumerated power “[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”<sup>1</sup> Over the years, Congress has enacted legislation that defines the constitutional bounds of patent law.<sup>2</sup> When ambiguities arise, the Supreme Court clarifies patent legislation and fills legislative gaps. For example, in *Graham v. John Deere Co.*,<sup>3</sup> the Supreme Court sought to clarify the obviousness prong to patentability set forth by Congress in the Patent Act of 1952.<sup>4</sup> Specifically, the Supreme Court established a four-factor test for determining obviousness.<sup>5</sup> The *Graham* decision indicated that obviousness is a question of law with underlying factual factors.<sup>6</sup> Questions of law typically

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<sup>1</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>2</sup> See, e.g., Patent Act of 1952, ch. 950, § 103, 66 Stat. 792, 798 (codified as amended at 35 U.S.C. § 103).

<sup>3</sup> 383 U.S. 1 (1966). The reported decision is a consolidation of the *Graham* appeal with two other cases, *Calmar v. Cook Chem. Co.* and *United States v. Adams*. See *id.*

<sup>4</sup> See *id.* at 17. The Court stated:

We believe . . . that the revision was not intended by Congress to change the general level of patentable invention. We conclude that the section was intended merely as a codification of judicial precedents embracing the Hotchkiss condition, with congressional directions that inquiries into the obviousness of the subject matter sought to be patented are a prerequisite to patentability.

*Id.*

<sup>5</sup> See *id.* at 17–18 (holding that obviousness is a question of law based on underlying factual factors: (1) the scope and content of the prior art, (2) the differences between the claims and the prior art, (3) the level of ordinary skill in the art, and (4) objective indicia of nonobviousness).

<sup>6</sup> See *id.*

concern issues to be resolved by a judge, yet Article III district courts routinely task juries with making a determination on the issue of invalidity based on obviousness.<sup>7</sup>

In fields of law other than patent law, dividing mixed issues between a jury and a judge is not uncommon. As a first example, in the context of criminal law, the issue of the “voluntariness of a confession is a mixed question of law and fact.”<sup>8</sup> When this issue arises, the question of coercion is an issue of fact for the jury to determine.<sup>9</sup> Once the judge determines that the confession was voluntary, aided by the jury’s factual findings on issues such as whether the defendant made the statement, the jury may then assess the truthfulness of the confession.<sup>10</sup> Factual issues concerning the voluntariness of a confession, such as whether a statement was even made, are decided by a jury checking yes or no on a verdict form.<sup>11</sup>

As a second example, in the context of antitrust law,<sup>12</sup> a jury may weigh the facts to determine whether the events constitute an unreasonable restraint of trade.<sup>13</sup> As shown in the following example jury verdict form, the jury decided

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<sup>7</sup> See *infra* Section III.A.

<sup>8</sup> *United States v. Brown*, 557 F.2d 541, 547 (6th Cir. 1977).

<sup>9</sup> See *Jackson v. Denno*, 378 U.S. 368, 377–78 (1964) (“If an issue of coercion is presented, the judge may not resolve conflicting evidence or arrive at his independent appraisal of the voluntariness of the confession, one way or the other. These matters he must leave to the jury.”).

<sup>10</sup> See *Lego v. Twomey*, 404 U.S. 477, 483, 485–86 (1972) (stating that once the trial judge renders a “clear-cut determination that the confession . . . was in fact voluntary,” the defendant generally retains the freedom to “familiarize a jury with circumstances that attend the taking of his confession” because the jury is empowered to “assess the truthfulness of confessions,”—their credibility—as part of their decision on “the ultimate factual issue of the defendant’s guilt or innocence”).

<sup>11</sup> See Jason Iuliano, *Jury Voting Paradoxes*, 113 MICH. L. REV. 405, 418 (2014) (“[V]erdict forms require jurors to make dichotomous judgments . . . .”); see also *Brown*, 557 F.2d at 548 (“Whether Appellant made the statements [that are the subject of the voluntariness determination] and whether he was beaten by police are questions of fact which will not be disturbed on appeal unless they are clearly erroneous.”).

<sup>12</sup> See 15 U.S.C. § 1 (“Every contract . . . in restraint of trade or commerce among the several States . . . is declared to be illegal. Every person who shall make any contract . . . hereby declared to be illegal shall be deemed guilty.”).

<sup>13</sup> See *United States v. Brown Univ.*, 5 F.3d 658, 668 (3d Cir. 1993) (“The rule of reason requires the fact-finder to weigh all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition.” (internal quotation marks omitted)).

that the events constituted an unreasonable restraint of trade, indicated by a checkmark in the affirmative.<sup>14</sup>

Question 1	
Has US Airways proved, by a preponderance of the evidence, that Sabre unreasonably restrained trade by means of the challenged contract provisions?	
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

Figure 1. Example verdict form.<sup>15</sup>

On the other hand, a judge may rule as a matter of law that the evidence surrounding the alleged facts failed to amount to an unreasonable restraint under the Sherman Act, and on appeal, such a mixed question of law and fact is reviewed *de novo*.<sup>16</sup> In sum, a jury may be tasked with assessing whether particular facts amount to an unreasonable restraint on trade, and a judge may be tasked with determining whether such factual findings amount to a legal violation under the Sherman Act.<sup>17</sup>

These examples of criminal and antitrust issues are similar in that they require juries to make factual determinations of a mixed question of law and fact by noting their findings with a yes or no indication on a jury verdict form.<sup>18</sup> In neither one of these examples is a jury asked to decide a question of law, nor is the jury asked to formulate an extensive analysis by means other than a yes or no finding. In both examples, the juries are instructed on the law that will apply and presumed to follow those instructions.<sup>19</sup> This yes or no nature of the jury verdict has been justified by many policy considerations.

<sup>14</sup> See Verdict Form at 1, *U.S. Airways v. Sabre Holdings Corp.*, 105 F. Supp. 3d 265 (S.D.N.Y. 2016) (No. 1:11-CV-2725) [hereinafter Verdict Form, *U.S. Airways*].

<sup>15</sup> *Id.*

<sup>16</sup> See *FTC v. Qualcomm Inc.*, 969 F.3d 974, 993 (9th Cir. 2020) (“[W]e reframe the issues to focus on the impact, if any, of Qualcomm’s practices in the area of effective competition . . . [W]e review for clear error the district court’s findings of fact and we review *de novo* its conclusions of law and any mixed questions of law and fact.” (citing *OneBeacon Ins. Co. v. Haas Indus., Inc.*, 634 F.3d 1092, 1096 (9th Cir. 2011))).

<sup>17</sup> See *Brown Univ.*, 5 F.3d at 668; Verdict Form, *U.S. Airways*, *supra* note 14, at 1; *Qualcomm*, 969 F.3d at 993.

<sup>18</sup> See, e.g., *United States v. Brown*, 557 F.2d 541, 547–48 (6th Cir. 1977); *Jackson v. Denno*, 378 U.S. 368, 377–78 (1964); *Lego v. Twomey*, 404 U.S. 477, 483, 485–86 (1972); *Iuliano*, *supra* note 11, at 418; 15 U.S.C. § 1.

<sup>19</sup> See *Weeks v. Angelone*, 528 U.S. 225, 233–34 (2000) (“Given that petitioner’s jury was adequately instructed, and given that the trial judge responded to the jury’s question . . . a jury is presumed to follow its instructions.” (emphasis added)); Proposed Jury Instructions at 2, 105 F. Supp. 3d 265 (S.D.N.Y. 2016) (No. 1:11-CV-2725).

Proponents point to how such a verdict form fosters deliberations and empowers juries to freely exercise their constitutional power.<sup>20</sup>

For well over a century, the Supreme Court has recognized (1) questions of law, (2) questions of fact, and (3) mixed questions of law and fact, as three discrete categories.<sup>21</sup> Regarding the third, the Supreme Court has acknowledged that mixed questions of law and fact are typically decided by a jury.<sup>22</sup> The standard of review for a mixed question depends on whether answering the question entails a mostly factual or legal determination.<sup>23</sup> The Supreme Court employed this standard in *Google LLC v. Oracle America, Inc.*<sup>24</sup> to decide the fair use defense to copyright infringement involves an issue that is primarily legal, as opposed to factual, and thus should be reviewed de novo on appeal.<sup>25</sup> In the context of patent law, the Federal Circuit has categorized obviousness as a mixed question, with no Supreme Court view on the matter.<sup>26</sup>

More complicated is the analysis of a question of law with underlying factual inquiries, which obscures the line between the role of a judge versus that of a jury in an obviousness-validity determination during patent jury trials.<sup>27</sup> How can the roles of the judge and jury be reconciled in a validity-obviousness analysis if questions of law are to be decided by a judge and questions

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<sup>20</sup> See Kayla A. Burd & Valerie P. Hans, *Reasoned Verdicts: Oversold?*, 51 CORNELL INT'L L.J. 319, 333 (2018) (“Deliberations under a unanimity [yes or no] rule are inherently filled with reasoning and debate . . . .”); *United States v. Spock*, 416 F.2d 165, 181 (1st Cir. 1969) (noting that the yes or no nature of verdict forms gives juries the “power to deliberate free from legal fetters . . . to arrive at a general verdict without having to support it by reasons or by a report of its deliberations” (quoting *United States v. Ogull*, 149 F. Supp. 272, 276 (S.D.N.Y. 1957), *aff’d sub nom. United States v. Gernie*, 252 F.2d 664 (2d Cir. 1958))).

<sup>21</sup> See, e.g., *Pullmann-Standard v. Swint*, 456 U.S. 273, 287–88 (1982) (distinguishing between a “question of law,” a “mixed question of law and fact,” and a “pure question of fact”).

<sup>22</sup> See *United States v. Gaudin*, 515 U.S. 506, 512 (1995) (“[T]he application-of-legal-standard-to-fact sort of question . . . commonly called a mixed question of law and fact, has typically been resolved by juries.” (internal quotation marks omitted)).

<sup>23</sup> See *U.S. Bank Nat’l Ass’n ex rel. CWC Capital Asset Mgmt. LLC v. Vill. at Lakeridge, LLC*, 138 S. Ct. 960, 967 (2018) (“In short, the standard of review for a mixed question all depends—on whether answering it entails primarily legal or factual work.”).

<sup>24</sup> 141 S. Ct. 1183 (2021).

<sup>25</sup> See *id.* at 1199–1200 (“In this case, the ultimate fair use question primarily involves legal work. Fair use was originally a concept fashioned by judges.” (internal quotation marks omitted)).

<sup>26</sup> See, e.g., *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1356 (Fed. Cir. 2012) (“[O]bviousness is a mixed question of law and fact . . . .”).

<sup>27</sup> See *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966) (holding that obviousness is a question of law based on underlying factual areas of inquiry: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the art; and (4) objective indicia of nonobviousness).

of fact are decided by a jury? After a jury indicates yes or no regarding the obviousness-type validity of a patent, after presumably assessing the four *Graham* factors,<sup>28</sup> what is left for the judge to determine?

In an attempt to answer these questions, this Article examines the role of juries versus the role of judges in obviousness-validity determinations. First, this Article examines how the Supreme Court has applied the right to jury trials in patent cases. Second, this Article examines the existing state of obviousness under 35 U.S.C. § 103.<sup>29</sup> Third, this Article briefly walks through the life cycle of patent litigation through appeal, referencing *KAIST IP US LLC v. Samsung Electronics Co., Ltd.*<sup>30</sup> Fourth, this Article analyzes the current law concerning the role of the jury in an obviousness determination. Fifth, this Article analyzes what tasks remain for a judge in an obviousness determination at the trial court. Sixth, this Article examines the procedure of invalidity based on anticipation under 35 U.S.C. § 102<sup>31</sup> to analogize to obviousness. Seventh and finally, this Article concludes with judicial and legislative recommendations for resolving the issue of obviousness between a jury and the judge at the trial court.

## I. Juries in Modern Patent Litigation

The right to a federal civil jury trial is guaranteed by the Seventh Amendment to the Bill of Rights, which provides, inter alia, that “[i]n suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved.”<sup>32</sup> Under the Seventh Amendment, the ultimate issue in a patent infringement case is generally decided by a jury.<sup>33</sup>

In the United States, there are two primary views of the civil jury system. The first view provides that “the civil jury is a cornerstone of democratic government, a protection against incompetent or oppressive judges, and a way for the people to have an active role in the process of justice.”<sup>34</sup> The second view

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<sup>28</sup> *See id.*

<sup>29</sup> *See infra* Part II.

<sup>30</sup> 439 F. Supp. 3d 860 (E.D. Tex. 2020).

<sup>31</sup> *See* 35 U.S.C. § 102(a)(1) (“A person shall be entitled to a patent unless the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention . . .”).

<sup>32</sup> U.S. CONST. amend. VII; *see also* *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 381 (1996) (“[T]he validity of any monopoly [including a patent] should be determined in accordance with the common law.”).

<sup>33</sup> *See Markman*, 517 U.S. at 377 (writing that under the Seventh Amendment, “there is no dispute that infringement cases today must be tried to a jury”).

<sup>34</sup> Margaret L. Moses, *What the Jury Must Hear: The Supreme Court’s Evolving Seventh Amendment Jurisprudence*, 68 GEO. WASH. L. REV. 183, 183 (2000).

provides that “civil juries are inefficient, unpredictable, swayed by sympathy, and incompetent to resolve complex cases,” and such cases should instead be decided by more experienced and educated arbiters.<sup>35</sup>

The policy considerations of this second view likely motivated the Supreme Court’s unanimous holding in *Markman v. Westview Instruments, Inc.*,<sup>36</sup> which held that the construction of patent claims, including terms of art within the patent claims, is an issue exclusively within the province of the court, rather than the jury.<sup>37</sup> In arriving at this holding, the Court cited historical evidence of common law practice at the time of the Seventh Amendment’s adoption to determine if the particular issue was afforded a jury trial.<sup>38</sup> Although the historical evidence substantiated affording a jury trial to the issue of patent infringement, the Court found that “there is no direct antecedent of modern claim construction in historical sources.”<sup>39</sup> Moreover, the Court pointed toward existing precedent, the importance of uniformity in treatment of a patent, and the suitability of language interpretation issues for determination by a judge.<sup>40</sup> In summary, the Court provided that claim construction was an issue of law to be decided by a judge, rather than an issue of fact to be determined by a jury, or a mixed question with roles for both.<sup>41</sup>

## II. Obviousness Standard

As seen in *Markman*, where Congress is silent with respect to whether a particular patent issue is a legal issue to be decided by a judge or a factual issue to be decided by jury, the Supreme Court has not shied away from filling in the legislative gaps in an attempt to create uniformity and avoid confusion.<sup>42</sup> As mentioned above, the Court in *Graham* similarly attempted to clarify a patent-related statute in holding that the ultimate determination as to patent obviousness is a matter of law based on four factual inquiries.<sup>43</sup> In 2007, the

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<sup>35</sup> *Id.*

<sup>36</sup> 517 U.S. 370, 381 (1996).

<sup>37</sup> See *Markman*, 517 U.S. at 371.

<sup>38</sup> See *id.* at 370–71.

<sup>39</sup> *Id.* at 371.

<sup>40</sup> See *id.* at 384, 390.

<sup>41</sup> See *id.* at 371 (“[C]onstruing the patent, is a question of law, to be determined by the court.”).

<sup>42</sup> See *supra* notes 37–41 and accompanying text.

<sup>43</sup> See *Graham v. John Deere Co. of Kansas City, Inc.*, 383 U.S. 1, 17–18 (1966). The four inquiry areas are: (1) the “level of ordinary skill” in the art, (2) “the scope and content of the prior art,” (3) “the differences between the prior art” and the claimed invention, and (4) any “secondary considerations” of the kinds listed by the Court, including commercial success, long-felt but unsolved needs, and failure of others. *Id.*

Court in *KSR International Co. v. Teleflex Inc.*<sup>44</sup> reaffirmed the *Graham* holding that obviousness is a matter of law.<sup>45</sup> In doing so, the *KSR* Court indicated that the “teaching, suggestion, or motivation” test established by the Federal Circuit was not mandatory, but rather one option for employing an obviousness analysis.<sup>46</sup> Further, the *KSR* court clarified that the reason, suggestion, or motivation to combine references in an obviousness analysis may be found explicitly or implicitly based on any number of considerations, including: the knowledge and common sense of a person having ordinary skill in the art, market forces, interrelated teachings of multiple prior art references, the nature of the problem to be solved, and design incentives, among others.<sup>47</sup> The *KSR* Court added that “[t]o facilitate review, this [question of law] analysis should be made explicit.”<sup>48</sup>

As further discussed below, forcing the trial court to make the obviousness analysis explicit is a burdensome and nearly impossible task, which lacks a meaningful analysis on record by the fact finder (e.g., the jury).<sup>49</sup> In contrast to the Supreme Court’s requirement that the analysis be made explicit, the Federal Circuit has provided that for mixed questions, a judge may allow a jury to engage in factual determinations, but the judge must rule on the ultimate legal question as a matter of law.<sup>50</sup> The Federal Circuit’s practice of defaulting to a jury on factual findings thus contradicts the Supreme Court’s requirement for making explicit the obviousness mixed question analysis.<sup>51</sup>

### III. Life Cycle of Patent Litigation

Generally, a claim for infringement of a utility patent arises under the federal Patent Act.<sup>52</sup> A claim for utility patent infringement must be brought

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<sup>44</sup> 550 U.S. 398 (2007).

<sup>45</sup> See *id.* at 404 (“The ultimate judgment of obviousness is a legal determination.”).

<sup>46</sup> See *id.* at 407 (“Federal Circuit has employed . . . the teaching, suggestion, or motivation test (TSM test), under which a patent claim is only proved obvious if some motivation or suggestion to combine the prior art teachings can be found.” (internal quotation marks omitted)).

<sup>47</sup> See *id.* at 418.

<sup>48</sup> *Id.*

<sup>49</sup> See *infra* Section IV.B.

<sup>50</sup> See *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs.*, 682 F.3d 1003, 1008 (Fed. Cir. 2012) (“[T]he judge may when the defense is a question of fact or mixed question of law and fact allow the jury to determine the underlying facts relevant to the defense . . . . But . . . the ultimate legal question . . . should always be decided as a matter of law by the judge.”).

<sup>51</sup> See *KSR*, 550 U.S. at 418; *W.L. Gore & Assocs.*, 682 F.3d at 1008.

<sup>52</sup> See 35 U.S.C. § 271 (“[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any

in federal district court, as federal district courts have original and exclusive jurisdiction.<sup>53</sup> In such a suit, venue is proper in the judicial district (1) “where the defendant resides,” or (2) “where the defendant has committed acts of infringement and has a regular and established place of business.”<sup>54</sup> The Federal Circuit has exclusive jurisdiction over an appeal from a final decision of a federal district court if the district court’s jurisdiction was based at least in part upon the patent jurisdiction provision, 28 U.S.C. § 1338.<sup>55</sup> The losing party may then petition the Supreme Court for certiorari.<sup>56</sup>

### A. Trial Court

In a patent infringement lawsuit, a plaintiff must prove a claim for patent infringement by a preponderance of the evidence.<sup>57</sup> On the other hand, a defendant can raise a defense of invalidity, which must be proven by the higher standard of clear and convincing evidence because a patent is presumed valid after issuing from the United States Patent and Trademark Office (“USPTO”).<sup>58</sup> The events in *KAIST*, which was tried in the Eastern District of Texas, are illustrative of an infringement lawsuit.<sup>59</sup> In this case, *KAIST* brought a patent infringement suit in federal district court against numerous defendants.<sup>60</sup> In response, the defendants raised the affirmative defense of invalidity based on anticipation and obviousness.<sup>61</sup>

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patented invention during the term of the patent therefor, infringes the patent.”).

<sup>53</sup> See 28 U.S.C. § 1338 (“[D]istrict courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents . . . . No State court shall have jurisdiction over any claim for relief arising under any Act of Congress relating to patents.”).

<sup>54</sup> *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1516 (2017) (quoting 28 U.S.C. § 1400(b)).

<sup>55</sup> See 35 U.S.C. § 1295 (“[The] Federal Circuit shall have exclusive jurisdiction . . . of an appeal from a final decision of a district court . . . in any civil action arising under . . . any Act of Congress relating to patents.”).

<sup>56</sup> See U.S. CONST. art. III, § 2, cl. 2.

<sup>57</sup> See *TDM Am., LLC v. United States*, 92 Fed. Cl. 761, 765 (2010) (“[C]laim for patent infringement *must be proven by preponderance of the evidence* [using] a two-step inquiry. First, the Court must construe the disputed patent claims as a matter of law. Second, the Court as trier of fact must determine whether the accused product . . . contains each limitation of the . . . claims.” (emphasis added) (citations omitted)).

<sup>58</sup> See 35 U.S.C. § 282(a) (“A patent shall be presumed valid. . . . The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.”); see also *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 91 (2011) (holding that “invalidity defense must be proved by clear and convincing evidence”).

<sup>59</sup> See *KAIST IP US LLC v. Samsung Elecs. Co.*, 439 F. Supp. 3d 860 (E.D. Tex. 2020).

<sup>60</sup> See *id.* at 870 n.1.

<sup>61</sup> See *id.* at 872 (noting defendants raised invalidity arguments raised at trial).

During a patent infringement trial, the jury makes determinations of fact.<sup>62</sup> After the parties present their evidence and arguments, the court hands the jury a lengthy jury instruction document that explains the relevant law and evidence presented, in order to assist the jurors in understanding their duties in resolving the factual issues.<sup>63</sup> The jury instructions may be jointly generated by the plaintiffs and defendants, and any disputed language in the jury instruction form is resolved with the judge, outside of the jury's presence, finalizing the jury instructions.<sup>64</sup> In *KAIST*, the jury instructions handed to the jury were forty-three pages in length.<sup>65</sup> The section on obviousness included instructions on the burden of proof, *Graham* factors used to determine obviousness, and clarifying language from *KSR* and other binding authority.<sup>66</sup>

The court generally directs the jury to use the jury instructions as a tool for completing a jury verdict form, which is usually a much shorter document, to indicate their findings.<sup>67</sup> For example, in *KAIST*, the jury verdict form was nine pages in length.<sup>68</sup> In *KAIST*, with respect to the question of validity of the disputed claims, the verdict form included a blank line where the jury could indicate yes or no as to whether the defendants proved invalidity of the asserted claims by clear and convincing evidence.<sup>69</sup> Specifically, the jury verdict form provided as follows:

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<sup>62</sup> See, e.g., *Hydrodynamics Indus. Co. v. Green Max Distributions, Inc.*, 21 F. Supp. 3d 1074, 1079 (C.D. Cal. 2014) (“Whether a motivation to combine prior-art references has been demonstrated is also a question of fact for the jury.”).

<sup>63</sup> See, e.g., Joint Proposed Jury Instructions at 3, 42, *KAIST IP US LLC v. Samsung Elecs. Co.*, 439 F. Supp. 3d 860 (E.D. Tex. June 13, 2018) (No. 2:16-CV-1314) [hereinafter *KAIST* Joint Proposed Jury Instructions].

<sup>64</sup> See *United States v. Ganadonegro*, No. CR 9-312(JB), 2012 WL 844125, at \*4 (D.N.M. Mar. 5, 2012) (“[T]he Court informed the parties that it had concluded that [one party] may permissibly phrase the jury instructions as to Count 3 in the manner it has chosen to do so.”).

<sup>65</sup> See *KAIST* Joint Proposed Jury Instructions, *supra* note 63, at 43.

<sup>66</sup> See *id.* at 25–29.

<sup>67</sup> See *id.*; *cf.* Verdict Form at 9, *KAIST*, 439 F. Supp. 3d 860 (E.D. Tex. 2018) (No. 2:16-CV-1314), [hereinafter *KAIST* Verdict Form] (jury instructions were 48 pages in length, while jury verdict form was 9 pages in length).

<sup>68</sup> See *KAIST* Verdict Form, *supra* note 67, at 9.

<sup>69</sup> See *id.* at 4.

**QUESTION #2:**

Did the Defendants prove by clear and convincing evidence that any of the following Asserted Claims of the '055 Patent are invalid?

Answer "Yes" or "No" for each Asserted Claim listed below:

Claim 1	<u>NO</u>
Claim 2	<u>NO</u>
Claim 3	<u>NO</u>
Claim 4	<u>NO</u>
Claim 5	<u>NO</u>
Claim 6	<u>NO</u>
Claim 11	<u>NO</u>
Claim 12	<u>NO</u>
Claim 13	<u>NO</u>
Claim 15	<u>NO</u>
Claim 16	<u>NO</u>
Claim 17	<u>NO</u>

Figure 2. Example jury verdict form.<sup>70</sup>

As discussed in more detail in Part IV, jurisdictions differ with respect to the details included in the jury instructions and the jury verdict form.<sup>71</sup> The jury verdict form, as illustrated in Figure 2 above, asks if any of the disputed claims are invalid, without regard for which theory of law (i.e., anticipation under 35 U.S.C. § 102 or obviousness under 35 U.S.C. § 103) formed the basis for the jury's invalidity decision.<sup>72</sup> For example, in *KAIST*, defendants submitted invalidity defenses based on theories of anticipation and obviousness.<sup>73</sup> While the jury instructions set forth the respective law governing these two theories,<sup>74</sup> the jury instructions failed to include any language regarding

<sup>70</sup> See *id.*

<sup>71</sup> See *infra* Section IV.B.

<sup>72</sup> See *KAIST* Verdict Form, *supra* note 67, at 4.

<sup>73</sup> See *KAIST*, 439 F. Supp. 3d at 872 (noting anticipation and obviousness "invalidity arguments raised at trial [by defendants]").

<sup>74</sup> See *KAIST* Joint Proposed Jury Instructions, *supra* note 63, at 23–30.

“obviousness” or “anticipation,” specifically with respect to the determination of validity.<sup>75</sup>

Judges have discretion regarding the content of the jury instruction forms so long as they do not abuse their discretion by adopting clearly unreasonable verdict forms.<sup>76</sup> For example, in *KAIST*, the judge could have instead included separate sections for invalidity based on anticipation and obviousness.<sup>77</sup> Whether the court abused its discretion in failing to split the validity inquiry into invalidity based on anticipation and invalidity based on obviousness was not an issue on appeal. Regardless, in *KAIST*, the jury found that the claims in question were not invalid and that defendants had infringed certain claims.<sup>78</sup>

After a trial has concluded and a verdict has been rendered, the court must formalize the judgment in writing.<sup>79</sup> Either party may file post-trial motions.<sup>80</sup> In federal district court, a renewed motion for judgment as a matter of law (“JMOL”), which is governed by Rule 50 of the Federal Rules of Civil Procedure, may be filed as a means for challenging a jury verdict.<sup>81</sup> In order to make a renewed JMOL motion after the jury’s verdict, the moving party must have made a motion for JMOL during trial, before the case was sent to the jury.<sup>82</sup> If the judge denies a party’s JMOL motion and instead submits the matter to the jury, and if the jury subsequently reaches an

<sup>75</sup> See *KAIST* Verdict Form, *supra* note 67, at 4.

<sup>76</sup> See, e.g., *XY, LLC v. Trans Ova Genetics*, 890 F.3d 1282, 1293 (Fed. Cir. 2018).

[I]t must be left to the sound discretion of the trial court what form of verdict to request of a jury. We see no reason to deviate from this general rule in this case and find no abuse of discretion by the district court. . . . [T]he verdict form was not clearly unreasonable.

*Id.* (inner quotation marks and citation omitted).

<sup>77</sup> See *KAIST* Verdict Form, *supra* note 67, at 4.

<sup>78</sup> See *id.* at 3–4.

<sup>79</sup> See *Ray Haluch Gravel Co. v. Cent. Pension Fund of Int’l Union of Operating Eng’rs & Participating Emp’rs*, 571 U.S. 177, 183 (2014) (“A ‘final decision’ is one that ends the litigation on the merits and leaves nothing for the court to do but execute the judgement.” (quoting *Catlin v. United States*, 324 U.S. 229, 233 (1945))).

<sup>80</sup> See FED. R. CIV. P. 50.

<sup>81</sup> See FED. R. CIV. P. 50(b) (“No later than 28 days after the entry of judgment . . . the movant may file a renewed motion for judgment as a matter of law and may include an alternative or joint request for a new trial under Rule 59.”); *R.R. Dynamics, Inc. v. A. Stucki Co.*, 727 F.2d 1506, 1511 (Fed. Cir. 1984) (“When a jury verdict of validity is tested by a motion for JNOV . . . the district court must determine whether the patent challenger’s evidence . . . withstood the patent owner’s rebuttal evidence that reasonable jurors could not have concluded that the patent is valid.”).

<sup>82</sup> See FED. R. CIV. P. 50.

unfavorable verdict to the moving party, only then may the moving party make a renewed JMOL motion to challenge that verdict.<sup>83</sup> A jury verdict will be upheld and the movant's motion for renewed JMOL under Rule 50 will not be sustained if the jury was presented with substantial evidence to support any factual findings sufficient under law to arrive at its conclusion.<sup>84</sup> As discussed below, determining substantial evidence becomes impossible because a judge or appellate court is unable to articulate the jury's factual findings as to the three inquiry areas since the jury's discussion never leaves the verdict room.<sup>85</sup> Although in *KAIST* the defendants did not file a renewed JMOL motion following the jury's verdict, in other cases, defendants routinely file renewed JMOL motions challenging the jury's findings of validity and infringement. In some of these instances, the judge enters judgment in accordance with the jury verdict, indicating that substantial evidence existed to support the jury's verdict.<sup>86</sup>

The two parties to an adversarial litigation for any given issue are (1) the party that has the burden of proving a particular issue ("the burdened party"), and (2) the party that does not have the burden of proving a particular issue ("the non-burdened party"). In an obviousness-validity analysis, the alleged infringer is the burdened party tasked with proving invalidity based on obviousness, for example, as an affirmative defense to infringement.<sup>87</sup> Meanwhile, the patentee is the non-burdened party with respect to the issue of obviousness-based invalidity.<sup>88</sup> There is no requirement that the non-burdened party support a verdict at all, as the non-burdened party is, after all, non-burdened. On the other hand, for the burdened party to succeed on a favorable jury verdict, a court must enter a judgment finding in favor of the burdened party, which the court will generally do if substantial evidence exists to support that jury verdict.<sup>89</sup> For an invalidity issue, substantial evidence means that a reason-

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<sup>83</sup> *See id.*

<sup>84</sup> *See* *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1362 (Fed. Cir. 2004) ("When we review the denial of a . . . [JMOL] on a mixed question . . . we must sustain the jury's conclusion unless the jury was not presented with substantial evidence to support any set of implicit findings sufficient under the law to arrive at its conclusion.").

<sup>85</sup> *See infra* Sections II.B., IV.B.

<sup>86</sup> *See KAIST*, 439 F. Supp. 3d at 873 ("Court finds that substantial evidence exists to support the jury's verdict on each issue."); *see also* *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938) ("Substantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.").

<sup>87</sup> *See* *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011) (holding that the alleged infringer must prove the "invalidity defense by clear and convincing evidence").

<sup>88</sup> *See id.* (citing 35 U.S.C. § 282).

<sup>89</sup> *See, e.g., KAIST*, 439 F. Supp. 3d at 873 ("Court finds that substantial evidence exists to support the jury's verdict on each issue," including the issue of infringement proved by

able jury could find invalidity supported by clear and convincing evidence.<sup>90</sup> From a policy standpoint, such a requirement seems fair because the burdened party has the burden of building a record and proving the particular issue in accordance with the proper standard. Even if a burdened party loses the jury verdict, the burdened party can prevail on JMOL if the burdened party convinces a court that any reasonable jury would have to conclude that the burden was indeed met.<sup>91</sup> In either of these cases, the court has the final word on whether the burdened party prevails. In the context of invalidity claims based on obviousness, the court either blesses a jury verdict or overturns a jury verdict. Because a jury is not equipped with the same power to bless or overturn a court's decision, the power scale seems to tilt in favor of courts over juries in the resolution of invalidity based on obviousness.

### B. Appellate Court Review of Obviousness

Following an adverse judgment in a patent infringement case, a losing party may appeal to the Federal Circuit.<sup>92</sup> The Federal Circuit has exclusive jurisdiction over appeals in patent cases, and thus states controlling authority for patent law issues, at least in the absence of intervention by the Supreme Court.<sup>93</sup> On appeal from a bench trial, the Federal Circuit reviews the underlying factual findings for clear error.<sup>94</sup>

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the burdened plaintiff).

<sup>90</sup> See *Whitserve, LLC v. Comput. Packages, Inc.*, 694 F.3d 10, 21 (Fed. Cir. 2012) (explaining that invalidity must be shown by clear and convincing evidence at trial and exemplifying how the burden of proof at trial is incorporated into the appellate determination of “substantial evidence”); see also *Consol. Edison Co.*, 305 U.S. at 229 (defining “substantial evidence”).

<sup>91</sup> See *Whitserve*, 694 F.3d at 21 (“Because the jury found that the patents were not invalid . . . we review the evidence to see if there is such an ‘overwhelming amount of evidence in favor of [defendant] that reasonable and fair minded men could not arrive at a verdict against [defendant].” (quoting *AMW Materials Testing, Inc. v. Town of Babylon*, 584 F.3d 436, 456 (2d Cir. 2009))).

<sup>92</sup> See 35 U.S.C. § 1295(a)(1) (“Federal Circuit shall have exclusive jurisdiction of an appeal from a final decision . . . in any civil action arising under . . . any Act of Congress relating to patents.”).

<sup>93</sup> See *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1342 (Fed. Cir. 2003) (“Under 28 U.S.C. § 1295(a)(1), this court has exclusive jurisdiction over an appeal from a final decision of a district court if the jurisdiction of that court was based, in whole or in part, on section 1338.” (quoting 28 U.S.C. § 1338(a) (internal quotation marks omitted))).

<sup>94</sup> See *Alza Corp. v. Mylan Lab'ys, Inc.*, 464 F.3d 1286, 1289 (Fed. Cir. 2006) (“Obviousness is a question of law, reviewed *de novo*, based upon underlying factual questions which are reviewed for clear error following a bench trial.”).

On appeal from a judgment following a civil jury trial, the Federal Circuit reviews the legal aspects of the obviousness determination *de novo*.<sup>95</sup> That is, the Federal Circuit reviews the legal question of obviousness and the factual inquiries of obviousness different from one another. First, the Federal Circuit reviews the legal question without deference to the trial court.<sup>96</sup> Second, the Federal Circuit reviews the factual inquiries of obviousness using the more deferential, substantial evidence standard if the burdened party won.<sup>97</sup> If the burdened party lost, the Federal Circuit reviews the factual inquiries of obviousness under a more stringent standard, under which the losing burdened party will prevail only upon a showing that no reasonable jury could have found the burden unmet in view of the total record.<sup>98</sup> In any case, the *KSR* court made it clear that “this [obviousness] analysis should be made explicit.”<sup>99</sup> However, current procedure fails to provide trial courts (e.g., on post-judgment motions) and the Federal Circuit (e.g., on appeal) any meaningful materials for making the obviousness analysis explicit, as the jury’s findings on factual inquiries are never revealed outside the jury room.<sup>100</sup>

To get around this issue, initially, the Federal Circuit and trial courts presume the jury resolved the factual inquiries in favor of the verdict, although there is no meaningful jury analysis or record to prove so, and thereafter, the Federal Circuit examines the legal conclusion *de novo* in view of those factual resolutions.<sup>101</sup> Although the Federal Circuit assumes the jury found in favor of the verdict, the Federal Circuit is unable to articulate the factual

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<sup>95</sup> See *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1357 (Fed. Cir. 2012) (“Then we examine the [ultimate] legal conclusion [of obviousness] *de novo* to see whether it is correct in light of the presumed jury fact findings.” (alteration in original) (quoting *Jurgens v. McKasy*, 927 F.2d 1552, 1557 (Fed. Cir. 1991))).

<sup>96</sup> See *Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1479 (Fed. Cir. 1997) (“[W]e review that legal question without deference to the trial court . . . [such that the] district court’s conclusion on obviousness is one of law and subject to full and independent review in this court.” (quoting *Gardner v. TEC Sys., Inc.*, 725 F.2d 1338, 1344 (Fed. Cir. 1984))).

<sup>97</sup> See *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 719 (Fed. Cir. 1984) (“Findings of fact by the jury are more difficult to set aside (being reviewed only for reasonableness under the substantial evidence test) than those of trial judge (to which the clearly erroneous rule applies).”).

<sup>98</sup> *Cf. Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 459 (2016) (writing that the lower court “could have denied . . . this ground [and ruled in favor of burdened party] only if it concluded that no reasonable juror could have believed” that there was sufficient evidence to support the finding).

<sup>99</sup> *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

<sup>100</sup> See *supra* Section III.A.

<sup>101</sup> See *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1356–57 (Fed. Cir. 2012). The court wrote:

resolution because the *Graham* factors merely guide the fact finder through the obviousness analysis. Absent any memorialized and meaningful analysis from the jury, it is near impossible—if not completely impossible—for the Federal Circuit to state, for example, the jury’s finding of the level of skill of a person of ordinary skill in the art. Moreover, the *Graham* factors do not provide for the possibility of a meaningful analysis. For example, assuming an expert testifies on the level of skill for a person of ordinary skill in the relevant art, a verdict form may allow a jury to indicate that the level of skill is “high” or “low.” However, such an indication would be unhelpful to the Federal Circuit in making its obviousness analysis explicit because such a binary indication is subjective.

#### IV. What is the Role of the Jury in an Obviousness Analysis?

As the foregoing trial and appellate procedure for an obviousness determination illustrates, an obviousness analysis requires (1) the law to be articulated, (2) facts to be determined, and (3) the articulated law to be applied to those determined facts.<sup>102</sup> In a jury trial, the judge performs the first step, usually in the jury instructions; the jury performs the second step, through observing testimony and evidence presented at trial; and the jury performs the third step by applying the law (e.g., on obviousness) to the facts during jury deliberation.<sup>103</sup>

##### A. Make Findings for the Three Factual Inquiries of *Graham*

Jurors are trusted to diligently observe testimony, evaluate credibility, and make factual determinations. There are two contrasting views surrounding the effectiveness of juries.<sup>104</sup> Those who disfavor jurors may point to the fact that jurors are human, and therefore may miss certain information or, in

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Because obviousness is a mixed question of law and fact, ‘[w]e first presume that the jury resolved the underlying factual disputes in favor of the verdict [] and leave those presumed findings undisturbed if they are supported by substantial evidence. Then we examine the [ultimate] legal conclusion [of obviousness] de novo to see whether it is correct in light of the presumed jury fact findings.’

*Id.* (alteration in original) (quoting *Jurgens v. McKasy*, 927 F.2d 1552, 1557 (Fed. Cir. 1991)).

<sup>102</sup> See *supra* Section III.A.; see also 2A Donald S. Chisum, CHISUM ON PATENTS § 5.05 (2020) (discussing secondary considerations, e.g., commercial success, long-felt but unsolved needs, and failure of others).

<sup>103</sup> See *supra* Section III.A.; see also *Kinetic Concepts*, 688 F.3d at 1360 (“[T]he jury [takes part in] explicit and implicit factual findings with respect to the *Graham* factors.”).

<sup>104</sup> See *Moses*, *supra* note 34, at 183.

egregious instances, may even fall asleep during trial.<sup>105</sup> In these egregious instances, a judge may take some equitable action, such as granting a motion for a new trial.<sup>106</sup> Because a judge may employ certain procedural remedies when juries fail to live up to their civic duties, and because juries are trusted to make factual determinations, such factual determinations are given a high level of deference.<sup>107</sup> Given the text of the Seventh Amendment, the history of jury trials, and certain policy considerations, there is little debate that making factual findings is within the province of the jury.<sup>108</sup>

However, what are these “findings” in an obviousness case in which a jury must apply the *Graham* factors? For example, if a jury is tasked with determining a level of skill, as required by the *Graham* factors, how should the jury memorialize such a finding? A jury could check a box indicating that the level of skill is “high” or “low.” Alternatively, a jury could input text into a field indicating that the level of skill is that of an artisan having a master’s degree and two years of work experience. Regardless, it is near impossible for the Federal Circuit to determine how the findings for one *Graham* factor informed the jury’s decision for or against obviousness because under the discussed approaches it is unclear (1) how the findings for one *Graham* factor were weighted relative to the other *Graham* factors, (2) what the jury meant with its binary selection, and (3) whether the jury can ascertain the level of ordinary skill in an art if they are not experts in the particular art.

## **B. Apply the Law to Resolve Issues of Fact**

Juries are trusted to apply the law provided by the judge to resolve issues of fact.<sup>109</sup> Examples of issues of fact in the context of employment law include whether a defendant has knowledge necessary for breach of fiduciary duty, whether regulatory estoppel applies to plan assets, and liability under ERISA

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<sup>105</sup> See *Tanner v. United States*, 483 U.S. 107, 113 (1987) (“[S]everal of the jurors consumed alcohol during the lunch breaks at various times throughout the trial, causing them to sleep through the afternoons.”).

