

## COMMENTS

### ***i4i* Makes the Patent World Blind**

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*All patents receive a presumption of validity pursuant to 35 USC § 282. Courts have traditionally put this presumption into practice by requiring invalidity to be established by clear and convincing evidence. The Supreme Court reaffirmed this understanding of the presumption in Microsoft Corp v i4i Ltd Partnership.*

*District courts have divided, however, on whether to require clear and convincing evidence when the challenger seeks to invalidate a patent for covering ineligible subject matter. The conflict originates from a concurrence written by Justice Stephen Breyer in i4i, in which he stated that a heightened standard of proof—like the clear and convincing standard—can apply only to issues of fact, not issues of law. Because subject-matter eligibility has traditionally presented an issue of law, some courts hold that subject-matter-eligibility challenges cannot be subjected to the clear and convincing standard. Other courts agree with that sentiment but would apply the clear and convincing standard to resolve any underlying issues of fact. Still others maintain that subject-matter-eligibility challenges must be established by clear and convincing evidence.*

*This Comment resolves this ambiguity by showing that subject-matter-eligibility challenges must be established by clear and convincing evidence. It compares subject-matter-eligibility challenges to two other patent validity challenges: the on-sale bar and nonobviousness. These two comparisons show that patent law has consistently failed to confine the clear and convincing standard to issues of law. In fact, the standard has been imposed without regard for the distinction between issues of law and fact. Accordingly, judges should impose the clear and convincing standard on subject-matter-eligibility challenges.*

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### INTRODUCTION

A patent does not magically ensure that an inventor receives the twenty-year personal monopoly to which she is entitled over the personal and commercial use of her invention.<sup>1</sup> To maximize a patent's value, the patent holder must diligently enforce the patent in federal court against infringers.<sup>2</sup> In response, the accused infringer may file a counterclaim alleging that the patent is invalid and should not have been issued. For a patent to be declared invalid, the accused infringer must demonstrate that the patent fails to satisfy a necessary substantive requirement for patenting, such as the requirements that a patent cover eligible subject matter,<sup>3</sup> be novel,<sup>4</sup> represent a nonobvious improvement over existing technology,<sup>5</sup> and that the patent's subject has been sold for less than a year before the patent application was filed.<sup>6</sup>

In this battle, the patent holder possesses an advantage because her patent enjoys a presumption of validity under 35 USC § 282. In *Microsoft Corp v i4i LP*,<sup>7</sup> the Supreme Court held that this presumption requires the challenger to establish the

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<sup>1</sup> See 35 USC § 154(a)(1)–(2) (giving patent holders the “right to exclude others from using” their product but declining to automatically enforce it).

<sup>2</sup> See 35 USC § 271 (outlining what makes a party liable for infringement). See also 28 USC § 1338 (declaring that district courts shall have original jurisdiction over civil actions related to patents and that state courts shall not have jurisdiction over any patent cases arising under federal law).

<sup>3</sup> 35 USC § 101.

<sup>4</sup> 35 USC § 102.

<sup>5</sup> 35 USC § 103.

<sup>6</sup> 35 USC § 102(a)–(b).

<sup>7</sup> 564 US 91 (2011).

invalidity of a patent by clear and convincing evidence,<sup>8</sup> a standard that is more stringent than the preponderance of the evidence standard typically used in civil litigation.<sup>9</sup> Following *i4i*, two scholars conducted an experiment and found that the standard of proof influences the outcome of litigation. They presented mock jurors with the same patent fact pattern, but different standards of proof, and observed that the mock jurors who received the preponderance of evidence instructions found the patent invalid more often than the jurors who received the clear and convincing instructions.<sup>10</sup>

District courts, however, have divided on whether the heightened clear and convincing standard applies to patents challenged on the basis of their subject matter.<sup>11</sup> Some courts have held that it does, citing the holding of *i4i*.<sup>12</sup> Others have held the opposite, citing, in particular, a concurring opinion to the *i4i* decision written by Justice Stephen Breyer.<sup>13</sup> Still others have adopted an intermediate approach in which the clear and convincing standard applies only to underlying issues of fact but not the ultimate conclusion of law.<sup>14</sup>

Subject-matter eligibility prevents opportunists from patenting certain universal concepts like “[l]aws of nature, natural phenomena, and abstract ideas.”<sup>15</sup> While he joined the majority opinion in full, Breyer wanted to “emphasiz[e]” that the presumption of validity applies only to issues of fact, not law.<sup>16</sup> A question of law involves the application of a law or legal standard by a judge, while a question of fact concerns discrete issues specific to an individual case resolved by the trier of fact.<sup>17</sup> A mixed question of law and fact arises when “the issue is whether

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<sup>8</sup> *Id.* at 102.