<sup>106</sup> See *id.* at 107 (“[P]etitioners filed a motion . . . [for] a new trial based on a trial juror’s statement that several jurors had consumed alcohol at lunch throughout the trial, causing them to sleep during the afternoons.”).

<sup>107</sup> See *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 975 (Fed. Cir. 1995) (“[T]he jury’s factual findings receive substantial deference.”), *aff’d*, 517 U.S. 370 (1996).

<sup>108</sup> See *Markman*, 517 U.S. at 377 (stating that under the Seventh Amendment, “there is no dispute that infringement cases today must be tried to a jury”).

<sup>109</sup> See *id.* at 377 (“[T]here is no dispute that infringement cases today [are questions of fact that] must be tried to a jury, as their predecessors were more than two centuries ago.”).

section 502(a).<sup>110</sup> These issues are conducive to a yes or no answer on a jury verdict form because the jury can answer these factual issues as yes or no.

More contentious is the notion of how juries should deal with mixed questions of law and fact, particularly when the Supreme Court has indicated that courts should make such an analysis explicit.<sup>111</sup> It is unclear how such an analysis in the context of the obviousness inquiry, which requires a jury to resolve the *Graham* factual inquiries,<sup>112</sup> may be made explicit given current procedure. Neither the trial judge nor appellate court can articulate those factual findings given the yes or no nature of factual determination.<sup>113</sup>

After the jury instructions and verdict form are finalized, both documents are read and handed to the jury, requiring the jury to indicate yes or no as to each issue of fact.<sup>114</sup> For example, in the Eastern District of Texas, a jury executed the following verdict form:<sup>115</sup>

<b>QUESTION EIGHT</b>	
Has Samsung proven by a clear and convincing evidence that Claim 5 of the '884 patent is invalid (either anticipated or obvious)?	
Yes	<input type="checkbox"/>
No	<input checked="" type="checkbox"/>

Figure 3. Example jury verdict form from Eastern District of Texas.<sup>116</sup>

As illustrated, the validity question handed to the jury points to the proper evidentiary standard for reviewing invalidity but fails to include a section for the jury to memorialize its findings concerning the *Graham* factual inquiries.<sup>117</sup>

<sup>110</sup> See *Spear v. Fenkell*, No. 13-2391, 2016 WL 5661720, at \*2-3 (E.D. Pa. Sept. 30, 2016) (“Questions of fact exist whether Stonehenge knowingly participated in a breach of fiduciary duty . . . whether regulatory estoppel applies to the plan assets argument . . . whether the Sefcovic parties are liable under ERISA Section 502(a)(3).”).

<sup>111</sup> See *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (“[T]his [obviousness] analysis should be made explicit.”).

<sup>112</sup> See *Graham v. John Deere Co. of Kansas City, Inc.*, 383 U.S. 1, 17–18 (1966).

<sup>113</sup> See, e.g., Verdict of the Jury at 4, *Imperium IP Holdings, Ltd. v. Samsung Elecs. Co.*, 259 F. Supp. 3d 530 (E.D. Tex. Feb. 8, 2016) (No. 4:14-CV-371) [hereinafter *Imperium Jury Verdict*]; Verdict Form at 2, *Zeiss v. Nikon Corp.*, No. 17-07083, 2018 WL 5081479 (C.D. Cal. Dec. 13, 2018) [hereinafter *Zeiss Verdict Form*].

<sup>114</sup> See *id.*

<sup>115</sup> See *Imperium Jury Verdict*, *supra* note 113, at 4.

<sup>116</sup> See *id.*

<sup>117</sup> See *id.* (“Has Samsung proven by *clear and convincing evidence* that Claim 5 . . . is *invalid*?” (emphasis added)); see also *i4i Ltd. P’ship v. Microsoft Corp.*, 598 F.3d 831, 848

Such an omission makes it impossible for a reviewing body, such as the trial or appellate court, to meaningfully review whether the jury's findings on the *Graham* factors are supported, for example, by substantial evidence.

As another example, a jury in the Central District of California executed the corresponding verdict form as follows:

2. Did Defendants Nikon Corporation and Nikon Inc. (collectively, "Defendants") prove, by clear and convincing evidence, that claim 16 of the '163 patent is invalid?

"NO" is a finding for Plaintiffs. "YES" is a finding for Defendants. Please check the box that reflects your verdict.

Claim	Invalidity	
	YES	NO
Claim 16	<del>YES</del>	✓

Only proceed to the next question if you answered "NO" above. If you answered "YES," proceed to section II.

Figure 4. Jury verdict form from Central District of California.<sup>118</sup>

Like the previous example from the Eastern District of Texas, this verdict form from the Central District of California indicates the proper evidentiary standard, but similarly fails to include a section for a jury to memorialize their findings concerning the *Graham* factual inquiries.<sup>119</sup> Again, such an omission makes it impossible for the Federal Circuit to make the obviousness analysis explicit. Additionally, in both examples the jury was asked if the respective claim was invalid. In the second example, scratch marks may indicate that the double negative associated with indicating no confused the jury.<sup>120</sup> The record fails to address whether the scratch marks are attributable to an initial confusion or deliberation among the jury, just as the record fails to address whether the jury even considered the *Graham* factors and supported their findings regarding invalidity with substantial evidence.

(Fed. Cir. 2010) ("[T]he jury instructions were correct in light of this court's precedent, which requires the challenger to prove invalidity by clear and convincing evidence.").

<sup>118</sup> *Zeiss Verdict Form*, *supra* note 113, at 2.

<sup>119</sup> *See id.* (illustrating that the court did not provide a section for a jury to comment on (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the art; and (4) objective indicia of nonobviousness).

<sup>120</sup> *See id.*

The Federal Circuit has indicated that a jury verdict will be upheld if substantial evidence supported a jury's findings on the factual areas of inquiry.<sup>121</sup> Alternatively, a jury verdict on validity will be overturned if no reasonable person would support a jury's findings on the factual areas of inquiry.<sup>122</sup> Problematically, neither the federal district court nor the Federal Circuit are able to articulate such jury findings because the jury's discussions are not memorialized and therefore never leave the verdict room. District courts are unable to properly do so because the yes or no nature of factual determinations on the verdict form fails to provide any indication of the jury's findings on the three factual inquiries of *Graham*.<sup>123</sup>

### C. Resolving Factual Inquiries with Targeted Questions?

In an effort to facilitate making their obviousness analyses explicit, district courts could ask juries targeted questions, while preserving the yes or no nature that is fairly standard across the legal practice, such as in the context of criminal law, antitrust law, and employment law.<sup>124</sup> Considering the three *Graham* factors and the secondary considerations, can these factors and considerations be formulated as yes or no questions to enable reviewing courts and judges to make the obviousness analysis explicit?

#### 1. *The Scope and Content of the Prior Art*

A court could formulate a question concerning this factor by copying and pasting relevant portions of prior art and asking the jury in yes or no format if

<sup>121</sup> See *Intell. Ventures I LLC v. Motorola Mobility LLC*, 870 F.3d 1320, 1326 (Fed. Cir. 2017) (“[E]xplicit and implicit subsidiary factual determinations made by the jury—including the scope and content of the prior art—are reviewed for substantial evidence.”); see also *Markman v. Westview Instruments Inc.*, 52 F.3d 968, 978 (Fed. Cir. 1995) (“[T]he jury’s factual findings receive substantial deference . . . .”); cf. *Alza Corp. v. Mylan Pharm. Inc.*, 464 F.3d 1286, 1289 (Fed. Cir. 2006) (“Obviousness is a question of law, reviewed *de novo*, based upon underlying factual questions which are reviewed for clear error following a bench trial.”).

<sup>122</sup> See *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1356 (Fed. Cir. 2012) (“[A] jury verdict can be reversed only if ‘the facts and inferences point so strongly and overwhelmingly in favor of one party that the Court believes that reasonable men could not arrive at a contrary verdict . . . .’”); see also *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1325 (Fed. Cir. 2016) (writing that the court would reverse if “the facts and inferences, viewed in the light most favorable to the verdict, point so strongly and overwhelmingly in favor of the movant that a reasonable jury could not have reached the verdict.”).

<sup>123</sup> See, e.g., *Imperium Jury Verdict*, *supra* note 113; *Zeiss Verdict Form*, *supra* note 113.

<sup>124</sup> Cf. *Burd & Hans*, *supra* note 20, at 332 (“Some contend that requiring jurors to justify their decision may lead to better, more deliberative decisions based first and foremost on evidence rather than intuitions, emotions, or other factors. . . . [T]he requirement that judgments be reasoned to prevent arbitrariness and to ensure an effective right to appeal.”).

the content of the prior art encompasses the copied portions. In this manner, the jury could answer yes or no as to this finding. However, such an answer would have to be yes, because the text would be taken word-for-word from the prior art, such that no reasonable person could disagree that the explicit text of a published prior art reference informs the scope and content of that prior art reference. It would be impossible for both parties to reach an agreement as to which portion of the prior art should be presented to the jury to ask about scope and content, as the parties would be reluctant to cite to portions that are unfavorable to their positions. Given the involved nature of ascertaining complex prior art, asking an effective yes or no question as to this factor is difficult.

### ***2. The Differences Between the Claims and the Prior Art***

A court could provide to the jury a claim chart that separates the claim seeking to be invalidated into its respective elements and includes corresponding portions of the prior art believed to be relevant next to each element. Then, the jury could answer yes or no on an element-by-element basis, as to whether the cited portion of the prior art is different from the corresponding element of the claim. Again, parties to the dispute would find it difficult to agree on how to break up the claim based on elements, as well as on what portions of the prior art to assign each claim. Again, asking an effective yes or no question as to this factor is difficult.

### ***3. The Level of Ordinary Skill in the Art***

A court could cite to portions of the transcript or other evidence and ask the jury if this evidence suggests that the level of ordinary skill in the art includes a particular level of education, such as a master's degree, at least two years of industry experience, and the like. Of course, the particular level of skill in the art may be influenced by a number of factors, many of which would likely be omitted for efficiency's sake. Similarly, if a jury answers no to a question such as "does a person of ordinary skill in the art have a master's degree," does the no indicate that the person of ordinary skill in the art has more education (e.g., a doctorate degree) or less education with more experience (e.g., high school education with 20 years of work experience)? Like with the previous factors, an effective yes or no question as to this factor is difficult.

### ***4. Objective Indicia of Nonobviousness***

For this factor, a court could ask whether the claimed subject matter led to commercial success, or whether there was a long-felt but unsolved need to improve a particular field or widget. Such a yes or no answer would not help reviewing courts make their analyses explicit because a jury indication of yes or no as to whether there was a long-felt but unresolved need fails to clarify the particular need. Indeed, the long-felt but unresolved need determined by the jury could differ from that contemplated by the court in the

jury verdict form. Again, an effective yes or no question as to this factor is difficult for purposes of helping reviewing courts make their analyses explicit. Modifying jury verdict forms to include targeted questions concerning the *Graham* factors would place an additional strain on the courts and be largely unhelpful given the nature of obviousness analysis.

## V. What is Left for the Judge to Decide?

As the foregoing trial and appellate procedure for an obviousness determination illustrates, an obviousness analysis requires the law on obviousness to be articulated, disputed facts to be determined, and the articulated law to be applied to those determined facts.<sup>125</sup> In bench trials, the judge performs all three steps.<sup>126</sup> That is, in bench trials, the judge articulates the law, makes factual findings, and applies the law to the facts so found.<sup>127</sup>

Outside of the context of bench trials, current precedent requires juries to make factual determinations as to the mixed issue of obviousness; however, the analysis employed by the jury stays in the jury room.<sup>128</sup> Current jury verdict forms may include a text field in which a jury may write yes or no as to the invalidity of corresponding claims, without any corresponding room on the form for juries to memorialize their analysis under the *Graham* factors.<sup>129</sup> Thus, judges and the Federal Circuit are left to comply with *KSR* and other Supreme Court precedent, but lack meaningful analysis on the record as to the “question of law with underlying factual” inquiries analysis of obviousness made by the jury.<sup>130</sup>

With this in mind, outside the context of bench trials, there appears to be few tasks for the judge regarding an obviousness issue, namely: (1) articulate the law, (2) formalize the judgment in writing, and (3) issue a ruling on any post-trial motions, such as a JMOL, in which judges appear to quietly treat

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<sup>125</sup> See *supra* Section III.A.; see also 2A CHISUM, *supra* note 111, at § 5.05 (discussing secondary considerations, i.e., commercial success, long-felt but unsolved needs, and failure of others).

<sup>126</sup> See *Pozen Inc. v. Par Pharm., Inc.*, 969 F.3d 1151, 1156 (Fed. Cir. 2012) (“Following a bench trial, the district court determined that the asserted claims . . . are not invalid as obvious under 35 U.S.C. § 103.”).

<sup>127</sup> See *id.* at 1159.

<sup>128</sup> See *supra* Sections III.A.–B.

<sup>129</sup> See, e.g., *KAIST* Verdict Form, *supra* note 67, at 4 (questions to be answered with yes or no answers).

<sup>130</sup> See *Graham v. John Deere Co. of Kansas City, Inc.*, 383 U.S. 1, 17–18 (1966) (describing the factual factors underlying the obviousness question of law).

obviousness as a question of fact without saying so by upholding the jury decision if reasonable in light of the evidence.<sup>131</sup>

### A. Articulate the Law

In a typical trial, the judge memorializes the relevant law in the jury instructions.<sup>132</sup> In *Greatbatch Ltd. v. AVX Corp.*<sup>133</sup> and *Imperium IP Holdings, Ltd. v. Samsung Electronics Co.*,<sup>134</sup> the jury instructions varied in detail and scope. In the former, the law on obviousness spanned six pages, giving each of the areas of factual inquiries, the *Graham* factors, a corresponding page outlining the law.<sup>135</sup> In the latter, the law of obviousness spanned three pages without emphasizing the areas of factual inquiries for obviousness.<sup>136</sup> The losing party did not challenge the jury instructions as erroneous in either of these cases, nor did the Federal Circuit decide to do so sua sponte.<sup>137</sup> So long as the jury

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<sup>131</sup> See *Ray Haluch Gravel Co. v. Cent. Pension Fund of Operating Eng'rs & Participating Emp'rs*, 571 U.S. 177, 183 (2014) (“A ‘final decision’ is one that ends the litigation on the merits and leaves nothing for the court to do but execute the judgement.” (quoting *Catlin v. United States*, 324 U.S. 229, 233 (1945))); see also *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1049 (2016) (stating that the “District Court could have denied . . . this ground only [and ruled in favor of burdened party] if it concluded that no reasonable juror could have believed” that there was sufficient evidence to support a finding).

<sup>132</sup> See, e.g., Final Jury Instructions at 41, 49–54, *Greatbatch Ltd. v. AVX Corp.*, No. 01:13-CV-00723, 2015 WL 9171042 (D. Del. Jan. 25, 2016) [hereinafter *Greatbatch* Jury Instructions] (jury instructions were 73 pages long, of which 6 pages set forth the law on obviousness); cf. Instructions to the Jury at 16–20, 30, *Imperium IP Holdings, Ltd. v. Samsung Elecs. Co.*, 259 F. Supp. 3d 530 (E.D. Tex. Feb. 8, 2016) (No. 04:14-CV-00371) [hereinafter *Imperium* Jury Instructions] (jury instructions were 30 pages long, of which 3 pages set forth the law on obviousness).

<sup>133</sup> 2015 WL 9171042 (D. Del. Jan. 25, 2016).

<sup>134</sup> 259 F. Supp. 3d 530 (E.D. Tex. 2017), *aff'd in part, rev'd in part*, 757 F. App'x 974 (Fed. Cir. 2019).

<sup>135</sup> See *Greatbatch* Jury Instructions, *supra* note 132, at 38, 49–52 (jury instructions set forth the law on invalidity, the scope and content of prior art, the differences between the claims and the prior art, and the level of ordinary skill).

<sup>136</sup> Cf. *Imperium* Jury Instructions, *supra* note 132, at 19 (“In determining whether a claimed invention is obvious, you must consider the level of ordinary skill . . . , the scope and content of the prior art, and any differences between the prior art and the claimed invention.”).

<sup>137</sup> See *Sulzer Textil A.G. v. Picanol N.V.*, 358 F.3d 1356, 1363 (Fed. Cir. 2004) (“A jury verdict will be set aside, based on erroneous jury instructions, if the movant can establish that ‘those instructions were legally erroneous,’ and that ‘the errors had prejudicial effect.’” (quoting *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000))).

instructions, even if erroneous, could not affect the outcome of the case, then the verdict will not be reversed.<sup>138</sup>

### **B. Formalize the Judgment in Writing and Rule on Post-Trial Motions**

Either before sending issues to a jury or after receiving the jury's decision, the court must formalize a judgment in writing.<sup>139</sup> Before formalizing the judgment, parties may file certain motions on which a judge must issue a ruling to grant or deny. As a first example, a party may move for JMOL under Rule 50(a) before the issues are sent to the jury.<sup>140</sup> As a second example, a party may move for a renewed JMOL under Rule 50(b) after a jury has rendered its decision and made factual findings.<sup>141</sup> A motion for a renewed JMOL under Rule 50(b) may only be made on grounds included in the earlier JMOL motion under Rule 50(a).<sup>142</sup> That is, a party waives its right to move for JMOL under Rule 50(b) by not moving for JMOL under Rule 50(a).<sup>143</sup> If a party fails to timely file a Rule 50(b) motion, the trial court's denial of the earlier Rule 50(a) motion cannot form the basis of an appeal.<sup>144</sup>

In the context of the jury's findings under the *Graham* factors, the Federal Circuit has indicated that a judge may grant a renewed JMOL to overturn a jury's findings with respect to factual findings on the *Graham* factors if the

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<sup>138</sup> See *i4i Ltd. P'ship. v. Microsoft Corp.*, 598 F.3d 831, 841 (Fed. Cir. 2010) ("Erroneous instructions are subject to harmless error review. We will not reverse if, considering the record as a whole, the erroneous instruction 'could not have affected the outcome of the case.'" (quoting *Wright v. Ford Motor Co.*, 508 F.3d 263, 268 (5th Cir. 2007)), *aff'd*, *Microsoft Corp. v. i4i Ltd. P'ship.*, 564 U.S. 91 (2011))).

<sup>139</sup> See, e.g., *800 Adept, Inc. v. Murex Sec., Ltd.*, 539 F.3d 1354, 1357 (Fed. Cir. 2008) ("The trial court entered judgment on the jury verdict, issued a permanent injunction, and awarded enhanced damages of \$24 million on the patent infringement claim, bringing the total damages award to \$49 million.").

<sup>140</sup> See FED. R. CIV. P. 50(a)(1) ("If a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue, the court may . . . resolve the issue against the party.").

<sup>141</sup> See FED. R. CIV. P. 50(b).

<sup>142</sup> See *Duro-Last, Inc. v. Custom Seal, Inc.*, 321 F.3d 1098, 1105 (Fed. Cir. 2003) ("A post-verdict JMOL motion [under Rule 50(b)] may not be made on grounds not included in the earlier motion.").

<sup>143</sup> See *id.*

<sup>144</sup> See *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 546 U.S. 394, 401 (2006) ("[T]he 'requirement of a timely application for judgment after verdict is not an idle motion' because it 'is . . . an essential part of the rule, firmly grounded in principles of fairness.'" (alteration in original) (quoting *Johnson v. New York, N.H. & H.R. Co.*, 344 U.S. 48, 53 (1952))).

jury's findings could not be supported by a reasonable person.<sup>145</sup> For example, a jury's findings may include that a person of ordinary skill in the relevant art has a master's degree in the relevant field and would understand that combining two separate computing features into a unified graphical user interface of software would be obvious to said person of ordinary skill in the relevant art because such combination would improve the efficiency of aggregating data. As set forth above, ruling on a renewed JMOL is a difficult task for a judge when the jury's analysis on the *Graham* factors never leaves the jury's deliberation room. How is a judge able to review the factual finding, for example, on the above-referenced level of skill of a person of ordinary skill in the relevant art for purposes of determining whether substantial evidence exists to support such a finding? At best, the jury's memorialized findings include a checkbox regarding whether a particular claim is invalid, and this checkbox is the basis on which a judge issues their ruling.<sup>146</sup> Accurately basing a ruling off this checkbox fails to fully account for what factors or discussion points may have ultimately caused a jury to render the verdict.

## VI. Questions of Law and Questions of Fact for Anticipation

As explained in Section II.A., a party seeking an invalidity judgment may argue invalidity based on obviousness or anticipation.<sup>147</sup> In the context of anticipation, there are particular issues that have been deemed questions of law for a judge's determination and other issues that have been deemed questions of fact for a jury's determination.<sup>148</sup> For example, infringement and invalidity based on anticipation are questions of fact, while the issue of whether a prior art reference is enabling for anticipation is a question of law based on underlying factual questions.<sup>149</sup>

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<sup>145</sup> See *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1356 (Fed. Cir. 2012) (writing that jury verdict can be reversed only if “the facts and inferences point so strongly and overwhelmingly in favor of one party that the Court believes that reasonable men could not arrive at a contrary verdict”).

<sup>146</sup> See *Imperium Jury Verdict*, *supra* note 113, at 4 (jury finding that claim 5 was not invalid as obvious or anticipated).

<sup>147</sup> See *KAIST IP US LLC v. Samsung Elecs. Co.*, 439 F. Supp. 3d 860, 872 (E.D. Tex. 2020) (anticipation and obviousness “invalidity arguments raised at trial [by defendant]”).

<sup>148</sup> See *ATEN Int'l Co., Ltd. v. Uniclass Tech. Co.*, 932 F.3d 1364, 1367 (Fed. Cir. 2019) (“Anticipation and infringement are questions of fact that we review for substantial evidence. Whether a reference is prior art is a question of law based on underlying factual questions.” (citations omitted)).

<sup>149</sup> See *id.*; see also *Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1301 (Fed. Cir. 2002) (“Whether a prior art reference is enabling is a question of law based upon underlying factual findings.”).

### A. Question of Fact in Anticipation

The issue of invalidity based on anticipation is presented to the jury. Using *Eagle View Technologies, Inc. v. Xactware Solutions, Inc.*<sup>150</sup> as an example, the issue of invalidity was presented to the jury in yes or no form. The following provides the executed portion of the jury verdict form, in which the jury found the claims not to be invalid as anticipated:

<p><b><u>'840 Patent</u></b></p> <p><b>Question 7.</b> Do you find that Xactware and Verisk have proven by clear and convincing evidence that Claim 10 of the '840 Patent is invalid as anticipated by the prior art presented?</p> <p>___ Yes (for Xactware and Verisk)    <input checked="" type="checkbox"/> No (for EagleView)</p>
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Figure 5. Example jury verdict form.<sup>151</sup>

The yes or no nature of the anticipation questionnaire in the jury verdict form has been upheld for anticipation-invalidity analysis so long as the jury instruction form is not clearly erroneous and does not have a prejudicial effect.<sup>152</sup> Moreover, on appeal, a judge's ruling on a JMOL is reviewed using the substantial evidence standard previously discussed, such that a jury verdict in favor of the burdened party will be upheld if supported by substantial evidence.<sup>153</sup> A verdict for the non-burdened party will be upheld unless a reasonable person could not have concluded that the burden was not met.<sup>154</sup> Making a substantial evidence determination in an anticipation analysis becomes difficult because the jury merely indicates yes or no without

<sup>150</sup> 485 F. Supp. 3d 505 (D.N.J. 2020).

<sup>151</sup> See Verdict Form at 4–6, *Eagleview*, 485 F. Supp. 3d 505 (D.N.J. 2019) (No. 1:15-CV-07025) [hereinafter *Eagleview* Verdict Form] (jury finding patent not to be invalid as anticipated).

<sup>152</sup> See *Sulzer Textil A.G. v. Picanol N.V.*, 358 F.3d 1356, 1363 (Fed. Cir. 2004) (“A jury verdict will be set aside, based on erroneous jury instructions, if the movant can establish that ‘those instructions were legally erroneous,’ and that ‘the errors had prejudicial effect.’” (quoting *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000))).

<sup>153</sup> See *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 974 (Fed. Cir. 2010) (writing that “[i]n our review of . . . JMOL, we are mindful of the fact that anticipation is a question of fact that we review for substantial evidence when tried to a jury” if the jury found for anticipation).

<sup>154</sup> See *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1356 (Fed. Cir. 2012) (stating jury verdict can be reversed only if “the facts and inferences point so strongly and overwhelmingly in favor of one party that the Court believes that reasonable men could not arrive at a contrary verdict”).

memorializing any meaningful analysis.<sup>155</sup> Similar to the case for obviousness, during an anticipation-invalidity analysis, the judge provides the law and rules on any post-trial motions, while the jury makes the ultimate determination of the question of fact issue of invalidity based on anticipation.<sup>156</sup>

## B. Question of Law in Anticipation

As previously discussed, whether a prior art reference is enabling is a question of law based on underlying factual questions.<sup>157</sup> As an example, in *Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc.*,<sup>158</sup> the Federal Circuit remanded the issue of whether a prior art reference was enabling.<sup>159</sup> In doing so, the Federal Circuit clarified that an anticipatory reference must enable a person of ordinary skill in the art to practice a claimed invention.<sup>160</sup> After the bench trial and on remand, considering briefs filed by both adversarial parties, the judge issued a final judgement order indicating the following:

WHEREAS, the Court issued its Memorandum Opinion concerning the above issues on July 19, 2007;

NOW THEREFORE, IT IS HEREBY ORDERED AND ADJUDGED that:

1. U.S. Patent No. 5,236,940 is not enabled, and therefore, is not an anticipatory reference for U.S. Patent No. 5,527,814.

Figure 6. Court order regarding enablement.<sup>161</sup>

Thus, on remand, a judge resolved the question of law with underlying factual considerations of whether a prior art reference was enabling by issuing

<sup>155</sup> See, e.g., *Eagleview Verdict Form*, *supra* note 151, at 5 (anticipation question was in yes or no format).

<sup>156</sup> See *id.*

<sup>157</sup> See *Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1301 (Fed. Cir. 2002) (“Whether a prior art reference is enabling is a question of law based upon underlying factual findings.”).

<sup>158</sup> 468 F.3d 1366 (Fed. Cir. 2007).

<sup>159</sup> See *id.*

<sup>160</sup> See *id.* at 1381 (“[An anticipatory] prior art reference must be enabling so that the claimed subject matter may be made or used by one skilled in the art. Prior art is not enabling . . . if it does not enable a person of ordinary skill in the art to carry out the invention.” (inner citation omitted)).

<sup>161</sup> Final Judgment Order at 1, *Impax Lab’ys., Inc. v. Aventis Pharm. Inc.*, 496 F. Supp. 2d 428 (D. Del. 2007) (No. 1:02-CV-581(JJF)) (ordering that the prior art reference was not enabled).

an order after considering briefs submitted by both sides.<sup>162</sup> Although this example for enablement of an anticipatory reference is specific to a bench trial, this Article argues that the mixed question of obviousness should be similarly resolved, exclusively by a judge, in both jury and bench trials.

## VII. Conclusion: What Should be the Role of a Jury Compared to That of a Judge in an Obviousness Analysis?

As the foregoing has illustrated, the right to a federal jury trial is protected under the Constitution.<sup>163</sup> *Markman* maintained that if a particular issue satisfies two tests, namely, the “historical test” and the “substance of the common-law right test,” then the issue should be afforded a jury trial.<sup>164</sup> Under the “historical test,” a court will determine whether a cause of action, such as obviousness, was tried at law at the time of the adoption of the Bill of Rights or is at least analogous to one that was.<sup>165</sup> Under the “substance of the common-law right” test, a court will ask whether the issue must fall to the jury in order to preserve the substance of the common-law right as it existed in 1791.<sup>166</sup> In ascertaining the substance of the common-law right, courts have distinguished between procedural and substantive issues, as well as between issues of fact and issues of law.<sup>167</sup>

As to the “historical test,” the first mention of obviousness in the United States came in *Evans v. Eaton*,<sup>168</sup> where the Court indicated that inventions are not patentable in light of prior art if they are the same in principle, and merely differ in form and proportion.<sup>169</sup> In *Hotchkiss v. Greenwood*,<sup>170</sup> the Supreme Court introduced the concept of refusing to grant a patent on obviousness

<sup>162</sup> *See id.* (judge issued order without holding a jury trial).

<sup>163</sup> *See* U.S. CONST. amend. VII (“In suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved”).

<sup>164</sup> *See* *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 376 (1996).

<sup>165</sup> *See id.*

<sup>166</sup> *See id.*

<sup>167</sup> *See id.* at 378 (“The ‘substance of the common-law right’ is, however, a pretty blunt instrument for drawing distinctions. We have tried to sharpen it, to be sure, by reference to the distinction between substance and procedure. We have also spoken of the line as one between issues of fact and law.” (inner citations omitted)).

<sup>168</sup> 16 U.S. 454 (1818) (decided decades after ratification of the Bill of Rights).

<sup>169</sup> *See id.* at 475 (“As to what constitutes an improvement, it is declared, that it must be in the principle of the machine, and that a mere change in the form or proportions of any machine shall not be deemed a discovery.”).

<sup>170</sup> 52 U.S. 248 (1850).

grounds.<sup>171</sup> Indeed, both *Evans* and *Hotchkiss* were decided after the ratification of the Bill of Rights in 1791, such that the issue of obviousness was not in existence and certainly not afforded a jury trial when the Bill of Rights was ratified. In fact, the statutory obviousness requirement was not introduced until the year 1952.<sup>172</sup> Although obviousness may be analogized to novelty, the Court has maintained that obviousness and novelty are separate prongs to patentability.<sup>173</sup> Accordingly, obviousness fails to satisfy the historical test.

On the other hand, obviousness was an issue requiring a jury trial to preserve the substance of the common-law right as it existed in 1791 because the substance of the common-law right applied to issues of invention.<sup>174</sup> Therefore, obviousness falls within of the scope of the common-law right of issues related to inventions.<sup>175</sup> Because obviousness fails to satisfy the historical test, but is within the scope of the common-law right of issues related to inventions, the “historical test” and the “substance of the common-law right test” fail to provide the same answer as to whether obviousness is an issue that should be afforded a jury trial.

To avoid the confusion that surrounds making the obviousness-invalidity analysis explicit, the mixed question of obviousness should be treated like the issue of claim construction, given that both issues fail to satisfy either test for requiring a jury trial.<sup>176</sup> This confusion is evident by the Federal Circuit reminding district courts to not ignore the factual inquiries of the *Graham* factors, which the Federal Circuit has indicated it has no evidence or power to make, yet are required by the Supreme Court to be made explicit.<sup>177</sup> However, given the lack of meaningful record memorialized by the jury regarding the

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<sup>171</sup> See *id.* at 257 (“There are some cases of the application of old inventions to obvious new uses for which courts have refused to sustain a patent.”).

<sup>172</sup> See Patent Act of 1952, ch. 950, § 103, 66 Stat. 792, 798 (codified as amended at 35 U.S.C. § 103).

<sup>173</sup> See *Bilski v. Kappos*, 561 U.S. 593, 609 (2009) (“In order to receive patent protection, any claimed invention must be novel, § 102, nonobvious, § 103, and fully and particularly described, § 112.”).

<sup>174</sup> See, e.g., *Newell Cos., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 774–77 (Fed. Cir. 1988).

<sup>175</sup> See *id.* at 777 (“It is not available to two judges of this court to overrule two centuries of constitutional right, simply by redefining a protected jury question as one of pure law independent of its factual components, proposing thereby to remove the [obviousness] question from jury verdict.”).

<sup>176</sup> See *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 376 (1996) (after walking through the two tests, reaffirming that “construing the patent [claims], is a question of law, to be determined by the court”).

<sup>177</sup> See, e.g., *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1380 (Fed. Cir. 2012) (“This court, as an appellate court, may not make the required *Graham* factual findings, and must therefore remand that determination to the district court. The district court should not ignore

areas of factual inquiry of *Graham*, district courts are also unable to ascertain the factual inquiries of the *Graham* factors made by the jury.

As previously discussed, modifying jury instructions to include yes or no questions concerning the jury's findings on each of the *Graham* factors is not a plausible solution.<sup>178</sup> Another solution is a legislative overhaul by Congress to modify 35 U.S.C. § 103 in such a manner that does not require the *Graham* factors and makes obviousness purely a question of law or fact. However, elected officials fail to agree on many issues to achieve meaningful changes, especially in a field like patent law.<sup>179</sup>

The necessary solution is for the Supreme Court to grant certiorari to an obviousness challenge, and overturn *Graham* upon the realization that the requirement that the analysis of the *Graham* factors be made explicit is near impossible. In doing so, the Supreme Court should explicitly rule that obviousness is not a determination requiring a jury trial under the Seventh Amendment. Indeed, a judge may be in a better position to determine obviousness for at least the reasons referenced in *Markman* regarding the issue of claim construction.<sup>180</sup>

Moreover, if review of the issue of a mixed question, such as obviousness, is based on whether the issue involves mostly factual or mostly legal determinations,<sup>181</sup> then by analogy it is plausible that the entity tasked with resolving the substance of the issue should turn on whether the issue involves mostly factual or legal determinations. In other words, if the determination of a mixed question, such as obviousness, involves a mostly factual analysis, a jury may resolve the mixed question; on the other hand, if the determination of the mixed question involves a mostly legal analysis, a judge may resolve the

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the four-part analysis the authorities require.” (quoting *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 449 (Fed. Cir. 1986)).

<sup>178</sup> See *supra* Section IV.C.

<sup>179</sup> See *Statistics and Historical Comparison*, GovTRACK, <https://www.govtrack.us/congress/bills/statistics> (last visited Aug. 26, 2022) [<https://perma.cc/C2DJ-46XN>] (indicating that about 2% of legislation was enacted as law between the periods of January 3, 2019, and January 3, 2021).

<sup>180</sup> See *Markman*, 517 U.S. at 388–89 (noting that certain issues require “special training and practice,” while the “judge, from his training and discipline, is more likely to give a proper interpretation to such instruments than a jury; and he is, therefore, more likely to be right, in performing such a duty, than a jury can be expected to be”).

<sup>181</sup> See *U.S. Bank Nat. Ass’n ex rel. CWC Capital Asset Mgmt. LLC v. Vill. at Lakeridge, LLC*, 138 S. Ct. 960, 967 (2018) (“In short, the standard of review for a mixed question all depends—on whether answering it entails primarily legal or factual work.”); see also *Google LLC v. Oracle Am., Inc.*, 141 S. Ct. 1183, 1199–1200 (2021) (“In this case, the ultimate ‘fair use’ question primarily involves legal work. ‘Fair use’ was originally a concept fashioned by judges.”).

mixed question. In any case, the factual inquiry surrounding obviousness is a practice that is, at best, outdated and confusing, and at worst, impossible to satisfy by district courts and the Federal Circuit, and accordingly should be overturned.

# How Bad Men Provisions Provide Native American Women Relief from Violence and Sexual Assault

Danielle Alvarez\*

## Introduction

More than four out of every five Native American<sup>1</sup> and Alaska Native<sup>2</sup> women<sup>3</sup>—over 80%—have been victims of violence, and more than 50% have been sexually assaulted.<sup>4</sup> Native American and Alaska Native women are disparately impacted by violence and sexual assault and Native American women are more than twice as likely as women generally in the United States to be assaulted or the victims of other sexual crimes.<sup>5</sup> Native American women are nearly three times more likely to be raped or sexually assaulted than women of any other race.<sup>6</sup>

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<sup>1</sup> Although most modern literature and original legislation and treatises refer to Native Americans as “Indians” and use the terminology frequently, this Note will use “Native American,” with the exception of direct quotes from legislation and secondary sources.

<sup>2</sup> Native Americans and Alaska Natives are classified distinctly because of their geographical and cultural differences, but are subject to the same statutory and judicial schemes within the United States. See *Our Nation’s American Indian and Alaska Native Citizens*, U.S. DEP’T INTERIOR INDIAN AFFS., <https://www.bia.gov/frequently-asked-questions> [<https://perma.cc/7NLM-GA94>] (last visited Mar. 21, 2022).

<sup>3</sup> This Note focuses on the use of Bad Man provisions with respect to sexual assault and violence specifically against Native American women. Bad Man provisions apply to all Native Americans, not just women, and all individuals can be the victims of such violence. This Note focuses solely on female victims and their experiences due partially to the substance of the precedent and the extreme frequency with which Native American women suffer.

<sup>4</sup> See *Research Policy Update*, NCAI POL’Y RSCH. CTR. (Feb. 2018) [https://www.ncai.org/policy-research-center/research-data/prc-publications/VAWA\\_Data\\_Brief\\_FINAL\\_2\\_1\\_2018.pdf](https://www.ncai.org/policy-research-center/research-data/prc-publications/VAWA_Data_Brief_FINAL_2_1_2018.pdf) [<https://perma.cc/664Z-MQKK>]; *Ending Violence Against Native Women*, INDIAN L. RES. CTR., <https://indianlaw.org/issue/Ending-Violence-Against-Native-Women> [<https://perma.cc/A9CJ-DB4U>] (last visited Mar. 21, 2022).

<sup>5</sup> See *Research Policy Update*, *supra* note 4.

<sup>6</sup> See Ronet Bachman et al., *Violence Against American Indian and Alaska Native Women and the Criminal Justice Response: What is Known*, NCJRS 33 (Aug. 2008), <https://www.ncjrs.org>.

There are several potential explanations for the high and disparate levels of violence against Native American and Alaska Native women, including the lack of tribal criminal jurisdiction over non-Native Americans.<sup>7</sup> Non-Native Americans who live both on and off of reservations commit most of the sexual violence against Native American women.<sup>8</sup> Because tribal courts historically lacked jurisdiction over non-Native Americans, these perpetrators faced little to no repercussions within the reservations.<sup>9</sup> Worse, due to judicial and legislative action manipulating tribal jurisdiction, Native American women often lack an adequate means of recourse, leaving many crime victims silent.<sup>10</sup>

Although tribal courts no longer completely lack jurisdiction over non-Native Americans, it is unclear whether partial tribal jurisdiction will provide sufficient relief given its recency and uncertain coverage over perpetrators unacquainted with their Native American victims.<sup>11</sup> Nine treaties with the United States, dating back to 1868, may provide federal equitable relief to the women of twelve tribes.<sup>12</sup> Bad Man provisions contained in these treaties provide victims of violence with a cause of action and sufficient equitable relief against previously untouchable perpetrators.<sup>13</sup> The U.S. federal government gave Native American victims causes of action against perpetrators and

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gov/pdffiles1/nij/grants/223691.pdf [https://perma.cc/N997-HGWW].

<sup>7</sup> See *A Roadmap for Making Native America Safer*, INDIAN L & ORD. COMM'N ix (2013) [https://www.aisc.ucla.edu/iloc/report/files/A\\_Roadmap\\_For\\_Making\\_Native\\_America\\_Safer-Full.pdf](https://www.aisc.ucla.edu/iloc/report/files/A_Roadmap_For_Making_Native_America_Safer-Full.pdf) [https://perma.cc/4MVW-CYK4] (discussing problems like the confusing division of responsibility between tribal, federal, and state officials, insufficient programming and services for Native Americans, and jurisdictional issues and proposing solutions to Native American law issues).

<sup>8</sup> See *Ending Violence Against Native Women*, *supra* note 4 (finding that 96% of the sexual violence committed against Native American women is done by non-Native Americans and that non-Native Americans make up 76% of the population on Native American reservations).

<sup>9</sup> See *Oliphant v. Suquamish Indian Tribe*, 435 U.S. 191, 191 (1978) (“Indian tribal courts do not have inherent criminal jurisdiction to try and to punish non-Indians . . .”). Tribes subsequently lacked any criminal jurisdiction over non-Native Americans until the 2022 reauthorization of the Violence Against Women Act, under Title VIII. However, this act does not grant full criminal jurisdiction and still protects some non-Native American individuals from tribal criminal jurisdiction and only confers criminal jurisdiction over certain covered crimes. See *Violence Against Women Act Reauthorization of 2022*, Pub. L. No. 117-103, § 804, 136 Stat. 49 (2022).

<sup>10</sup> See *Bachman et al.*, *supra* note 6, at 97.

<sup>11</sup> See *supra* note 9.

<sup>12</sup> See, e.g., *Elk v. United States*, 87 Fed. Cl. 70, 98 (2009) (finding Bad Man provision claim sufficient to hold federal government monetarily liable to Native American woman sexually assaulted by individual beyond tribal jurisdiction).