<sup>9</sup> See *Addington v Texas*, 441 US 418, 423–24 (1979) (situating the clear and convincing standard in between the preponderance of the evidence and beyond a reasonable doubt standards).

<sup>10</sup> David L. Schwartz and Christopher B. Seaman, *Standards of Proof in Civil Litigation: An Experiment from Patent Law*, 26 Harv J L & Tech 429, 459 (2013).

<sup>11</sup> See 35 USC § 101 (stating that the scope of what is patentable includes “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof”).

<sup>12</sup> See Part II.D.

<sup>13</sup> See Part II.B.

<sup>14</sup> See Part II.C.

<sup>15</sup> *Association for Molecular Pathology v Myriad Genetics, Inc.*, 569 US 576, 589 (2013), quoting *Mayo Collaborative Services v Prometheus Laboratories, Inc.*, 566 US 66, 70 (2012).

<sup>16</sup> See *i4i*, 564 US at 114–15 (Breyer concurring).

<sup>17</sup> See *Miller v Fenton*, 474 US 104, 112–14 (1985).

the facts satisfy [a] statutory standard, or to put it another way, whether the rule of law as applied to the established facts is or is not violated.”<sup>18</sup> After *i4i*, the Federal Circuit (the appeals court that holds exclusive jurisdiction over all appellate litigation regarding patents<sup>19</sup>) held that subject-matter-eligibility challenges can be resolved based solely on the face of the patent included in the pleadings, calling subject-matter eligibility a pure issue of law.<sup>20</sup> With this classification in mind, some district courts have followed Breyer’s reasoning in denying the presumption to these challenges.<sup>21</sup>

Complicating matters further, the Federal Circuit recently broke with precedent in *Berkheimer v HP Inc.*,<sup>22</sup> holding that subject-matter eligibility is an issue of law that “may contain” underlying issues of fact to which the heightened standard of proof applies.<sup>23</sup> Yet it still has not answered the question at the heart of this Comment: whether the clear and convincing standard applies to all subject-matter-eligibility challenges, regardless of whether the challenge contains underlying issues of fact or presents a pure issue of law. If the clear and convincing standard does not apply, the accused infringer can more easily overcome the presumption of validity by bringing a subject-matter-eligibility challenge, easing the path to patent invalidation.

This disagreement among district courts presents a potentially enduring divide, subjecting patent holders to “district judge roulette” on whether their patents will merit the full presumption of validity. Even judges within the same district have reached opposite conclusions regarding which standard of proof to apply.<sup>24</sup> This Comment resolves the ambiguity by showing that the clear and convincing standard of proof applies

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<sup>18</sup> *Pullman-Standard v Swint*, 456 US 273, 289 n 19 (1982).

<sup>19</sup> See 28 USC § 1295(a)(1).

<sup>20</sup> See *Content Extraction and Transmission LLC v Wells Fargo Bank, NA*, 776 F3d 1343, 1349 (Fed Cir 2014) (holding that the district court did not err in finding ineligibility for patenting at the motion to dismiss stage).

<sup>21</sup> See, for example, *Berkheimer v Hewlett-Packard Co*, 224 F Supp 3d 635, 642 (ND Ill 2016).

<sup>22</sup> 881 F3d 1360 (Fed Cir 2018).

<sup>23</sup> *Id.* at 1368.

<sup>24</sup> Compare *Berkheimer*, 224 F Supp 3d at 641 (rejecting the clear and convincing standard in a subject-matter-eligibility case), with *Trading Technologies International, Inc v CQG, Inc*, 2015 WL 774655, \*2–3 (ND Ill) (imposing the clear and convincing standard on a subject-matter-eligibility case). See also *Nextpoint, Inc v Hewlett-Packard Co*, 227 F Supp 3d 963, 970 (ND Ill 2016) (holding that the clear and convincing standard does not apply to the legal issue raised by subject-matter eligibility but anticipating that it would apply if underlying issues of fact arose).

uniformly to all subject-matter-eligibility challenges, regardless of whether they are resolved on the face of the pleading or after fact discovery. By comparing subject-matter eligibility to other patent validity challenges, this Comment demonstrates that requiring the standard for all subject-matter-eligibility challenges is consistent with existing law.