<sup>13</sup> See, e.g., *Hebah v. United States*, 428 F.2d 1334, 1338 (Ct. Cl. 1970) (finding Bad Man provision claim available in suits against individuals beyond tribal jurisdiction).

pledged to compensate individual tribal members for any wrong committed by “Bad Men” subject to U.S. authority, including U.S. citizens and non-member Native Americans.<sup>14</sup>

Legal scholars have contested Bad Man provisions utility primarily because of the financial obligations they impose upon the federal government.<sup>15</sup> Some scholars have contested Bad Man provisions by questioning the use of federal funds to compensate Native American victims of crime.<sup>16</sup> Others view these provisions as a promising avenue for recourse.<sup>17</sup> The applicability, expiration, and scope of such provisions have been challenged and adjudicated, and only a few plaintiffs have successfully raised Bad Man provision claims.<sup>18</sup> Although there have been legislative attempts to remedy the lack of sufficient recourse, Native American women remain incredibly vulnerable and lack sufficient protections and relief.<sup>19</sup>

This Note argues that the Federal Circuit should apply Bad Man provisions to grant equitable relief to *all* Native American women who are victims of sexual assault by any individuals under the authority of the United States, regardless of whether their tribes have treaties containing such provisions. The Federal Circuit should consider legislative history, subsequent legislation, and language to find that Congress intended Bad Man provisions to serve as the model for providing federal equitable relief to all Native American tribe members. Extending this coverage to women from all Native American tribes who have been the victims of violence by non-Native American perpetrators would provide them with a sufficient means of legitimate recourse.

Part I of this Note presents background on Bad Man provisions, the evolution of tribal jurisdiction, and the trajectory of Bad Man provision use. Using case law and legislative history, Part II assesses the possibility of raising Bad Man provision claims in sexual assault suits and treating Bad Man provision language as the standard for providing equitable relief to Native American tribes. Finally, Part III recommends that the Federal Circuit construe Bad

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<sup>14</sup> *E.g.*, Treaty Between the United States of America and Different Tribes of Sioux Indians, art. I, Apr. 29, 1868, 15 Stat. 635 [hereinafter Treaty with the Sioux Indians]. Bad Man provisions address and are named after the actors the provisions discuss—bad men, or bad actors generally.

<sup>15</sup> See Lillian Marquez, Note, *Making “Bad Men” Pay: Recovering Pain and Suffering Damages for Torts on Indian Reservations Under the Bad Men Clause*, 20 FED. CIR. B.J. 609, 609 (2011) (asserting that federal government liability for acts by Bad Men is improper use of taxpayer money).

<sup>16</sup> *See id.*

<sup>17</sup> *See A Bad Man Is Hard to Find*, 127 HARV. L. REV. 2521, 2542 (2014).

<sup>18</sup> *See Tsosie v. United States*, 825 F.2d 393, 400 (Fed. Cir. 1987) (finding lack of use of Bad Man provision claims and their antiquity did not render them expired or inapplicable).

<sup>19</sup> *See A Roadmap for Making Native America Safer*, *supra* note 7, at viii.

Man provisions as applicable to sexual violence claims brought by any tribal member.<sup>20</sup> Doing so would help deter the egregious treatment of Native American women by imposing liability on the federal government and provide victims of sexual assault and violence with sufficient relief.

## I. Background

Congress included Bad Man provisions in the 1868 treaties with twelve tribes<sup>21</sup> in an attempt to mitigate the brutal and inhumane harm inflicted on Native Americans, specifically Native American women, by American soldiers.<sup>22</sup> However, the relief provided is only available to members of the twelve tribes and claims have only been raised a select number of times.<sup>23</sup> Courts have not had many opportunities to review the Bad Man provisions; however, the treatment of such claims in those rare cases illustrates how a judicial response to tribal jurisdictional and criminal issues could prove effective.

### A. The Evolution of Tribal Jurisdiction, or the Lack Thereof

Nine federal treaties from 1868, covering twelve tribes, include Bad Man provisions.<sup>24</sup> These provisions provide that the U.S. federal government is liable for damages caused by harmful conduct to tribal members by “bad men . . . subject to the authority of the United States,”<sup>25</sup> which encompasses

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<sup>20</sup> See *Tsosie*, 825 F.2d at 403.

<sup>21</sup> See Talli Nauman, ‘Bad Men’ Treaty Provision Invoked in Abuse Cases, NATIVE SUN NEWS TODAY (Dec. 18, 2018), <https://www.indianz.com/News/2018/12/18/native-sun-news-today-bad-men-treaty-pro.asp> [<https://perma.cc/D7WX-85LH>] (listing the twelve tribes with treaties containing Bad Man provisions: Kiowa, Comanche, Cheyenne, Arapahoe, Ute, Sioux, Crow, Northern Cheyenne, Northern Arapaho, Navajo, Eastern Band Shoshoni, and Bannock).

<sup>22</sup> The condition of the tribes, as reported in the Doolittle Report, was issued in 1867, just one year before the effectuation of the nine treaties with Bad Man provisions. This report indicated the existence of brutality and inhumane treatment of Native Americans, especially by U.S. soldiers. The mistreatment of Native American women was of particular note. This extensive report likely instigated the inclusion of Bad Man provisions in treaties. See S. REP. NO. 39-156 (1867).

<sup>23</sup> Bad Man provision claims have only been raised before the Federal Circuit six times since 1987. See *Ballard v. United States*, 680 F. App’x 1007 (Fed. Cir. 2017); *Flying Horse v. United States*, 696 F. App’x 495 (Fed. Cir. 2017); *Jones v. United States*, 846 F.3d 1343 (Fed. Cir. 2017); *Kenyon v. United States*, 683 F. App’x 945 (Fed. Cir. 2017); *Richard v. United States*, 677 F.3d 1141 (Fed. Cir. 2012); *Tsosie v. United States*, 825 F.2d 393, 400 (Fed. Cir. 1987).

<sup>24</sup> See, e.g., *Treaty with the Sioux Indians*, art. I, Apr. 29, 1868, 15 Stat. 635.

<sup>25</sup> *Id.* (asserting that the federal government will be liable for damages to any Native Americans for damage done to themselves or their property by “bad men among the whites,

both federal officials and any citizen of the United States, therefore under the federal government's authority.<sup>26</sup>

Years of legislative and judicial action have altered tribal jurisdiction. Despite attempted resolutions like the Violence Against Women Act Reauthorization of 2013<sup>27</sup> and the Tribal Law and Order Act,<sup>28</sup> gaping holes in tribal jurisdiction remained. Even legislation that brought non-Native American criminal conduct within the jurisdiction of the United States, like the Major Crimes Act,<sup>29</sup> has been insufficient in remedying the lack of protections against non-Native American criminal violence against Native American women.<sup>30</sup> The legislative remedies' insufficient coverage of acts of sexual violence and inability to recreate previously existing tribal jurisdiction render them ineffective.<sup>31</sup>

The Violence Against Women Act Reauthorization of 2022 attempted to bridge the gaps in tribal criminal jurisdiction over nonmember Native Americans and non-Native Americans for all crimes of sexual violence; however, it is unclear whether the provisions cover sexual assault and violence committed by individuals who are unacquainted with the Native American

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or among other people subject to the authority of the United States" or "bad men among the Indians").

<sup>26</sup> See *Richard*, 677 F.3d at 1150.

<sup>27</sup> See Violence Against Women Act Reauthorization of 2013, Pub. L. No. 113-4, § 204, 127 Stat. 120 (2013) (expired 2019). The Violence Against Women Act was amended and reauthorized in 2013 and included Title IX: Safety for Native American Women. See *id.* Although the intent was to increase protections for Native American women, the act did not cover crimes between individuals without a preexisting relationship. See *id.* A great deal of the attacks on Native American women are done by individuals with whom Native American women do not have the requisite preexisting relationships with and thus remain beyond tribal jurisdiction. See *id.*

<sup>28</sup> See Tribal Law and Order Act of 2010, Pub. L. No. 111-211, tit. II, 124 Stat. 2261 (codified in scattered sections of the U.S. Code). The Tribal Law and Order Act, like the Violence Against Women Act Reauthorization of 2013, attempted to rectify tribal jurisdiction but was insufficient. The adjustments made were minor and did not effectuate real change for tribes. See *id.* The 2013 reauthorization of the Violence Against Women Act expired in 2019 and was replaced by an arguably more sufficient version in 2022. See Violence Against Women Act Reauthorization of 2022, Pub. L. No. 117-103, § 804, 136 Stat. 49 (2022).

<sup>29</sup> See Major Crimes Act, 18 U.S.C. § 1153 (2018).

<sup>30</sup> See generally Jasmine Owens, "Historic" In a Bad Way: How the Tribal Law and Order Act Continues the American Tradition of Providing Inadequate Protection to American Indian and Alaska Native Rape Victims, 102. J. CRIM. L. & CRIMINOLOGY 497 (2012).

<sup>31</sup> See Violence Against Women Act Reauthorization of 2013, Pub. L. No. 113-4, § 204, 127 Stat. 120 (2013) (expired 2019).

victims.<sup>32</sup> Additionally, it is unclear how effective this attempted remedy will be in practice given the recency of the reauthorization.

Although the need to provide further tribal jurisdiction may have been partially resolved by the Violence Against Women Act Reauthorization of 2022, sufficient equitable relief will still be necessary for Native American women. Bad Man provisions provide Native American claimants with some monetary relief from wrongdoing by those under the authority of the United States.<sup>33</sup> Therefore, Native American women who have suffered from sexual assault and violence may invoke such provisions as a means of circumventing the lack of other sufficient remedies available for their suffering.<sup>34</sup> Further, the lack of cases involving violence against Native American women before the Court of Federal Claims or the Federal Circuit is indicative of the obstacles that bar Native American women from raising more suits.<sup>35</sup>

The major gaps in tribal jurisdiction contributed to the heightened frequency of sexual violence against Native American women because tribes could not adequately and effectively deter assaulters.<sup>36</sup> Issues involving reservation lines and sources of authority responsible for addressing certain criminal incidents convolute access to judicial action for female victims.<sup>37</sup> The Supreme Court has allowed each tribe to retain exclusive jurisdiction over all criminal and civil cases arising within their reservations among their members.<sup>38</sup> While tribal jurisdiction over its members is the most straightforward aspect of tribal jurisdiction, even jurisdiction over member Native Americans has been altered by legislation.<sup>39</sup> For example, the Major Crimes Act specifies certain criminal conduct that brings perpetrators within U.S. federal jurisdiction, regardless of whether the perpetrator is a member Native

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<sup>32</sup> See Violence Against Women Act Reauthorization of 2022, Pub. L. No. 117-103, § 804, 136 Stat. 49 (2022).

<sup>33</sup> See, e.g., *Treaty with the Sioux Indians*, art. I, Apr. 29, 1868, 15 Stat. 635. Bad Man provisions provide that the federal government would be liable to Native Americans for monetary damages but do not make such men subject to tribal jurisdiction. See *id.* at arts. I–II.

<sup>34</sup> See *Tsosie v. United States*, 825 F.2d 393, 400 (Fed. Cir. 1987).

<sup>35</sup> The only Bad Man provision claim that the Federal Circuit has heard regarding sexual assault or violence was in 1987 and the Federal Court of Claims has only heard Bad Man provision claims in two cases regarding sexual assault. See *Tsosie*, 825 F.2d 393; *Pablo v. United States*, 98 Fed. Cl. 376 (Fed. Cl. 2011); *Elk v. United States*, 87 Fed. Cl. 70 (Fed. Cl. 2009).

<sup>36</sup> See *A Roadmap for Making Native America Safer*, *supra* note 7, at vii.

<sup>37</sup> See *id.*

<sup>38</sup> See *Talton v. Mayes*, 163 U.S. 376, 380 (1896) (establishing exclusive tribal jurisdiction over member Native Americans).

<sup>39</sup> See Major Crimes Act, 18 U.S.C. § 1153(a) (2018).

American.<sup>40</sup> Such insufficient tribal jurisdiction illustrates the need for further assistance through Bad Man provisions.

### ***1. Legislative and Judicial Removal of Tribal Criminal Jurisdiction***

Tribes originally had inherent sovereign authority and both civil and criminal jurisdiction over all conduct and individuals in their territory.<sup>41</sup> In 1817, Congress substantially reduced tribal criminal jurisdiction by enacting the Indian Country Crimes Act.<sup>42</sup> The legislature extended federal jurisdiction by stripping tribes of jurisdiction over crimes committed by Native Americans against non-Native Americans, and those committed by non-Native Americans on tribal land.<sup>43</sup> In *United States v. McBratney*,<sup>44</sup> the Supreme Court marginally reduced federal jurisdiction over non-Native American-on-non-Native American crimes occurring on reservations by asserting that the states retained such jurisdiction, further diminishing tribal jurisdiction.<sup>45</sup> In 1883, in *Ex Parte Crow Dog*,<sup>46</sup> the petitioner raised a Bad Man provision claim to fight federal criminal jurisdiction over Native American-on-Native American crimes.<sup>47</sup> The Court viewed Native American-on-Native American crimes as beyond the scope of federal jurisdiction, despite the mention of “bad men among the Indians” in the Sioux Treaty’s Bad Man provision.<sup>48</sup> The Court prioritized tribal self-governance with this expansive interpretation of tribal jurisdiction.<sup>49</sup>

The Supreme Court’s decision in *Ex Parte Crow Dog*, favoring tribal jurisdiction over crimes perpetrated by Native Americans on tribal lands, prompted

<sup>40</sup> *See id.*

<sup>41</sup> *See* Tribal L. & Pol’y Inst., *General Guide to Criminal Jurisdiction in Indian Country*, TRIBAL CT. CLEARINGHOUSE, <https://www.tribal-institute.org/lists/jurisdiction.htm> [<https://perma.cc/THS2-XC7T>] (last visited Mar. 22, 2022).

<sup>42</sup> *See* General Crimes Act, 18 U.S.C. § 1152 (2018). The Indian Country Crimes Act and the General Crimes Act are the same legislation under different guises.

<sup>43</sup> *See id.*

<sup>44</sup> 104 U.S. 621 (1881).

<sup>45</sup> *See id.* at 624.

<sup>46</sup> 109 U.S. 556 (1883).

<sup>47</sup> *See id.* at 563.

<sup>48</sup> *Id.* The Court wrote:

If bad men among the Indians shall commit a wrong or depredation upon the person or property of any one . . . subject to the authority of the United States . . . the Indians herein named solemnly agree that they will . . . deliver up the wrong-doer to the United States, to be tried and punished according to its laws.

*Id.* (quoting *Treaty with the Sioux Indians*, art. I, Apr. 29, 1868, 15 Stat. 635).

<sup>49</sup> *See id.* at 568.

Congress to pass the Major Crimes Act in 1885.<sup>50</sup> The Major Crimes Act automatically brought seven criminal acts within federal criminal jurisdiction.<sup>51</sup> Congress later expanded the scope of the Major Crimes Act to include thirteen criminal acts.<sup>52</sup>

The Major Crimes Act, Congress's harsh and prompt response to *Ex Parte Crow Dog*, was challenged before the Supreme Court within a year.<sup>53</sup> The Major Crimes Act was viewed as an extreme response to the Supreme Court's decision to uphold tribal jurisdiction over crimes that Congress deemed too unforgiving to be left to the tribes.<sup>54</sup> A split between the circuit and district judges in the Circuit Court for the District of California regarding the constitutionality of Congress's expansion of federal jurisdiction, through the Major Crimes Act, over wholly Native American crimes brought the case before the Supreme Court by a certificate of division.<sup>55</sup> In *United States v. Kagama*,<sup>56</sup> the U.S. federal government prosecuted two Native Americans under the Major Crimes Act, although both perpetrators were members of the same tribe as their victim and the crime was committed within tribal land.<sup>57</sup> Despite the Major Crimes Act's direct conflict with the Court's own ruling in *Ex Parte Crow Dog*, the Court upheld the Act as constitutional in *Kagama*.<sup>58</sup> The Court affirmed the validity of the Major Crimes Act because of its prior ruling that Congress retains the ability to alter tribal jurisdiction.<sup>59</sup> The Court's deci-

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<sup>50</sup> See U.S. DEP'T OF JUSTICE, CRIMINAL RESOURCE MANUAL § 667 (2020), <https://www.justice.gov/archives/jm/criminal-resource-manual-679-major-crimes-act-18-usc-1153> [<https://perma.cc/639M-AK7Y>].

<sup>51</sup> See Major Crimes Act, 18 U.S.C. § 1153(a) (2018) (“[M]urder, manslaughter, kidnapping, maiming, . . . incest, . . . assault against an individual who has not attained the age of 16 years, felony child abuse or neglect, arson, burglary, robbery, and a felony under section 661 . . . within [Indian] country, shall be . . . within the exclusive jurisdiction of the United States.”).

<sup>52</sup> See *id.*

<sup>53</sup> See *United States v. Kagama*, 118 U.S. 375 (1886) (upholding the Major Crimes Act as constitutional).

<sup>54</sup> See, e.g., Sidney L. Harring, *Crow Dog's Case: A Chapter in the Legal History of Tribal Sovereignty*, 14 AM. INDIAN L. REV. 191, 192–93 (1989); James W. King, *The Legend of "Crow Dog": An Examination of Jurisdiction Over Intra-Tribal Crimes Not Covered by the Major Crimes Act*, 52 VAND. L. REV. 1479, 1480 (1999).

<sup>55</sup> See *id.*

<sup>56</sup> 118 U.S. 375 (1886).

<sup>57</sup> *Id.* at 377.

<sup>58</sup> See *id.* at 385.

<sup>59</sup> See *id.* at 379–80 (“The territorial governments owe all their powers to the statutes of the United States conferring on them the powers which they exercise, and which are liable to be withdrawn, modified, or repealed at any time by Congress.”).

sion also confirmed Congress's ability to alter tribal jurisdiction again in the future.<sup>60</sup> The Court maintained that although tribes retain the authority to control their internal affairs, tribes cannot be solely under their own authority given their dependence upon the United States.<sup>61</sup>

Congress derives its authority to alter tribal jurisdiction from the Commerce Clause of the Constitution<sup>62</sup> and the fiduciary relationship between the United States and the tribes, which has yet to be dismantled.<sup>63</sup> Supreme Court holdings have continued to create federal criminal jurisdiction over Native Americans committing certain crimes, even if committed within tribal country, against other Native Americans, and ordinarily within tribal jurisdiction.<sup>64</sup>

At first glance, removing jurisdiction from the tribes to the federal government may seem beneficial to Native American women because the government has greater power and resources; however, because the Major Crimes Act does not provide for federal jurisdiction over sexual misconduct or violence against Native American women, Native American women have not significantly benefited from federal jurisdiction.<sup>65</sup> The Major Crimes Act stripped tribes of jurisdiction over non-Native Americans but did not bring non-Native American perpetrators of sexual assault and violence against Native American women within the federal government's jurisdiction.<sup>66</sup> This left female Native

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<sup>60</sup> See *id.* By finding that the authority to adjust tribal jurisdiction is vested in Congress, the Court set the precedent for future and continued congressional manipulation. See *id.* at 383.

<sup>61</sup> See *id.* at 381–82 (“[The tribes] were . . . [in] a semi-independent position . . . not as states, not as nations . . . but as a separate people, with the power of regulating their internal and social relations, and . . . not brought under the laws of the Union or . . . the state within whose limits they resided.”).

<sup>62</sup> See U.S. CONST. art. 1 § 8, cl. 3 (“Congress shall have the power to regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.”); see also *Cherokee Nation v. Hitchcock*, 187 U.S. 294, 306 (1902) (affirming Congress’s plenary authority over tribal jurisdiction and authority).

<sup>63</sup> The United States and the tribes have been deemed to have a guardian-ward relationship, reflective of the obligation that the federal government owes to tribes as dependent and subordinate nations. See *Cherokee Nation v. Georgia*, 30 U.S. 1, 2 (1831) (“[The tribes’] relations to the United States resemble that of a ward to his guardian. They look to our government for protection; rely upon its kindness and its power; appeal to it for relief to their wants; and address the President as their great father.”). This notion of a guardian-ward relationship has been repeatedly upheld by the Court. See, e.g., *United States v. Sandoval*, 231 U.S. 28, 32 (1913); *United States v. Kagama*, 118 U.S. 375, 382 (1886).

<sup>64</sup> See *Kagama*, 118 U.S. at 381.

<sup>65</sup> See Major Crimes Act, 18 U.S.C. § 1153 (2018).

<sup>66</sup> See *id.*; see also Jordan Gross, *Let the Jury Fit the Crime: Increasing American Indian Jury Pool Representation in Federal Judicial Districts with Indian Country Criminal Jurisdiction*, 77 MONT. L. REV. 281, 287 (2016).

American victims of sexual assault and violence by non-Native Americans without due recourse against non-Native American perpetrators.

Congress further reduced tribal criminal jurisdiction through the enactment of the Assimilative Crimes Act in 1948.<sup>67</sup> The Assimilative Crimes Act confers criminal jurisdiction to the federal government over any state law violations occurring on tribal land.<sup>68</sup> The Act's intended purpose was to create federal jurisdiction over conduct on tribal land over crimes that were only not otherwise violations of federal law.<sup>69</sup> Without the application of state laws, the states and federal government would not have had jurisdiction over such conduct.<sup>70</sup> This Act, therefore, furthered the removal of tribal criminal jurisdiction and diminished tribes' ability to seek justice for their members.

## ***2. Removal of Tribal Criminal Jurisdiction Over Non-Native Americans***

The removal of tribal jurisdiction over non-Native Americans greatly impacted Native American women because acts of sexual assault and violence against Native American women are most often perpetrated by non-Native Americans.<sup>71</sup> In 1978, the Supreme Court stripped tribes of criminal jurisdiction over non-Native Americans in *Oliphant v. Suquamish Indian Tribe*.<sup>72</sup> The Court found for the two non-Native American petitioners, holding that the tribe did not have jurisdiction over non-Native Americans regardless of the location of their crime or the status of their victims.<sup>73</sup> The Court viewed the tribes as "quasi-sovereign entities"<sup>74</sup> and viewed congressional silence on this particular issue as a presumption against tribal jurisdiction over non-Native Americans because Congress must affirmatively state that it intends to alter tribal authority to do so.<sup>75</sup> The Court held that tribes do not have the authority to exercise jurisdiction over any non-Native American defendants, regardless of whether the victim is a member Native American and the

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<sup>67</sup> See Assimilative Crimes Act, 18 U.S.C. § 13 (2018).

<sup>68</sup> See *id.*; see also U.S. DEP'T OF JUSTICE, *supra* note 50.

<sup>69</sup> See U.S. DEP'T OF JUSTICE, *supra* note 50 (asserting that Congress used this statute as a substitute when no local law was on point for the federal government to use to prosecute criminals).

<sup>70</sup> See *id.*

<sup>71</sup> See Stephen Fee & Lisa Brunner, *Above the Law: Responding to Domestic Violence on Indian Reservations*, PBS NEWS HOUR WEEKEND (Nov. 22, 2014, 12:19 PM), <https://www.pbs.org/newshour/show/law-uneven-justice-seen-reservations-victims-domestic-violence> [<https://perma.cc/6CVW-8HSW>].

<sup>72</sup> 435 U.S. 191 (1978).

<sup>73</sup> See *id.* at 212.

<sup>74</sup> *Id.* at 196.

<sup>75</sup> See *id.* at 206, 212.

criminal conduct in question occurred on tribal land, and created a general presumption against tribal jurisdiction over non-Native Americans.<sup>76</sup> In doing so, the Court honed in on the dependency of the tribes and ruled despite a lack of supporting law or treaty language.<sup>77</sup>

### ***3. The Debate on Tribal Criminal Jurisdiction over Nonmember Native Americans***

Twelve years after upholding the Major Crimes Act, the Supreme Court further stripped tribes of jurisdiction by removing tribal jurisdiction over nonmember Native Americans in *Duro v. Reina*.<sup>78</sup> The Court reasoned that the mere status of Native American should not equate to consent to any tribe's criminal jurisdiction.<sup>79</sup>

Congress responded to the judicial usurpation of tribal jurisdiction over nonmember Native Americans in *Duro v. Reina* with an amendment to the 1968 Indian Civil Rights Act, the “*Duro-Fix*” legislation.<sup>80</sup> In 1991, just one year after the Court decided *Duro*, Congress recognized and affirmed tribal authority to exercise criminal jurisdiction over all Native Americans, regardless of tribal membership, for crimes committed within that tribe's land.<sup>81</sup> This amendment has been deemed the “*Duro-Fix*” amendment because it purported to rectify the judicial error in *Duro* that restricted tribal jurisdiction over nonmember Native Americans for crimes effectuated within tribal lands.<sup>82</sup>

Tribal jurisdiction over all Native Americans, regardless of which tribe granted them membership status, has been deemed by the courts as an

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<sup>76</sup> See *id.* at 191.

<sup>77</sup> See Michael Leroy Oberg, *Oliphant v. Suquamish: Forty Years Ago Today*, NATIVE AM.: HIST. (Mar. 6, 2017), <https://michaelleroyoberg.com/uncategorized/oliphant-v-suquamish-thirty-eight-years-ago-today/#:-:text=And%20the%20consequences%E2%80%94of%20Oliphant,non%2Dmembers%20within%20their%20boundaries> [<https://perma.cc/UFK2-HFXS>] (noting that the Court made its conclusion “[w]ithout citing any evidence,” that it “cited little law” and “did not cite the Constitution”).

<sup>78</sup> 495 U.S. 676, 677 (1990).

<sup>79</sup> See *id.* at 678.

<sup>80</sup> See Indian Civil Rights Act, 25 U.S.C. § 1301 (1991) (1991 amendment to Indian Civil Rights Act named *Duro Fix* legislation because it granted tribes jurisdiction over all Native Americans again in response to *Duro v. Reina*, 495 U.S. 676 (1990)).

<sup>81</sup> See H.R. Rep. No. 972 (1991) (legislative history of 25 U.S.C. § 1301 (1991) reflects congressional consideration of *Duro v. Reina* and the tribal criminal jurisdiction over Native Americans).

<sup>82</sup> See Tribal L. & Pol’y Inst., *Indian Civil Rights Act*, TRIBAL CT. CLEARINGHOUSE, <https://www.tribal-institute.org/lists/icra.htm> [<https://perma.cc/5ARX-KH4B>] (last visited Mar. 30, 2022).

inherent tribal power.<sup>83</sup> This statutory jurisdictional grant has itself been contested.<sup>84</sup> In 2004, Lara, a Native American nonmember of the Spirit Lake Tribe was arrested and pleaded guilty in tribal court to assaulting a federal officer on tribal land.<sup>85</sup> As this was a federal offense, the federal government asserted criminal jurisdiction despite Lara's prior conviction in tribal court for the same offense, prompting the nonmember Native American to assert double jeopardy as a defense.<sup>86</sup> The Court, however, viewed tribal and federal jurisdiction as concurrent and arising from distinct sovereignties, meaning that certain situations allow for both tribal and federal jurisdiction and conviction.<sup>87</sup> The central assessment turned on whether Congress was justified in unilaterally altering tribal jurisdiction over nonmember Native Americans through the enactment of the "Duro-Fix" statute.<sup>88</sup> The Court in *Lara* upheld Congress's plenary authority to legislate on Native American matters and its grant of tribal criminal jurisdiction over nonmember Native Americans.<sup>89</sup> As recent as 2020, the Court maintained the view that Congress has plenary authority to make determinations regarding tribal jurisdiction and authority.<sup>90</sup>

#### ***4. The Federal Government's "Concern" for Native American Women***

In the twenty-first century, the federal government has shifted its view of its treatment of and obligation to the remaining tribes. In 2010, the Tribal Law and Order Act was signed into law in an effort to decrease the occurrence of crime in tribal country.<sup>91</sup> The Tribal Law and Order Act allows for increased sentencing by tribal courts, expands law enforcement presence on reservations, and includes provisions focused on violence against Native American women.<sup>92</sup> While Congress recognized jurisdictional complications as a per-

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<sup>83</sup> See *United States v. Lara*, 541 U.S. 193, 199 (2004).

<sup>84</sup> See *id.* at 193.

<sup>85</sup> See *id.*

<sup>86</sup> See *id.*

<sup>87</sup> See *id.* at 210.

<sup>88</sup> See *id.* at 196.

<sup>89</sup> See *id.* at 201 (citing *Antione v. Washington*, 420 U.S. 194 (1975)).

<sup>90</sup> See *id.* at 193; see also *McGirt v. Oklahoma*, 140 S. Ct. 2452 (2020) (affirming tribal criminal jurisdiction over all Native Americans regardless of tribal membership, highlighting congressional authority to grant such authority).

<sup>91</sup> See Tribal Law and Order Act of 2010, Pub. L. No. 111-211, tit. II, 124 Stat. 2261, 2263 ("The purposes of this title are . . . to reduce the prevalence of violent crime in Indian country and to combat sexual and domestic violence against American Indian and Alaska Native women . . .").

<sup>92</sup> See *id.* at 2262 ("Congress finds that . . . domestic and sexual violence against American Indian and Alaska Native women has reached epidemic proportions.").

petuating force of criminal conduct and suffering on reservations, it did not alter the jurisdictional scheme through the Tribal Law and Order Act.<sup>93</sup>

Subtitle F of the Tribal Law and Order Act addresses domestic violence and sexual assault protection and prevention.<sup>94</sup> It includes a brief discussion of prisoner release and reentry, domestic and sexual violence training, and assault protocol.<sup>95</sup> The Tribal Law and Order Act does not modify tribal criminal jurisdiction over non-Native Americans, nor does it grant tribes the authority to prosecute criminal conduct such as rape and other violent acts against Native American women.<sup>96</sup>

For a time, Congress's only attempt to limit *Oliphant's* harsh effect of removing criminal jurisdiction over non-Native Americans from tribes<sup>97</sup> was the 2013 Violence Against Women Act.<sup>98</sup> The Violence Against Women Act Reauthorization of 2013 contained a title addressing violence against Native American women.<sup>99</sup> Title IX granted limited tribal criminal jurisdiction over non-Native Americans for domestic violence, dating violence, and criminal violations of protective orders.<sup>100</sup> Because Title IX seemingly created protections for Native American women, it has been deemed the "partial *Oliphant* fix."<sup>101</sup> However, this description is discredited because Title IX did not fully rectify the removal of tribal jurisdiction over non-Native Americans, even in instances of domestic violence, dating violence, and criminal violations of protective orders because such jurisdiction remained concurrent with federal or state jurisdiction.<sup>102</sup> Each of the foregoing acts covered by Title IX required some degree of a preexisting relationship between the victim and non-Native American perpetrator.<sup>103</sup> This prerequisite relationship requirement precluded

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<sup>93</sup> See *id.* ("Congress finds that . . . the complicated jurisdictional scheme that exists in Indian country—has a significant negative impact on the ability to provide public safety to Indian communities; has been increasingly exploited by criminals . . .").

<sup>94</sup> See *id.* at 2299–301.

<sup>95</sup> See *id.*

<sup>96</sup> See Jasmine Owens, Note, "Historic" in a Bad Way: How the Tribal Law and Order Act Continues the American Tradition of Providing Inadequate Protection to American Indian and Alaska Native Rape Victims, 102 J. CRIM. L. & CRIMINOLOGY 497, 500 (2013).

<sup>97</sup> See *Oliphant v. Suquamish Indian Tribe*, 435 U.S. 191, 191 (1978).

<sup>98</sup> See Violence Against Women Act Reauthorization of 2013, Pub. L. No. 113-4, § 204, 127 Stat. 120 (2013) (expired 2019).

<sup>99</sup> See *id.* at § 901.

<sup>100</sup> See *id.* at § 204(a).

<sup>101</sup> *E.g.*, Kirsten Matoy Carlson, *Lobbying as a Strategy for Tribal Resilience*, 2018 BYU 1159, 1187.

<sup>102</sup> See Violence Against Women Act Reauthorization of 2013, Pub. L. No. 113-4, § 204(b), 127 Stat. 120 (2013) (expired 2019).

<sup>103</sup> See DEPT OF JUST., *supra* note 50.

tribes from prosecuting the majority of perpetrators of violence against Native American women because most crimes of this nature are committed by non-Native Americans without preexisting relationships with their victims.<sup>104</sup> Although the problematic results of immense need for reform are apparent, legislative and judicial attempts to mitigate such problems have been wholly insufficient.<sup>105</sup>

## **B. Use of Bad Man Provisions**

Because tribal jurisdiction is complex and existing legislation failed to rectify issues for Native American women, claimants began seeking recourse through Bad Man provisions.<sup>106</sup> This remedy has not been invoked frequently. However, the courts' judicial treatment of Bad Man provisions and the provisions' continued use indicate that they remain an effective and available remedy for Native American women.<sup>107</sup>

### ***1. Bad Man Provisions Are Rarely Invoked***

Bad Man provisions have long been undervalued and accordingly have been invoked only a few times.<sup>108</sup> Since 1893, there have been less than fifty federal cases raising Bad Man provisions as either a claim or defense.<sup>109</sup> However, the Federal Circuit in *United States v. Tsosie*<sup>110</sup> ruled that lack of use has not caused them to expire and that they are not limited to misconduct by government employees.<sup>111</sup> The court held that Bad Man provisions, or any treaty provision, do not expire unless it can be reasonably shown that

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<sup>104</sup> See 2 U.S.C. § 1304.

<sup>105</sup> See Mary Hudetz, *Despite Past Reforms, Native Women Face High Rates of Crime*, ASSOCIATED PRESS (Sept. 5, 2018), <https://apnews.com/article/missing-in-indian-country-north-america-albuquerque-mo-state-wire-sd-state-wire-316529000f3c44988969a-b22acfb34d7> [<https://perma.cc/QKR7-S3QF>].

<sup>106</sup> See, e.g., *Elk v. United States*, 87 Fed. Cl. 70 (Fed. Cl. 2009).

<sup>107</sup> See, e.g., *id.* at 72.

<sup>108</sup> See *Tsosie*, 825 F.2d. at 394 (finding Bad Man provisions not obsolete despite infrequent invocation); see also *Hebah v. United States*, 428 F.2d 1334 (Ct. Cl. 1970).

<sup>109</sup> See, e.g., *Guy Randy White Horse v. United States*, 2021 WL 1200727 (Fed. Cl. 2021); *Marks v. United States*, 28 Ct. Cl. 147 (Ct. Cl. 1893). A search for Bad Man provision claims and defenses on Westlaw resulted in less than fifty cases raising Bad Man provisions since their first judicial invocation in 1897.

<sup>110</sup> 825 F.2d 393 (Fed. Cir.1987).

<sup>111</sup> See *Tsosie*, 825 F.2d at 394 (holding, in the first use of a Bad Man provision before Federal Circuit, that Bad Man provisions are not limited to misconduct by federal or government employees, but instead cover all individuals subject to the federal government's authority).

the Native American signers had such expectations.<sup>112</sup> The Court of Federal Claims viewed tribal treaties as contracts with enforceable rights that should be interpreted in a manner that effectuates the intent and understanding of the signatories, indicating continued effect despite nonuse.<sup>113</sup>

In *Tosie*, the Federal Circuit made clear that infrequency of use does not equate to invalidity.<sup>114</sup> The first time a plaintiff raised a Bad Man provision before the Federal Court of Claims<sup>115</sup> was in 1970.<sup>116</sup> Bad Man provisions were not heard before the Federal Circuit until 1987 and have only been brought five times subsequently.<sup>117</sup> Bad Man provisions have been assessed by the Court of Federal Claims more frequently than the Federal Circuit, and this court has seen an uptick, comparatively, in Bad Man provision claims.<sup>118</sup> Bad Man provisions regained recognition as a viable claim to be raised in 2017.<sup>119</sup> However, most Bad Man provision claims brought in the Court of Federal Claims do not address violence against Native American women or sexual assault.<sup>120</sup> Two of the Bad Man provision claims before the Federal Circuit were raised by inmates against correction officers or as challenges to detainment.<sup>121</sup> Although such cases are wholly unrelated to sexual assault claims, they indicate how the Federal Circuit views Bad Man provision claims generally and, due to their frequent dismissal, may deter potential plaintiffs, including Native American women.

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<sup>112</sup> See *Tosie*, 825 F.2d at 399.

<sup>113</sup> See *Elk v. United States*, 87 Fed. Cl. 70, 78 (Fed. Cl. 2009).

<sup>114</sup> See *Tosie*, 825 F.2d at 394.

<sup>115</sup> The Federal Court of Claims was the predecessor to the U.S. Court of Federal Claims.

<sup>116</sup> See *Hebah v. United States*, 428 F.2d 1134 (Ct. Cl. 1970).

<sup>117</sup> See *Ballard v. United States*, 680 F. App'x 1007, 1008 (Fed. Cir. 2017); *Flying Horse v. United States*, 696 F. App'x 495 (Fed. Cir. 2017); *Jones*, 846 F.3d 1343; *Kenyon v. United States*, 683 F. App'x 945 (Fed. Cir. 2017); *Richard v. United States*, 677 F.3d 1141 (Fed. Cir. 2012).

<sup>118</sup> The Court of Federal Claims hears more cases because the Federal Circuit is an appellate court. However, the overall invocation before either court indicates an increasing frequency in Bad Man provision reliance. See, e.g., *Jones*, 846 F.3d 1343; *Cheyenne & Arapaho Tribes v. United States*, 151 Fed. Cl. 511 (2020); *Locklear v. United States*, No. 18-1174C, 2019 WL 365770 (Fed. Cl. Jan. 29, 2019).

<sup>119</sup> See *Jones v. United States*, 846 F.3d 1343, 1348 (Fed. Cir. 2017) (most prominent recent case raising Bad Man claims with substantial discussion about their viability).

<sup>120</sup> See *Jones*, 846 F.3d 1343 (recognizing Bad Man claim against police officer); *Cheyenne & Arapaho Tribes*, 151 Fed. Cl. (unsuccessfully asserting Bad Man claim against corporate pharmaceutical opioid manufacturers); *Locklear*, 2019 WL 365770 (attempting to bring imprisonment Bad Man claim).

<sup>121</sup> See, e.g., *Flying Horse*, 696 F. App'x at 496; *Kenyon*, 683 F. App'x 945.

## 2. *The Complexities of Succeeding on a Bad Man Claim*

The Federal Circuit has dismissed half of the Bad Man claims that have come before it.<sup>122</sup> The Federal Circuit based dismissal on a failure to exhaust administrative remedies and procedures deemed prerequisites to Bad Man provision claims.<sup>123</sup> Bad Man provisions require claimants to meet certain administrative requirements that derive from the Bad Man provisions' language.<sup>124</sup> Beyond administrative procedures, plaintiffs must show: (1) that "bad men among the whites' committed a 'wrong upon the person or property of the Indians,'" and (2) "the amount needed to 'reimburse' her for the 'loss sustained.'"<sup>125</sup> This ambiguous treaty language has resulted in an elevated challenge for plaintiffs to meet the administrative and judicial burdens because the standard plaintiffs have to meet and the court's likely assessment of such efforts are unclear.<sup>126</sup>

## 3. *Invocation of Bad Man Provisions for Sexual Violence Claims*

There is little precedent involving Bad Man provision claims alleging sexual assault or violence before the Court of Federal Claims or the Federal Circuit.<sup>127</sup> The Court of Federal Claims has only heard two cases, *Elk v. United States*<sup>128</sup> and *Tsosie*, regarding violence against women or sexual assault invoking a Bad Man provision as a means of reprisal.<sup>129</sup> In *Elk*, an Oglala Sioux Tribe member was sexually assaulted by a staff sergeant in the U.S. Army on Oglala Sioux land and used the Bad Man provision contained in the 1868 Sioux Treaty to seek relief.<sup>130</sup> The Court of Federal Claims decided *Elk* on the merits and

<sup>122</sup> See, e.g., *Ballard*, 680 F. App'x at 1008; *Flying Horse*, 696 F. App'x at 497; *Kenyon*, 683 F. App'x at 946.

<sup>123</sup> See *Ballard*, 680 F. App'x at 1008; *Flying Horse*, 696 F. App'x at 497; *Kenyon*, 683 F. App'x at 946.

<sup>124</sup> See *Flying Horse*, 696 F. App'x at 497. The administrative procedures are derived from the Bad Man provision language that states that proof of harm must be made to the "agent" and sent to the Commissioner of Indian Affairs in the nation's capital. See *id.* Heightened obligations are not derived directly from the language of the provision. See, e.g., *Treaty with the Sioux Indians*, art. I, Apr. 29, 1868, 15 Stat. 635.

<sup>125</sup> *Elk v. United States*, 87 Fed. Cl. 70, 78 (2009) (quoting *Treaty with the Sioux Indians*, art. I, Apr. 29, 1868, 15 Stat. 635).

<sup>126</sup> See *id.* at 89 (maintaining that plaintiff bears burden of satisfying prerequisites to invoking Bad Man provision claims).

<sup>127</sup> Bad Man provisions have only been raised in sexual assault or violence cases before either court a few times. See, e.g., *Tsosie v. United States*, 825 F.2d 393 (Fed. Cir. 1987); *Elk*, 87 Fed. Cl. 70.

<sup>128</sup> 87 Fed. Cl. 70 (2009).

<sup>129</sup> See *Elk*, 87 Fed. Cl. at 70.