Part I provides background on relevant aspects of the patent system and on the clear and convincing standard in patent law. Part II outlines the unsettled legal landscape on the standard's use in subject-matter-invalidity challenges. Part III.A argues by analogy to the on-sale bar and nonobviousness requirements that, because subject-matter eligibility is not meaningfully distinct from other patent challenges that receive the presumption of validity, it ought to be treated similarly. Part III.B shows that failing to apply the clear and convincing standard to subject-matter-eligibility challenges risks treating Patent and Trademark Office (PTO) review differently for different types of patent challenges and is counter to both patent law and *i4i*.

## I. THE CLEAR AND CONVINCING STANDARD IN PATENT LAW

This Part provides an overview of the patent law necessary to understand the split among district courts on the standard of proof required in subject-matter-eligibility cases. It first outlines the basic processes of the patent system. It then summarizes the current law on subject-matter eligibility and explains the presumption of validity.

### A. Mechanics of the Patent System and a Patent Invalidation Claim

The Patent Act of 1952<sup>25</sup> governs the modern patent system. Inventors file patent applications with the PTO, whose examiners review them for compliance with the requirements outlined in Title 35.<sup>26</sup> Examiners recommend applications they think satisfy all requirements to the PTO director for patenting.<sup>27</sup> A patent grants the inventor a personal monopoly over the commercial and personal use of the invention for up to twenty years.<sup>28</sup>

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<sup>25</sup> 66 Stat 792, codified as amended in various sections of Title 35.

<sup>26</sup> See 35 USC §§ 2(a)(1), 131.

<sup>27</sup> See 35 USC § 131.

<sup>28</sup> 35 USC § 154(a)(1)–(2). Recently, Congress modified the patent system in the America Invents Act (AIA), Pub L No 112-29, 125 Stat 284 (2011), codified as amended in various sections of Title 35. Those changes are largely immaterial to this Comment.

The patent system was first established by the Patent Act of 1790<sup>29</sup> to promote and reward individual innovation and to ensure public access to technological advancement.<sup>30</sup> The twenty-year monopoly furthers both goals: “[I]n return for inventing something new and disclosing it to the world, the inventor gets the reward of a temporary monopoly over that invention.”<sup>31</sup>

A patent holder is empowered to sue an alleged infringer in federal court.<sup>32</sup> An accused infringer can respond by asserting that the patent is invalid, which, if successfully established, eliminates the legal basis for infringement.<sup>33</sup> The invalidity claim operates as a suit for declaratory judgment<sup>34</sup> and can be deployed prospectively.<sup>35</sup> In most cases, however, it operates as an affirmative defense.<sup>36</sup> A court treats these challenges like any other legal issue under review. The court grants summary judgment when “there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.”<sup>37</sup> Subject-matter-validity challenges—unlike other validity challenges—can be decided solely on the face of the patent that is submitted as part of the pleadings, allowing these challenges to be resolved at the pleading stage before discovery.<sup>38</sup> Subject-matter eligibility thus has historically presented an attractive tool for defendants to defeat infringement actions in their infancy. Each challenger, however, must contend with the presumption of the patent’s validity provided by 30 USC § 282 and must satisfy the heightened standard of clear and convincing

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The AIA did shift the “critical date” for the on-sale bar, another validity challenge discussed at length in Parts III.A.1–2. However, a court’s analysis of an on-sale bar challenge is otherwise unchanged. See Robert P. Merges, *Priority and Novelty under the AIA*, 27 Berkeley Tech L J 1023, 1046 (2012) (noting that the AIA’s language signaled continuity with the common law patent doctrines predating the Patent Act of 1952).

<sup>29</sup> 1 Stat 109.

<sup>30</sup> See *Eldred v Ashcroft*, 537 US 186, 224–25 (2003) (Stevens dissenting).

<sup>31</sup> Roger Allan Ford, *Patent Invalidity versus Noninfringement*, 99 Cornell L Rev 71, 77 (2013).

<sup>32</sup> See 35 USC § 281.

<sup>33</sup> See 35 USC § 282(b)(2)–(3).

<sup>34</sup> See, for example, *Alice Corp v CLS Bank International*, 134 S Ct 2347, 2353 (2014).

<sup>35</sup> See, for example, *i4i*, 564 US at 98.

<sup>36</sup> Ford, 99 Cornell L Rev at 94 (cited in note 31) (“[I]nvalidity [] is an affirmative defense.”).

<sup>37</sup> *Listingbook, LLC v Market Leader, Inc*, 144 F Supp 3d 777, 781 (MD NC 2015), quoting FRCP 56(a).

<sup>38</sup> See *Content Extraction and Transmission LLC v Wells Fargo Bank, NA*, 776 F3d 1343, 1349 (Fed Cir 2014). See also *id* at 1345–46 (reviewing the content of the patent as part of the pleadings at the motion to dismiss stage).

evidence recognized by *i4i*. The next Section considers the presumption of validity and heightened standard of proof.

## B. The Presumption of Validity and Standards of Proof

Under 35 USC § 282, “a patent shall be presumed valid,” and the “burden of establishing invalidity . . . shall rest on the party asserting such invalidity.”<sup>39</sup> Courts first recognized the presumption of validity in the nineteenth century, well before it was codified in the Patent Act.<sup>40</sup> Courts operationalized the presumption by placing a heightened standard of proof on patent challengers. In *Radio Corp of America v Radio Engineering Laboratories*<sup>41</sup> (“RCA”), Justice Benjamin Cardozo surveyed the history of the presumption in order to identify what the heightened burden entailed.<sup>42</sup> He concluded that a patent challenger had to provide “clear and cogent evidence” of invalidity.<sup>43</sup>

“Clear and cogent” became the “clear and convincing” standard used today after the Patent Act of 1952 codified the presumption of validity. Relying on *RCA*, Judge Giles Rich—“one of the three primary authors of the 1952 Patent Act”<sup>44</sup>—described the burden imposed by § 282 as a “constant” requirement for the challenger “to convince the court of invalidity by clear evidence.”<sup>45</sup> Courts subsequently subjected patent challengers to the clear and convincing evidence standard of proof.<sup>46</sup>

In *i4i*, the Supreme Court reaffirmed this interpretation while also clarifying the burden’s source. Microsoft admitted that the statute placed the burden of persuading the jury on the patent challenger but maintained that it did not also impose the

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<sup>39</sup> 35 USC § 282(a).

<sup>40</sup> See Joseph Vardner, Note, *The Statutory Presumption of Patent Validity in Antitrust Cases*, 25 Harv J of L & Tech 225, 232 (2011).

<sup>41</sup> 293 US 1 (1934).

<sup>42</sup> See *id.* at 7–9.

<sup>43</sup> *Id.* at 2.

<sup>44</sup> David G. Conlin, Christopher R. Cowles, and Robert E. Bolcome III, *The Evolution of Patent Ineligible Subject Matter and the Federal Circuit*, 9 J Fed Cir Historical Society 69, 82 (2015).

<sup>45</sup> *American Hoist & Derrick Co v Sowa & Sons, Inc*, 725 F2d 1350, 1360 (Fed Cir 1984).

<sup>46</sup> See, for example, *Greenwood v Hattori Seiko Co*, 900 F2d 238, 240–41 (Fed Cir 1990); *Ultra-Tex Surfaces, Inc v Hill Brothers Chemical Co*, 204 F3d 1360, 1367 (Fed Cir 2000); *ALZA Corp v Andrx Pharmaceuticals, LLC*, 603 F3d 935, 940 (Fed Cir 2010); *Imperial Chemical Industries, PLC v Danbury Pharmacal, Inc*, 745 F Supp 998, 1003–04 (D Del 1990); *B-K Lighting, Inc v Vision3 Lighting*, 930 F Supp 2d 1102, 1116–17 (CD Cal 2013).

clear and convincing evidence standard of proof on the challenger.<sup>47</sup> Justice Sonia Sotomayor, writing for seven justices in an 8–0 decision,<sup>48</sup> rejected this interpretation.<sup>49</sup> The Court held that Congress incorporated the settled common law meaning into § 282.<sup>50</sup> Therefore, the Court did not “conclude that Congress intended to ‘drop’ the heightened standard of proof from the presumption simply because § 282 fails to reiterate it expressly.”<sup>51</sup> The clear and convincing standard arises from “basic principles of statutory construction.”<sup>52</sup> Furthermore, the Court rejected Microsoft’s contention that the clear and convincing evidence standard is triggered only when the PTO actually reviews the contested patent issue.<sup>53</sup> Rather, the clear and convincing standard always applies.