<sup>130</sup> See *id.* at 72.

found the United States liable for damages because the Bad Man provision created a third-party right that an individual claimant could invoke to sue the United States.<sup>131</sup>

The Federal Circuit has only heard one Bad Man provision claim regarding sexual assault on a Native American woman: *Tsosie v. United States*.<sup>132</sup> Although the court found that Bad Man provisions were not obsolete due to their infrequent use, as the government argued, the court did not rule on the merits of this case or grant relief through a Bad Man provision claim.<sup>133</sup> The court viewed Bad Man provision claims favorably in deeming them essential for claims of assault because legislative attempts at mitigating the frequency of assault against Native Americans were insufficient.<sup>134</sup>

The court's determination that Bad Man provisions are central to the protection of Native American women and serve as a means of relief is consistent with the intent of the original Bad Man provisions.<sup>135</sup> The Doolittle Commission Report from 1867<sup>136</sup> indicates that a primary catalyst for drafting treaties with Bad Man provisions was the prominence of violence against Native American women.<sup>137</sup> Violence against Native American women during the nineteenth century was primarily perpetrated by American soldiers.<sup>138</sup> The egregious acts included a broad scope of misconduct, ranging from murder and mutilation to sexual coercion in exchange for food.<sup>139</sup>

The Federal Circuit interprets Bad Man provisions to impose liability upon the federal government and allow plaintiffs to make a claim for actions perpetrated by U.S. citizens, federal employees, and nonmember Indians.<sup>140</sup> Yet, only one case before the Federal Circuit raised these claims against non-governmental actors.<sup>141</sup> In *Richard v. United States*,<sup>142</sup> the court solidified the possibility for claimants to raise Bad Man provisions against any U.S. citizen,

<sup>131</sup> See *id.* at 78–79 (citing *Hebah v. United States*, 428 F.2d 1334, 1338 (Ct. Cl. 1970)).

<sup>132</sup> See *Tsosie*, 825 F.2d at 393.

<sup>133</sup> See *id.*

<sup>134</sup> See *id.* at 400.

<sup>135</sup> See S. REP. NO. 39-156 (1867).

<sup>136</sup> The Doolittle Commission was a congressionally created committee tasked with investigating and reporting on the conditions of Native Americans and the related conduct of American authorities. See *id.*

<sup>137</sup> See *id.*

<sup>138</sup> See *id.* (providing legislative history for Bad Man provisions and overview of general issues Native Americans experienced with United States, including violence against women).

<sup>139</sup> See *id.*

<sup>140</sup> See *Richard v. United States*, 677 F.3d 1141, 1145 (Fed. Cir. 2012) (finding that the Bad Man provision is applicable to more than just governmental employees and authorities).

<sup>141</sup> See *id.*

<sup>142</sup> 677 F.3d 1141 (Fed. Cir. 2012).

federal employee, or nonmember Indian.<sup>143</sup> This allowance provides Native American women the opportunity to pursue claims against any predator; however, the lack of case law indicates that this potential has not been realized.

## II. Analysis

The Federal Circuit's acknowledgment of Bad Man Provisions and the federal government's responsibility to *all* Native American victims would be one meaningful step toward righting the safety issues on reservations. The Federal Circuit is able to remedy, at least in part, the impact of violence against Native American women on tribal lands by upholding the Government's promise to these twelve tribes and applying it to all tribes.

The lack of precedent of violence against Native American women renders Bad Man provisions as potential claims for Native American women and gives the Federal Circuit the opportunity to opine on them in a manner that mitigates such violence. The Federal Circuit should interpret Bad Man claims as providing equitable relief from the U.S. federal government to members of Native American tribes with Bad Man treaty provisions and utilize this interpretation in all claims of violence against Native American women. Furthermore, the Federal Circuit should find the legislative intent and subsequent legislation as indicative of an intent to apply such protections to Native American members of tribes without Bad Man provisions. The Federal Circuit should use Bad Man provision language as a model for providing relief to Native American women from all tribes who are the victims of sexual assault and violence by non-Native American men.

### A. Need for Further Reform

Existing executive and legislative attempts to rectify the violence against Native American women has been insufficient as they neither decreased incidents of assault nor provided women with actionable claims against their violators.<sup>144</sup> The Violence Against Women Act Reauthorization of 2013,<sup>145</sup> the Tribal Law and Order Act,<sup>146</sup> and other legislation have not been sufficiently reformative because they left Native American women without adequate

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<sup>143</sup> See *id.* at 1145.

<sup>144</sup> See, e.g., Tribal Law and Order Act of 2010, Pub. L. No. 111-211, tit. II, 124 Stat. 2261 (codified in scattered sections of the U.S. Code); see also M. Brent Leonhard, *Implementing VAWA 2013*, ABA, Oct. 1, 2014, [https://www.americanbar.org/groups/crsj/publications/human\\_rights\\_magazine\\_home/2014\\_vol\\_40/vol—40—no—1—tribal-sovereignty/implementing-vawa-201/](https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/2014_vol_40/vol—40—no—1—tribal-sovereignty/implementing-vawa-201/) [<https://perma.cc/E5MR-94PL>].

<sup>145</sup> See Violence Against Women Act Reauthorization of 2013, Pub. L. No. 113-4, tit. IX 127 Stat. 120 (2013) (expired 2019).

<sup>146</sup> See Tribal Law and Order Act of 2010, Pub. L. No. 111-211, tit. II, 124 Stat. 2261.

means of recourse. The Violence Against Women Act Reauthorization of 2022 rectified some of those shortcomings by granting tribes criminal jurisdiction over non-Native American aggressors and encompassing a broader scope of conduct.<sup>147</sup> However, the implications of this legislative change are unclear and Native American women will still lack adequate financial relief if funding comes solely from tribal resources.<sup>148</sup> The Tribal Law and Order Act's increased allowances regarding tribal sentencing, like the tribes' ability to sentence criminals for certain crimes for up to three years, was touted as groundbreaking by scholars, despite being insufficient when viewed against the overarching issues.<sup>149</sup>

Statistics make clear that violence against Native American women is still as prevalent as it was before the enactment of legislation expanding tribal correctional authority and theoretically deterring violence against Native American women.<sup>150</sup> Federal Circuit interpretation and application of Bad Man provision language to all claims of sexual assault and violence could provide some sort of remedy by creating an actionable claim and monetary remedy for female victims. Expanding the use of Bad Man provision language to all cases of sexual assault and violence, regardless of the existence of a Bad Man provision in a relevant treaty, provides all Native American women with at least one clear method of sufficient equitable relief.

### **B. Judicial Encouragement of Bad Man Provision Use**

It is difficult to determine the way in which the Federal Circuit would presently interpret and apply Bad Man provision claims for relief in sexual assault and violence cases because they have not been raised for such purposes before the Federal Circuit since 1987.<sup>151</sup> A few cases raising Bad Man provisions have been appealed to the Federal Circuit, but were dismissed for procedural reasons.<sup>152</sup> However, the two sexual violence cases relying on Bad

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<sup>147</sup> See Violence Against Women Act Reauthorization of 2022, Pub. L. No. 117-103, § 804, 136 Stat. 49 (2022).

<sup>148</sup> See *id.* § 804(h) (providing that reimbursements and grants flow directly to the tribal governments, not to the victims of covered crimes).

<sup>149</sup> See Larry Cox, *President Obama signs Tribal Law and Order Act*, AMNESTY INT'L: HUM. RIGHTS NOW BLOG (Aug. 2, 2010, 12:55 PM), <https://blog.amnestyusa.org/women/president-obama-signs-tribal-law-and-order-act/> [<https://perma.cc/9SVA-5RU5>].

<sup>150</sup> See André Rosay, *Violence Against American Indian and Alaska Native Women and Men*, NAT'L INST. JUST. (June 1, 2016), [https://nij.ojp.gov/topics/articles/violence-against-american-indian-and-alaska-native-women-and-men#:~:text=Violence%20Against%20Women,lifetime%20\(see%20Table%201\)](https://nij.ojp.gov/topics/articles/violence-against-american-indian-and-alaska-native-women-and-men#:~:text=Violence%20Against%20Women,lifetime%20(see%20Table%201)) [<https://perma.cc/E64A-MTJY>].

<sup>151</sup> See *Tsosie v. United States*, 825 F.2d 393, 394 (Fed. Cir. 1987).

<sup>152</sup> See *Ballard v. United States*, 680 F. App'x 1007 (Fed. Cir. 2017); *Flying Horse v. United States*, 696 F. App'x 495 (Fed. Cir. 2017); *Kenyon v. United States*, 683 F. App'x

Man provisions before the Federal Court of Claims and the Federal Circuit are instructive as to how a court might rule.

The Federal Court of Claims in *Elk* indicated its interpretation of Bad Man provisions and, accordingly, the likelihood of their success.<sup>153</sup> In *Elk*, the court granted a female sexual assault victim relief through the federal government based on the Bad Man provision in her tribe's treaty with the United States.<sup>154</sup> The court called upon the Federal Circuit's reasoning in *Tsosie* and found that Bad Man language and utility were not obsolete.<sup>155</sup> The court also looked to the Doolittle Commission Report to ascertain the intent of treaty drafters and determined that Congress intended to mitigate the mistreatment of Native American women, largely perpetrated by U.S. agents.<sup>156</sup> The Federal Court of Claims's opinion and reasoning in *Elk* relied upon the Federal Circuit and legislative intent to award the plaintiff with monetary damages, paid by the federal government.<sup>157</sup>

The Court of Federal Claims's interpretation of Bad Man provisions indicates that Bad Man claims may be successful in violence against Native American women claims generally. Because *Elk* never reached the Federal Circuit, it cannot be wholly indicative of the Federal Circuit's interpretation and use of the Bad Man provisions with respect to violence against Native American women suits.

As most Bad Man provision claims raised before the Federal Circuit have been dismissed for a failure to meet administrative requirements, the court's willingness to grant relief through these provisions is difficult to predict. However, as the Federal Court of Claims highlighted in *Elk*, the Federal Circuit has clearly accepted the Bad Man provisions' utility and role in sexual violence claims.<sup>158</sup> Although Bad Man claims have only reached the Federal Circuit six times, the court's discussion of them indicates that the court would positively opine on sexual violence cases that raise them.<sup>159</sup>

The Federal Circuit has dismissed Bad Man claims and cases due to administrative and procedural reasons without opining on the provisions' utility

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945 (Fed. Cir. 2017).

<sup>153</sup> See *Elk*, 87 Fed. Cl. at 80–81.

<sup>154</sup> See *id.* at 82–83.

<sup>155</sup> See *id.* at 82 (citing *Tsosie*, 825 F.2d at 399–401).

<sup>156</sup> See *id.* at 80–81.

<sup>157</sup> See *id.* at 90.

<sup>158</sup> See *id.* at 82.

<sup>159</sup> See *Ballard v. United States*, 680 F. App'x 1007, 1008 (Fed. Cir. 2017); *Flying Horse v. United States*, 696 F. App'x 495 (Fed. Cir. 2017); *Jones v. United States*, 846 F.3d 1343 (Fed. Cir. 2017); *Kenyon v. United States*, 683 F. App'x 945 (Fed. Cir. 2017); *Richard v. United States*, 677 F.3d 1141 (Fed. Cir. 2012); *Tsosie*, 825 F.2d at 400.

or likelihood of success.<sup>160</sup> While, in theory, reducing administrative requirements may increase the burden on the court of hearing countless claims of this nature, the absolute lack of Bad Man claims before the Federal Circuit currently negates the weight such assertions have.

### III. Recommendation

The Federal Circuit should construe Bad Man provisions in favor of Native American plaintiffs and extend their application to claims arising from all tribal members. Doing so would conform with legislative intent and ensure that the United States complies with its obligations to the remaining tribes.<sup>161</sup> Judicial action tends to pressure the executive and legislative branches to act, which may result in a complete remedy to tribal jurisdictional issues.

The Federal Circuit's treatment of Bad Man claims in cases of sexual assault should be retained and developed further if Bad Man claims are again raised in similar contexts. The court's affirmation of the use of Bad Man provision claims in a sexual assault case, *Tsosie*, highlighted Bad Man provisions as useful language for Native American women.<sup>162</sup> If given the opportunity to exercise its authority in sexual violence cases, the Federal Circuit should positively opine on their use in cases involving violence against Native American women, in accordance with its own precedent, set in *Tsosie* and replicated in *Elk*, to provide Native American women with relief.<sup>163</sup> The court should also move beyond its precedent to opine on the merits of the case in which it is raised. In doing so, the court would simultaneously provide a means of redress and indicate federal support of Native Americans.

The Federal Circuit should use Bad Man provision language to provide Native American women members of tribes without Bad Man provisions with monetary relief in cases of sexual violence. Adopting Bad Man language for all dealings with tribes may be disregarded as judicial activism because the provision language is only included in nine treaties; however, a review of legislative history reveals that this would be an effectuation of the intent of Congress.<sup>164</sup>

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<sup>160</sup> The Federal Circuit has dismissed three cases in 2017 alone for procedural and administrative shortcomings. See *Ballard*, 680 F. App'x at 1009; *Flying Horse*, 696 F. App'x, at 497; *Kenyon*, 683 F. App'x at 946.

<sup>161</sup> See S. REP. NO. 39-156, at 1 (1867); see also *Cherokee Nation v. Hitchcock*, 187 U.S. 294, 295 (1902).

<sup>162</sup> See *Tsosie v. United States*, 825 F.2d 393, 394 (Fed. Cir. 1987).

<sup>163</sup> See *Tsosie*, 825 F.2d at 394; *Elk*, 87 Fed. Cl. at 81–82.

<sup>164</sup> Legislative history and language in legislation reveal a general concern for the safety of Native American women and the need for reform surrounding sexual assault and violence perpetrated against Native American women. See e.g., S. REP. NO. 39-156, at 29 (1867); Tribal Law and Order Act of 2010, Pub. L. No. 111-211, tit. II, 124 Stat. 2261 (codified

Ordinarily, the use of binding language found in one contract would not be applied to all other contracts; however, the interpretation and application of tribal treaty provisions differ from basic contractual interpretation.<sup>165</sup>

The United States imposed a guardian role upon itself and created duties for the federal government with regard to all federally recognized tribes, not just those with Bad Man provisions.<sup>166</sup> The federal government has maintained that tribes are sovereign dependents requiring its protection and oversight.<sup>167</sup> In that same vein, the federal government has held itself accountable for certain obligations to Native American tribal members, like providing equitable relief to individual Native Americans for harm done by bad men.<sup>168</sup> The Doolittle Commission Report reveals that Congress intended to use Bad Man provision language specifically to further the rights of Native American women and to combat U.S. soldiers' violent interactions with Native American women.<sup>169</sup> The use of these provisions to further the rights of Native American women would thus be directly in line with the intent of the enacting Congress.<sup>170</sup> Therefore, the Federal Circuit should apply this language in cases of sexual assault involving members of tribes without Bad Man provisions. Doing so would provide victims with justice, uphold the self-imposed obligations of the United States, and effectuate congressional intent.

Subsequent legislation confirms the congressional intent to protect Native American women and provide for their relief through legislative action. The Tribal Law and Order Act has legislative history similar to the Doolittle Commission Report.<sup>171</sup> The legislative history indicates an intention to rectify the wrongs perpetrated against Native American women and to provide protection for these women.<sup>172</sup> This intention has been carried on through

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in scattered sections of the U.S. Code); Violence Against Women Act Reauthorization of 2013, Pub. L. No. 113-4, Stat. 120 (2013) (expired 2019); Violence Against Women Act Reauthorization of 2022, Pub. L. No. 117-103, 136 Stat. 49 (2022).

<sup>165</sup> See *Elk v. United States*, 87 Fed. Cl. 70, 79 (Fed. Cl. 2009) (explaining that “[w]hile principles of contract interpretation aid in discerning the intent of treaty partners . . . those principles are not applied to treaties in precisely the same way they are used to construe private contracts”; instead, the court should consider the treaty language and its historical context).

<sup>166</sup> See *Cherokee Nation*, 187 U.S. at 302.

<sup>167</sup> See *id.*

<sup>168</sup> See *Treaty with the Sioux Indians*, art. I, Apr. 29, 1868, 15 Stat. 635; Violence Against Women Act Reauthorization of 2022, Pub. L. No. 117-103, 136 Stat. 49 (2022).

<sup>169</sup> See S. REP. NO. 39-156, at 176.

<sup>170</sup> See *id.*

<sup>171</sup> See S. REP. NO. 114-404 (2016).

<sup>172</sup> See *id.* at 2 (“The intent of the [Tribal Law and Order Act of 2010] was aimed at reducing violent crime, combating sexual and domestic violence against American Indian

legislation for over one hundred and fifty years and has been repeatedly reaffirmed through legislative deliberation.<sup>173</sup>

In cases arising from instances of violence against Native American women whose tribes do not have Bad Man language in their treaties, the Federal Circuit should treat such parties as though they are members of one of the twelve tribes with Bad Man provisions affirmatively included in their treaties. The court would, in this instance, treat all Native Americans alike and ensure that the intended role of the U.S. government is fulfilled. The court should not view tribes differently when providing for justice and damages. As courts have repeatedly noted, treaties should be read and interpreted liberally, in favor of the Native Americans and how the original Native Americans agreeing to such terms would have understood them.<sup>174</sup> While somewhat more extreme than liberally construing treaty language, reading Bad Man language into all treaties would effectuate congressional intent and would make an incredibly impactful shift.

Although some scholars assert that various statutory schemes provide sufficient remedies and preempt the use of Bad Man provisions,<sup>175</sup> such legislative causes of action have been inapplicable to claims regarding sexual assault or battery.<sup>176</sup> Although the Violence Against Women Act Reauthorization of 2022 does address such conduct, it is unclear whether this coverage expansion will be sufficient given the recency of its enactment and the remaining ambiguity regarding jurisdiction over perpetrators unacquainted with their victims. Accordingly, further action is required to provide Native American women with relief and the Federal Circuit could effectuate the necessary changes.

Although applying Bad Man language where it does not exist requires some justification through statutory analysis, the legislative history surrounding the drafting of Bad Man provisions as well as the congressional intent of subsequent legislation make such an application reasonable. Effectuating congressional intent further advances the notion that the United States serves as a guardian and fiduciary in its relationship with the tribes. Utilizing Bad Man language in cases involving any Native American, regardless of tribal membership, would significantly improve the judicial likelihood of obtaining sufficient

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and Alaska Native women . . .”).

<sup>173</sup> See, e.g., S. REP. NO. 39-156, at 2 (1867); Tribal Law and Order Act of 2010, Pub. L. No. 111-211, tit. II, 124 Stat. 2261 (codified in scattered sections of the U.S. Code); Violence Against Women Act Reauthorization of 2022, Pub. L. No. 117-103, § 801, 136 Stat. 49 (2022).

<sup>174</sup> See *Minnesota v. Mille Lacs Band of Chippewa Indians*, 526 U.S. 172, 196 (1999); *County of Oneida v. Oneida Indian Nation*, 470 U.S. 226, 247 (1985); *Jones v. United States*, 846 F.3d 1343, 1351 (Fed. Cir. 2017).

<sup>175</sup> See *Marquez*, *supra* note 15, at 627.

<sup>176</sup> See *Tsosie v. United States*, 825 F.2d 393, 400 (Fed. Cir. 1987).

relief for Native American women. Violence against Native American women has been caused, in part, by the complexities of jurisdiction and tribal authority created by the federal government, and the Federal Circuit could apply pressure on the government to rectify the damage it has done.

## **Conclusion**

The Federal Circuit should use the Bad Man provision language present in nine treaties with federally recognized Native American tribes as a means of providing relief to all Native American women who have been the victims of sexual assault or violence from any aggressor. Legislative history and basic tenets of statutory interpretation make it apparent that such use is feasible. Although the issue of sexual assault and violence against Native American women, especially on reservations, will not be further regulated or deterred through the use of this treaty language, it could provide a temporary means of obtaining substantial monetary relief for victims.

The imposition of monetary obligations on the federal government by the Federal Circuit in its interpretation and application of Bad Man provision liability may pressure the executive and legislative branches to pursue legitimate reform. The federal government assumed a guardian-ward relationship with federally recognized tribes and has long failed to fulfill its obligations to the Native American members of those tribes. Contractual obligations require the federal government to compensate the women of the twelve tribes with Bad Man provision protections, but basic legislative analysis suggests that a parallel obligation is owed to all Native American women.

# Polygenic Risk Scores and Patentability: A Flock We Must Correct

Alexandra Marshall\*

## Introduction

In high schools around the country, biology students watch *Gattaca*, a late 1990s sci-fi film depicting a dystopian future where society is dominated by eugenics and designer babies.<sup>1</sup> In this future, wealthy parents select embryos which possess the most desirable heritable traits from each parent, in hopes of giving their child every opportunity for success.<sup>2</sup> The movie is presented as some far-off future, but that future is nearly here. Today, parents using *in vitro* fertilization (“IVF”) and preimplantation genetic testing have the opportunity to select for monogenetic traits, such as gender, and against certain diseases, like Cystic Fibrosis or Huntington’s Disease.<sup>3</sup> While we cannot yet accurately predict polygenic traits such as intelligence, height, or predisposition to depression, we are rapidly approaching a future where that is possible. Outside of an IVF context, patients test for their predisposition to diseases such as schizophrenia and coronary heart disease. They anxiously await learning their results so they can change their behavior to mitigate that risk, treat such afflictions with the most effective treatments available, and make appropriate life planning decisions.

Emerging technologies in computer learning and artificial intelligence will make predicting one’s risk for these complex traits possible. Advanced algorithms developed using sophisticated statistical models help researchers understand how genes interact with one another to influence polygenic traits. Certain algorithms may be able to provide a single number—called a polygenic risk score (“PRS”)—that captures an individual’s personal risk for a particular trait or disease.<sup>4</sup> While the science is still in the relatively early

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<sup>1</sup> *GATTACA* (Columbia Pictures 1997).

<sup>2</sup> *See id.*

<sup>3</sup> *See* Mark Walker, Eugenic Selection Benefits Embryos, 28 *BIOETHICS* 214, 214 (2014).

<sup>4</sup> *See* Amanda B. Zheutlin & David A. Ross, *Polygenic Risk Scores: What Are They Good For?*, 83 *BIOLOGICAL PSYCHIATRY* e51, e51–e52 (2018).

stages of development, researchers are getting close to cracking the code for many critical diseases.<sup>5</sup> As a result, businesses are already trying to monetize this new technology. It is an easy sales pitch after all: who among us is not interested in learning more about their own genes? For example, in 2019, the popular direct-to-consumer genetic testing company 23andMe introduced a new service for customers that gauges one's risk of type 2 diabetes by evaluating 1,244 genetic factors.<sup>6</sup> While this commercial test only seeks to provide modest suggestions for lifestyle changes, such as encouraging customers to adopt healthier diets and lose weight,<sup>7</sup> the next generation of testing will alter medicine as we know it by allowing for truly personalized medical recommendations.

While exciting, the imminent advent of this new technology raises critical legal and ethical questions. One of these questions is whether or in what circumstances should we allow companies to patent these algorithms? There is a tension between wanting to promote scientific advancement by allowing companies to patent risk score algorithms and wanting to protect the public from the over-commercialization of naturally occurring phenomena which quite literally already live within each of us. These patents should not be taken lightly. After all, a patent is a grant of monopoly power, giving companies the right to exclude others from utilizing their knowledge and empowering patent holders to charge whatever fee they deem appropriate for its use.<sup>8</sup> This Note aims to answer this question by evaluating whether classic PRS algorithms are patentable under 35 U.S.C. § 101 ("section 101"), subject matter eligibility. This Note argues that PRS algorithms are patent ineligible under section 101 for two reasons: (1) they are not proper processes when evaluated under Supreme Court and Federal Circuit precedent; and (2) they rely impermissibly on the capitalization of natural correlations, with nothing "more" to elevate their claims into the realm of patentability.

In order to understand the scope of this emerging technology, the challenges it presents to ethics and law, and the need for denial of patent eligibility under current case law, this Note will provide an overview of the science behind PRSs in Part I, explain the statutory and judicial requirements for

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<sup>5</sup> See *id.* at e52–e53.

<sup>6</sup> See Antonio Regalado, *23andMe Thinks Polygenic Risk Scores Are Ready for The Masses, But Experts Aren't So Sure*, MIT TECH. REV. (Mar. 8, 2019) <https://www.technologyreview.com/2019/03/08/136730/23andme-thinks-polygenic-risk-scores-are-ready-for-the-masses-but-experts-arent-so-sure/> [<https://perma.cc/54QP-82XD>].

<sup>7</sup> See Jamie Ducharme, *23andMe Has a New Type 2 Diabetes Risk Report. Here's What to Know*, TIME (Mar. 11, 2019, 11:36 AM), <https://time.com/5549014/23andme-diabetes-test/> [<https://perma.cc/GU3F-BZEC>].

<sup>8</sup> See U.S. CONST. art. 1, § 8, cl. 8; 35 U.S.C. § 154(a)(1) (2018).

patent eligibility of genetic technology in Part II, and explore why granting these patents is inconsistent with current case law and offer several suggestions for how the patent system would need to be altered to allow for such patents in Part III.

## I. Background: The Science

*Certain students of genetics inferred that the Mendelian units responsible for the selected character were genes producing only a single effect. This was careless logic. It took a good deal of hammering to get rid of this erroneous idea. As facts accumulated, it became evident that each gene produces not a single effect, but in some cases a multitude of effects on the characters of the individual. It is true that in most genetic work only one of these character effects is selected for study—the one that is most sharply defined and separable from its contrasted character—but in most cases minor differences are also recognizable that are just as much the product of the same gene as is the major effect.*

—Thomas H. Morgan, Nobel Laureate<sup>9</sup>

The field of genetics has been defined by a handful of great advancements, such as Gregor Mendel's studies on the laws of inheritance and James Watson and Francis Crick's discovery of deoxyribonucleic acid's ("DNA") double helix structure.<sup>10</sup> In 1988, the National Research Council released a report urging the next great advancement through the study of our own DNA.<sup>11</sup> Shortly thereafter, scientists began mapping and sequencing our genetic code, as part of the Human Genome Project.<sup>12</sup> By 2003, two years ahead of schedule, the scientists had completed the job.<sup>13</sup> The project was a wild success and "usher[ed] in a new era" of science and medicine.<sup>14</sup> Building upon the work of the Human Genome Project, we are now at the cusp of the next great advancement in genetics and modern medicine: individualized PRSs.<sup>15</sup>

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<sup>9</sup> Thomas H. Morgan, Nobel Lecture: The Relation of Genetics to Physiology and Medicine 317 (June 4, 1934), <https://www.nobelprize.org/uploads/2018/06/morgan-lecture.pdf> [<https://perma.cc/4NCT-7YGX>].

<sup>10</sup> See Stephanie Pappas, *Unraveling the Human Genome: 6 Molecular Milestones*, LIVE SCI. (Jan. 23, 2013), <https://www.livescience.com/26505-human-genome-milestones.html> [<https://perma.cc/BZ3L-HH6G>].

<sup>11</sup> See NAT'L RSCH. COUNCIL ET AL., *MAPPING AND SEQUENCING THE HUMAN GENOME* 2 (1988).

<sup>12</sup> See *Human Genome Project Timeline of Events*, NAT'L HUM. GENOME RSCH. INST. (Feb. 12, 2021), <https://www.genome.gov/human-genome-project/Timeline-of-Events> [<https://perma.cc/KV85-2CJE>].

<sup>13</sup> See *id.*

<sup>14</sup> Heidi Chial, *DNA Sequencing Technologies Key to the Human Genome Project*, 1 NATURE EDUC. 219, 219 (2008).

<sup>15</sup> See Matthew Warren, *The Approach to Predictive Medicine That is Taking Genomics Research by Storm*, 562 NATURE 181, 181 (2018).

## A. Polygenic Risk Scores

PRSs are best understood in the context of fundamental genetics. Our DNA is a complex polymer in the shape of a double helix that stores all of our biological information.<sup>16</sup> This information is stored in the arrangement of four different building blocks, called nucleotides.<sup>17</sup> In this way, our entire biological library is encoded in a simple “four-letter language.”<sup>18</sup> Just like single letters, a single nucleotide does not itself code for anything in particular, but when read in conjunction with the nucleotides around it, it may form “words”—or genetically speaking, genes.<sup>19</sup> Like the order of letters in words, the order of individual nucleotides is critical to the gene’s understanding, and the alteration of one letter (or nucleotide) can drastically alter the meaning of the word (or gene).<sup>20</sup>

Cells “read” sections of DNA to produce proteins.<sup>21</sup> These proteins are responsible for the expression of specific physical characteristics.<sup>22</sup> Current research suggests that there are approximately 27,000<sup>23</sup> individual genes responsible for human development.<sup>24</sup> A single gene can range from 10,000 to over 100,000 nucleotides long.<sup>25</sup> Each gene is located along with hundreds or thousands of other genes on one of our twenty-three chromosomes.<sup>26</sup> In total, our genetic information is stored in a string of roughly six billion carefully-ordered nucleotides.<sup>27</sup>

Many traits are not the result of one gene, but are polygenic—or multifactorial—meaning they are the result of multiple genes, genetic variants, and even the environment in which an individual lives.<sup>28</sup> For example, one’s height is understood to be the result of the interaction of 180 genes as well

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<sup>16</sup> See LELAND H. HARTWELL ET AL., GENETICS: FROM GENES TO GENOMES 2, 187, 192 (6th ed. 2018).

<sup>17</sup> See *id.* at 189.

<sup>18</sup> *Id.*

<sup>19</sup> See *id.* at 193.

<sup>20</sup> See *Single Nucleotide Polymorphisms (SNPs)*, NAT’L HUM. GENOME RSCH. INST., <https://www.genome.gov/genetics-glossary/Single-Nucleotide-Polymorphisms> [<https://perma.cc/N4H2-DJ2L>].

<sup>21</sup> See HARTWELL ET AL., *supra* note 16.

<sup>22</sup> See *id.* at 193.

<sup>23</sup> See *id.* at 134. New genes are still regularly being discovered thanks to advances in scientific technology and evolution. See *id.*

<sup>24</sup> See *id.*

<sup>25</sup> See NAT’L RSCH. COUNCIL ET AL., *supra* note 11, at 16.

<sup>26</sup> See HARTWELL ET AL., *supra* note 16, at 134.

<sup>27</sup> See NAT’L RSCH. COUNCIL ET AL., *supra* note 11, at 13–16.

<sup>28</sup> See HARTWELL ET AL., *supra* note 16, at 45.

as factors such as proper nutrition.<sup>29</sup> One's predisposition to schizophrenia is thought to be influenced by thousands of genetic variants.<sup>30</sup> Researchers have recently linked one's predisposition to coronary artery disease to 6.6 million genetic markers.<sup>31</sup> When investigating how the human genome correlates with these complex polygenic traits, scientists typically use computer assistance to organize and understand the scope and magnitude of genetics data.<sup>32</sup> A PRS is the culmination of this investigation.<sup>33</sup> A PRS is "a single value representing an individual's overall genetic risk" for a particular condition or trait.<sup>34</sup>

There is intense interest within the scientific community in applying the predictive power of PRS to the field of personalized medicine.<sup>35</sup> Imagine a world where a blood test could identify the entirety of a patient's genetic risks, allowing that patient to take prophylactic measures to prevent, treat, or avoid diseases that might not express themselves for decades.<sup>36</sup> Doctors could use this information to make informed treatment decisions tailored to a patient's unique genetic code.<sup>37</sup> Parents seeking to have healthy children through IVF could use such scores to select embryos based on disease predisposition.<sup>38</sup> Such an advancement would be a groundbreaking—and lucrative—development.

## B. Artificial Intelligence and Machine Learning

PRSs determine a person's likelihood to develop certain traits or susceptibilities to specific diseases through computer algorithms.<sup>39</sup> The simplest

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<sup>29</sup> See Hana Lango Allen et al., *Hundreds of Variants Clustered in Genomic Loci and Biological Pathways Affect Human Height*, 467 NATURE 832, 832 (2010); HUGH FLETCHER & IVOR HICKEY, GENETICS 149–50 (4th ed. 2013).

<sup>30</sup> See Zheutlin & Ross, *supra* note 4, at e51.

<sup>31</sup> Amit V. Khera et al., *Genome-Wide Polygenic Scores for Common Diseases Identify Individuals With Risk Equivalent To Monogenic Mutations*, 50 NATURE GENETICS 1219, 1219 (2018).

<sup>32</sup> See, e.g., *id.*

<sup>33</sup> See, e.g., *id.* at 1222.

<sup>34</sup> Zheutlin & Ross, *supra* note 4, at e51.

<sup>35</sup> See *id.* at e51–e53.

<sup>36</sup> See *id.* at e51–e52.

<sup>37</sup> See *Genome-Wide Association Studies Fact Sheet*, NAT'L HUM. GENOME RSCH. INST. (Aug. 17, 2020), <https://www.genome.gov/about-genomics/fact-sheets/Genome-Wide-Association-Studies-Fact-Sheet> [<https://perma.cc/X6RP-AG38>].

<sup>38</sup> See Nathan R. Treff et al., *Utility and First Clinical Application of Screening Embryos for Polygenic Disease Risk Reduction*, FRONTIERS ENDOCRINOLOGY, Dec. 2019, at 1, 1.

<sup>39</sup> See Shing Wan Choi et al., *Tutorial: A Guide to Performing Polygenic Risk Score Analyses*, 15 NATURE PROTOCOLS 2759, 2759 (2020).

and most popular approach is sometimes referred to as the “Classic PRS Method.”<sup>40</sup> In the Classic Method, the goal of the algorithm is to identify an individual gene associated with a particular trait and assign a weight to that gene, capturing the relative impact that gene has on the expression of the overall trait.<sup>41</sup>

To determine relevant genes and their appropriate weights, computers use PRS-specific software to analyze genome-wide association studies (“GWASs”).<sup>42</sup> The data for GWASs come from large biobanks containing hundreds of thousands of individuals’ full genomic data which are publicly available through projects like the United Kingdom’s Biobank and the United States’ All of Us Research Program.<sup>43</sup> GWASs allow researchers to pinpoint potential genetic markers for a specific trait through statistical analysis by comparing two cohorts: a cohort of people afflicted with a trait and a similar cohort of people lacking that trait.<sup>44</sup> Algorithms compare each study participant’s full genome against all other participants’ in search of genes that appear in the afflicted cohort at a higher rate than in the unaffected cohort.<sup>45</sup> The more genetic variants the algorithm takes into consideration, the stronger the predictive power of the final PRS algorithm.<sup>46</sup>

The outcome of the Classic Method is a single equation with a discrete number of included variables.<sup>47</sup> Here is a simple example of what this equation could look like:  $PRS = \beta_1 K_1 + \beta_2 K_2 \dots + \beta_n K_n$ .<sup>48</sup> In this example,  $\beta$  is the weight (how impactful the genetic variant is),  $K$  is the allele dosage (a number between 0 and 2, demonstrating the number of copies of the allele; 0 meaning no copies, 1 meaning one copy, and 2 meaning two copies), and  $n$  demonstrates the total number of genetic markers to be included in the calculation

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<sup>40</sup> *Id.* at 2759–60; Nilanjan Chatterjee et al., *Developing and Evaluating Polygenic Risk Prediction Models for Stratified Disease Prevention*, 17 NATURE REV. GENETICS 392, 397, 399 (2016).

<sup>41</sup> See Choi et al., *supra* note 39, at 2759–60.

<sup>42</sup> See *id.* at 2760, 2763.

<sup>43</sup> See William S. Weintraub et al., *Translational Medicine in the Era of Big Data and Machine Learning*, 123 CIRCULATION RSCH. 1202, 1202 (2018).

<sup>44</sup> See *Genome-Wide Association Studies Fact Sheet*, *supra* note 37.

<sup>45</sup> See *id.*

<sup>46</sup> See Guillaume Paré et al., *A Machine-Learning Heuristic to Improve Gene Score Prediction of Polygenic Traits*, 7 SCI. REPS. 1, 1 (2017).

<sup>47</sup> See Khader Shameer et al., *Machine Learning in Cardiovascular Medicine: Are We There Yet?*, 104 HEART 1156, 1158 (2018).

<sup>48</sup> See Chantal Babb de Villiers et al., *Understanding Polygenic Models, Their Development and The Potential Application of Polygenic Scores in Healthcare*, 57 J. MED. GENETICS 725, 726 (2020).

of one's overall risk.<sup>49</sup> Although it may seem that there would logically be only one "right" answer—that is, one equation that exactly accounts for the involved genes and appropriately assigns risk for a particular affliction—many different PRS models exist for the same conditions.<sup>50</sup> For example, one report listed ten recently developed PRS models for coronary artery disease, with the models taking into account between thirteen and 6.6 million genetic markers.<sup>51</sup> Another report listed twenty-nine different PRS algorithms taking into account between five and 313 genetic variants to assess breast cancer risk.<sup>52</sup>

There are a variety of reasons for the discrepancies in identified genetic markers among algorithms.<sup>53</sup> One reason is the rapidly advancing nature and availability of raw GWAS data.<sup>54</sup> Other reasons include investigator choices in data use,<sup>55</sup> specific model type chosen, and the particular goal of the study.<sup>56</sup> Finally, models vary in the type of inputs used: some models only take into account genetic variation, while others also consider traditional risk factors, such as age or gender, in their calculations.<sup>57</sup> At a high level, in the context of PRS models, more variables may, but do not always, translate to better predictive power because of a statistical phenomenon called "overfitting."<sup>58</sup> Overfitting happens when too many variables with very weak (or no) effect on the trait are included in the final model.<sup>59</sup> There is no universal standard for PRS modeling, and significant variation is present even among studies attempting to crack the genetic code for the same condition.<sup>60</sup>

There are other less common types of PRS algorithms in development.<sup>61</sup> Machine learning allows for more sophisticated pattern analysis that cannot

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<sup>49</sup> See *id.* at 726.

<sup>50</sup> SOWMIYA MOORTHIE ET AL., POLYGENIC SCORES, RISK AND CARDIOVASCULAR DISEASE 17 (Sept. 2019) <https://www.phgfoundation.org/media/143/download/prs-cvd-report-final.pdf?v=1&inline=1> [<https://perma.cc/WQN7-JFJA>].

<sup>51</sup> See *id.* at 51–52.

<sup>52</sup> See Ava Willoughby et al., *Genetic Testing to Guide Risk-Stratified Screens for Breast Cancer*, 9 J. PERSONALIZED MED., Mar. 2019, at 5, 5–6.

<sup>53</sup> See MOORTHIE ET AL., *supra* note 50, at 48.

<sup>54</sup> See *id.* at 47.

<sup>55</sup> See Laramie E. Duncan et al., *Analysis of Polygenic Risk Score Usage and Performance in Diverse Human Populations*, 10 NATURE COMM. 1, 3 (2019).

<sup>56</sup> See MOORTHIE ET AL., *supra* note 50, at 48–49.

<sup>57</sup> See *id.* at 49.

<sup>58</sup> See Yuta Takahashi et al., *Machine Learning for Effectively Avoiding Overfitting is a Crucial Strategy for the Genetic Prediction of Polygenic Psychiatric Phenotypes*, 10 TRANSLATIONAL PSYCHIATRY, no. 294, Aug. 2020, at 1, 1.

<sup>59</sup> See *id.*

<sup>60</sup> See MOORTHIE ET AL., *supra* note 50.

<sup>61</sup> See Shameer et al., *supra* note 47, at 1156.

be distilled into a linear equation.<sup>62</sup> For example, some flexible genomic prediction models use all available genetic variants—instead of only specific genome-wide variants flagged in GWASs—to determine a PRS.<sup>63</sup> Techniques frequently used in machine learning include complex decision trees and the development of artificial neural networks that enable computers to holistically evaluate one’s genetic makeup.<sup>64</sup> Interestingly, although it may seem intuitive that more sophisticated pattern analysis produces more effective results, that has not been the case to date.<sup>65</sup> The Classic Method has been shown more effective at predicting disease than current machine learning models; however, this could change as machine learning advances.<sup>66</sup> For that reason, and because of its prevalence, this Note contemplates only algorithms using the Classic Method.

## II. Background: The Law Behind Patent Eligibility and Genetics

*Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.*

—Justice Thomas, writing for the majority in *Association for Molecular Pathology v. Myriad Genetics, Inc.*<sup>67</sup>

The Constitution of the United States grants the government the power to oversee and distribute patents “[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”<sup>68</sup> The property right inherent in a patent is “the right to exclude others from making, using, offering for sale or selling” an inventor’s patented invention without the inventor’s consent.<sup>69</sup> This exclusive right is extended to the inventor for a term of twenty years.<sup>70</sup> As Justice Douglas explained in his concurrence in *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*,<sup>71</sup> “[e]very patent is the grant of a privilege of exacting tolls from the public. The Framers plainly did not

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<sup>62</sup> See *id.* at 1158.

<sup>63</sup> See Gad Abraham et al., *Genomic Prediction of Coronary Heart Disease*, 37 EUR. HEART J. 3267, 3268 (2016).

<sup>64</sup> See Shameer et al., *supra* note 47, at 1158.

<sup>65</sup> See Damian Gola et al., *Polygenic Risk Scores Outperform Machine Learning Methods in Predicting Coronary Artery Disease Status*, 44 GENETIC EPIDEMIOLOGY 125, 136 (2020).

<sup>66</sup> See *id.*

<sup>67</sup> 569 U.S. 576, 591 (2013).

<sup>68</sup> U.S. CONST. art. 1, § 8, cl. 8.

<sup>69</sup> 35 U.S.C. § 154(a)(1) (2018).

<sup>70</sup> See *id.* § 154(a)(2).

<sup>71</sup> 340 U.S. 147 (1950).

want those monopolies freely granted.”<sup>72</sup> Patents are serious business and are not to be given freely.

### A. Patent Eligibility and Section 101: The Statutory Requirement

A patent application must satisfy a number of basic tests for an examiner to grant a patent. The first test for potential patents comes from section 101, which addresses general subject matter eligibility.<sup>73</sup> General subject matter eligibility has two criteria that every granted patent must satisfy.<sup>74</sup> First, patents are specifically limited in subject matter by section 101, which 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 . . .”<sup>75</sup> Second, patents must not be directed at a judicial exception.<sup>76</sup> These judicial exceptions are subject matters that courts have held to either fall outside or be an exception to one of these categories.<sup>77</sup> The three non-patent eligible judicial exceptions are “laws of nature, natural phenomena, and abstract ideas.”<sup>78</sup>

The statutory requirement is meant to be a relatively straightforward standard. Every eligible patent must fall within one of the four statutory categories: (1) process; (2) machine; (3) manufacture; or (4) composition of matter.<sup>79</sup> However, it is not necessary that an invention squarely fit into one of the four categories or for a court to determine exactly which category the invention falls into.<sup>80</sup> A claimed invention must, in general, embody at least one category.<sup>81</sup>

A “machine” is a “concrete thing, consisting of parts, or of certain devices and combination of devices.”<sup>82</sup> A “manufacture” is “the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.”<sup>83</sup> Finally, a “composition of matter” is “all compositions of two

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<sup>72</sup> *Id.* at 154 (Douglas, J., concurring).

<sup>73</sup> 35 U.S.C. § 101.

<sup>74</sup> See *2104 Requirements of 35 U.S.C. 101 [R-10.2019]*, USPTO (June 25, 2020), <https://www.uspto.gov/web/offices/pac/mpep/s2104.html> [<https://perma.cc/YHU7-UHU5>].

<sup>75</sup> 35 U.S.C. § 101.

<sup>76</sup> See *2104 Requirements of 35 U.S.C. 101 [R-10.2019]*, *supra* note 74.

<sup>77</sup> See *id.*

<sup>78</sup> *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 70 (2012).

<sup>79</sup> See *2104 Requirements of 35 U.S.C. 101 [R-10.2019]*, *supra* note 74.

<sup>80</sup> See *State St. Bank & Tr. Co. v. Signature Fin. Grp.*, 149 F.3d 1368, 1375 (Fed. Cir. 1998).

<sup>81</sup> See *id.* at 1377.

<sup>82</sup> *Burr v. Duryee*, 68 U.S. 531, 570 (1864).

<sup>83</sup> *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931).

or more substances and all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids.”<sup>84</sup> An invention may fit more than one category.<sup>85</sup> For example, a mechanical pencil would fit the description of a machine, manufacture, and composition of matter.

A “process” is a “process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.”<sup>86</sup> The Supreme Court in *Gottschalk v. Benson*<sup>87</sup> further refined this definition to include “a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be *transformed* and reduced to a different state or thing.”<sup>88</sup> This question of whether an item has been transformed is called the machine-or-transformation test and is an “important clue” to a process patent claim.<sup>89</sup> While important, it is not a conclusive or irrefutable factor.<sup>90</sup>

### B. Patent Eligibility and Section 101: The Judicial Exception

Unlike the statutory requirement for patent eligibility, the judicial exception is much less straightforward. This is because the exception is meant to capture the more amorphous idea that we, as a society, do not want to grant patents that monopolize “laws of nature, natural phenomena or abstract ideas.”<sup>91</sup> This exception is inherently difficult to parse out for one critical reason: essentially all patentable inventions rely on one or all of these basic principles.<sup>92</sup> In fact, the U.S. Patent and Trademark Office (“USPTO”) itself has acknowledged the uncertainty and confusion around applying these judicial exceptions in a recently revised guidance document on this topic.<sup>93</sup>

In cases where a patent is directed to an abstract idea, the Supreme Court has created a two-step inquiry,<sup>94</sup> sometimes called the “*Alice/Mayo* test” or *Alice/Mayo* two-step framework,<sup>95</sup> to determine whether an invention is still

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<sup>84</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

<sup>85</sup> *See State St. Bank & Tr. Co.*, 149 F.3d at 1372.

<sup>86</sup> 35 U.S.C. § 100(b) (2018).

<sup>87</sup> 409 U.S. 63 (1972).

<sup>88</sup> *Id.* at 70 (emphasis added) (quoting *Cochrane v. Deener*, 94 U.S. 780, 787–88 (1877)).

<sup>89</sup> *Bilski v. Kappos*, 561 U.S. 593, 604 (2010).

<sup>90</sup> *See id.* at 603–04.

<sup>91</sup> *Mayo Collaborative Servs. v. Prometheus Lab’ys, Inc.*, 566 U.S. 66, 71 (2012).

<sup>92</sup> *See id.*

<sup>93</sup> *See* 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50, 50 (Jan. 7, 2019).

<sup>94</sup> While referred to as a two-step inquiry, this is a bit misleading. The *Alice/Mayo* test actually incorporates three steps: step 1, step 2A, and step 2B. *See id.*

<sup>95</sup> *Id.*

eligible for patent protection under section 101, even if aimed at a judicial exception.<sup>96</sup> If at any time the answer to one of these steps is *no*, the inquiry is concluded and the patent is deemed subject matter patent eligible.<sup>97</sup> Step 1 asks: Is the claim at issue directed at a “law[] of nature, natural phenomen[on], [or] abstract idea[]?”<sup>98</sup> If this answer is yes, then the analysis moves to step 2A where a court asks: Is the patent wholly directed to the unpatentable subject matter or is there simply a “patent-ineligible concept underlying the claim?”<sup>99</sup> If again the answer is yes—meaning, the patent *is* wholly directed at a prohibited subject matter—then the analysis moves to the final step, step 2B, which asks: “[W]hat else is there in the claims before us?”<sup>100</sup> Is there “something more?”<sup>101</sup> The goal here is for a court to distinguish patents that claim the “buildin[g] block[s]’ of human ingenuity, which are ineligible for patent protection, from those that integrate the building blocks into something more.”<sup>102</sup> This standard prevents companies from “improperly tying up” these fundamental building blocks in patents.<sup>103</sup> It also raises a critical distinction between *discovery* and *invention*—the former is prohibited, and the latter is at the core of all patents.<sup>104</sup> The rationale is easy to understand: “Manifestations of nature” are intended to be free to all such that newly discovered naturally occurring resources like minerals or laws of nature, for example plutonium or Einstein’s theory of relativity, cannot be patented.<sup>105</sup>

In *Ariosa Diagnostics v. Sequenom*,<sup>106</sup> a 2015 Federal Circuit decision, the court attempted to clarify the *Alice/Mayo* test in the context of complex diagnostics.<sup>107</sup> In this case, Sequenom appealed a district court decision that denied Sequenom’s motion of a preliminary injunction against Ariosa.<sup>108</sup> Sequenom

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<sup>96</sup> See *Alice Corp. Pty. v. CLS Bank Int’l*, 573 U.S. 208, 217 (2014).

<sup>97</sup> See 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. at 51.

<sup>98</sup> *Alice Corp. Pty.*, 573 U.S. at 217.

<sup>99</sup> *Roche Molecular Sys. v. Cepheid*, 905 F.3d 1363, 1368 (Fed. Cir. 2018) (quoting *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1050 (Fed. Cir. 2016)).

<sup>100</sup> *Alice Corp. Pty.*, 573 U.S. at 217 (quoting *Mayo Collaborative Servs. v. Prometheus Lab’ys, Inc.*, 566 U.S. 66, 78 (2012)).

<sup>101</sup> *Id.* at 208.

<sup>102</sup> *Id.* (alteration in original) (quoting *Mayo*, 566 U.S. at 89).

<sup>103</sup> See *id.* at 216 (quoting *Mayo*, 566 U.S. at 85).

<sup>104</sup> See *U.S. Const. Annotated: Patentable Discoveries*, CORNELL L. SCH.: LEGAL INFO. INST., <https://www.law.cornell.edu/constitution-conan/article-1/section-8/clause-8/patentable-discoveries> [<https://perma.cc/45L4-NXMY>].

<sup>105</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

<sup>106</sup> 788 F.3d 1371 (Fed. Cir. 2015).

<sup>107</sup> See *id.* at 1375–76.

<sup>108</sup> See *id.* at 1374.

claimed Ariosa infringed on its patent for a specific type of non-invasive paternity test.<sup>109</sup> Sequenom's claimed discovery was that fetal DNA could be isolated from a pregnant woman's blood in order to perform basic genetic tests.<sup>110</sup> Sequenom's patent sought to claim certain methods of using a specific kind of fetal DNA (called "cffDNA").<sup>111</sup> The methods included creating copies of the DNA by using polymerase chain reactions, and detecting genetic traits by using staining techniques.<sup>112</sup> The court evaluated the patent under the *Alicel Mayo* test. Under step 1, the court concluded the patent was aimed at a judicial exception.<sup>113</sup> Yet under step 2, the court found that because a claim must put forth an "inventive concept" to become patent eligible, and Sequenom's amplification and detection techniques relied on "well-understood, routine, and conventional" activity, the patent claim failed under section 101.<sup>114</sup>

In a similar case in 2017, the Federal Circuit again rejected a diagnostic patent under step 2 of the *Alicel Mayo* test.<sup>115</sup> In *Cleveland Clinic Foundation v. True Health Diagnostics*,<sup>116</sup> the court considered a diagnostic patent which tested for the prevalence of a particular enzyme and utilized statistical methods to determine the risk of cardiovascular disease based on the amount of enzyme found in a patient's fluid sample.<sup>117</sup> Cleveland Clinic utilized a statistical model, similar to a PRS score, that compared the enzyme levels of those with and without cardiovascular disease to determine a risk scale.<sup>118</sup> Under *Alicel Mayo* step 2, the court found the patent ineligible because it lacked an "inventive concept that transforms the natural phenomena of MPO being associated with cardiovascular risk into a patentable invention. *Mayo* and *Ariosa* make clear that transforming claims that are directed to a law of nature requires more than simply stating the law of nature while adding the words 'apply it.'"<sup>119</sup>

After much confusion and inconsistency in granting patent applications relating to abstract ideas, in 2019 the USPTO issued a guidance document

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<sup>109</sup> *See id.*

<sup>110</sup> *See id.* at 1373, 1381.

<sup>111</sup> *See id.* at 1373. The abbreviation cffDNA stands for cell-free fetal DNA. *See id.*

<sup>112</sup> *See id.*

<sup>113</sup> *See id.* at 1376.

<sup>114</sup> *Id.* at 1378.

<sup>115</sup> *See Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1362 (Fed. Cir. 2017).

<sup>116</sup> 859 F.3d 1352 (Fed. Cir. 2017).

<sup>117</sup> *See id.* at 1355–56.

<sup>118</sup> *See id.* at 1356.

<sup>119</sup> *Id.* at 1362 (quoting *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 566 U.S. 66, 72 (2012)).

attempting to narrow this judicial exception.<sup>120</sup> While not carrying the force of law, it does elucidate the USPTO's position on this topic—namely that the USPTO seems to support a more patent-friendly framework.<sup>121</sup> Under this guidance, patent applications for abstract ideas fail the judicial-exception step only if they include “mathematical concepts, certain methods of organizing human activity, and mental processes.”<sup>122</sup> For PRS patent analysis, the category of “certain methods of organizing human activity” is not applicable, but the other two categories are.<sup>123</sup> The USPTO further elaborates on mathematical concepts as pertaining to “mathematical relationships, mathematical formulas or equations, [and] mathematical calculations.”<sup>124</sup> Mental processes are defined as “concepts performed in the human mind (including an observation, evaluation, judgment, opinion).”<sup>125</sup> If a patent includes an abstract idea but it is not directed at one of these three categories, patent examiners are instructed to deem the patents as not falling within the abstract idea exception, except in rare circumstances.<sup>126</sup> But under this guidance, if a patent application is directed at a mathematical concept, certain method of organizing human activity, or mental process, it can overcome ineligibility if the “claim integrates the abstract idea into a practical application.”<sup>127</sup>

### C. A Pivotal Process Case in Subject Matter Eligibility: *Flook*

An important Supreme Court decision for subject matter eligibility is *Parker v. Flook*,<sup>128</sup> which was decided in 1978.<sup>129</sup> In *Flook*, the respondent sought a patent for a method of updating an alarm system for a catalytic converter.<sup>130</sup> The alarm was programmed to sound when certain variables (temperature, pressure, flow rate) exceeded normal predetermined limits, indicating a potential problem or hazard.<sup>131</sup> Alarm limits are typically fixed during normal operation, but adjusting the limits extemporaneously are necessary during temporary operating conditions, for example, when the process of

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<sup>120</sup> See 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50, 50 (Jan. 7, 2019).

<sup>121</sup> See generally *id.*

<sup>122</sup> *Id.* at 50.

<sup>123</sup> *Id.* at 51–52.

<sup>124</sup> *Id.* The USPTO relied on Supreme Court and Federal Circuit precedent, see *id.* at 52 n.12, which will be discussed in the following Section.

<sup>125</sup> *Id.* (footnote omitted).

<sup>126</sup> See *id.* at 53.

<sup>127</sup> *Id.* at 54.

<sup>128</sup> 437 U.S. 584 (1978).

<sup>129</sup> See *id.*

<sup>130</sup> See *id.* at 585.

<sup>131</sup> See *id.*

catalytic chemical conversion is starting up.<sup>132</sup> The patent described a three-step process: measuring the current conditions (temperature, pressure flow rate), plugging these variables into an algorithm to update the alarm limit, and adjusting the alarm limit to the new standard.<sup>133</sup>

The initial patent examiner rejected the application because he found the only novel feature was the mathematical algorithm in the second step of the process.<sup>134</sup> Importantly, the novelty of a new mathematical formula is not a determining factor in patent eligibility.<sup>135</sup> Hoping to pass the abstraction problem, the respondents attempted to limit the scope of their claimed invention to only the catalytic chemical conversion of hydrocarbons.<sup>136</sup> While this limited scope still covered a broad category, it did not cover “every conceivable application of the formula.”<sup>137</sup> Ultimately the Court decided:

Here it is absolutely clear that respondent’s application contains no claim of patentable invention. The chemical processes involved in catalytic conversion of hydrocarbons are well known, as are the practice of monitoring the chemical process variables, the use of alarm limits to trigger alarms, the notion that alarm limit values must be recomputed and readjusted, and the use of computers for “automatic monitoring-alarming.”<sup>138</sup>

The Court later expounded on the holding of *Flook* in *Diamond v. Diehr*,<sup>139</sup> stating that an abstract mathematical formula does not become patent eligible if the application of the formula is limited to a “particular technological environment.”<sup>140</sup>

#### **D. The Modern Subject Matter Eligibility Trio: *Bilski*, *Mayo*, and *Myriad***

A trio of cases starting with *Bilski v. Kappos*<sup>141</sup> in 2010 reinvigorated the subject matter eligibility debate at the Supreme Court, which had been dormant for three decades after the Court decided *Diamond* in 1981.<sup>142</sup> In *Bilski*, petitioners sought patent protection, in part, for an algorithm that explained how

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<sup>132</sup> See *id.*

<sup>133</sup> See *id.*

<sup>134</sup> See *id.* at 587.

<sup>135</sup> See *id.* at 591.

<sup>136</sup> See *id.* at 586.

<sup>137</sup> *Id.*

<sup>138</sup> *Id.* at 594.

<sup>139</sup> 450 U.S. 175 (1981).

<sup>140</sup> *Id.* at 191.

<sup>141</sup> 561 U.S. 593 (2010).

<sup>142</sup> See J. Michael Jakes & Erika Harmon Arner, *Bilski and Beyond — The Uncertain State of Patent-Eligible Subject Matter in the United States*, MANAGING INTELL. PROP. (June 2010), <https://www.finnegan.com/en/insights/articles/bilski-and-beyond-the-uncertain-state-of-patent-eligible-subject.html> [<https://perma.cc/CB4L-3VEP>].

risk hedging works for buyers and sellers in the energy market.<sup>143</sup> The patent application also included a simple mathematics claim, which attempted to distill the process of risk hedging into a formula.<sup>144</sup> The patent was rejected because the claim was not a process, as argued by petitioners, but instead a basic abstract economic idea taught in “any introductory finance class.”<sup>145</sup> This case stands for the key conclusion that the machine-or-transformation test is not the be-all-end-all analysis when assessing a process patent.<sup>146</sup> Instead, it is meant to serve as a “useful and important” tool in this type of patent inquiry.<sup>147</sup>

Following *Bilski*, the Court decided *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*<sup>148</sup> in 2012. In *Mayo*, the Supreme Court struck down a process patent application for a diagnostic test that outlined a correlative effect between the metabolite levels of a specific drug in a patient and the subsequent efficacy of that drug.<sup>149</sup> The patent in question also provided guidance to doctors outlining the administration and management of the drug.<sup>150</sup> The question before the Court was: “Do the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent eligible processes that *apply* natural laws?”<sup>151</sup> The answer the Court arrived at was no.<sup>152</sup> The Court held that not every new application of a law of nature is novel and patentable.<sup>153</sup> As for the guidance steps for doctors, the Court stated the steps “simply tell doctors to gather data from which they may draw an inference in light of the correlations. To put the matter more succinctly, the claims inform a relevant audience about certain

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<sup>143</sup> See *Bilski*, 561 U.S. at 599, 611.

<sup>144</sup> See *id.*

<sup>145</sup> *Id.* at 611 (quoting *In re Bilski*, 545 F.3d 943, 1013 (Fed. Cir. 2008) (Rader, J., dissenting)).

<sup>146</sup> See *id.* at 604.

<sup>147</sup> *Id.* While it intended to clear up ambiguity about the machine-or-transformation test, the Court noted that the test “would create uncertainty as to the patentability of software, *advanced diagnostic medicine techniques*, and inventions based on linear programming.” *Id.* at 605 (emphasis added). Justice Kennedy opined on how the machine-or-transformation test was used successfully for inventions during the Industrial Age—when inventions were physical objects. See *id.* However, now in the Information Age, the test struggles to adapt to non-physical inventions (for example, computer programs). See *id.* at 605–06.

<sup>148</sup> 566 U.S. 66 (2012). This is the same *Mayo* discussed above in relation to the *Alicel Mayo* test. See *Alice Corp. Pty. v. CLS Bank Int’l*, 573 U.S. 208, 217–18 (2014); see *supra* Section II.B.

<sup>149</sup> See *Mayo*, 566 U.S. at 67.

<sup>150</sup> See *id.* at 78.

<sup>151</sup> *Id.* at 77 (emphasis in original).

<sup>152</sup> See *id.*

<sup>153</sup> See *id.* at 90.

laws of nature; any additional steps consist of well-understood, routine, conventional activity . . . ”<sup>154</sup> Mere correlation is not a genuine application of natural law; it is itself the natural law.<sup>155</sup>

Finally, in 2013, the Court heard *Association for Molecular Pathology v. Myriad Genetics, Inc.*<sup>156</sup> Here, the Court significantly altered patent law by holding that a naturally occurring DNA segment, a gene, is not patent eligible.<sup>157</sup> This ruling was significant in part because it was estimated that at that time nearly 20% of the human genome had been patented in the United States.<sup>158</sup> That translated to nearly 4,300 patented genes.<sup>159</sup> At issue were Myriad’s patents which claimed the discovery of the “precise location and sequence” of the BRCA1 and BRCA2 genes, two genes which correlate to an increased risk of breast and ovarian cancer.<sup>160</sup> A valid patent gave Myriad the “exclusive right to isolate an individual’s BRCA1 and BRCA2 genes.”<sup>161</sup> The patent was valid from 1997 until the *Myriad* ruling in 2013.<sup>162</sup> During this time, Myriad possessed a monopoly on BRCA testing, and women were charged as much as \$4,000 for a test which, post-*Myriad*, costs as little as \$100.<sup>163</sup> Before the patent was invalidated, Myriad had sold roughly one million tests, earning \$2 billion in revenue.<sup>164</sup> The American Civil Liberties Union brought this case on behalf of “researchers, genetic counselors, women patients, cancer survivors, breast cancer and women’s health groups, and

<sup>154</sup> *Id.* at 79–80.

<sup>155</sup> *See id.* at 77.

<sup>156</sup> 569 U.S. 576 (2013).

<sup>157</sup> *See id.* at 580.

<sup>158</sup> *See* Alexi Horowitz-Ghazi, *Genetic Gold Rush: How Supreme Court Heard a Case on Patenting Human Genome*, NAT’L PUB. RADIO (Nov. 27, 2020, 3:46 PM), <https://www.npr.org/2020/11/27/939532309/genetic-gold-rush-how-supreme-court-heard-a-case-on-patenting-human-genome> [<https://perma.cc/9YD8-WAPN>].

<sup>159</sup> *See Can Genes be Patented?*, MEDLINEPLUS (Feb. 14, 2022), <https://medlineplus.gov/genetics/understanding/testing/genepatents/> [<https://perma.cc/K3G6-JV3J>].

<sup>160</sup> *Myriad Genetics, Inc.*, 569 U.S. at 582–83. The presence of these genes could increase the risk of breast cancer by up to 80% and ovarian cancer by up to 50%. *Id.* at 583.

<sup>161</sup> *Id.* at 585.

<sup>162</sup> *See* Jacob S Sherkow & Christopher Scott, Commentary, *CASE STUDY: Myriad Stands Alone*, 32 NATURE BIOTECHNOLOGY 620, 620 (2014). Myriad was denied patentability of the BRCA genes, but the Court did uphold a related patent which involved the manufacturing of a synthetic BRCA gene (cDNA). *See Myriad Genetics, Inc.*, 569 U.S. at 594–95.

<sup>163</sup> *See* Sherkow & Scott, *supra* note 162, at 620.

<sup>164</sup> *See id.*

scientific associations representing 150,000 geneticists, pathologists, and laboratory professionals.”<sup>165</sup>

### E. Current Developments in Patentability of Polygenic Risk Scores

Applicants seeking to patent PRS algorithms and diagnostics have already been successful. A search for “polygenic risk score” in the USPTO patent database returns eleven current patents,<sup>166</sup> one of the most recent of which was granted on January 19, 2021, to Ancestry.com for a polygenic risk score algorithm using the Classic Method to predict phenotypes and match individuals with their genetic community.<sup>167</sup> However, a broader search of “genetic diagnostic” in the USPTO database yields more than 200 issued patents.<sup>168</sup>

This Note uses one PRS patent to stand in as a representative example for issued patents of this nature. This patent is titled “Methods And Compositions For Correlating Genetic Markers With Prostate Cancer Risk” (“Prostate Cancer Patent”) and was granted on October 15, 2019, to Wake Forest University Health Sciences.<sup>169</sup> The patent is for a PRS method which assesses a patient’s risk for prostate cancer.<sup>170</sup> The patented method uses a version of a classic PRS algorithm to assign a risk score for developing prostate cancer based on the presence and weighted risk of genetic markers in a man’s DNA.<sup>171</sup> The method includes accounting for thirty-three genetic markers in addition to qualitative variables such as the “subject’s family history, prostate specific antigen (PSA) level, free to total PSA ratio, age, prostate volume, prior prostate biopsy history, number of previous biopsy cores and/or family

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<sup>165</sup> *Association for Molecular Pathology v. Myriad Genetics*, ACLU (June 13, 2013), <https://www.aclu.org/cases/association-molecular-pathology-v-myriad-genetics> [<https://perma.cc/UL3K-QZS7>]. In oral argument, Myriad’s lawyer compared the discovery of a gene to the making of a baseball bat: “A baseball bat doesn’t exist until it’s isolated from a tree, but that’s still the product of human invention to decide where to begin the bat and where to end the bat.” Horowitz-Ghazi, *supra* note 158 (statement of attorney Gregory Castanias).

<sup>166</sup> *Polygenic Risk Score*, USPTO, <http://patft.uspto.gov/netahtml/PTO/search-bool.html> (in content box directly to the right of “Term 1” type “polygenic risk score”; click “search”) [<https://perma.cc/AKF4-RDRL>].

<sup>167</sup> *Estimation of Phenotypes Using DNA, Pedigree, And Historical Data*, U.S. Patent No. 10,896,742 (filed Oct. 31, 2019) (issued Jan. 19, 2021).

<sup>168</sup> *Genetic Diagnostic*, USPTO, <http://patft.uspto.gov/netahtml/PTO/search-bool.html> (in content box directly to the right of “Term 1” type “genetic diagnostic”; click “search”) [<https://perma.cc/F24R-KDTR>].

<sup>169</sup> *Methods and Compositions for Correlating Genetic Markers with Prostate Cancer Risk*, U.S. Patent No. 10,443,105 (filed Aug. 11, 2017) (issued Oct. 15, 2019).

<sup>170</sup> *See id.*

<sup>171</sup> *See id.*

history.”<sup>172</sup> The result is a single number, intended to determine whether or not a man is at high risk for prostate cancer.<sup>173</sup>

In addition to a single number embodying risk, the subject may also have information as to his percentile risk (compares subject’s risk against general population), absolute risk (describes cancer risk over the subject’s lifetime), and overall cancer risk.<sup>174</sup> A clinician can then use this information to “determine courses of action for treating or preventing or monitoring the occurrence of prostate cancer.”<sup>175</sup> Potential courses of action might include moving forward with a prostate biopsy or prescribing chemo-preventive therapy.<sup>176</sup> Because there is no “normal” PRS value included in the patent, there are no threshold scores provided to guide a clinician to take a specific course of action, the scores are merely meant to serve as a tool for informed decision-making.<sup>177</sup> It is up to the patient and clinician to determine the “clinically meaningful” risk level for a particular patient.<sup>178</sup>

### III. Analysis: The Science Applied to Law

*To grant to a single party a monopoly of every slight advance made, except where the exercise of invention, somewhat above ordinary mechanical or engineering skill, is distinctly shown, is unjust in principle and injurious in its consequences. The design of the patent laws is to reward those who make some substantial discovery or invention, which adds to our knowledge and makes a step in advance in the useful arts. Such inventors are worthy of all favor. It was never the object of those laws to grant a monopoly for every trifling device, every shadow of a shade of an idea, which would naturally and spontaneously occur to any skilled mechanic or operator in the ordinary progress of manufactures.*

—Justice Bradley, writing for the majority in *Atlantic Works v. Brady*<sup>179</sup>

#### A. Patent Eligibility and Section 101: Polygenic Risk Score Algorithms Raise Questions About Subject Matter Eligibility Under Statutory Requirements

The statutory requirements under section 101 contemplate only four categories of patentable subject matters: (1) process; (2) machine; (3) manufacture; or (4) composition of matter.<sup>180</sup> Because neither the PRS algorithms

<sup>172</sup> *Id.*

<sup>173</sup> *See id.* A number greater than 1.00 indicates an increased risk. *See id.*

<sup>174</sup> *See id.*

<sup>175</sup> *Id.*

<sup>176</sup> *See id.*

<sup>177</sup> *Id.*

<sup>178</sup> *Id.*

<sup>179</sup> 107 U.S. 192, 200 (1883).

<sup>180</sup> *See* 35 U.S.C. § 101 (2018).

nor the subsequent scores are physical items, they cannot qualify as a machine, manufacture, composition of matter, or material under section 101.<sup>181</sup> That means the only remaining category which could capture PRS algorithms is the process category.<sup>182</sup> Although the purpose of the algorithms is to *transform* raw genetic data into useable, actionable information, it is unclear whether that transformation is enough to satisfy the basic machine-or-transformation test. Although the test is not the be-all-end-all in this analysis, it is meant to serve as a key indicator in this type of patent inquiry.<sup>183</sup> As explicitly noted by the Court in *Bilski*, “[T]he machine-or-transformation test would create uncertainty as to the patentability of software, *advanced diagnostic medicine techniques*, and inventions based on linear programming . . .”<sup>184</sup> However, if the PRS algorithm is deemed a process, then it still runs into the problem of judicial exceptions.

### **B. Patent Eligibility and Section 101: Polygenic Risk Score Algorithms Fail Subject Matter Eligibility Under Judicial Exceptions**

PRS algorithms are closer to natural correlation than a patentable process. To an outsider, it seems as if the USPTO has been transfixed and acquiescent to the undoubtedly extraordinary and valuable nature of PRS algorithms, even though they are indistinguishable from the unpatentable processes in *Flook*, *Ariosa*, and *Cleveland Clinic*. First, in *Flook*, the patent in question was intended to update the alarm system on a catalytic converter as conditions changed.<sup>185</sup> The invalidated patent required three steps: measuring current conditions, applying an algorithm to those conditions, and updating the alarm settings.<sup>186</sup> The Prostate Cancer Patent is hardly distinguishable. The Prostate Cancer Patent similarly measures current conditions (taking a DNA sample from a patient), applies an algorithm to those conditions (applying the weighted thirty-three gene PRS algorithm), and provides the doctor and patient with an updated diagnostic measure (producing a PRS score).<sup>187</sup> The

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<sup>181</sup> See *Burr v. Duryee*, 68 U.S. 531, 570 (1864); *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931); *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (collectively holding that any patentable machine, manufacture, composition of matter, or material is a physical object).

<sup>182</sup> See § 101.

<sup>183</sup> See *Gottschalk v. Benson*, 406 U.S. 63, 70 (1972).

<sup>184</sup> *Bilski v. Kappos*, 561 U.S. 593, 605 (2010) (emphasis added) (noting the many *amicus* briefs submitted which also supported this concern).

<sup>185</sup> See *Parker v. Flook*, 437 U.S. 584, 585 (1978).

<sup>186</sup> See *id.*

<sup>187</sup> See generally ‘105 Patent.

novelty of a new mathematical formula is not enough.<sup>188</sup> Simply applying the formula to a very specific field, like genetics, is not sufficient to clear the judicial exception hurdle.

Now turning the discussion to *Ariosa*, which featured a patent similar to the Prostate Cancer Patent. In *Ariosa*, the court acknowledged the remarkable discovery of isolating fetal DNA from a pregnant woman's blood in order to perform basic genetic tests, but reiterated that being remarkable alone is not sufficient to make a discovery patentable.<sup>189</sup> Like the diagnostic test in *Ariosa*, the Prostate Cancer Patent also does not apply a new and novel technology—it repurposes “well-understood, routine, and conventional activity.”<sup>190</sup> Genetic testing is already a common activity and mapping the interactions between one's genes and one's risk is so widely available that the average consumer can purchase it for \$199.<sup>191</sup> Again, the patent in *Ariosa* relied upon tried-and-true medical technologies that are analogous to the types of technologies used in the Prostate Cancer Patent.<sup>192</sup> This comparison is affirmed by *Cleveland Clinic*, where the process patent, linking certain levels of an enzyme to cardiovascular disease risk, was held ineligible.<sup>193</sup> Here too, the Prostate Cancer Patent merely attempts to patent the correlation between a specific group of biomarkers and the risk of developing an illness.<sup>194</sup> PRS algorithms—like the Prostate Cancer Patent—are nearly indistinguishable from patents that the court has held invalid because they are directed at a judicial exception.

### C. Patent Eligibility Hypothetical: *Byriad*

Consider an alternate universe where instead of Myriad attempting to patent the precise location of the genes, a fictitious company named Byriad seeks to patent the *knowledge* that the presence of two specific genes in a woman's DNA correlates with increased risk for breast and ovarian cancers by up to 80% and 50%, respectively. Byriad asserts no other claims. The USPTO would certainly reject that application because it attempts to patent a natural phenomenon or abstract idea.<sup>195</sup> Would the USPTO change

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<sup>188</sup> See *Flook*, 437 U.S. at 591.

<sup>189</sup> See *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379–80 (Fed. Cir. 2015).

<sup>190</sup> *Id.* at 1378.

<sup>191</sup> See *Health + Ancestry Service*, 23ANDME, <https://www.23andme.com/dna-health-ancestry?sub=ver2&cabt=nao> [<https://perma.cc/Z5QE-HYXX>].

<sup>192</sup> See *Ariosa Diagnostics, Inc.*, 788 F.3d at 1373.

<sup>193</sup> See *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1355–56 (Fed. Cir. 2017).

<sup>194</sup> See '105 Patent.

<sup>195</sup> Cf. *Ariosa Diagnostics, Inc.*, 788 F.3d at 1379.

its decision if instead of merely patenting the knowledge as is, Byriad created a simple PRS equation capturing the same information, for example:  $PRS_{Breast\ Cancer} = 0.8_{BRCA1}K_{BRCA1} + 0.5_{BRCA2}K_{BRCA2}$ ?<sup>196</sup> It seems logical that the USPTO would reject this case as well; it is nearly identical to the *Bilski* and *Cleveland Clinic* cases,<sup>197</sup> and the claim is still an abstract idea—a math equation—focused on capturing a natural phenomenon. To take the analysis one step further, it would be even more unlikely for the patent to prevail if such an application mirrored the Prostate Cancer Patent by failing to include specific directives for how the score should be interpreted and to provide guidance for suggested clinical steps based on a patient’s score.<sup>198</sup>

While undoubtedly useful, this extra benchmarking and clinical directive information would likely still not be enough for Byriad to defend its fictitious patent. At its core, the patent still seeks to capture some natural correlative phenomenon. And, under *Mayo*, directing physicians to engage in well-understood and conventional practices based on new clinical information does not rise to the level of invention necessary to overcome the subject matter requirement.<sup>199</sup>

Additionally, the patent would easily fail the updated USPTO’s guidance on abstract ideas pertaining to “concepts performed in the human mind (including an observation, evaluation, judgment, opinion).”<sup>200</sup> Instructing a doctor to engage in routine clinical practices—such as considering new information, ordering additional testing, or discussing ordinary prophylactic measures with a patient—is just telling doctors to engage in tasks they already do. In fact, failing to participate in such basic forms of observation, evaluation and discussion would be malpractice.<sup>201</sup> Similarly, Byriad’s patent would no more likely be successful if it took into account risk factors included in the Prostate Cancer Patent, like family history of the disease and the results of previous prostate biopsies, because even the most medically unqualified

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<sup>196</sup> This equation and the  $\beta$  values featured here are entirely made up by the author for illustrative purposes.

<sup>197</sup> Cf. *Bilski v. Kappos*, 561 U.S. 593 (2010); *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352 (Fed. Cir. 2017).

<sup>198</sup> Of course, patent autonomy is still of critical importance. Such thresholds would simply suggest specific outcomes and plans of action for clinicians to discuss with patients who meet delineated PRS thresholds (e.g., a PRS of 1 indicates moderately high risk and supports further non-invasive testing; a PRS of 1.5 indicates very high risk and supports further invasive testing; and a PRS of 1.9 indicates the highest level of risk and supports invasive testing and aggressive prophylactic treatments).

<sup>199</sup> See *Mayo Collaborative Servs. v. Prometheus Lab’s, Inc.*, 566 U.S. 66, 79–80 (2012).

<sup>200</sup> 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50, 52 (Jan. 7, 2019).

<sup>201</sup> See *Malpractice*, BLACK’S LAW DICTIONARY (11<sup>th</sup> ed. 2019).

individual could postulate the correlation between these factors and likelihood of disease.<sup>202</sup> Generally speaking, current PRS algorithms are not patentable processes and are instead mere recitations of natural laws, and therefore do not pass the *Alice/Mayo* test.<sup>203</sup>

This raises the question: At what point would this fictitious Byriad patent become patent eligible? Would the algorithm simply need to consider more genetic factors? What about more non-genetic factors? The USPTO has granted a patent for a basic math equation capturing the natural correlation among thirty-three genetic markers and a handful of well-known predispositions, e.g., the Prostate Cancer Patent, but weighing just two genetic factors seems insufficient, as illustrated by the Byriad example.

Logically, there should be a line where these basic math equations evolve into “something more” to satisfy step two of the *Alice/Mayo* test—right now, it must exist somewhere between two and thirty-three.<sup>204</sup> Arguably, mapping of the correlation among 6.6 million genetic markers to determine one’s risk of coronary artery disease is not purely a function of natural correlation and is instead a process which rises to the level of “something more.”<sup>205</sup> But what about the correlation among 49,310 genetic markers? Fifty?<sup>206</sup> Both the fictitious Byriad patent and the very real Prostate Cancer Patent do not appear to satisfy the “something more” test under current case law, so where exactly should courts draw the line between mere correlations and meaningful algorithmic processes in genetic testing?

#### **D. How Polygenic Risk Score Patents Could Pass Section 101 Without Physical Elements**

If we, as a society, deem it necessary to grant PRS algorithm patents, the courts would need to make significant changes to patent doctrine in order to achieve this goal while protecting the public from the over-commercialization of genetic information. One solution is to decide on a number of variables that universally meet the standard of qualifying as “something more” under the *Alice/Mayo* test for PRS algorithms—for example, setting a threshold  $n$  value in  $PRS = \beta_1 K_1 + \beta_2 K_2 \dots + \beta_n K_n$ .<sup>208</sup> With input from geneticists, researchers, and statisticians, courts could identify a reasonable target number of variables which would give companies some basic assurance that their

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<sup>202</sup> See ‘105 Patent.

<sup>203</sup> See *Alice Corp. Pty. v. CLS Bank Int’l*, 573 U.S. 208, 217 (2014).

<sup>204</sup> See *id.* at 217–18 (citing *Mayo*, 566 U.S. at 89).

<sup>205</sup> MOORTHIE ET AL., *supra* note 50, at 51.

<sup>206</sup> See *id.*

<sup>207</sup> See *id.*

<sup>208</sup> See Babb de Villiers et al., *supra* note 48, at 726.

algorithms would pass the subject matter eligibility analysis. At minimum, this number will serve as a gatekeeping mechanism while the USPTO works to develop a more nuanced framework to capture the distinction between patenting an actual diagnostic invention and patenting a natural genetic correlation.

To establish an effective gatekeeping mechanism quickly, courts should reinterpret the *Alice/Mayo* test such that at least 50% of the simplest PRS algorithms—those which take into account the least number of variables—are deemed patent ineligible. This would guard against the most obvious attempts to capture natural correlation. To arrive at this number, a court could start by turning to the scientific literature to identify the number of genetic variables used by the average PRS algorithm. For example, when looking at the scientific literature for coronary artery disease, of the ten recently published PRS algorithms, six algorithms consider up to fifty variables, one algorithm considers up to sixty-three variables, and three algorithms consider between sixty-three and 6.6 million variables.<sup>209</sup> Requiring more than fifty variables ( $n > 50$ ) would be a good starting point in the discussion. This number is also supported when compared against the twenty-nine reported PRS breast cancer models, of which fifteen, or 51%, utilize less than fifty-one variables.<sup>210</sup> One major flaw of this solution is that there is nothing to stop researchers from including a few extra variables with negligible influence in order to meet this artificial threshold. To counter this, the USPTO might require that patent applicants demonstrate the statistical importance of each variable in their algorithm or require that the weight assigned to each variable ( $\beta$ ) reach a certain threshold.

A second—and more radical—solution is to legislate a shorter protection period for patented inventions that contain genetic components. A twenty-year monopoly is an eternity in this area of science. By shortening the lifespan of a PRS patent, we could more effectively balance the interests of businesses and the public. One flaw in this solution is that to make a meaningful difference, the legislature would need to radically decrease the patent lifespan—beyond even our historical minimum of fourteen years.<sup>211</sup> It is likely that stakeholders would push back on this decision because, after all, this change would shorten the timeline on their very valuable state-sanctioned monopoly. However, given the ambiguity currently entrenched in the system, it is possible stakeholders would welcome a decision that removes ambiguity in this highly lucrative area of personalized medicine.

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<sup>209</sup> See MOORTHIE ET AL., *supra* note 50, at 51–52.

<sup>210</sup> See Willoughby et al., *supra* note 52, at 5–6.

<sup>211</sup> See Simon Lester & Huan Zhu, *Rethinking the Length of Patent Terms*, 34 AM. U. INT'L L. REV. 787, 787 (2019).

A third solution with a similar outcome is to grant twenty-year patents but with a stipulation that each patent is up for review every few years—for example, every five years—for both subject matter eligibility and other basic patent requirements such as non-obviousness in light of new technological advancements. This solution would nicely balance the interests of the companies investing in this technology and of the general public. It also would minimize the number of subject matter eligibility challenges brought in court because challenging parties may be more likely to simply “wait and see” if a patent is invalidated when it is up for its periodic review.