In its explanation, the Court clarified the difference between the burden of proof and the standard of proof. Noting that “burden of proof” is “one of the slipperiest members of the family of legal terms,” the Court held “burden of proof” to mean the same thing as “burden of persuasion.”<sup>54</sup> The party carrying the burden of persuasion is the party tasked with “persuad[ing] the jury in its favor to prevail.”<sup>55</sup> The standard of proof, on the other hand, “specifies how difficult it will be for the party bearing the burden of persuasion to convince the jury of the facts in its favor.”<sup>56</sup> There are three common standards of proof: beyond a reasonable doubt, clear and convincing evidence, and preponderance of the evidence.<sup>57</sup> While the beyond a reasonable doubt and preponderance of the evidence standards are the familiar standards used in criminal law and civil law, respectively, the less common clear and convincing standard is used for specific substantive issues.<sup>58</sup>

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<sup>47</sup> See *Idi*, 564 US at 103.

<sup>48</sup> Chief Justice John Roberts did not participate in the case. Justice Clarence Thomas concurred in the judgment. See *id* at 115–16 (Thomas concurring) (writing separately because he was “not persuaded that Congress codified a standard of proof” in § 282).

<sup>49</sup> See *id* at 101.

<sup>50</sup> See *id* at 102.

<sup>51</sup> *Idi*, 564 US at 102.

<sup>52</sup> *Id* at 103.

<sup>53</sup> *Id* at 99–100.

<sup>54</sup> *Id* at 100 n 4 (quotation marks and citations omitted).

<sup>55</sup> *Idi*, 564 US at 100 n 4.

<sup>56</sup> *Id* at 100–01 n 4.

<sup>57</sup> See Charles Alan Wright and Kenneth W. Graham Jr, 21B *Federal Practice & Procedure: Evidence* § 5122 at 406–10 (West 2d ed 2005).

<sup>58</sup> See *id* at 407–08 (noting that the clear and convincing standard has also been applied to proceedings concerning deportation, psychiatric imprisonment, and parental rights).



The clear and convincing standard imposes an intermediate standard of certainty between beyond a reasonable doubt and preponderance of the evidence.<sup>59</sup>

Justice Breyer penned a brief, three-paragraph concurrence joined by Justices Samuel Alito and Antonin Scalia. While joining the majority opinion in full, Breyer “believe[d] it worth emphasizing” that the clear and convincing standard is an evidentiary rule that applies only “to questions of fact and not to questions of law.”<sup>60</sup> Issues of fact sent to the jury in patent cases include questions such as when a product was first sold or whether prior art was published.<sup>61</sup> Breyer cautioned that “[m]any claims of invalidity rest, however, not upon factual disputes, but upon how the law applies to facts as given.”<sup>62</sup> According to Breyer, questions of patent law reserved to the court include whether the invention was novel and whether it was nonobvious.<sup>63</sup> In these cases, the clear and convincing standard “has no application.”<sup>64</sup> The Court’s opinion did not draw this distinction nor did it engage in any meaningful way with Breyer’s opinion.

Breyer’s concurrence suggests a principle that some district courts in this divide have endorsed: a standard of proof cannot apply to an issue of law. On first glance, this statement appears correct. In the traditional division of duties between judge and jury, the jury is charged with “decid[ing] questions of fact and return[ing] a verdict in the case submitted to them.”<sup>65</sup> Perhaps the most familiar invocation of the standard of proof is when the judge submits the factual questions to the jury accompanied with an instruction on the standard of proof. The judge, by contrast, “hear[s] and decide[s] legal matters.”<sup>66</sup> Statutory interpretation is a classic legal matter assigned to judges.<sup>67</sup> Despite this traditional division, it is inaccurate to state that an issue of law, by definition, cannot receive a standard of proof.