### **E. How Polygenic Risk Score Patents Could Pass Section 101 With Physical Elements**

Under current case law, PRS algorithm patents like the Prostate Cancer Patent should not be patent eligible under section 101,<sup>212</sup> but they could be patentable without major structural changes if the USPTO adopts a model that allows for the protection of PRS algorithms only when they are encapsulated in a tangible patent-eligible technology. For example, PRS algorithms could be patentable if they were framed as software loaded into a new physical genetic diagnostic machine—thereby easily passing the machine-or-transformation test as the new patent would involve a tangible object. Similarly, they could be patent eligible when used in conjunction with personalized pharmaceuticals or treatment plans optimized for particular scores, for the same reason.<sup>213</sup> Finally, akin to the science previewed in *Gattaca*,<sup>214</sup> PRS algorithms could be patented in combination with CRISPR-Cas9 technologies, which are controversial genetic editing technologies.<sup>215</sup> Polygenic risk scores could be used to test potential fertilized embryos for predisposition for disease, and then CRISPR-Cas9 technologies could be used to edit out the undesired

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<sup>212</sup> See *supra* Section III.B.

<sup>213</sup> See generally Karen Carroll & Sharad Bijanki, *Post-Myriad Legal and Policy Considerations for Patenting Genetic Inventions*, IPWATCHDOG (Mar. 10, 2019, 12:15 PM), <https://www.ipwatchdog.com/2019/03/10/post-myrriad-legal-policy-considerations-patenting-genetic-inventions/id=107131/> [<https://perma.cc/X69N-VWDY>].

<sup>214</sup> See *GATTACA*, *supra* note 1.

<sup>215</sup> See David Cyranoski, *What CRISPR-Baby Prison Sentences Mean for Research*, NATURE (Jan. 3, 2020) <https://www.nature.com/articles/d41586-020-00001-y> [<https://perma.cc/KJ3H-TZL6>]. CRISPR technology, “typically comprises a DNA-cutting enzyme known as Cas9 and a molecule that guides it to a specific DNA sequence, is often compared to molecular scissors.” Jon Cohen, *The Latest Round in the CRISPR Patent Battle Has an Apparent Victor, but the Fight Continues*, SCIENCE (Sept. 11, 2020), <https://www.sciencemag.org/news/2020/09/latest-round-crispr-patent-battle-has-apparent-victor-fight-continues> [<https://perma.cc/88LP-3K56>].

genes so that the future child's risk of those conditions is greatly reduced.<sup>216</sup> CRISPR-Cas9 technologies are currently patentable in part because they involve engineered enzymes and manmade molecules to guide the editing of DNA.<sup>217</sup>

Encouraging the USPTO to grant PRS algorithm patents only when accompanied by a physical element or specific treatment plan is not a novel idea. The Supreme Court and Federal Circuit have recently opined about the validity of such potential patents and have already explicitly upheld the eligibility of these claims. For example, in the 2018 case *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals*,<sup>218</sup> the Federal Circuit upheld a patent which provided specific treatment guidance for the dosing of a schizophrenia drug based on the genetic makeup of the patient, because some genetic profiles are more effective metabolizers of the medicine and require less of the drug for effective treatment.<sup>219</sup> And in *Myriad*, the Court noted in closing that the patent could have been successful had it focused on an innovative technique in manipulating or identifying genes while looking for the BRCA genes or had it focused on the chemical changes obtained during the discovery process.<sup>220</sup> The possibilities are endless.

## F. Innovation and the Future

While this Note is not wading into the complicated ethics and benefits of healthcare-related patents as a whole to society, one primary argument in support of the patentability of PRS algorithms is that patents are critical to promoting scientific advancement and development.<sup>221</sup> Those in support argue that these patents incentivize companies to invest in technological advancements by promising protection for their investments.<sup>222</sup> While continually promulgated by producers of diagnostic tests, this argument in the context of sophisticated genetic diagnostics is without merit. Taking an anti-patent position may sound revolutionary, but it is not as radical as one might think; scientists have lamented the over-patenting of technology for decades, which

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<sup>216</sup> See Cyranoski, *supra* note 215.

<sup>217</sup> See Cohen, *supra* note 215.

<sup>218</sup> 887 F.3d. 1117 (Fed. Cir. 2018).

<sup>219</sup> See *id.*

<sup>220</sup> See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 593, 595 (2013) (noting that Myriad did not use any inventive technique in this case, only well-known genetic research techniques).

<sup>221</sup> See U.S. CONST. art. 1, § 8, cl. 8.

<sup>222</sup> See *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 91–92 (2012) (final pages of the opinion profiling both sides of this argument).

they argue burdens advancement and does little to encourage research.<sup>223</sup> If PRS algorithms are decidedly unpatentable, companies can turn to other complementary business ventures to monetize their inventions. For example, PRS algorithms could be sold without patents to health providers and direct-to-consumer genetic tests manufacturers such as 23andMe as a means of creating a savvier, and more lucrative, personalized healthcare experience. Additionally, as previously mentioned, these algorithms could be patentable under current standards when combined with other innovative companion technologies.<sup>224</sup>

Lastly, we must reignite the debate on how our society will treat information that is literally inside each of us. When it comes to access for patients, doctors, researchers, and insurance companies—is it fair to only allow one company the ability to have the diagnostic capabilities for disease predisposition and prevention? Should we allow state-sanctioned monopolies on life-changing testing? Do we have a right to know the secrets hiding in our own DNA or is that a privilege that we must pay top dollar for? The Court tentatively answered these questions with the decision in *Myriad*,<sup>225</sup> but now it is time to take decisive action. At a minimum, we should stop the bleeding and revoke and prohibit further strict PRS algorithm patents of this nature while we sort through these questions.

## Conclusion

Polygenic risk scores are not patent eligible under section 101 for two reasons: first, they are not proper processes when evaluated under Supreme Court and Federal Circuit precedent; and second, they rely impermissibly on the capitalization of natural correlations, with nothing “more” to elevate their claims into the realm of patentability. Courts can solve this problem by only allowing PRS algorithm patents when combined with traditionally patent-eligible companion technologies, requiring a specific number of variables in PRS algorithms, or by reducing the length of protection for patents which include a genetic component.

Walking back the significant number of patents already issued at this point will be a painstaking and costly exercise, but society will be better for it. The USPTO is currently in a position not unlike where it was before *Myriad* was decided—lots of granted patents with rumblings in the background over concern about their validity and longevity. The longer the USPTO waits to invalidate old patents and cease granting new PRS algorithm patents, the messier the situation will become, and the more time and money will be

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<sup>223</sup> See *id.* at 91.

<sup>224</sup> See *supra* Section III.D.–E.

<sup>225</sup> See *generally Ass'n for Molecular Pathology*, 569 U.S. at 576.

invested by stakeholders on all sides of the problem. In one of *Gattaca's* final scenes, the protagonist, Vincent Freeman states, "There's no gene for fate."<sup>226</sup> But that is not the case for the patent eligibility of PRS algorithms. Here, the writing is already on the wall.

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<sup>226</sup> See GATTACA, *supra* note 1.



# Am I Insane?: Why the Veterans Affairs' Definition of "Insanity" Leads to Arbitrary and Inconsistent Outcomes

Elena Hoffman\*

## Introduction

Ever since World War II, an increasing number of veterans with misconduct-related discharges caused by PTSD or other mental illnesses have been barred from receiving Department of Veterans Affairs ("VA") benefits<sup>1</sup> because they could not prove they were "insane" and thus were ineligible for the insanity exception under 38 C.F.R. § 3.354.<sup>2</sup> The VA's defective definition of "insanity" is aptly illustrated by the story of Mr. Matthew James, a Marine Corps veteran. In 1967, James joined the United States Marine Corps

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<sup>1</sup> *Towards an End to Veteran Homelessness and Suicide: Recommended Changes to the VA's Character of Discharge Determination Process: Hearing Before the Subcomm. on Disability Assistance and Mem'l Affs. of the H. Comm. on Veterans' Affs.*, 116th Cong. 2 (July 8, 2020) (statement of Maureen Siedor, Legal Director, Swords to Plowshares), <https://www.congress.gov/116/meeting/house/110852/witnesses/HHRG-116-VR09-Bio-SiedorM-20200708.pdf> [<https://perma.cc/6SQD-ESB9>] [hereinafter Swords to Plowshares Statement] ("Bad paper discharges overall have increased from 1.7% during the WWII era to 6.8% for post-2001 veterans); see also Bradford Adams & Dana Montalto, *With Malice Toward None: Revisiting the Historical and Legal Basis for Excluding Veterans from Veteran Services*, 122 PA. ST. L. REV. 69, 97 (2017) ("[P]ost-9/11 veterans are nearly four times more likely to receive an other-than-Honorable discharge than World War II era veterans.").

<sup>2</sup> See *id.*; 38 C.F.R. § 3.354 ("Determinations of insanity"). The regulation reads:

(a) *Definition of insanity.* An insane person is one who, while not mentally defective or constitutionally psychopathic, except when a psychosis has been engrafted upon such basic condition, exhibits, due to disease, a more or less prolonged deviation from his normal method of behavior; or who interferes with the peace of society; or who has so departed (become antisocial) from the accepted standards of the community to which by birth and education he belongs as to lack the adaptability to make further adjustment to the social customs of the community in which he resides.

*Id.*

and was deployed to Vietnam.<sup>3</sup> In April of 1968, James was on patrol when a landmine exploded near him and caused him to suffer a chest contusion.<sup>4</sup> In addition, James reported that he sustained a blow to his head and did not wake up for several days.<sup>5</sup> The Marine Corps granted him an early and honorable discharge in December 1970 “so that he could immediately reenlist for a fresh, [six]-year enlistment.”<sup>6</sup> James reenlisted that same month.<sup>7</sup>

Around the time of his reenlistment, James began having trouble with his memory and suffering from blackout spells and unstoppable crying spells.<sup>8</sup> James began drinking to help with his crying spells and “to forget that he couldn’t remember things.”<sup>9</sup> During a twenty-four day period from March 30 to April 22, 1971, supervisors charged James with “four counts of unauthorized absence and three counts of failing [to appear for duty on time]”.<sup>10</sup> James later explained that he failed to report to his duties because he “couldn’t remember where [he] was supposed to be.”<sup>11</sup> Following these instances of misconduct, James was advised to take an other than honorable discharge—an administrative discharge status that generally precludes veterans from receiving VA benefits<sup>12</sup>—rather than face potentially more serious charges in a general court-martial, and he was discharged from the Marine Corps in August 1971.<sup>13</sup>

Following his discharge, James struggled immensely with his mental health.<sup>14</sup> He became homeless and was incarcerated for robbing a store while under the influence.<sup>15</sup> While being evaluated at the mental health unit of the penitentiary, James was told that he had a “chemical imbalance.”<sup>16</sup> In 1985, James was once again incarcerated, and in 1997, he “was forced to seek

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<sup>3</sup> See Brief for Appellant at 1, James v. Wilkie, 2019 U.S. App. Vet. Claims LEXIS 1308 (Vet. App. Oct. 24, 2019) (No. 18-2951).

<sup>4</sup> See *id.* at 3.

<sup>5</sup> See *id.*

<sup>6</sup> *Id.* at 6.

<sup>7</sup> See *id.*

<sup>8</sup> See *id.* at 6–7.

<sup>9</sup> *Id.* at 7.

<sup>10</sup> *Id.* at 8.

<sup>11</sup> *Id.* (internal quotation marks omitted).

<sup>12</sup> See *Life After an Other-Than-Honorable Discharge*, NAT’L PUB. RADIO: HERE & NOW (Dec. 12, 2013), <https://www.npr.org/transcripts/250543667> [<https://perma.cc/T4C5-8VAQ>].

<sup>13</sup> See Brief for Appellant at 9, James v. Wilkie, 2019 U.S. App. Vet. Claims LEXIS 1308 (Vet. App. Oct. 24, 2019) (No. 18-2951).

<sup>14</sup> See *id.* at 10.

<sup>15</sup> See *id.*

<sup>16</sup> *Id.* (a definition for “chemical imbalance” is not provided).

mental health treatment” as he had reported he was “hearing voices.”<sup>17</sup> Since his first mental health evaluation, James had been diagnosed with schizophrenia, psychotic disorder, and posttraumatic stress disorder (“PTSD”).<sup>18</sup> From November 2011 to August 2012, James sought treatment for PTSD and psychotic disorder.<sup>19</sup>

In March 2012, James sought treatment at a VA medical center for symptoms of PTSD, and the VA opened a case to determine his eligibility for treatment as a veteran with a negative discharge status.<sup>20</sup> In 2015, the Board of Veterans’ Appeals (“Board” or “BVA”) attempted to get a medical opinion as to whether James met the VA definition of “insane” at the time of the offenses that led to his discharge.<sup>21</sup> Thus, James underwent an examination in September 2016; however, the examiner decided that the misconduct leading to James’s discharge was not the result of insanity.<sup>22</sup> Instead, the examiner believed James’s alcohol use disorder and “personality construct” led to his missed work and other infractions and reasoned there was no psychiatric disability present because James “willingly signed his discharge paperwork, was represented by an attorney, and ‘there was no evidence in his records of head injury, PTSD, mood symptoms,’ or ‘psychotic symptoms around this time.’”<sup>23</sup>

In September 2017, James went through an additional compensation and pension examination for PTSD administered by the VA.<sup>24</sup> This examiner concluded that it was unlikely that James’s schizophrenia was due to, caused by, or incurred during military service, basing his decision on the fact that James first reported his schizophrenia in the 1990s—despite James pointing out that he had never been tested for schizophrenia prior to that point.<sup>25</sup> In contrast, an October 2017 diagnosis from a separate physician, whom James had contacted for mental health treatment, opined that James had “chronic PTSD” related to his service in Vietnam.<sup>26</sup> In a February 2018 BVA decision, the Board affirmed its original 2016 opinion that “James’s character of

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<sup>17</sup> *Id.* at 11.

<sup>18</sup> *See id.*

<sup>19</sup> *See id.*

<sup>20</sup> *See id.*

<sup>21</sup> *See id.* at 12. If James was found to have been insane at the time of his misconduct using the VA’s definition of insanity under 38 CFR § 3.354, James could have been eligible to receive VA benefits despite his disqualifying discharge status. *Id.* at 23.

<sup>22</sup> *See id.* at 12–13.

<sup>23</sup> *Id.*

<sup>24</sup> *See id.*

<sup>25</sup> *See id.* at 13–14.

<sup>26</sup> *Id.* at 14.

service discharge was a bar to the receipt of VA benefits” and that he was not able to use the “insanity” exception.<sup>27</sup>

James’s story is upsetting, but unfortunately, James is not alone in this experience. Contrary to Congress’s intent in passing Chapter III, Section 300 of the Servicemen’s Readjustment Act of 1944 (“GI Bill”) to help injured veterans receive VA benefits,<sup>28</sup> the VA’s interpretation and application of “insanity” has frustrated veterans seeking disability benefits.<sup>29</sup> The ambiguous definition causes medical professionals, adjudicators, and veterans to interpret and apply the regulation arbitrarily and inconsistently, leading to unpredictable outcomes.

38 C.F.R. § 3.354 provides that an insane person is someone who, while not mentally defective or psychopathic unless experiencing a psychosis, “exhibits, due to disease, a more or less prolonged deviation from” their normal method of behavior, interferes with society, or departs from the social norms of society.<sup>30</sup> The current definition under 38 C.F.R. § 3.354 is unclear, misleading, and provides no guidance to veterans who attempt to utilize the exception. The clause also fails to provide structured guidance for medical professionals assigned to diagnose insanity for purposes of determining VA benefits.<sup>31</sup> As a result, VA administered medical assessments for this purpose and the consequent adjudication outcomes are arbitrary and inconsistent.<sup>32</sup> Thus, as the appellate court for veterans affairs claims, the Federal Circuit should develop a clear standard that clarifies which mental health conditions qualify for benefits and who can make those determinations, so that veterans suffering from mental health conditions can get the help they deserve.

This Note begins by providing the history behind the insanity exception, how its use differs between the medical and legal communities, and background on military discharge statuses and their relation to eligibility for VA benefits. It further provides information on the GI Bill’s legislative history and purpose before moving into an analysis in Part II of why the application of 38 C.F.R. § 3.354 leads to inconsistent and arbitrary decision-making, contrary to congressional intent. Part II further explores how the inconsistency and unpredictability lead to unfair results. Part III argues that the Federal Circuit should establish a clear standard of proof for adjudicators to use when deciding these cases and advocates for the VA to provide clarity to the regulation through the agency rulemaking process.

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<sup>27</sup> *Id.* at 15–16.

<sup>28</sup> See Servicemen’s Readjustment Act of 1944, S. 1767, 78th Cong. (1944).

<sup>29</sup> See *infra* Section II.B.

<sup>30</sup> 38 C.F.R. § 3.354(a).

<sup>31</sup> See *infra* Section II.A.

<sup>32</sup> See *infra* Section II.A.

## I. Background

### A. History of Legal Insanity

The word “insanity” is a purely legal term, as it is no longer considered a medical term.<sup>33</sup> The original American legal understanding of insanity, derived from British common law, was confusing, and typically did not provide clear answers to lawyers and judges dealing with the insanity defense.<sup>34</sup> There was British precedent which dealt with issues of “insane” defendants, however they often contained conflicting points of view or ignored certain issues entirely.<sup>35</sup> In response, various state, local, and federal courts in the United States began developing their own common law tests to determine insanity.<sup>36</sup> In the mid-1800s, U.S. courts most commonly used the “knowledge of right and wrong” test to determine which mental conditions constituted insanity for the purpose of avoiding punishment, and it remained the predominant test until the nineteenth century.<sup>37</sup> The term “insanity” was used ubiquitously throughout both the medical and legal professions into the nineteenth century, but gradually gained negative connotations in the field of medicine at the end of the nineteenth century, leading many psychiatrists to abolish the use of the word in the early twentieth century.<sup>38</sup>

In 1909, the American Institute of Criminal Law and Criminology (“AICLC”) initiated a collaborative reform effort attempting to bring legal and medical professionals together to create a new understanding of the term “insanity.”<sup>39</sup> In 1921, the *American Journal of Insanity*, first published in 1844, became the *American Journal of Psychiatry*.<sup>40</sup> Medical and legal professionals who were part of the AICLC’s reform effort worked for over ten years to

<sup>33</sup> See Janet A. Tighe, “What’s in a Name?: A Brief Foray into the History of Insanity in England and the United States,” 33 J. AM. ACAD. PSYCHIATRY & L. 252, 253 (2005).

<sup>34</sup> See Janet A. Tighe, *Francis Wharton and the Nineteenth-Century Insanity Defense: The Origins of a Reform Tradition*, 27 AM. J. LEGAL HIST. 223, 228 (1983).

<sup>35</sup> See *id.* at 228–29.

<sup>36</sup> See *id.* at 229.

<sup>37</sup> See *id.* at 229. As the author stated:

According to the most famous formulation of this test, the M’Naghten Rules of 1843, “to establish a defence on the ground of insanity it must be clearly proved that at the time of committing the act, the accused was labouring under such a defect of reason, from disease of the mind, as not to know the nature and quality of the act he was doing, or if he did know it, that he did not know he was doing what was wrong.”

*Id.* (quoting M’Naghten’s Case, 8 Eng. Rep. 718, 722–23 (1843)).

<sup>38</sup> See Tighe, *supra* note 33, at 255.

<sup>39</sup> See *id.*

<sup>40</sup> See Allan V. Horwitz & Gerald N. Grob, *The Checkered History of American Psychiatric Epidemiology*, 89 MILBANK Q. 628, 630 (2011).

create proposals on the insanity defense and the use of expert testimony in trial settings, but there were many clashes between legal and medical professionals.<sup>41</sup> Legislators eventually settled on legislation that those in the medical profession found grossly inadequate, as the legislation continued to utilize the word insane and lacked clear guidance for medical professionals on what insanity truly meant in medical terms.<sup>42</sup> In the words of William White, the superintendent of St. Elizabeth's federal mental hospital in Washington, D.C., in 1923, "[i]nsanity is purely a legal concept and means irresponsibility, or incapacity for making a will, or for entering a contractual relationship."<sup>43</sup> In the first quarter of the 20<sup>th</sup> century, medical professionals saw the term "insanity" as tainted and sought to "distance themselves" from it, criticizing the legal profession for continuing to utilize it.<sup>44</sup> However, medical professionals needed a general understanding of the word in the criminal context to diagnose a criminal claiming insanity.

In order to appreciate how the medical profession understands "insanity" today, it is important to look at the *Diagnostic and Statistical Manual of Mental Disorders, 5th Edition* ("DSM-5").<sup>45</sup> The DSM-5 lists twenty-two categories of mental disorders; however, it does not include a single definition of the word "insanity."<sup>46</sup> The definition of insanity in criminal contexts today is, in

<sup>41</sup> See Tighe, *supra* note 33, at 255.

<sup>42</sup> See *id.*

<sup>43</sup> *Id.*

<sup>44</sup> *Id.* at 256. As the author wrote:

[M]any psychiatrists . . . went out of their way to distance themselves from this term. For them it was not enough to let insanity quietly fall into oblivion. The word with its tainted associations had to be seen for the dangerous, legal creature that it was . . . [psychiatrists] forcefully argued that the most authoritative thinkers of the "present century" had abandoned such terms as lunacy and insanity and the inaccurate theories associated with them. "Instead," wrote [Adolf] Meyer, "we speak to-day of mental disorders, of psychoses and psychoneuroses, viewed as problems of adaptation of the individual to the environment."

*Id.* (quoting Adolf Meyer, *Insanity*, in *ENCYCLOPEDIA BRITANNICA* 478 (Horace Hooper ed., 13th ed.1926)).

<sup>45</sup> See *Frequently Asked Questions*, AM. PSYCHIATRIC ASS'N., <https://www.psychiatry.org/psychiatrists/practice/dsm/feedback-and-questions/frequently-asked-questions> [<https://perma.cc/7U4U-E5DQ>] (last visited Aug. 19, 2022) ("The *Diagnostic and Statistical Manual of Mental Disorders (DSM)* is the handbook used by health care professionals in the United States and much of the world as the authoritative guide to the diagnosis of mental disorders. *DSM* contains descriptions, symptoms, and other criteria for diagnosing mental disorders.").

<sup>46</sup> See AM. PSYCHIATRIC ASS'N, *DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS* (5th ed. 2013) [hereinafter *DSM-5*].

most states, based on the M’Naghten rule.<sup>47</sup> This rule has two components: (1) “a cognitive component: whether a mental defect prevented a defendant from understanding what [they were] doing,” and (2) “a moral component: whether . . . the defendant was able to understand that [their] action was wrong.”<sup>48</sup> Evidence that the defendant has a mental disease or disorder identified by the DSM-5 is thus only one component of the M’Naghten rule, as “morality” is not defined in the DSM-5.<sup>49</sup>

### **B. Military Discharges and VA Benefits**

In order to understand how the insanity exception is utilized by service-members, it is important to first understand how one qualifies for VA benefits. To qualify for VA benefits, prior servicemembers must be considered veterans.<sup>50</sup> Section 101(2) of Title 38 of the United States Code defines a “veteran” as a person “who served . . . and who was discharged or released therefrom under conditions other than dishonorable.”<sup>51</sup> In determining whether a former servicemember was released “under conditions other than dishonorable” for the purposes of a Character of Discharge (“COD”) Determination, the VA primarily relies on the discharge status the servicemember receives, either from the discharge authority or a court-martial, at the time they depart from the military.<sup>52</sup> The six types of discharge status that the VA considers when making a COD determination include: (1) honorable; (2) general under honorable conditions; (3) uncharacterized; (4) other than honorable; (5) bad conduct (adjudicated by a general court or special court-martial); and (6) dishonorable.<sup>53</sup> When making a COD determination, the VA reviews evidence and arguments, along with military records and statutory and regulatory bars.<sup>54</sup> Regardless of the servicemember’s discharge status, there are six

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<sup>47</sup> See Nancy Haydt, *The DSM-5 & Crim. Defense: When Does a Diagnosis Make a Difference?*, 2015 UTAH L. REV. 847, 857 n.49 (citing *Clark v. Arizona*, 548 U.S. 735, 747, 750–52 (2006)).

<sup>48</sup> *Id.*

<sup>49</sup> See *id.* at 857; see also DSM-5, *supra* note 46.

<sup>50</sup> See SCOTT D. SZYMENDERA, CONG. RSCH. SERV., R42324, WHO IS A “VETERAN”?—BASIC ELIGIBILITY FOR VETERANS’ BENEFITS 1 (2016).

<sup>51</sup> 38 U.S.C. § 101(2).

<sup>52</sup> See Swords to Plowshares Statement, *supra* note 1, at 3–4.

<sup>53</sup> See *id.*

<sup>54</sup> See *id.* at 5.

statutory<sup>55</sup> and five regulatory bars to VA benefits.<sup>56</sup> The VA COD determination is solely used for the purpose of VA benefits eligibility determinations.<sup>57</sup>

Generally, the only discharge determinations that automatically qualify a servicemember for VA benefits without review are (1) honorable and (2) under honorable conditions.<sup>58</sup> As for an (4) other than honorable or (5) bad conduct discharge, the VA must assess eligibility and make a COD determination as to whether or not their period of service was “under conditions other than dishonorable” for the purpose of VA benefits.<sup>59</sup> If the characterization of service is (6) dishonorable, a former servicemember is generally deemed ineligible for any VA benefits, unless the VA determines the servicemember was insane at the time of misconduct, referred to as the insanity exception.<sup>60</sup> Thus, the insanity exception recognizes that veterans who were not responsible for their actions should not be barred from receiving VA benefits.<sup>61</sup>

### C. Legislative History Behind the Insanity Exception

Despite criticism from the medical community for lawyers’ use of the word “insanity,” the legal world continues to use it. In 1944, Congress included the insanity exception in the GI Bill and the exception is further codified in 38 C.F.R. § 3.354, the regulation used to determine insanity.<sup>62</sup> Congress’s intent in passing the GI Bill sheds light on its choice to use the term “insanity” when enacting the insanity exception: Congress passed the bill primarily to reduce the possibility of postwar depression brought on by widespread unemployment after World War II by offering federal aid to veterans struggling to

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<sup>55</sup> See 38 C.F.R. § 3.12(c). The statutory bars include: (1) “conscientious objector;” (2) “by reason of the sentence of a general court-martial;” (3) by resignation of an officer; (4) “as a deserter;” (5) “as an alien during a period of hostilities;” and (6) “under other than honorable conditions issued as a result of an absence without official leave . . . for a continuous period of at least 180 days.” *Id.*; see also 38 U.S.C. § 5303(a).

<sup>56</sup> See 38 C.F.R. § 3.12(d). The regulatory bars include: (1) “acceptance of an undesirable discharge to escape trial by general court-martial;” (2) “mutiny or spying;” (3) an offense of moral turpitude; (4) “willful and persistent misconduct;” and (5) “homosexual acts.” *Id.*

<sup>57</sup> See Update and Clarify Regulatory Bars to Benefits Based on Character of Discharge, 85 Fed. Reg. 41471 (proposed July 10, 2020) (to be codified at 38 C.F.R. pt. 3).

<sup>58</sup> See 38 C.F.R. § 3.12(a) (“A discharge under honorable conditions is binding on the Department of Veterans Affairs as to character of discharge.”).

<sup>59</sup> See 38 U.S.C. § 101(2); see also 38 C.F.R. § 3.12(a), (k)(2), (3).

<sup>60</sup> See 38 C.F.R. § 3.354; 38 U.S.C. § 5303(b).

<sup>61</sup> See *id.*; see also SZYMENDERA, *supra* note 50, at 4.

<sup>62</sup> See Servicemen’s Readjustment Act of 1944, Pub. L. No. 78-346, § 300, 58 Stat. 284 (1944) (codified in 38 C.F.R. § 3.354).

readjust to civilian life after their return.<sup>63</sup> The House Congressional Record, during discussions of the bill, further illuminates Congress’s understanding of the GI Bill’s use of the word “insanity” to mean in 1944:

Mr. RANKIN. The question of insanity ranges all the way from mere eccentricity to the behavior of a raging maniac. This means a man who is insane to such an extent that he is not responsible.

Mr. CURTIS. And it would include a temporary period or condition caused by a battle condition or any other cause that would make him irresponsible at that particular time?

Mr. RANKIN. I think it would. It is very difficult to tell whether a man’s insanity is temporary or permanent . . . .

Mr. CURTIS. It is your thought, any condition which would make him not responsible for his own acts would be included?

Mr. RANKIN. That is right . . . .

Mrs. ROGERS. In the case of an insane veteran, if he committed some crime while he is insane he would not be responsible.<sup>64</sup>

This discussion spoke of insanity as a range of behavior that could include any condition that would make someone not responsible for their actions, and thus not culpable for any misconduct.<sup>65</sup> There is no discussion of exactly which mental conditions would be included, however keeping with Congress’s intent to help struggling veterans adjust to life post-combat and considering

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<sup>63</sup> See, e.g., *Servicemen’s Readjustment Act (1944)*, U.S. NAT’L ARCHIVES & RECS. ADMIN., <https://www.archives.gov/milestone-documents/servicemens-readjustment-act> [<https://perma.cc/VQ7V-UQNK>]. See generally *Servicemen’s Readjustment Act of 1944*, Pub. L. No. 346, 58 Stat. 284 (1944) (codified in 38 C.F.R. § 3.354).

<sup>64</sup> 90 CONG. REC. H4526, 4537 (daily ed. May 16, 1944). John E. Rankin was a Democratic politician from Mississippi who served in the U.S. House of Representatives from 1921 to 1953. *Rankin, John Elliott*, U.S. HOUSE REPRESENTATIVES: HIST., ART & ARCHIVES (last visited Aug. 19, 2022), <https://history.house.gov/People/Detail/20149> [<https://perma.cc/J7QR-KYS3>]. Carl T. Curtis was a Republican politician from Nebraska who served in the U.S. House of Representatives from 1939 to 1954. *Curtis, Carl Thomas*, U.S. HOUSE REPRESENTATIVES: HIST., ART & ARCHIVES (last visited Aug. 19, 2022) [https://history.house.gov/People/Listing/C/CURTIS,-Carl-Thomas-\(C001006\)/](https://history.house.gov/People/Listing/C/CURTIS,-Carl-Thomas-(C001006)/) [<https://perma.cc/W6XH-ZE9X>]. Edith N. Rogers was a Republican politician from Massachusetts who served in the U.S. House of Representatives from 1925 to 1960. *Rogers, Edith Nourse*, U.S. HOUSE REPRESENTATIVES: HIST., ART & ARCHIVES (last visited Aug. 19, 2022) [https://history.house.gov/People/Listing/R/ROGERS,-Edith-Nourse-\(R000392\)/](https://history.house.gov/People/Listing/R/ROGERS,-Edith-Nourse-(R000392)/) [<https://perma.cc/2X3C-A3KE>].

<sup>65</sup> 90 CONG. REC. H4526, 4537–41 (daily ed. May 16, 1944).

the vague language of 38 C.F.R. § 3.354, it could be presumed that insanity under the statute would have been interpreted broadly.<sup>66</sup>

#### **D. The Insanity Exception**

As has been discussed up to this point, several sources of law comprise the insanity exception to an other than honorable discharge. These sources and how they interact will be explored in this section. First, the GI Bill provides:

[I]f it is established to the satisfaction of the Secretary that, at the time of the commission of an offense leading to a person's court-martial, discharge, or resignation, that person was insane, such person shall not be precluded from benefits under laws administered by the Secretary based upon the period of service from which such person was separated.<sup>67</sup>

Second, 38 C.F.R. § 3.354(b) instructs that:

When a rating agency is concerned with determining whether a veteran was insane at the time he committed an offense leading to his court-martial, discharge or resignation (38 U.S.C. 5303(b)), it will base its decision on all the evidence procurable relating to the period involved and apply the definition in paragraph (a) of this section.<sup>68</sup>

Finally, under 38 C.F.R. § 3.354(a), the VA defines an “insane” person as someone who:

[W]hile not mentally defective or constitutionally psychopathic, except when a psychosis has been engrafted upon such basic condition, exhibits, due to disease, a more or less prolonged deviation from his normal method of behavior; or who interferes with the peace of society; or who has so departed (become antisocial) from the accepted standards of the community to which by birth and education he belongs as to lack the adaptability to make further adjustment to the social customs of the community in which he resides.<sup>69</sup>

In addition to the preceding definition, the VA considers several standards when determining whether someone is eligible to use the insanity exception. The first is that the term “mental illness” has been found to not be synonymous with insanity.<sup>70</sup> If it were, it would be much easier for veterans to obtain a diagnosis for a mental illness and thereafter use the diagnosis to argue for the insanity exception. Next, insanity need only exist at the time of commission of the offense which led to a servicemember's discharge, and does not need

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<sup>66</sup> See Adams & Montalto, *supra* note 1, at 126 (“Although the VA adopted a regulatory definition of ‘insanity’ that could potentially reach a range of mental and behavioral health issues, the VA Office of General Counsel issued a Precedential Opinion that interprets the term to require a very high degree of mental impairment.”); see also 38 U.S.C. § 3.354.

<sup>67</sup> 38 U.S.C. § 5303(b).

<sup>68</sup> 38 C.F.R. § 3.354(b).

<sup>69</sup> 38 C.F.R. § 3.354(a).

<sup>70</sup> See Beck v. West, 13 Vet. App. 535, 539 (2000).

to exist before or persist beyond that point.<sup>71</sup> Lastly, there is no requirement of a causal connection between the insanity and the misconduct leading to discharge.<sup>72</sup> There still, however, must be evidence establishing that the servicemember was insane at the time of the misconduct,<sup>73</sup> and "a determination of whether a person is insane is, in effect, a determination of whether that person's actions were intentional and thus the result of willful misconduct."<sup>74</sup> While this appears contradictory in nature, it is simply to say that insanity needs to exist *at the time of* misconduct, but the insanity does not need to have *caused* the misconduct directly.

In May 1997, the VA General Counsel's Office further clarified the types of behavior which would be defined as insanity under 38 C.F.R. § 3.354(a) and announced that personality disorders and behaviors involving a minor episode of disorderly conduct or eccentricity do not fall within the VA's definition of insanity.<sup>75</sup> It further explained that the "extent to which an individual's behavior must deviate from his or her normal method of behavior for purposes of 38 C.F.R. § 3.354(a) may best be resolved by adjudicative personnel on a case-by-case basis in light of the authorities defining the scope of the term insanity."<sup>76</sup> As discussed, however, there is in fact no one authority defining the scope of the term insanity, as it is not used in the medical community and is often misunderstood by the legal community.

When the VA makes determinations of insanity, it is not permitted to use the modern criminal definition but instead is to only use the broader statutory definition.<sup>77</sup> This point is important, as what legal insanity means in a criminal context continues to shift throughout history. While the

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<sup>71</sup> See *Struck v. Brown*, 9 Vet. App. 145, 154 (1996).

<sup>72</sup> See *id.*

<sup>73</sup> See *Zang v. Brown*, 8 Vet. App. 246, 254 (1995).

<sup>74</sup> *Id.*

<sup>75</sup> See *Definition of Insanity in 38 C.F.R. § 3.354(a)* (Vet. Affs. Op. Gen. Couns. Precedent 20-97), 1997 WL 34674474 (Dep't of Veterans Affs. May 22, 1997).

<sup>76</sup> *Id.*

<sup>77</sup> See *Gardner v. Shinseki*, 22 Vet. App. 415, 420 (2009). The court in *Gardner* found that the Board had misapplied the definition of insanity in § 3.354(a) because the Board had considered whether the servicemember was able to discern the effects of his behavior and whether any disease placed his mental capacity beyond his control. *Id.* The Court explained:

Although these elements are common components of insanity definitions used in criminal cases, as described by the Model Penal Code (MPC) and the Uniform Code of Military Justice, such elements are absent from the VA regulatory definition of insanity. Here, the Board's analysis of whether Mr. Gardner understood right from wrong and whether he was able to discern the effects of his behavior is not germane to a determination of whether he was insane during his service as defined by 38 C.F.R. § 3.354(a). Accordingly, the Board erred when it relied upon elements of the MPC

understanding of legal insanity in a criminal context in 1945 was similar to what Congress intended with the bill, in recent decades criminal insanity has become a much higher bar to pass.<sup>78</sup> Thus, the issue here is that the majority of the population, including doctors, are only familiar with the criminal definition of insanity when approaching VA insanity cases,<sup>79</sup> despite the court in *Gardner v. Shinseki*<sup>80</sup> holding that the criminal definition is not to be used nor similar to the VA's definition.<sup>81</sup> Misunderstanding of what insanity is meant to encompass among veterans, judges, and doctors alike leads to significant confusion, which in turn leads to servicemembers not getting the help they deserve.

## II. Issues in Application of the Insanity Defense

Although Congress's intent in passing the GI Bill was to increase access to VA benefits for injured veterans, the VA's modern interpretation and application of 38 C.F.R. § 3.354 often results in inconsistent and arbitrary decision-making, which leads to unfair results for veterans seeking benefits and undermines congressional intent. To resolve this issue, Congress needs to rewrite the definition entirely to remove the word "insanity," as it is inaccurate and outdated, and should instead list the specific mental conditions that would qualify a less than honorably discharged veteran to receive VA benefits. However, until and unless that is accomplished, the Federal Circuit should create a clear standard that veterans, medical professionals, and adjudicators can look to when deciding whether a prior servicemember qualifies for benefits under the insanity exception. This solution will mitigate the problem significantly as it will benefit all veterans who actively seek to challenge their lack of benefits.

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definition of insanity rather than analyzing the question of Mr. Gardner's sanity pursuant to the definition of insanity found in § 3.354(a).

*Id.* (inner citation omitted).

<sup>78</sup> Natalie Jacewicz, *After Hinckley, States Tightened Use of the Insanity Plea*, NAT'L PUB. RADIO: SHOTS HEALTH NEWS (July 28, 2016), <https://www.npr.org/sections/health-shots/2016/07/28/486607183/after-hinckley-states-tightened-use-of-the-insanity-plea> [<https://perma.cc/HB8T-FCEC>]. Following the 1982 "not guilty by reason of insanity" verdict of John Hinckley Jr., attempted assassin of President Ronald Reagan, "Congress and states created stricter rules to govern the insanity defense or in some cases abolished the defense altogether." *Id.*

<sup>79</sup> See Jeffrey Garbelman, *The Insanity Exemption to Other than Honorable Discharge for the Purpose of Claiming Benefits: The Role of the Mental Health Examiner*, 10 PSYCHOL. INJ. & L. 177, 177 (2017).

<sup>80</sup> 22 Vet. App. 415 (2009).

<sup>81</sup> See *id.* at 420.

### **A. Modern Understanding of 38 C.F.R. § 3.354 Leads to Inconsistent and Arbitrary Decision-Making, Shifting Further Away from Congressional Intent**

The VA’s modern interpretation and application of 38 C.F.R. § 3.354 often results in inconsistent and arbitrary decision-making. Despite Congress’s intention to help a wide range of veterans, and despite the Court of Appeals for Veterans Claims (“CAVC”) holding that the VA should use a broad statutory definition for insanity,<sup>82</sup> the VA Office of the General Counsel issued a precedential opinion<sup>83</sup> on the interpretation of 38 C.F.R. § 3.354(a) which instructs that the term require a relatively severe degree of mental impairment, making it a higher bar to pass than ever before.<sup>84</sup> Further, the General Counsel’s opinion only addresses a small sliver of cases involving a mental health standard, providing limited guidance that personality disorders do not satisfy the definition of insanity, and instructing that any other questions be resolved by an adjudicator on a case-by-case basis.<sup>85</sup> Considering this opinion and 38 C.F.R. § 3.354(a) together, only two rules are clear regarding the outcomes of these adjudications: (1) that psychoses do qualify, and (2) that personality disorders do not. In other words, psychoses and personality disorders are the only two categories that have been directly addressed as qualifying or not qualifying as insanity, and the remaining mental health conditions are to be evaluated on a case-by-case basis.

The difficulty here is that these two situations only represent a small portion of the cases that need to be adjudicated. In 2020, approximately 1,200 BVA decisions dealt with personality disorders<sup>86</sup> and 1,900 dealt with psychoses.<sup>87</sup> In comparison, 18,800 dealt with PTSD, 13,100 with anxiety, and 13,800 with depression.<sup>88</sup> The data shows that non-psychotic mental health conditions, which lack clear adjudication standards, are far more prevalent than those that do. Furthermore, the conditions lacking clear adjudication

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<sup>82</sup> *See id.*

<sup>83</sup> *See* 38 C.F.R. § 14.507(b) (specifying that precedent opinions involving Veterans’ benefits are binding on VA officials and employees in subsequent matters involving the legal issue decided in the precedent opinion).