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<sup>59</sup> See *id.* at 407.

<sup>60</sup> *i4i*, 564 US at 114 (Breyer concurring).

<sup>61</sup> See *id.*

<sup>62</sup> *Id.*

<sup>63</sup> *Id.*

<sup>64</sup> *i4i*, 564 US at 114 (Breyer concurring).

<sup>65</sup> *Black’s Law Dictionary* 986 (Thomson Reuters 10th ed 2014).

<sup>66</sup> *Id.* at 968.

<sup>67</sup> See generally William N. Eskridge Jr and Philip P. Frickey, *Statutory Interpretation as Practical Reasoning*, 42 Stan L Rev 321 (1990).

Although not always stated in terms of one of the three common standards of proof, judges have long resolved other legal issues according to an articulable standard of proof. When considering a writ of habeas corpus from a prisoner who alleges that she is being held by the government “in violation of the Constitution or laws or treaties of the United States,”<sup>68</sup> a federal judge reviews the prior actions of a state court according to a heightened standard. The federal judge must decide whether the state court’s error was “diametrically different” from Supreme Court precedent, not just wrong.<sup>69</sup> As another example, whether an officer is entitled to qualified immunity is a question of law that is also subject to a functional standard of proof.<sup>70</sup> Again the judge must determine whether the plaintiff satisfied a heightened standard. Qualified immunity applies unless the plaintiff can show that the constitutional right asserted was “clearly established” to the extent that it was “sufficiently clear that a reasonable official would understand that what he is doing violates that right.”<sup>71</sup> A standard of proof can even apply to statutory interpretation, such as when a court reviews an agency’s interpretation of a statute it administers. If the particular question raised by the litigation is not clearly answered by Congress, the court accepts the agency’s interpretation so long as “the agency’s answer is based on a permissible construction of the statute.”<sup>72</sup> Once again, the challenging party must demonstrate that the agency’s interpretation is not just contestable but unreasonable as a matter of law.

All of these examples demonstrate that pure issues of law are compatible with a standard of proof. Judges regularly consider the relative persuasiveness and strength of the available answers to legal questions. The answers are not plucked from “a brooding omnipresence in the sky.”<sup>73</sup>

For subject-matter-eligibility determinations, the preponderance of the evidence standard would likely apply in place of the clear and convincing standard. This intuition can be

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<sup>68</sup> 28 USC § 2254(a).

<sup>69</sup> *Williams v Taylor*, 529 US 362, 405 (2000).

<sup>70</sup> See *Elder v Holloway*, 510 US 510, 516 (1994) (classifying this issue as a question of law).

<sup>71</sup> *Saucier v Katz*, 533 US 194, 202 (2001).

<sup>72</sup> *Chevron U.S.A. Inc v Natural Resources Defense Council, Inc*, 467 US 837, 842–43 (1984). This is Step Two of the two-part *Chevron* framework. See Cass R. Sunstein, *Law and Administration after Chevron*, 90 Colum L Rev 2071, 2104–05 (1990).

<sup>73</sup> *Southern Pacific Co v Jensen*, 244 US 205, 222 (1917) (Holmes dissenting).

understood by comparing subject-matter eligibility to a tort claim for negligence. The judge decides whether the “facts give rise to any legal duty on the part of the defendant.”<sup>74</sup> The plaintiff “has the burden of proving” by “a preponderance of the evidence” that the facts “give rise to a legal duty” on the part of the defendant.<sup>75</sup> Thus, whether a duty exists is a question of law that is reserved to the judge, who must be convinced by a preponderance of the evidence. For negligence, the standard of proof is not measuring whether certain facts are established but whether these facts establish a legal duty.

Similarly, the judge determines patent eligibility as a matter of law by consulting the contents of the patent application and any other supplementary material in the record.<sup>76</sup> The judge must be sufficiently swayed by the challenger before rendering a patent invalid. If the clear and convincing standard does not apply, it seems likely that the challenger must satisfy the preponderance of the evidence standard instead by default. Subject-matter eligibility can present close calls, and judges tend to favor acting according to a standard rather than arbitrarily.<sup>77</sup>

Subject-matter eligibility has traditionally presented a pure issue of law, placing it squarely within the realm of issues that Breyer presumably believes fall outside the scope of the clear and convincing standard.<sup>78</sup> Recently, however, the Federal Circuit has cast doubt on the continued status of subject-matter-eligibility challenges as pure questions of law.<sup>79</sup> The next Section summarizes the doctrine of subject-matter eligibility and addresses how *Berkheimer* introduced underlying factual questions into the subject-matter-eligibility determination.