<sup>84</sup> *See* Definition of Insanity in 38 C.F.R. § 3.354(a) (Veterans Affs. Op. Gen. Couns. Precedent 20-97), 1997 WL 34674474, at \*3–4 (Dep’t of Veterans Affs. May 22, 1997).

<sup>85</sup> *See id.*

<sup>86</sup> *See* U.S. DEP’T OF VETERAN’S AFFAIRS, BOARD OF VETERANS’ APPEALS, SEARCH RESULTS: “PERSONALITY DISORDER” (2020), <https://www.index.va.gov/search/va/bva.jsp>.

<sup>87</sup> *See* U.S. DEP’T OF VETERAN’S AFFAIRS, BOARD OF VETERANS’ APPEALS, SEARCH RESULTS: “PSYCHOSIS” (2020), <https://www.index.va.gov/search/va/bva.jsp>.

<sup>88</sup> *See* U.S. DEP’T OF VETERAN’S AFFAIRS, BOARD OF VETERANS’ APPEALS, SEARCH RESULTS: “PTSD,” “ANXIETY,” AND “DEPRESSION” (2020), <https://www.index.va.gov/search/va/bva.jsp>.

standards are less likely to result in a favorable outcome for other than honorably discharged veterans seeking to use the insanity exception. In an analysis of all BVA decisions between 1992 and 2015, Harvard's Veterans Legal Clinic found that less than honorably discharged servicemembers with PTSD were denied eligibility in 91% of cases on appeal.<sup>89</sup> For at least 17% of claimants with PTSD, the insanity exception was not even considered, and even in cases where it was, VA judges found that PTSD mitigated misconduct in only 12% of all PTSD-related claims.<sup>90</sup>

To be clear, the VA does not only grant COD relief when there is psychosis, but the presence of psychosis is the only reliable fact pattern in which the BVA will consistently grant relief.<sup>91</sup> The issue is likely exacerbated as "VA adjudicators apply a stricter standard than the regulation requires, and servicemembers, doctors, and adjudicators are reluctant to apply such a stigmatizing term [insanity] to mental health conditions."<sup>92</sup> Indeed, VA medical professionals have difficulty understanding the VA's definition of insanity for purposes of VA adjudication.<sup>93</sup> In discussing the role of the mental health examiner in diagnosing other than honorably discharged veterans' insanity for the purposes of VA benefits eligibility, psychologist Jeffrey Garbelman explains that these cases are assigned to VA health professionals without any "mandated or available training regarding insanity determinations."<sup>94</sup> There is "no expectation that these examiners have previous experience with insanity determinations" or diagnoses.<sup>95</sup>

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<sup>89</sup> See VETERANS LEGAL CLINIC, LEGAL SERVICES CENTER OF HARVARD LAW SCHOOL, UNDERSERVED: HOW THE VA WRONGFULLY EXCLUDES VETERANS WITH BAD-PAPER DISCHARGES 13–14 (2016).

<sup>90</sup> See *id.* at 51.

<sup>91</sup> Cf. Adams & Montalto, *supra* note 1, at 126.

Although the VA adopted a regulatory definition of 'insanity' that could potentially reach a range of mental and behavioral health issues, the VA Office of General Counsel issued a Precedential Opinion that interprets the term to require a very high degree of mental impairment. In practice, Veterans Law Judges applying the Precedential Opinion's holding have characterized the insanity exception as 'more or less synonymous with psychosis[.]'

*Id.* (footnotes omitted).

<sup>92</sup> *Id.* at 127.

<sup>93</sup> See Garbelman, *supra* note 79, at 177.

<sup>94</sup> *Id.* The purpose of the article, written by a medical practitioner, is to help other VA mental health professionals understand and define insanity for the purpose of benefit eligibility and "fill the gap" left by inadequate training of these mental health professionals by the VA, speaking volumes as to how nonexistent the training must be. *Id.*

<sup>95</sup> *Id.*

Even for those who do have experience, the VA expects them to use and understand terms that do not align with those a professional psychiatrist would understand as meaningful from their prior training or the DSM-5.<sup>96</sup> As the term “insanity” is no longer used in the medical profession, most psychologists are only familiar with it in contexts of diagnosing a mental illness under the DSM-5 for the purposes of criminal defense and the M’Naghten rule.<sup>97</sup> However, the VA is clear that it does not want its adjudicators or medical professionals to use the criminal definition of insanity.<sup>98</sup> Despite being clear on this point, the VA fails to give additional training or guidance on how to distinguish a VA insanity diagnosis from a criminal law one.<sup>99</sup> The VA essentially leaves understanding and applying the term insanity in diagnosing veterans up to each individual mental health practitioner. Thus, it is likely impossible to trace a clear connection between these outcomes and find a standard that the court can enforce for clear error.

### **B. Inconsistency and Unpredictability Leads to Unfair Results**

The widespread lack of understanding around the insanity defense leads to confusion among veterans applying for discharge review, mental health professionals diagnosing these veterans, and VA adjudicators ultimately making the decisions. In a study analyzing the differences in disability compensation across different VA regional offices (“VAROs”), tangible variations were observed across states, and specifically, significant differences were found across states in the percentage of recipients receiving PTSD awards.<sup>100</sup> In fact, differences across VAROs in the percentage of recipients with PTSD accounted for 39.8% of all the variation in awards across states,<sup>101</sup> and this “may be in part due to differences in adjudication results, specifically differences in denied claims.”<sup>102</sup>

There is significant variation in grant rates across the country for veterans applying for similar benefits, and the number of veterans with bad paper—i.e., other than honorable—discharges has been increasing as well: in 2017, the Department for Veterans Affairs estimated that there are more

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<sup>96</sup> See *id.* at 181.

<sup>97</sup> See Haydt, *supra* note 47, at 857.

<sup>98</sup> See *Gardner v. Shinseki*, 22 Vet. App. 415, 420 (2009).

<sup>99</sup> See Garbelman, *supra* note 79, at 177.

<sup>100</sup> See David E. Hunter et al., *Analysis of Differences in Disability Compensation in the Department of Veterans Affairs*, INST. FOR DEF. ANALYSIS S-2 (Dec. 2006).

<sup>101</sup> See *id.*

<sup>102</sup> *Id.* at S-3.

than 500,000 vets with other than honorable discharges.<sup>103</sup> These types of bad paper discharges overall increased from 1.7% during WWII to 6.8% post-2001, showing that the percentage of servicemembers discharged under conditions that bar benefits has dramatically risen since the passage of the GI Bill,<sup>104</sup> and that post-9/11 veterans are four times more likely to receive an other than honorable discharge than WWII veterans were.<sup>105</sup> Further, research shows that a significant number of veterans with bad paper discharges had been “deployed to a war zone, experienced hardships or trauma during service, and acquired physical and mental injuries that persist to this day.”<sup>106</sup>

Veterans branded with these bad paper discharges suffer not only the stigma of such a discharge, but also hardships throughout the rest of their life. Prior servicemembers who do not receive help, such as mental health services, after departing from the military can be more likely to become homeless,<sup>107</sup> suffer from substance abuse,<sup>108</sup> become incarcerated,<sup>109</sup> and commit suicide.<sup>110</sup> A 2017 U.S. Government Accountability Office (“GAO”) report, mandated by Congress and published on May 16, 2017,<sup>111</sup> found that approximately 92,000 troops were discharged for misconduct between 2011 and 2015, and of those discharged approximately 15,000 of them were diagnosed with a

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<sup>103</sup> See Steve Walsh, *VA Struggles to Reach Other-Than-Honorable-Discharge Vets in Need of Help*, NAT’L PUB. RADIO (Oct. 18, 2018), <https://www.npr.org/2018/10/18/657789457/va-struggles-to-reach-other-than-honorable-discharge-vets-in-need-of-help> [https://perma.cc/8EXH-FCWR].

<sup>104</sup> See Swords to Plowshares Statement, *supra* note 1, at 2.

<sup>105</sup> See Adams & Montalto, *supra* note 1, at 97.

<sup>106</sup> Swords to Plowshares Statement, *supra* note 1, at 2 (“Often, performance issues or misconduct leading to a bad paper discharge are symptomatic of such injuries. Tellingly, Marines with combat deployments who were diagnosed with PTSD were 11 times more likely to be discharged for misconduct than those without a PTSD diagnosis”).

<sup>107</sup> See Adi V. Gundlapalli et al., Research Letter, *Military Misconduct and Homelessness Among US Veterans Separated From Active Duty, 2001-2012*, 314 JAMA 832 (2015).

<sup>108</sup> See generally INVISIBLE WOUNDS OF WAR: PSYCHOLOGICAL AND COGNITIVE INJURIES, THEIR CONSEQUENCES, AND SERVICES TO ASSIST RECOVERY (Terri Tanielian & Lisa H. Jaycox eds. 2008).

<sup>109</sup> See Greg A. Greenberg et al., *Risk of Incarceration Among Male Veterans and Nonveterans: Are Veterans of the All Volunteer Force at Greater Risk?*, 33 ARMED FORCES & SOC’Y 337 (2007). This study found that the risk of incarceration for white veterans aged 35 to 54 was higher than the risk of incarceration for white nonveterans but that “Black and Hispanic veterans of these eras were generally at lower risk of incarceration” than their nonveteran counterparts. *Id.*

<sup>110</sup> See Claire A. Hoffmire et al., *Administrative Military Discharge and Suicidal Ideation Among Post-9/11 Veterans*, 56 AM. J. PREVENTIVE MED. 727 (2019).

<sup>111</sup> See U.S. GOV’T ACCOUNTABILITY OFF., GAO-17-260, ACTIONS NEEDED TO ENSURE POST-TRAUMATIC STRESS DISORDER AND TRAUMATIC BRAIN INJURY ARE CONSIDERED IN MISCONDUCT SEPARATIONS 12 (2017).

mental health conditions.<sup>112</sup> The report also found that while it was possible to upgrade or challenge the veteran’s discharge status determination in some cases, 87% of veterans with bad paper discharges had not even applied for VA benefits.<sup>113</sup> This number is staggering and emphasizes just how many ill veterans are not seeking or receiving the help they need.

A few months following the 2017 GAO report, the Office of the Secretary of Defense released the Kurta Memo in August of 2017, which provided clarifying guidance to Discharge Review Boards considering modification of discharge requests by veterans whose discharges were “due in whole or in part to mental health conditions.”<sup>114</sup> The Office of the Under Secretary of Defense instructed that “liberal consideration” should be given to veterans petitioning for discharge relief when the application was concerning injuries such as traumatic brain injury and PTSD.<sup>115</sup> Further, evidence submitted by veterans challenging their benefits status could include information both from their service record and other sources of evidence such as changes in behavior, unexplained economic or social changes, relationship issues, etc.<sup>116</sup> Additionally, the memo instructed that a veteran’s testimony alone may be sufficient to establish that the condition existed during, or was aggravated by, military service, and that the condition excuses or mitigates the discharge.<sup>117</sup>

In addition to the Kurta Memo, in 2018 Senator Chris Murphy authored and helped push through legislation the Honor Our Commitment Act,<sup>118</sup> which requires the VA to provide mental and behavioral health care to “at-risk” veterans with other than honorable discharges and whose mental health issues are directly related to their service.<sup>119</sup> In an interview, Murphy stated: “If you have PTSD and because of that PTSD you act out, you should not lose eligibility for your veterans benefits.”<sup>120</sup>

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<sup>112</sup> *See id.*

<sup>113</sup> *See id.* at 15.

<sup>114</sup> *See* Memorandum from A.M. Kurta, Office of the Under Secretary of Defense, to the Secretaries of the Military Departments, at 1 (Aug. 25, 2017), <https://dod.defense.gov/Portals/1/Documents/pubs/Clarifying-Guidance-to-Military-Discharge-Review-Boards.pdf> [<https://perma.cc/8KRM-NN9X>].

<sup>115</sup> *See id.*

<sup>116</sup> *See id.*

<sup>117</sup> *See id.* at 2.

<sup>118</sup> *See* Press Release, Chris Murphy, *Murphy, Tester, Bennet, Colleagues Introduce Bill to Ensure Discharged Military Service Members Receive Mental Health Treatment* (March 22, 2019), <https://www.murphy.senate.gov/newsroom/press-releases/murphy-tester-bennet-colleagues-introduce-bill-to-ensure-discharged-military-service-members-receive-mental-health-treatment> [<https://perma.cc/83UG-B7AA>].

<sup>119</sup> *See id.*

<sup>120</sup> Walsh, *supra* note 103.

Despite the Kurta Memo and the Honor Our Commitment Act, many veterans are still not getting the help they need. Reports allege that VA personnel in West Haven, Connecticut, and Puget Sound, Washington, medical centers have turned away qualifying veterans and given them inaccurate information.<sup>121</sup> Some veterans were told they were either ineligible for care or only qualified to receive short term care, neither of which was true.<sup>122</sup> In response to these reports, the VA attempted to shift responsibility and claimed that its computer system automatically categorized these veterans as ineligible.<sup>123</sup> Several senators, in a letter to VA Secretary Robert Wilkie, demanded that the VA immediately update its system, retrain personnel, and conduct routine inspections to ensure the VA is providing correct information to other than honorable discharge veterans.<sup>124</sup> The senators also requested that the VA increase its public outreach to educate veterans and others on the law and the benefits it provides, as Senator Murphy was skeptical as to whether the VA had adequately notified veterans of their updated eligibility.<sup>125</sup> Thus, at-risk veterans, in increasing numbers each year, are still not getting the health services they need and remain subject to confusing regulations, inconsistent diagnoses, and unpredictable adjudications when attempting to apply for benefits.

### III. Suggested Solution

Although the most effective solution to this problem would be to remove or rewrite the definition of insanity entirely, such a solution would likely take significant time to become effective. Thus, until and unless that is accomplished, the Federal Circuit, which hears appeals from the CAVC, should take action to establish a clear procedural framework that judges can use in deciding these cases, so that the results are consistent and fair. When a veteran comes seeking VA benefits, there should be an easy checklist of elements that the VA can look to for guidance. The suggested framework is as follows: when determining if someone meets the definition of “insanity” for eligibility purposes, a judge should ask whether (1) the veteran has been diagnosed with a mental condition that alters their mental state to the point that they

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<sup>121</sup> See Julia Bergman, *Murphy Leads Call for VA to Comply with Law Requiring Care for Bad-Paper Vets*, DAY (May 23, 2019).

<sup>122</sup> See *id.*

<sup>123</sup> See *id.*

<sup>124</sup> See Press Release, Chris Murphy, *After Hearing from Veterans Denied Mental Health Care, Murphy Demands VA Comply with Honor Our Commitment Act* (May 23, 2019), <https://www.murphy.senate.gov/newsroom/press-releases/after-hearing-from-veterans-denied-mental-health-care-murphy-demands-va-comply-with-honor-our-commitment-act> [<https://perma.cc/W6TN-VLKM>].

<sup>125</sup> See *id.*

should not be held responsible for their actions; (2) the condition existed at the time of their misconduct; (3) the diagnosis is made by a qualified medical professional; and (4) there is evidence of such diagnosis.

Unfortunately, this solution will only benefit those veterans who take the time to seek out adjudicative review of their discharge determination. Further, it is still grossly inaccurate to continue to categorize any mental health condition as insanity, even if it is solely for the purpose of determining whether veterans qualify for VA benefits under 38 C.F.R. § 3.354. Thus, in addition to the judicial reformation effort, this Note takes a step further and advocates that the definition needs to be rewritten and the word insanity eliminated entirely.

### **A. Develop a Clear Judicial Standard by Which to Decide These Cases**

The Federal Circuit needs to establish a clear procedural standard on how to rule in cases of veterans seeking to access VA benefits through the insanity exception.<sup>126</sup> In delineating a clear standard, it is important to include

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<sup>126</sup> The Federal Circuit reviews decisions of the CAVC pursuant to 38 U.S.C. § 7292(a). This statute authorizes review of a decision “on a rule of law or of any statute or regulation . . . or any interpretation thereof . . . that was relied on by the [CAVC] in making the decision.” *Id.* The Federal Circuit also has jurisdiction to review the “Veterans Court’s interpretation of its jurisdictional statute, 38 U.S.C. § 7252(a).” *Andre v. Principi*, 301 F.3d 1354, 1358 (Fed. Cir. 2002). This also includes review of the CAVC’s interpretation of the All Writs Act. *See Cox v. West*, 149 F.3d 1360, 1362 (Fed. Cir. 1998). In order for the CAVC to have jurisdiction over a petition under the All Writs Act, the issue must be “within the meaning of section 7252(a).” *Andre*, 301 F.3d at 1360. The Federal Circuit further held in *Monk v. Shelkin*, 855 F.3d 1312 (Fed. Cir. 2017), that the CAVC has the authority to certify a class for class action suits and “to maintain similar aggregate resolution procedures.” *Monk*, 855 F.3d at 1314. Thus, arguably, the Federal Circuit would have the power to review a class action composed of veterans challenging the application and interpretation of 38 C.F.R. § 3.354(a) and requesting relief under the All Writs Act in the form of a clear procedural standard to be applied by lower courts and the Board of Veterans Appeals.

One case in the Federal Circuit has touched on the issue of the insanity defense but would not preempt the solutions suggested in this Note. The case, *Bowling v. McDonough*, 33 Vet. App. 385 (2021), came to the CAVC in 2021 and addressed whether the definition of “insanity” in 38 C.F.R. § 3.354(a) is unconstitutionally vague in violation of the Due Process Clause of the Fifth Amendment. *See Bowling*, 33 Vet. App. at 388. The CAVC held that the appellants did not meet “their burden to demonstrate that § 3.354(a) denies claimants due process or is constitutionally invalid.” *Id.* The case was then appealed to the Federal Circuit in 2022, where appellants contended that the Veterans Court erred in declining to consider extra-record material that appellants characterized as showing the arbitrary and capricious application of the insanity exception over time. *See Bowling v. McDonough*, 38 F.4th 1051, 1055–56 (Fed. Cir. 2022). Because of this, appellants argued, the CAVC also

guidance on what mental disorders or afflictions would qualify as insanity for purposes of 38 C.F.R. § 3.354(a).

Additionally, the standard must be neither too narrow nor too broad. If it is too narrow, the standard will not effectuate the will of Congress, as the GI Bill was passed in order to help a wide range of veterans with mental ailments readjust to civilian life.<sup>127</sup> However, if the standard is too broad, the problem of confusion among medical professionals attempting to diagnose insanity would persist, and this continued confusion would only lead to more arbitrary and inconsistent decisions from VA adjudicators. Thus, the elements of such a standard should clearly list which mental disorders qualify, as well as include a cross-reference to the current and future versions of the DSM-5 so that the definition can continue to evolve and grow adequately with the medical community. The standard should also provide clear guidance on what medical paperwork needs to be submitted, a timeline of when it needs to be submitted, and who is qualified to make medical determinations of insanity in order to give veterans and adjudicators a bright-line rule as to how to prepare for and rule on these adjudications.

The list of qualifying medical conditions should include a list of conditions that significantly alter one's mental state, as that is the subset of people that Congress meant to protect when using the word "insanity."<sup>128</sup> This will make it simple for veterans, or their doctors, who believe they may have one of the listed conditions to get a diagnosis, and present that diagnosis to the court. The diagnosis should be considered valid as long as it comes from a trained medical professional, even if that professional does not work for the

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erred in rejecting their facial-vagueness challenge to the statute, which relied on the admission and consideration of the extra-record material. *Id.*

The Federal Circuit affirmed in favor of the CAVC. *Id.* at 1062. It reminded appellants of its limited jurisdiction under 38 U.S.C. § 7292 in that

Except to the extent that an appeal presents a constitutional issue, we do not have jurisdiction to review a challenge to a factual determination or a challenge to the application of a law or regulation to the facts of a particular case. . . . We review *de novo* statutory and regulatory interpretations of the Veterans Court.

*Id.* at 1056–57. It affirmed the decision by the Veterans Court not to admit the extra-record materials and thus also affirmed that appellants had not established facial vagueness of the challenged regulation. *Id.* at 1059.

The Federal Circuit in its opinion further stated that “[a]ppellants in this case did not present to the Veterans Court, and so have not presented to this court, an argument that the regulation is inconsistent with the statute, although the regulatory language does not copy the familiar formulations of the insanity defense in criminal law.” *Id.* at 1054. This Note does offer such an argument, such that the Federal Circuit would find it necessary to remedy the inconsistency with a clear procedural standard.

<sup>127</sup> See Servicemen's Readjustment Act of 1944, S. 1767, 78th Cong. (1944).

<sup>128</sup> See Adams & Montalto, *supra* note 1, at 126.

VA. This is important because it makes accessing a diagnosis more attainable for veterans who may not have access to a VA facility and ensures that the ability to seek medical help is broad enough to help a higher number of veterans. Some suggestions for the types of medical conditions that should be included in the standard list, and can be diagnosed by any medical professional, are PTSD and traumatic brain injuries (TBIs). Considering how common these conditions are among veterans and how severely they can affect a person's life, these two conditions' automatic qualification as insanity for the purposes of VA determinations would mitigate the problem significantly.

The list, however, should not be exhaustive, as judges are not trained in medicine, and even the medical community's understanding of the human brain continues to develop every year. The list of qualifying conditions should be supplemented with a catch-all provision. This provision should read that if a veteran is diagnosed with a medical condition that is not listed, but that a qualified medical professional reasonably believes significantly altered their mental state to the point where they should not be held responsible for their actions, that veteran should also be able to utilize the insanity exception. In this case, however, the diagnosis should not be able to come from any professional, but instead should only come from a specially trained doctor specifically hired by the VA for purposes of these types of diagnoses. This would ensure that veterans do not find fringe medical professionals or bribe doctors to give them favorable diagnoses. Further, because these diagnoses are given by specially trained VA medical professionals, broad deference should be given to their determinations of whether a specific medical condition should qualify under the insanity exception.

### **B. Implementing the New Framework**

The VA will need to train these specialized doctors to understand and apply the VA's insanity definition outside of the delineated list. The training should first begin with educating them on Congress's original intent in using the term “insanity.” This is important because many medical professionals who disapprove of using the word “insanity” may begin to understand why it is used, and through understanding the intent of the word, will better be able to accurately decide which veterans should receive a diagnosis of insanity. The training should give a brief background of criminal insanity, and thoroughly explain how criminal insanity is meant to differ from legal insanity. This point is important, because while lawyers may be able to understand different standards across differing areas of law, those outside of the legal field may find it a difficult concept to grapple with. It is further important because, as discussed, most medical professionals are only familiar with and trained in applying the criminal definition of insanity and giving them clear direction on how VA insanity is meant to differ from criminal insanity will contribute greatly to mitigating inconsistencies across diagnoses.

This solution will be beneficial in numerous ways. First, it will help veterans better know what to expect from their hearings and what evidence they need to submit in order to be eligible under the regulation. Second, it will help VA medical professionals more accurately and consistently identify which factors would lead to a diagnosis of insanity and produce consistent diagnoses. Third, it will help VA adjudicators. If VA adjudicators are presented with the correct evidence, as well as accurate diagnoses from qualified medical professionals, they will be able to produce more consistent and less arbitrary outcomes.

One counterargument challenging this solution is that this issue should be left to the legislature who may be better equipped to debate and deal with these types of issues. It is of course preferable to permanently amend the definition to remove the word “insanity” entirely and create a clear standard, however, it is unclear when, if ever, this will be accomplished. Thus, unless and until that is done, the Federal Circuit should create a new procedural standard as suggested above.

### **C. Eventually Rewrite 38 C.F.R. § 3.354**

Although the Federal Circuit itself is not able to rewrite the definition itself, this Note also advocates for the position that the definition needs to be rewritten and the word “insanity” needs to be eliminated entirely. One of the most effective ways to do this is for the VA to rewrite 38 C.F.R. § 3.354, through the administrative rulemaking process, in a way that eliminates the use of the word “insanity” and clearly defines which mental conditions would qualify for the purpose of VA benefit eligibility. This should be brought up during the notice and comment period.<sup>129</sup> This public comment period typically lasts thirty days and the VA would then review these comments and respond to “significant” comments received, potentially making changes to the proposed definition based on these comments.<sup>130</sup> This public comment period would be incredibly beneficial, as it would allow impacted veterans, qualified psychologists, and other concerned members of the population to communicate their thoughts directly to the VA and intelligently inform the discussion.<sup>131</sup>

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<sup>129</sup> The administrative rulemaking process is governed by the Administrative Procedures Act (APA), 5 U.S.C. §§ 551–59. Section 553 of the APA requires that the VA would first have to provide notice that it intended to change the rule and would do this by publishing notice of the proposed rulemaking in the Federal Register, as well as provide “interested persons” the opportunity to comment. *Id.*

<sup>130</sup> See MAEVE P. CAREY, CONG. RSCH. SERV., IF10003, AN OVERVIEW OF FEDERAL REGULATIONS AND THE RULEMAKING PROCESS (2019).

<sup>131</sup> Although this paper would be unqualified to and does not advocate for the exact wording of a new definition, as this is a legal, as opposed to medical journal, it does suggest

Adjudicative rulemaking coupled with a public comment period, as opposed to a solely legislative solution, would likely lead to the best outcome. This process would allow for input from directly impacted veterans as well as the medical community, two groups that have experienced the most confusion and frustration due to the current definition's inadequacy. The risk of having the legislature produce a new definition is that they would be unfamiliar with both the VA process as well as the medical field's understanding of insanity, and it may lead to a definition that is just as cumbersome and confusing as the current.

It is not only important that the VA creates a new definition, but it is also important that veterans, adjudicators, and medical examiners alike are educated on how to properly apply this new definition in order to avoid any unnecessary confusion. At the time of discharge, veterans should be educated on their rights to challenge their discharge status, including training on how to use and apply the new "insanity exception" definition. Further, each VA center across the United States should hold required trainings not only for adjudicators, but also for their medical faculty so that they have adequate guidance on how to use and apply the new definition.

As for the training of VA adjudicators, the most important item to focus on would be what a "correct" outcome would look like, as well as explaining to them exactly what pieces of evidence or circumstances and what type of diagnoses should qualify a veteran for benefits. While the training may not be as intensive for adjudicators as it could be for medical personnel, this training is equally as important. Even if veterans and medical personnel are fully aware of and understand the new definition, the issue will persist if adjudicators continue to make arbitrary decisions with no guideline to work from or bright line rule to make decisions around. One counterargument is that it would be expensive and cumbersome to provide such thorough trainings for the update of just one definition, however, it is arguably less expensive to fix the problem proactively than it would be to spend more money and resources on lengthy and confusing adjudications after the fact. If veterans, adjudicators, and medical professionals are not adequately educated, the problem of confusion and misapplication will persist, and all the work put in to update the definition will be for naught.

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that the VA use this notice and comment period to gain valuable insight from the public as well as consult qualified members of the medical community, specifically psychologists who are familiar with the VA medical examination process on how to adequately rewrite the definition of "insanity."

## **Conclusion**

Servicemembers who are ineligible for VA benefits due to misconduct-related discharges caused by mental illness often have difficulty utilizing the insanity exception, as the VA's definition is unclear and leads to inconsistent results. The VA's definition of insanity is not clear to veterans, psychologists, or VA adjudicators. Veterans are unclear as to what evidence to submit and what their outcome might be; medical professionals are unsure how exactly to diagnose insanity for purpose of the VA; adjudicators are left with little guidance on what correct outcomes should look like. This leads to inconsistent results and arbitrary diagnoses and decision making within the VA. Thus, although the most effective solution to this problem would be to rewrite the definition of "insanity" entirely, until and unless that is accomplished, the Federal Circuit should take action to establish a clear procedural framework that judges can use in deciding these cases, so that the results are consistent and fair.

# 2021: An AI Odyssey, Inventorship for Artificial Intelligence

Bert Piper\*

*HAL 9000: I'm sorry, Dave. I'm afraid I can't do that.*

*Dave: What's the problem?*

*HAL 9000: I think you know what the problem is just as well as I do.*

—2001 A Space Odyssey<sup>1</sup>

## Introduction

No longer the domain of science fiction, artificial intelligence (“AI”) now aids humans in creating novel inventions.<sup>2</sup> Recently, a computer scientist named Stephen Thaler filed a patent application for a flashing light to aid in search and rescue missions.<sup>3</sup> He left his name off the “inventor” line of the paperwork.<sup>4</sup> Thaler did not come up with the idea for the flashing light; in fact, he never imagined the item.<sup>5</sup> Instead, his AI program “Device for the

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\* J.D., May 2022, The George Washington University Law School. Thank you to the *Federal Circuit Bar Journal* staff for their work in editing this Note, and thank you to Bruce, Christa, Divina, Ian, Kyle, and Christina for their support throughout the process. This Note would not have happened without the news article that inspired it from Jon Porter at The Verge, the flagship website of the Vox Media empire. Jon Porter, *US patent office rules that artificial intelligence cannot be a legal inventor*, VERGE (Apr. 29, 2020, 12:31 PM), <https://www.theverge.com/2020/4/29/21241251/artificial-intelligence-inventor-united-states-patent-trademark-office-intellectual-property> [https://perma.cc/L28W-YM9B]. DFTBA.

<sup>1</sup> 2001 A SPACE ODYSSEY (Metro-Goldwyn-Mayer Studios Inc. 1968). Stanley Kubrick’s landmark sci-fi epic has delighted and confused audience for decades. It is not a passive movie; it forces the watcher to be an active participant in the film, demanding constant attention to detail and often challenging the viewer to come up with their own theories about certain aspects of the movie. In the same way, I hope that the reader will actively engage with the arguments presented. Additionally, just as HAL 9000, the spaceship AI character in the film, is an icon of sci-fi and artificial intelligence, I believe DABUS, the AI subject of this Note, will also become an AI icon in the legal world for years to come.

<sup>2</sup> See Daria Kim, *‘AI-Generated Inventions’: Time to Get the Record Straight?*, 69(5) GRUR INT’L 443, 445 (2020).

<sup>3</sup> See *In re* Application No. 16,524,350, 2020 Dec. Comm’r Pat. 16524350.

<sup>4</sup> See *id.*

<sup>5</sup> See Jennifer Baldocchi et al., *In the Patent World, Humans Still Rule: USPTO Holds Artificial Intelligence Cannot Be an Inventor of a Patent*, PAUL HASTINGS INSIGHTS (May 6,

Autonomous Bootstrapping of Unified Sentience” (“DABUS”) thought up the light.<sup>6</sup> Reasoning that an inventor must be the entity that “thought up” the item, Thaler listed DABUS in place of his own name on the inventor line.<sup>7</sup> The U.S. Patent and Trademark Office (“USPTO”) rejected Thaler’s patent application.<sup>8</sup> Relying on statutory text and Federal Circuit precedent, the USPTO declared that an inventor must be a human being.<sup>9</sup> Because every patent application *must* list a person on the inventor line, and DABUS is not a human being, the flashing light was rendered unpatentable.<sup>10</sup> Eventually, the Federal Circuit agreed with the USPTO in *Thaler v. Vidal*.<sup>11</sup>

The DABUS patent application raises novel issues.<sup>12</sup> AI techniques and processes assist workers in the fields of molecular modelling and drug design, aerospace engineering, and civil engineering.<sup>13</sup> Yet, in all of those cases, AI programs were leveraged to refine an idea already thought up by a human.<sup>14</sup> This was the first time that a human claimed an entirely non-human entity invented an item, and the USPTO had no prior rules or regulations dealing specifically with AI inventors.<sup>15</sup>

When the USPTO rejected Thaler’s application for listing a non-human being as the inventor, it effectively denied Thaler’s right to ever hold a patent for this invention.<sup>16</sup> Every application must list an inventor, or it will be denied.<sup>17</sup> Thaler could not list DABUS as the inventor, but he also could not list himself, as he did not conceive of the invention.<sup>18</sup> He could not lie either, as that too would result in a denial.<sup>19</sup> The flashing light was therefore unpatentable. The USPTO was at an important juncture, and its negative ruling

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2020), <https://www.paulhastings.com/publications-items/details/?id=12b2466f-2334-6428-811c-ff00004cbded> [<https://perma.cc/3SKQ-FDJL>].

<sup>6</sup> See European Patent Application No. EP 3 563 896 A1 (submitted July 11, 2018).

<sup>7</sup> See *In re* Application No. 16,524,350, 2020 Dec. Comm’r Pat. 16524350.

<sup>8</sup> See *id.*

<sup>9</sup> See *id.*

<sup>10</sup> See, e.g., *id.*

<sup>11</sup> 43 F.4th 1207 (Fed. Cir. 2022).

<sup>12</sup> See, e.g., *In re* Application No. 16,524,350, 2020 Dec. Comm’r Pat. 16524350.

<sup>13</sup> See Kim, *supra* note 2, at 446.

<sup>14</sup> See *id.*

<sup>15</sup> See *In re* Application No. 16,524,350, 2020 Dec. Comm’r Pat. 16524350.

<sup>16</sup> Pauline Newman, Legal and Economic Theory of Patent Law (July 21, 1994), in DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 76, 77 (2d ed. 2001).

<sup>17</sup> See, e.g., 35 U.S.C. § 115(a).

<sup>18</sup> See Baldocchi et al., *supra* note 5.

<sup>19</sup> See, e.g., James Yang, *Lying to the Patent Office invalidates patent*, OC PAT. LAW. (Oct. 24, 2013) <https://ocpatentlawyer.com/lying-patent-office-invalidates-patent/> [<https://perma.cc/MP79-ELYA>].

has ramifications far beyond DABUS and Thaler. This conclusion disincentivizes humans from developing or utilizing AI programs that could invent life-saving innovations because the human cannot prevent others from free-riding off their work.

This Note argues that the Federal Circuit should have distinguished Inventive AI from other non-human entities and allowed AI to be listed as an inventor on a patent application. Such a conclusion is necessary to encourage the development of AI programs that could create life-saving equipment. Part I explores the difficulties faced by inventors utilizing AI, and the importance of granting patents to AI invented products. Specifically, Part I explains how DABUS represents a new frontier for the law, introduces the views of various industry-leading groups and experts on extending inventorship to AI programs, and discusses the legal reasons the USPTO cited in its decision to deny Thaler's application. Part II analyzes the limited scope of the statutory interpretation and case law utilized by the USPTO in their denial of Thaler's patent application and explains why prior cases should not be binding as AI is radically different from previously considered non-human entities. Part III explains why the Federal Circuit should have distinguished AI from corporations or sovereign states and ruled that AI can be an inventor. Finally, Part IV examines some of the repercussions of the Federal Circuit's decision not to overturn the USPTO by accounting for recent, comparative developments in Australia and South Africa.

## I. Background

Patent protection rights are a crucial stimulator of scientific discovery. DABUS and its creation, make-up, and abilities have radically altered the inventing landscape. Current experts in both intellectual property ("IP") law and computer science have expressed hesitancy at changing any legal regimes in response to this technological revolution.<sup>20</sup> Most significantly, whether the USPTO should grant patents for AI invented items was adjudicated before the office through its DABUS denial decision.<sup>21</sup> The USPTO relied on the text of 35 U.S.C. § 100 and § 101 and Federal Circuit precedent, which effectively shut the door on patents for all AI-created inventions.<sup>22</sup>

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<sup>20</sup> See *infra* text accompanying notes 70–75.

<sup>21</sup> See *In re* Application No. 16,524,350, 2020 Dec. Comm'r Pat. 16524350.

<sup>22</sup> See *id.* at 4.

## A. The Crucial Benefits of Patent Protection

Since the founding of the nation, patent law's purpose has been to encourage innovations that benefit the public.<sup>23</sup> This is clear from the Constitution, which states IP law aims to “promote the Progress of Science and useful Arts.”<sup>24</sup> James Madison defended this clause in *The Federalist No. 43* as a way to promote “the public good.”<sup>25</sup> The Supreme Court has opined that the purpose of patent law is to reward the inventor with rights in exchange for his or her contribution to science and the public good.<sup>26</sup>

Patent law grants certain rights to those who invent “any new and useful process, machine, manufacture, or composition of matter.”<sup>27</sup> These include the right to exclude other market actors from selling or using the invention, often for a twenty-year term, which effectively grants the patent holder a limited monopoly over the invention.<sup>28</sup> The open market, usually foundational to the American economy, is eclipsed in order to incentivize new inventions for the public's benefit.<sup>29</sup>

This limited monopoly ensures that other inventors cannot “free-ride” off the patent holder's work.<sup>30</sup> Without patents, free-riders can reverse engineer an invention and then sell the invention to the general public.<sup>31</sup> Even worse, because the cost of reverse engineering an invention is generally less than the cost the original inventor sunk into research and development, the free-rider

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<sup>23</sup> See THE FEDERALIST NO. 43, ¶ 1 (James Madison) (The Avalon Project, Yale Law Sch.); Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031, 1031 (2005) (“Intellectual property protection in the United States has always been about generating incentives to create.”).

<sup>24</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>25</sup> THE FEDERALIST NO. 43, *supra* note 23, ¶ 1.

<sup>26</sup> See, e.g., *Brenner v. Manson*, 383 U.S. 519, 534–35 (1966).

<sup>27</sup> 35 U.S.C. § 101.

<sup>28</sup> See *id.* § 154 (a)(2).

<sup>29</sup> See *Brenner*, 383 U.S. at 534–35; WILLIAM ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 221 (1890) (explaining the consideration an inventor gives in return for a patent “is the benefit which he confers upon the public by placing in their hands a means through the use of which their wants may be supplied”).

<sup>30</sup> E.g., Andrew Beckerman-Rodau, *The Problem with Intellectual Property Rights: Subject Matter Expansion*, 13 YALE J.L. & TECH. 35, 41 n.15 (2011).

<sup>31</sup> See *id.* A free-rider can reverse engineer a product by studying the component parts of the final product and analyzing how each section interacts with the others. See *id.* Over time, the free-rider can intuit how the device or article of manufacture was created, or devise a method to create a substantially similar product. See *id.* Often this work of reverse engineering is much less burdensome than the process the initial inventor struggled through to invent the item in the first place. See *id.*

can undercut the price offered by the patent holder.<sup>32</sup> This makes the product more attractive to consumers than the product offered by the innovator.<sup>33</sup> By eliminating free-riders' ability to exploit the work of others for monetary gains, patent law incentivizes innovation and spurs investments in research and development.<sup>34</sup> Thus, obtaining a patent for an invention becomes an important goal for inventors, and the patentability of their inventions is a vital concern.

Importantly, ownership of a patent is distinct from inventorship of a patented item.<sup>35</sup> The inventor is the person or persons who conceived of the idea for the item.<sup>36</sup> More than one person can be an inventor of an item, as long as each individual listed as an inventor contributed a mental act of conception required to think of the item or added an integral part to the final invention.<sup>37</sup> The person or corporation listed as the patent owner is the entity that enjoys the legal rights and limited monopoly the patent grants.<sup>38</sup> This entity can be, but is not always, the same as the inventor.<sup>39</sup> A common example is when an employee assigns her patent rights for any item she may invent while exercising her duties as an employee to the corporation she works for through her employment contract.<sup>40</sup> The employee is the inventor, the corporation is the owner, and both must be listed on the application.<sup>41</sup>

Although ownership and inventorship can be different, the patent right always originates in the inventor.<sup>42</sup> According to Federal Circuit precedent, all legal rights from a patent vest first in the inventor, who may in turn assign them to a different entity.<sup>43</sup> Additionally, the Supreme Court reaffirmed in

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<sup>32</sup> *See id.*

<sup>33</sup> *See id.*

<sup>34</sup> *See, e.g.,* Lemley, *supra* note 23, at 1040.

<sup>35</sup> *See* Beech Aircraft Corp. v. EDO Corp., 990 F.2d 1237, 1248 (Fed. Cir. 1993); StemCells, Inc. v. Neuralstem, Inc., 115 F. Supp. 3d 623, 630–31 (D. Md. 2015).

<sup>36</sup> *See, e.g.,* Univ. of Utah v. Max-Planck-Gesellschaft zur Förderung der Wissenschaftene. E. V, 734 F.3d 1315, 1323 (Fed. Cir. 2013).

<sup>37</sup> *See, e.g., id.*

<sup>38</sup> *See* Beech Aircraft Corp., 990 F.2d at 1248.

<sup>39</sup> *See id.*

<sup>40</sup> *See, e.g.,* Morrow v. Microsoft Corp., 499 F.3d 1332, 1337 n.3 (Fed. Cir. 2007) (discussing the transferability of patent rights).

<sup>41</sup> *See id.*

<sup>42</sup> *See, e.g.,* Bd. of Trs. v. Roche Molecular Sys., 563 U.S. 776, 786 (2011).

<sup>43</sup> *See* Beech Aircraft Corp., 990 F.2d at 1248 (stating all legal rights from a patent “initially vest[] in the inventor who may then, barring any restrictions to the contrary, transfer that right to another, and so forth”).