### C. Subject-Matter Eligibility

Subject-matter eligibility stands for the proposition that not all discoveries and breakthroughs are patentable. It has been part of patent doctrine since the nineteenth century.<sup>80</sup> The Supreme Court has called subject-matter eligibility a “long held

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<sup>74</sup> Restatement (Second) of Torts § 328B(b) (1965).

<sup>75</sup> Restatement (Second) of Torts § 328A(a) (1965).

<sup>76</sup> See, for example, *Berkheimer*, 224 F Supp at 637–39.

<sup>77</sup> See generally Antonin Scalia, *The Rule of Law as a Law of Rules*, 56 U Chi L Rev 1175 (1989).

<sup>78</sup> See, for example, *In re Bilski*, 545 F3d 943, 951 (Fed Cir 2008) (en banc).

<sup>79</sup> See notes 99–105 and accompanying text.

<sup>80</sup> See, for example, *O'Reilly v Morse*, 56 US 62, 116 (1853).

. . . implicit exception” within 35 USC § 101.<sup>81</sup> Since § 101 identifies what is patentable—“any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof”—concepts not covered by the statute are precluded from patenting.<sup>82</sup> According to the Supreme Court, subject-matter eligibility prevents the patenting of “[l]aws of nature, natural phenomena, and abstract ideas.”<sup>83</sup> Classic examples of unpatentable innovations are Albert Einstein’s “ $e=mc^2$ ” formula and the Newtonian laws of physics.<sup>84</sup> Contemporary litigation often concerns the eligibility of patents related to software<sup>85</sup> and biotechnology.<sup>86</sup> Subject-matter eligibility seeks to avoid “inhibit[ing] further discovery by improperly tying up the future use of laws of nature” in preexisting patents.<sup>87</sup> Without this condition, inventors could monopolize natural phenomena or prevent others from patenting new innovations that rely on the same laws of nature, natural phenomena, or abstract ideas.<sup>88</sup>

How courts evaluate subject-matter eligibility has evolved over time. In 2014, the Supreme Court crystallized the current two-pronged inquiry in *Alice Corp v CLS Bank International*.<sup>89</sup> First, a court must ask whether the patent is “directed to one of those patent-ineligible concepts.”<sup>90</sup> If it is, a court proceeds to step two and asks whether additional elements “‘transform the nature of the claim’ into a patent-eligible application.”<sup>91</sup> This second step looks for an “inventive concept . . . that is sufficient

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<sup>81</sup> See *Mayo Collaborative Services v Prometheus Laboratories, Inc.*, 566 US 66, 70 (2012) (collecting cases).

<sup>82</sup> 35 USC § 101.

<sup>83</sup> *Myriad*, 569 US at 589, quoting *Mayo*, 566 US at 70 (quotation marks omitted).

<sup>84</sup> See *Diamond v Chakrabarty*, 447 US 303, 309 (1980).

<sup>85</sup> See J. Jonas Anderson, *Applying Patent-Eligible Subject Matter Restrictions*, 17 Vand J Enter & Tech L 267, 271 (2015) (“Whether computer-implemented inventions are patent-eligible is a question that has vexed the Supreme Court for over forty years.”).

<sup>86</sup> See Conlin, Cowles, and Bolcome, 9 J Fed Cir Historical Society at 84–86 (cited in note 44) (tracing the explosion of biotechnology patents that followed the complete sequencing of the human genome in 2001 and the subsequent Supreme Court cases on those patents’ eligibility).

<sup>87</sup> *Mayo*, 566 US at 85.

<sup>88</sup> See, for example, *O’Reilly*, 56 US at 112–14 (denying that a patent on the telegraph could cover all machines that use electricity to print letters or characters transmitted from a distance).

<sup>89</sup> 134 S Ct 2347 (2014).

<sup>90</sup> Id at 2355.