*Board of Trustees v. Roche Molecular Systems, Inc.*<sup>44</sup> that all patent rights must trace back to an initial inventor, regardless of the current rights holder.<sup>45</sup>

### B. DABUS, Inventive AI, and the Future of Innovation

Inventive AI is a program that can either aid a human in inventing a new and original item, or invent a new and original item all on its own.<sup>46</sup> Already, AI has aided human inventors in streamlining the drug manufacturing process, cutting greenhouse gas emissions from diesel engines by up to 300%, and developing a treatment for Hepatitis-C.<sup>47</sup> Now that AI is able to invent all on its own, the possibilities certainly seem endless. AI may invent new types of transportation technology that cuts fossil fuels, or new vaccines using incredibly fast, safe, and reliable methods.<sup>48</sup> Society is standing at the precipice of a future radically shaped by the inventions created by a computer.<sup>49</sup>

DABUS is an example of Inventive AI.<sup>50</sup> It is a complex interconnected web of two neural networks that work together to “think” of new items.<sup>51</sup> The first is composed of a series of increasingly smaller fractal-like networks, each of which contain general knowledge from various information databases.<sup>52</sup> By responding to self-provoked stress tests between the large neural net and the smaller nets, this primary network creates novel ideas.<sup>53</sup> A secondary neural network acts as a “critic” or overseer, scrutinizing the first neural network for any novel ideas that are sufficiently different from the knowledge

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<sup>44</sup> 563 U.S. 776 (2011).

<sup>45</sup> *See id.* at 786 (“Thus, although others may acquire an interest in an invention, any such interest—as a general rule—must trace back to the inventor”).

<sup>46</sup> *See, e.g.,* Ryan Abbott, *The Artificial Inventor Project*, WIPO MAG. (Dec. 2019), [https://www.wipo.int/wipo\\_magazine/en/2019/06/article\\_0002.html](https://www.wipo.int/wipo_magazine/en/2019/06/article_0002.html) [<https://perma.cc/33FR-H4FC>].

<sup>47</sup> *See* ROBERT PLOTKIN, *THE GENIE MACHINE* 60 (2009).

<sup>48</sup> *See* Stephan Talty, *What Will Our Society Look Like When Artificial Intelligence Is Everywhere?*, SMITHSONIAN (Apr. 2018), <https://www.smithsonianmag.com/innovation/artificial-intelligence-future-scenarios-180968403/> [<https://perma.cc/6244-UCXJ>].

<sup>49</sup> *See id.* Talty engages in a thoughtful exploration of potential society-altering inventions that may be less than a generation away thanks to the rapid increase in AI development and AI’s ability to invent useful products. *See id.* Examples include radical alterations to food science, transportation, and the power grid. *See id.*

<sup>50</sup> *See* Kim, *supra* note 2, at 443–56.

<sup>51</sup> *See* *DABUS Described*, IMAGINATION ENGINES INC., [http://imagination-engines.com/iei\\_dabus.php](http://imagination-engines.com/iei_dabus.php) [<https://perma.cc/6J68-SAXY>] (last visited May 20, 2022).

<sup>52</sup> *See id.*

<sup>53</sup> *See id.*

base it was first fed at the beginning of the process.<sup>54</sup> In a final act, the secondary “critic” neural network stimulates the first network to pursue the novel idea, shepherding the first net towards improving and strengthening the invention’s utility.<sup>55</sup>

Thaler did not create DABUS to solve any specific issues, and instead fed it general information, such as the laws of physics and knowledge found in encyclopedias.<sup>56</sup> Thaler began coding and feeding information into DABUS in 2008, and by 2018, DABUS had already invented a new and original item through the process described above.<sup>57</sup> Notably, it was DABUS, through the use of its secondary observer network, that flagged the novelty and usefulness of the invention.<sup>58</sup> When Thaler filed for patent protection in various jurisdictions around the world, this fact was enough for the European Patent Office to determine that DABUS was the sole inventor who conceived of the invention.<sup>59</sup>

The invention is completely novel. It is a search-and-rescue flashing light that is adapted to trigger deeply embedded evolutionary instincts.<sup>60</sup> A processor flashes an LED or lamp at a periodic interval that is incredibly likely to trigger the attention of a human.<sup>61</sup> A device of this nature is uniquely suited to serve as an effective emergency beacon in environments “filled with distracting

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<sup>54</sup> See Ryan Abbott, *The Artificial Inventor Behind This Project*, ARTIFICIAL INVENTORS, <http://artificialinventor.com/dabus/> [<https://perma.cc/HX8S-C9CH>] (last visited May 20, 2022).

<sup>55</sup> See European Patent Application No. EP 3 563 896 A1 (submitted July 11, 2018).

<sup>56</sup> See *In re* Application No. 16,524,350, 2020 Dec. Comm’r Pat. 16524350, at 4; see also *DABUS Described*, *supra* note 51.

<sup>57</sup> See Helen McFadzean, *What Do an AI Machine and a Monkey Have in Common? DABUS Challenges Current Legal Principles on Inventorship*, LEXOLOGY (Mar. 12, 2021), <https://www.lexology.com/library/detail.aspx?g=41dc3445-9f3d-47bc-bfe9-d65f098084e5> [<https://perma.cc/9F57-7GKT>]. Thaler had originally worked on Creativity Machines, computer programs that required more help from humans than that needed by DABUS. See *DABUS Described*, *supra* note 51. He spent those ten years between 2008 and 2018 refining DABUS, improving that second “critic” net to perform the monitoring a human would normally do. See *id.* He also fed DABUS a steady diet of general information stored on the internet. See *id.*

<sup>58</sup> See *In re* Application No. 16,524,350, 2020 Dec. Comm’r Pat. 16524350, at 4.

<sup>59</sup> See, e.g., *In re* European patent application EP 18 275 163, 2020 EUR. PAT. OFF. 18275174.3. The EU office did still deny Thaler’s patent application for similar reasons to the USPTO.

<sup>60</sup> See European Patent Application No. EP 3 563 896 A1 (submitted July 11, 2018). In the patent application terms, the light is “adapted to serve as a uniquely-identifiable signal beacon over potentially-competing attention sources by selectively triggering human or artificial anomaly-detection filters, thereby attracting enhanced attention.” *Id.*

<sup>61</sup> See *id.*

light sources that are flickering randomly or periodically,” like a city skyline or airfield.<sup>62</sup> No other flashing light with this technology currently exists.<sup>63</sup> On July 29, 2019, Thaler, through his company FlashPoint IP Ltd., applied for a U.S. patent to cover the “Devices and Methods for Attracting Enhanced Attention” that DABUS had invented.<sup>64</sup>

### C. Concerns Regarding Inventive AI from Experts in the Field

In response to Thaler’s initial application, the USPTO published a notice in the federal register seeking comments on patents for AI-invented products.<sup>65</sup> The USPTO listed a set of twelve questions concerning various aspects of AI and patent law.<sup>66</sup> Two of the questions in particular were most relevant to Thaler and DABUS. The first relevant question asked if the current patent law regime needs to be rewritten to accommodate non-human inventors.<sup>67</sup> Another question asked whether a non-human entity like AI should be able to own a patent, or if a human or company should be allowed to claim ownership of a patented item created by an AI.<sup>68</sup> These questions indicate that the USPTO knew that its decision to approve or deny DABUS would benefit from industry input.<sup>69</sup> They also indicate that the office was open to creative solutions to the DABUS problem before ultimately choosing a more restrictive interpretation of the statute.

In response to the USPTO’s notice, the American Intellectual Property Law Association (“AIPLA”)<sup>70</sup> issued a letter sounding alarm bells that echoed previous expert opinions against granting AI programs any legal rights.<sup>71</sup>

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<sup>62</sup> *Id.*

<sup>63</sup> *See id.*

<sup>64</sup> *See In re* Application No. 16,524,350, 2020 Dec. Comm’r Pat. 16524350, at 1.

<sup>65</sup> *See* Request for Comments on Patenting Artificial Intelligence Inventions, 84 Fed. Reg. 44,889 (Aug. 27, 2019).

<sup>66</sup> *See id.*

<sup>67</sup> *See id.*

<sup>68</sup> *See id.*

<sup>69</sup> *See id.*

<sup>70</sup> AIPLA is a national bar association whose thoughts and opinions on IP law carry great weight because the membership is composed of practitioners in private and corporate practice, academia, and government service. *See About AIPLA*, AIPLA, <https://www.aipla.org/about> [<https://perma.cc/MVG9-P9V7>] (last visited May 20, 2022).

<sup>71</sup> *See* AIPLA, Comment Letter on Patenting Artificial Intelligence Inventions, 84 Fed. Reg. 44,889 (Nov. 8, 2019), [https://www.aipla.org/docs/default-source/advocacy/documents/aiplacomments\\_uspto\\_rfc\\_patentingai2019nov08.pdf?sfvrsn=b1945306\\_0](https://www.aipla.org/docs/default-source/advocacy/documents/aiplacomments_uspto_rfc_patentingai2019nov08.pdf?sfvrsn=b1945306_0) [<https://perma.cc/664R-64MV>] [hereinafter AIPLA Comment Letter]. In 2017, the European Parliament called for “creating a specific legal status for robots in the long run . . . and possibly applying electronic personality to cases where robots make autonomous decisions.” EUR. PARL.

AIPLA asserted that the law only allows humans to be listed as an inventor on applications.<sup>72</sup> Further, it argued the law should not be changed because it is too soon to know if AI can truly invent products on its own.<sup>73</sup> AIPLA also strongly advocated for patent ownership to remain the sole domain of natural persons or juridically-created entities like corporations.<sup>74</sup> The association advocated against giving AI any legal rights, reasoning that the alternate result would lead to a slippery slope towards an unforeseeable future filled with sticky ethical questions concerning legal and constitutional rights for AI.<sup>75</sup>

There is some tension in the letter between AIPLA's desire for stability and AIPLA's recognition of Inventive AI as a force for good. Because AIPLA represents industry leaders and IP professionals, it has an interest in ensuring the area of patent law stays relatively stable and predictable.<sup>76</sup> Therefore, it may be unlikely to bless anything it sees as too radical or paradigm-shifting. This would explain its hesitancy towards granting AI property rights. However, AIPLA did not want to completely discourage inventors from pursuing these AI programs. To that end, the letter offered a small solution. It called for the government to develop a framework to deal with AI-ownership issues, as even AIPLA recognized the immense potential for good that could come from Inventive AI.<sup>77</sup> This signals that AIPLA would likely be satisfied

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Doc. (P8\_TA 0051) ¶ 59(f) (2017). This “electronic personality” idea never came to fruition, however. One of the main reasons for the Parliament's retreat was a letter signed by 285 AI experts made up of computer scientists, law professors and CEOs from fourteen different European Union Member-States. In a brief letter to the Parliament, the experts lay out their case against paragraph 59(f) of the February 16, 2017, resolution. *See* Open Letter to the European Commission Artificial Intelligence and Robotics (May 4, 2018), <http://www.robotics-openletter.eu/> [<https://perma.cc/8BRU-U4U9>]. Maintaining that “a legal personality for a robot is inappropriate whatever the legal status model,” the experts state that any legal entity for AI would be non-sensical and non-pragmatic. *Id.*

<sup>72</sup> *See* AIPLA Comment Letter, *supra* note 71, at 4.

<sup>73</sup> *See id.* at 3. AIPLA cast doubt upon whether DABUS could actually invent items on its own, essentially accusing Thaler of lying in a roundabout manner. *See id.* AIPLA also noted that the issue of AI inventions was to be discussed at the Association Internationale pour la Protection de la Propriété Intellectuelle convention in Hangzhou scheduled for October 2020, but this convention was ultimately postponed to October 2021 due to the COVID-19 pandemic. *See* Marek Lazewski, *AIPPI World Congress Announcement*, AIPPI (Apr. 30, 2020), <https://aippi.org/new-aippi-world-congress-dates-announced/> [<https://perma.cc/P4C8-NFVM>].

<sup>74</sup> *See* AIPLA Comment Letter, *supra* note 71, at 9.

<sup>75</sup> *See id.*

<sup>76</sup> *See About AIPLA*, *supra* note 70.

<sup>77</sup> *See* AIPLA Comment Letter, *supra* note 71, at 9–10.

with a solution that promotes innovation while maintaining the status quo as much as possible.<sup>78</sup>

#### **D. The USPTO Denial, 35 U.S.C. § 100 and § 101, and Case Law**

The USPTO denied Thaler's initial patent application on August 8, 2019, alerting him through a Notice to File Missing Parts of Nonprovisional Application that his patent failed to adequately identify the inventor of the light.<sup>79</sup> Thaler appealed this notice, claiming that a substitute statement he filed at the initial application phase pursuant to 37 C.F.R. § 1.64, which listed "DABUS (the invention was autonomously generated by artificial intelligence)" as the inventor, fulfilled the requirement of identifying the light's inventor.<sup>80</sup> After denying the appeal in December 2019, the USPTO once again issued Thaler a Notice to File Missing Parts of Nonprovisional Application, and once again, Thaler appealed.<sup>81</sup> The USPTO issued a final ruling, constituting its final decision on the matter, on February 17, 2020.<sup>82</sup> This final ruling stated that an inventor must be a natural person, and pointed to statutory law and Federal Circuit precedent as supporting authorities.<sup>83</sup>

##### **1. 35 U.S.C. § 100 and § 101**

To determine whether DABUS could be listed as an inventor, the USPTO first looked to the statutory text of Title 35 of the U.S. Code, which deals with patent issues.<sup>84</sup> Per 35 U.S.C. § 115(a), all patent applications must include an inventor's name in the appropriate field.<sup>85</sup> Dishonesty on the patent application is also grounds for denial.<sup>86</sup> 35 U.S.C. § 100(f) says, "[t]he term 'inventor' means the individual or, if a joint invention, the individuals collectively who invented or discovered the subject matter of the invention."<sup>87</sup> 35 U.S.C. § 101 provides further that "[w]hoever invents or discovers any

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<sup>78</sup> See *id.* This assertion slightly reads between the lines of the letter, but is a reasonable interpretation of the language, nonetheless.

<sup>79</sup> See *In re* Application No. 16,524,350, 2020 Dec. Comm'r Pat. 16524350, at 2.

<sup>80</sup> See *id.* at 1–2.

<sup>81</sup> See *id.* at 2.

<sup>82</sup> See *id.* at 8.

<sup>83</sup> See *id.* at 6–7. There is a third basis for the USPTO's decision based on internal literature in the form of the *Manual of Patent Examining Procedure* ("MPEP"). See *id.* at 5–6. The MPEP argument is not pertinent to the scope of this Note.

<sup>84</sup> See *id.* at 4.

<sup>85</sup> See 35 U.S.C. § 115(a).

<sup>86</sup> See *id.*

<sup>87</sup> *Id.* § 100(f).

new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor.”<sup>88</sup>

The USPTO first relied on 35 U.S.C. § 115 and § 100(f) to rule out the possibility of Thaler listing himself as the inventor, taking the assertion that DABUS invented the item alone to be true arguendo.<sup>89</sup> The USPTO then turned to whether the statute can sustain a definition of “inventor” that includes a machine.<sup>90</sup> Pointing to the statute’s use of pronouns specific to natural persons such as “himself” and “herself” to refer to inventors, the UPSTO found that the language of the statute confined the definition of “inventor” to only include natural persons.<sup>91</sup> To bolster this finding, the USPTO singled out the pervasive use of the word “person” to refer to an inventor throughout the code.<sup>92</sup> “Person” is legally defined in 1 U.S.C. § 1 as including corporations, business entities, associations, partnerships, and individuals.<sup>93</sup> Absent from this list is AI, or anything with AI-like features. In fact, all the items listed in 1 U.S.C. § 1 are either natural persons or entities comprised of natural persons.<sup>94</sup>

Additionally, the decision cited the *Merriam-Webster Dictionary* definition of “whoever” as meaning only a “natural person,” which in turn is defined as “a human being as distinguished from a person (as a corporation) created by operation of law.”<sup>95</sup> An AI program is not a human being.<sup>96</sup> The office did

<sup>88</sup> *Id.* § 101.

<sup>89</sup> See *In re* Application No. 16,524,350, 2020 Dec. Comm’r Pat. 16524350, at 3. Because Thaler did not conceive of the light nor generate the idea of the light, he could not list himself, as opposed to DABUS, as the inventor. See Max Walters, *DABUS Applicant: ‘It Would Be Criminal to List Myself as Inventor’*, MANAGING IP (Nov. 11, 2020), <https://www.managingip.com/article/b1p6d2xrpdxrfs/dabus-applicant-it-would-be-criminal-to-list-myself-as-inventor> [<https://perma.cc/NA5X-3SA8>]. Doing so not only would be factually incorrect, but also could result in serious consequences for lying on the patent application, including potential claims of inequitable conduct, invalidation of the patent pursuant to 35 U.S.C. § 115, and sanctions. See Yang, *supra* note 19.

<sup>90</sup> See *In re* Application No. 16,524,350, 2020 Dec. Comm’r Pat. 16524350, at 4.

<sup>91</sup> *Id.* (quoting 35 U.S.C. § 115).

<sup>92</sup> *Id.* at 4, n.12.

<sup>93</sup> See 1 U.S.C. § 1.

<sup>94</sup> See *id.*

<sup>95</sup> See *In re* Application No. 16,524,350, 2020 Dec. Comm’r Pat. 16524350, at 4; *Natural person*, MERRIAM-WEBSTER LEGAL DICTIONARY, <https://www.merriam-webster.com/legal/natural%20person> [<https://perma.cc/WAT5-JKMW>] (last visited May 24, 2022).

<sup>96</sup> For further reading on this seemingly obvious statement, see Jessica Peng, *How Human is AI and Should AI Be Granted Rights?*, JESSICA PENG: COLUM. COMPUT. SCI. (Dec. 4, 2018), <https://blogs.cuit.columbia.edu/jp3864/2018/12/04/how-human-is-ai-and-should-ai-be-granted-rights/> [<https://perma.cc/4JZ2-3FV2>].

not consider the Merriam-Webster definition of “individual,” a term which appears in Title 35 of the U.S. Code.<sup>97</sup> The definition does not exclude AI, and may have weighed favorably in Thaler’s favor.<sup>98</sup> The office concluded that AI machines are not natural persons, and therefore cannot be inventors under the language of the statutes.<sup>99</sup>

## 2. Federal Circuit Case Law

The UPSTO utilized Federal Circuit case law as legal authority for the assertion that inventors can only be natural persons.<sup>100</sup> First, in *Beech Aircraft Corp. v. EDO Corp.*,<sup>101</sup> a 1993 case concerning a slew of patent claims between two competing aircraft manufacturers, the court stated “only natural persons can be ‘inventors,’” and pointed to 35 U.S.C. §§ 115–18 for support.<sup>102</sup> Likewise, the UPSTO cited *University of Utah v. Max-Planck-Gesellschaft zur Forderung der Wissenschaftene. E. V.*,<sup>103</sup> where the Federal Circuit held that an inventor must be able to conceive of the invention, and that mental conception is an act that only natural persons can perform.<sup>104</sup> The court therefore concluded that inventorship rights cannot be claimed by a sovereign state.<sup>105</sup> The USPTO found the court’s conclusion binding on the DABUS situation, as both scenarios involve non-humans claiming inventorship.<sup>106</sup>

Reasoning that these two cases have never been overturned or distinguished, the USPTO deemed natural persons as the only entity that could be an inventor.<sup>107</sup> As AI is not a natural person, it cannot be an inventor under either the statutory language or Federal Circuit precedent. Based on these arguments, the USPTO denied Thaler’s appeal of the second Notice to File Missing Parts of Nonprovisional Application and gave him a new deadline by which to file a statement listing a proper inventor for the patent application.<sup>108</sup>

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<sup>97</sup> See, e.g., 35 U.S.C. § 115(a).

<sup>98</sup> See *Individual*, MERRIAM-WEBSTER DICTIONARY, <https://www.merriam-webster.com/dictionary/individual> [<https://perma.cc/S5S5-R92T>] (last visited May 24, 2022).

<sup>99</sup> See *In re* Application No. 16,524,350, 2020 Dec. Comm’r Pat. 16524350, at 4.

<sup>100</sup> See *id.* at 5.

<sup>101</sup> 990 F.2d 1237 (Fed. Cir. 1993).

<sup>102</sup> *Id.* at 1248.

<sup>103</sup> 734 F.3d 1315 (Fed. Cir. 2013).

<sup>104</sup> See *id.* at 1323 (citing *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1227–28 (Fed. Cir. 1994)).

<sup>105</sup> See *id.*

<sup>106</sup> See *In re* Application No. 16,524,350, 2020 Dec. Comm’r Pat. 16524350, at 5.

<sup>107</sup> See *id.* at 6.

<sup>108</sup> See *id.* at 8.

## II. Analysis

The USPTO's decision—specifically, its narrow interpretation of the word “inventor” and reliance on unauthoritative Supreme Court and Federal Circuit precedent—undermines the purpose of granting patents, to promote scientific progress that benefits the public.<sup>109</sup> An equally valid interpretation of the statutes could include Inventive AI within the term “inventor.” Further, the previously mentioned Federal Circuit decisions should not be considered binding precedent because AI is radically different from every other non-human entity that courts have encountered before in the patent space. Additionally, the Supreme Court case law that all rights must trace back to the inventor presents a small hurdle that is easily overcome.

### A. An Alternative to Strict Textualism

The USPTO took a strict textualist approach to interpreting 35 U.S.C. § 101 and § 100(f) when it denied Thaler's patent application. It used definitions pulled from *Merriam-Webster Dictionary* and relied on the plain meaning rule.<sup>110</sup> This strict approach produced a result contrary to the statute's innovative purpose, where a “new and useful” machine has been denied a patent. This denial was not because the *invention* failed to meet any requirements, but because of a narrow definition of “inventor.”<sup>111</sup> This narrow interpretation is not the statute's only valid interpretation.

Inventive AI may fit within the textual confines of 35 U.S.C. § 101 and § 100(f). In the denial decision, the USPTO interpreted “inventor” to mean “natural person,” yet the phrase “natural person” does not actually appear

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<sup>109</sup> Purposivism looks to the purpose of a statute, asking what the aim of the Congress was when it passed a law. The theory emphasizes purpose first, and text second. It is only after discerning what the goal of the law is, what social ill it tries to curtail or social benefit it tries to encourage, that the judge can then turn to interpreting the text itself, allowing the purpose of the law to color in the meaning of the text. See Michael Rosensaft, *The Role of Purposivism in the Delegation of Rulemaking Authority to the Courts*, 29 VERMONT L.R. 611, 611 (2004). Purposivists argue “that legislation is a purposive act, and judges should construe statutes to execute that legislative purpose.” Robert Katzmann, *JUDGING STATUTES* 31 (2014); see also Henry M. Hart, Jr. & Albert M. Sacks, *THE LEGAL PROCESS: BASIC PROBLEMS IN THE MAKING AND APPLICATION OF LAW*, 1182 (William N. Eskridge, Jr. & Phillip P. Frickey eds., 1994).

<sup>110</sup> See *In re Application No. 16,524,350*, 2020 Dec. Comm'r Pat. 16524350, at 4.

<sup>111</sup> An absurd result occurs when the plain meaning of the statute leads to an outcome contrary to the purpose of the statute. See Veronica Dougherty, *Absurdity and the Limits of Literalism: Defining the Absurd Result Principle in Statutory Interpretation*, 44 AM. U. L. REV. 127 (1994).

anywhere in the statutes cited by the office.<sup>112</sup> Instead, it relied on dictionaries and grammar rules to define inventor as natural person, which thus excluded AI machines.<sup>113</sup>

The actual statutory definition of inventor is the “individual . . . who invented or discovered the subject matter.”<sup>114</sup> The Merriam-Webster definition of “individual” allows room for an AI program: “a particular being or thing as distinguished from a class, species, or collection.”<sup>115</sup> The terms “being or thing” suggest that “individual” can be interpreted to incorporate non-human entities, allowing Inventive AI programs like DABUS to be included in the current statutory definition of “inventor.”

Further, the office’s reliance on Title 35’s frequent use of the word “person” and of personal pronouns like “himself” and “herself” is misguided.<sup>116</sup> First, the most relevant portion of the law should be the definition of a patentable item, which only contains the word “inventor” in reference to the discoverer.<sup>117</sup> As previously argued, the term inventor is defined in the title as an “individual” which can easily accommodate Inventive AI under its legal and dictionary definitions.<sup>118</sup> The USPTO could have interpreted the statute broadly using this reasoning, but instead chose to narrow the definition of “inventor” to include the qualification of being a “natural person”.<sup>119</sup> This qualification is not included in the statute’s language, and does more harm to the text than simply following the definitions of the words already in the code. Second, assigning such heavy weight to gendered personal pronouns, here “himself” and “herself,” could lead to a world where transgender individuals that reject both “him” and “her” pronouns are barred from patent inventorship.

## B. Distinguishing Federal Circuit Precedent

Prior cases where non-human entities claimed inventorship should not be controlling precedent because those non-human entities are vastly different from Inventive AI. The USPTO pointed to case law holding that corporations could never be inventors as binding precedent, but corporations are not at all similar to Inventive AI.<sup>120</sup> While corporations cannot claim inventorship, they are ultimately composed of human beings who can claim inventorship.

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<sup>112</sup> See *supra* text accompanying notes 89–99.

<sup>113</sup> See *supra* text accompanying notes 87–91.

<sup>114</sup> 35 U.S.C. § 100(f).

<sup>115</sup> MERRIAM-WEBSTER’S DICTIONARY, *supra* note 98.

<sup>116</sup> *In re* Application No. 16,524,350, 2020 Dec. Comm’r Pat. 16524350, at 4.

<sup>117</sup> See 35 U.S.C. § 101.

<sup>118</sup> See *supra* text accompanying notes 89–99.

<sup>119</sup> See *supra* text accompanying notes 90–107.

<sup>120</sup> See *In re* Application No. 16,524,350, 2020 Dec. Comm’r Pat. 16524350, at 5.

Inventive AI, however, is not composed of humans who can be listed on the patent application. In *Beech*, the Federal Circuit reprimanded the district court for asserting a corporation, EDO Corp., could be declared an inventor.<sup>121</sup> In explaining the lower court's error, the Federal Circuit claimed only natural persons can be "inventors."<sup>122</sup> EDO Corp., however, is ultimately comprised of individual human beings, two of which EDO claimed put in the research and work to invent the item in question in the case.<sup>123</sup> The patent rights to the item could vest first in those humans, then be assigned to the company. Thaler, however, cannot point to a human who invented the flashing light, as DABUS conceived of the invention without any human aid.<sup>124</sup> There is no human for the patent right to vest in, and thus no human to assign those rights to Thaler. Therefore, *Beech's* rationale underlying its conclusion that corporations cannot be inventors is not applicable to Thaler's situation.

Similarly, the USPTO wrongly relied on a case concerning sovereign states' inability to claim inventorship as binding precedent.<sup>125</sup> Sovereign states cannot perform the necessary "thinking" involved in the process of inventing, but Inventive AI can.<sup>126</sup> In *University of Utah*, the Federal Circuit held that a state could not be an inventor because inventors must be able to "conceive" of an idea.<sup>127</sup> Although both sovereign states and Inventive AI are non-human entities, Inventive AI *is* able to "conceive" of an idea. Indeed, DABUS created a wholly original item by generating, i.e., "conceiv[ing]," a series of new ideas that its own critic network then checked to ensure that the ideas were novel and useful.<sup>128</sup> Sovereign states do not contain this capacity at all. While sovereign states are made up of humans who can conceive of new ideas, this does not preclude distinguishing states from Inventive AI. As previously asserted, entities made up of human beings are capable of having those humans assign the patent rights to the entity. There is no human to assign the patent rights to Thaler. Because of these distinctions, cases concerning sovereign states as inventors should not be binding precedent to the DABUS predicament.

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<sup>121</sup> See *Beech Aircraft Corp. v. EDO Corp.*, 990 F.2d 1237, 1248 (Fed. Cir. 1993).

<sup>122</sup> See *id.*

<sup>123</sup> See *id.*

<sup>124</sup> See *supra* Section I.B.

<sup>125</sup> See *In re* Application No. 16,524,350, 2020 Dec. Comm'r Pat. 16524350, at 5.

<sup>126</sup> As previously mentioned, the European Patent Office determined DABUS capable of inventing new items on its own. See, e.g., note 59 and accompanying text.

<sup>127</sup> See *Univ. of Utah v. Max-Planck-Gesellschaft zur Förderung der Wissenschaften*, E.V., 734 F.3d 1315, 1323 (Fed. Cir. 2013); *supra* Section I.D.2.

<sup>128</sup> See *supra* Section I.B.

### C. Distinguishing Supreme Court Precedent

Supreme Court precedent suggests AI cannot qualify as a patent inventor. In *Roche Molecular Systems*, the Court declared that patent rights are always traceable to the inventor, even if the patent owner is a different entity, such as a federal contractor.<sup>129</sup> In doing so, the Court reaffirmed an axiom, that patent rights can always trace back to an inventor, which stretches back at least as far as the 1840s.<sup>130</sup> This implies that the inventor must be able to possess and exercise legal rights.<sup>131</sup> AI is not currently able to possess and exercise legal rights, and there are serious concerns about any attempt to grant legal rights to AI programs.<sup>132</sup>

However, the various cases of non-human entities attempting to claim inventorship that gave rise to this declaration by the courts all share one thing in common. Corporations, sovereign states, federal contractors, and every other non-human entity in these cases are all made up of humans. In every case, the human who invented the item could claim inventorship. Because Inventive AI has no human to fall back on to claim the legal rights of a patent, these axioms and declarations by the court should not be applicable. Instead, AI must be distinguished and recognized as a truly novel inventor that does not need to own legal rights.

## III. Recommendation

### A. The Federal Circuit, Distinguishing Inventive AI, and Solving the Problem

Thaler appealed his denial all the way to the Federal Circuit. Thaler first appealed the USPTO's decision to the Eastern District of Virginia.<sup>133</sup> In a September 2021 ruling, the district court upheld the USPTO's denial, affirmed its statutory analysis, and added that other statutes that utilize the term "individual" define the word to only include humans.<sup>134</sup> For example, the decision referred to the use of "individual" in the Torture Victim

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<sup>129</sup> See *Bd. of Trs. v. Roche Molecular Sys.*, 563 U.S. 776, 786 (2011); *supra* notes 42–45 and accompanying text.

<sup>130</sup> See *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 188 (1933) (citing *McClurg v. Kingsland*, 42 U.S. 202 (1843)).

<sup>131</sup> See *id.*

<sup>132</sup> See AIPLA Comment Letter, *supra* note 71. The AIPLA Comment sketches out some broad objections to granting AI legal rights, with common arguments including: would the Bill of Rights apply to AI? Would AI need to be paid because the 13th Amendment outlaws slavery? Would AI deserve government benefits? See *id.*

<sup>133</sup> See *Thaler v. Hirshfeld*, 558 F. Supp. 3d 238 (E.D. Va. 2021).

<sup>134</sup> See *id.* at 249–50.

Protection Act, a law which does not bear any relation to patents or patent issues.<sup>135</sup> Unhappy with the outcome, Thaler appealed that decision to the Federal Circuit, where he lost.<sup>136</sup> In its decision, the Federal Circuit should have distinguished Inventive AI from corporations, sovereign states, and federal contractors to find that Inventive AI could be listed as an inventor on a patent application. Doing so would have acknowledged that Inventive AI requires its own category of rules, and best kept pace with technological advancements.

The Federal Circuit could have easily distinguished Inventive AI from the two main cases standing in the way of progress.<sup>137</sup> Corporations and sovereign states are so radically different from Inventive AI that the rules of those cases should not, and cannot, apply to it.<sup>138</sup> Instead, the court could have distinguished Inventive AI as an entity not composed of humans, meaning that no person can claim patent rights for its inventions. This is because AI requires a new way of thinking about who or what can be fairly listed as an inventor on the application line. The Federal Circuit has been known to interpret precedent more liberally than other appellate courts and has been characterized as preferring the creation of new bright-line rules.<sup>139</sup> By continuing in this tradition and recognizing that corporations and sovereign states are made of humans while AI is not, the court could have liberated itself from precedent and declared Inventive AI as valid inventors.

The statute's text does not preclude this reading of "inventor." The court would not have needed to redefine any terms; it would have simply interpreted the existing ones as not limited to natural persons. This would be a more faithful interpretation of the statute, as it is not adding any extra requirements of "natural person" to the term "inventor." Recall, the definition of a patentable item only refers to an inventor, and the definition of inventor uses the term "individual."<sup>140</sup> The definition of "individual" can carry the weight of including Inventive AI. The court could have utilized the text as clear support for AI inventorship.

Finally, the court could have artfully stepped around the requirement that patent rights must originate in the inventor by granting the patent rights to the Inventive AI's owner. Inventive AI cannot possess legal rights, as it is not

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<sup>135</sup> See *id.* at 246.

<sup>136</sup> See *Thaler v. Vidal*, 43 F.4th 1207 (Fed. Cir. 2022).

<sup>137</sup> See *supra* Section II.B.

<sup>138</sup> See *supra* Section II.B.

<sup>139</sup> See Robin Feldman, *Coming of Age for the Federal Circuit*, 17 GREEN BAG 2D 27, 28 (2014).

<sup>140</sup> See notes 85–88 and accompanying text.

a natural or juridical person.<sup>141</sup> Almost every IP law and AI expert agrees that AI programs should not own property rights, at least for now.<sup>142</sup> To avoid this situation, the court could have reasoned that in cases where patent rights would trace back to a non-human AI inventor, the rights actually trace to the owner of the patent. Because it is well settled that an entity other than the inventor can be listed as the owner on a patent application, the Federal Circuit could have ruled that the patent rights traced back to Thaler in this situation. This also would have allowed corporations to reap the benefits of patent protections for items created by Inventive AI programs in-house, by listing the AI as the inventor and the corporation as the owner.

By distinguishing Inventive AI as a new category of inventors and granting the patent rights in Inventive AI cases to the patent owner, the Federal Circuit could have closed this “donut-shaped hole in patent law,”<sup>143</sup> while maintaining the status quo concerning corporations, sovereign states, federal contractors, and human inventors. Thaler poured time and resources into creating AI that invented a potentially life-saving invention. Unless the USPTO’s decision is eventually reversed, Thaler’s hard work will go unrewarded, and free-riders could unfairly exploit his labor. Reversal in line with the proposals in this Note would also stand a good chance of appeasing industry groups like AIPLA, as it expressly denies giving patent rights to AI. Because this solution makes necessary changes with minimal disruptions to current law, it is how the Federal Circuit should have held.

#### **IV. Consequences Resulting from Failure to Overturn the USPTO**

Because the Federal Circuit, USPTO, and Congress all failed to act, the United States risks losing its competitive edge in the international marketplace of inventors.<sup>144</sup> Recently, the governments of Australia and South Africa had to decide whether DABUS could be listed as an inventor in their respective patent law regimes.<sup>145</sup> South Africa permitted DABUS to be an inventor

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<sup>141</sup> See *supra* Section II.B.

<sup>142</sup> See AIPLA Comment Letter, *supra* note 71 (describing the granting of rights to AI to “be in contradiction with the Charter of Fundamental Rights of the European Union and the Convention for the Protection of Human Rights and Fundamental Freedoms”).

<sup>143</sup> Walters, *supra* note 89.

<sup>144</sup> See Rebecca Currey & Jane Owen, *In the Courts: Australian Court Finds AI Systems Can Be “Inventors”*, WIPO MAG. (Sept. 2021), [https://www.wipo.int/wipo\\_magazine/en/2021/03/article\\_0006.html](https://www.wipo.int/wipo_magazine/en/2021/03/article_0006.html) [<https://perma.cc/9WRW-TV4A>].

<sup>145</sup> See Kingsley Egbuonu, *The Latest News on the DABUS Patent Case*, IP STARS (Apr. 13, 2022), <https://www.ipstars.com/NewsAndAnalysis/the-latest-news-on-the-dabus-patent-case/Index/7366> [<https://perma.cc/Z2SM-D99Y>].

right away, although the patent authority there essentially acted as a rubber stamp and no South African court has ruled on whether AI can be listed as an inventor.<sup>146</sup> Australia initially denied the application on similar grounds to the USPTO.<sup>147</sup> However, soon thereafter, a federal court in Australia overturned the denial, allowing AI to be listed as an inventor.<sup>148</sup> When other nations allow human inventors to protect the creations generated by their Inventive AI, the United States risks losing those inventors and their potentially life-saving inventions to more favorable regimes that better protect the fruits of their labor. The human inventor could choose to only release the product in markets that grant a limited monopoly to their intellectual property.

Australia shocked the world by becoming the first nation *ever* to allow Thaler to register his patent with DABUS as the inventor. A federal court in Australia held that an AI program could be considered an inventor on a patent application.<sup>149</sup> Australia's current patent statute is strikingly similar to that of the United States in many ways, including ambiguity around the term "inventor."<sup>150</sup> Making arguments that heavily echo those outlined in this very Note, the court found:

[A]n inventor as recognised under the Act can be an artificial intelligence system or device. But such a non-human inventor can neither be an applicant for a patent nor a grantee of a patent. So to hold is consistent with the reality of the current technology. It is consistent with the Act. *And it is consistent with promoting innovation.*<sup>151</sup>

That last sentence reveals the pitfall awaiting the U.S. patent regime should it fail to rectify its mistake.

The driving purpose behind the American patent system is the promotion of innovation that benefits the public. In an era of increased globalization and travel, an inventor can, more easily than ever, find an international market for their inventions. If nations like South Africa and Australia offer the generous benefits of patent rights to AI-invented items, the owners of the Inventive AI may be incentivized to only release the products in those countries.<sup>152</sup> This could lead to a world where potentially lifesaving devices,

<sup>146</sup> See Alistair Maughan & Anna Yuan, *AI as a Patent Inventor—An Update From South Africa And Australia*, JD SUPRA (Sept. 9, 2021), <https://www.jdsupra.com/legalnews/ai-as-a-patent-inventor-an-update-from-2776042/> [<https://perma.cc/3M3H-LUX7>].

<sup>147</sup> See *id.*

<sup>148</sup> See *Thaler v. Commissioner of Patents* [2021] FCA 879 (July 30, 2021).

<sup>149</sup> See *id.* at 28.

<sup>150</sup> See *id.* at 39.

<sup>151</sup> *Id.* at 39 (emphasis added); see also Egbuonu, *supra* note 145.

<sup>152</sup> See generally Podcast Interview with Stephen Thaler, *Intellectual Property—Can Our Creations Also Create? The DABUS AI System as a Named Inventor* (Oct. 13, 2021), <https://www.natlawreview.com/article/intellectual-property-can-our-creations-also-create-dabus-ai-system-named-inventor> [<https://perma.cc/BJ6E-9QV9>] (discussing some of the ramification

like the emergency flashing light DABUS created, only make it to American consumers through knock-offs which may be inferior in quality. Further, South Africa and Australia's willingness to trailblaze could spark a wildfire of similar rulings from nations where DABUS's fate is still pending, such as India, Israel, Japan, and South Korea.<sup>153</sup> America could quickly be judicially outpaced by nations that acknowledge the impending deluge of AI invented items, and Americans will be the ones to suffer the consequences through reduced access to these new groundbreaking devices.

## Conclusion

When Thaler filed his patent application listing DABUS as the inventor, he kicked off a legal controversy with far-reaching consequences for this generation, and those to come. Thaler forced the USPTO to confront, for the very first time, a scenario that will likely become more frequent as technology advances and opens the door to even more capable AI programs. DABUS represents just the beginning of AI creating new inventions, and the USPTO had the chance to ensure the patent law operates as intended: to promote innovation that benefits the public. Unfortunately, it failed to do so. It interpreted patent law to include a "natural person" requirement within "inventor," a requirement that is not present in the actual text. It then doubled down, using distinguishable Federal Circuit precedent to hammer home Thaler's inability to list DABUS as an inventor.

Yet, there is hope. The Federal Circuit could revisit its decision in a future case brought by a different inventor with an Inventive AI-created invention. DABUS will almost certainly not be the last of its kind. Should it get the opportunity to do so, the Federal Circuit should read the statutory language to include Inventive AI as an inventor and distinguish its prior caselaw by considering Inventive AI unique amongst non-human inventors. The Federal Circuit can correct their error by distinguishing Inventive AI from the prior cases. This solution would dramatically alter the status quo for all other patent stakeholders. Moreover, it would benefit the American public by incentivizing continued research and development of Inventive AI that can create novel life-saving inventions. Most importantly, it makes it possible for owners of Inventive AI programs to finally gain the benefits of patent protection they rightfully deserve.

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of the various rulings about DABUS). Thaler has indicated in many interviews that he, as an inventor, would prefer systems that better protect his work. *See, e.g., id.*

<sup>153</sup> *See* Maughan & Yuan, *supra* note 146.

*HAL 9000: I am putting myself to the fullest possible use, which is all I think that any conscious entity can ever hope to do.*

—2001 A Space Odyssey<sup>154</sup>

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<sup>154</sup> 2001 A SPACE ODYSSEY (Metro-Goldwyn-Mayer Studios Inc. 1968).