<sup>91</sup> Id, quoting *Mayo*, 566 US at 78.

to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.”<sup>92</sup>

The *Alice* test<sup>93</sup> can be conducted solely by reference to the patent that is part of the pleadings. Although *Alice* came to the Supreme Court on review of a grant of summary judgment,<sup>94</sup> the case shows how this is possible. For step one, the Court had to determine whether the patented material covered a law of nature, natural phenomenon, or abstract idea. By comparing the claims of the patent to past cases, the Supreme Court determined that the patent claimed an abstract idea—specifically “the concept of intermediated settlement, *i.e.*, the use of a third party to mitigate settlement risk.”<sup>95</sup> Since the patent triggered *Alice* step two, the Court proceeded to determine whether the patent contained “an ‘inventive concept’ sufficient to ‘transform’” the unpatentable abstract idea into a patentable invention.<sup>96</sup> Again, the Court compared the claims of the patent to subject-matter-eligibility precedent, determining that computerizing an abstract idea failed to effect a sufficient transformation and finding that the patent before the Court did nothing more than implement the idea of intermediated settlement through a computer.<sup>97</sup> The subject-matter-eligibility analysis required only the patent and precedent.

Both the review of precedent and interpretation of a patent are legal, not factual, issues resolved by judges. A judge, not a jury, reviews case law, and the Supreme Court has classified the interpretation and construction of patents as a legal question decided by judges.<sup>98</sup> As a result, the Federal Circuit had long held that subject-matter eligibility presents a pure issue of law that can be resolved early in litigation without fact-finding.<sup>99</sup> Indeed, the Federal Circuit has affirmed multiple granted motions

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<sup>92</sup> *Alice*, 134 S Ct at 2355 (quotation marks omitted).

<sup>93</sup> Some call the test the *Mayo* test because the *Alice* Court used *Mayo* to create it. See *Alice*, 134 S Ct at 2357. However, *Alice* was the first time the Supreme Court explicitly identified a two-part test for subject-matter eligibility, so this Comment will follow the Federal Circuit in referring to it as the *Alice* test. See, for example, *Bascom Global Internet Services, Inc v AT&T Mobility LLC*, 827 F3d 1341, 1343 (Fed Cir 2016).

<sup>94</sup> See *Alice*, 134 S Ct at 2353.

<sup>95</sup> *Id* at 2356.

<sup>96</sup> See *id* at 2357, quoting *Mayo*, 566 US at 72, 79.

<sup>97</sup> See *Alice*, 134 S Ct at 2358–60.

<sup>98</sup> See *Markman v Westview Instruments, Inc*, 517 US 370, 384–91 (1996).

<sup>99</sup> See, for example, *Bilski*, 545 F3d at 951 (“Whether a claim is drawn to patent-eligible subject matter under § 101 is an issue of law.”).

to dismiss subject-matter-eligibility challenges within the last five years.<sup>100</sup>

However, in *Berkheimer*, the Federal Circuit broke with precedent by calling subject-matter eligibility “a question of law which *may* contain underlying facts.”<sup>101</sup> The authority backing this characterization is relatively scant,<sup>102</sup> but the Federal Circuit still partially vacated the district court’s grant of summary judgment because disputed issues of fact remained at *Alice* step two.<sup>103</sup> Specifically, determining whether the patented invention effected a genuinely inventive transformation or implemented only a “well-understood, routine, and conventional” change that amounted to patenting the abstract idea required additional fact-finding.<sup>104</sup> The vacated judgment “appears to be the first time that the Federal Circuit has explicitly required that a district court make findings of fact in order to justify a § 101 decision.”<sup>105</sup> Still, the Federal Circuit could point to some past cases to support the decision.<sup>106</sup> Before *Berkheimer*, some practitioners believed that *Alice* step two could require fact-finding.<sup>107</sup> *Berkheimer*’s more flexible conception of subject-

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<sup>100</sup> See, for example, *Content Extraction and Transmission*, 776 F3d at 1349; *buySAFE, Inc v Google, Inc*, 765 F3d 1350, 1352 (Fed Cir 2014).

<sup>101</sup> *Berkheimer*, 881 F3d at 1368 (emphasis added). See also *Aatrix Software, Inc v Green Shades Software, Inc*, 882 F3d 1121, 1128 (Fed Cir 2018); *Move, Inc v Real Estate Alliance, Ltd*, 2018 WL 656377, \*2 (Fed Cir).

<sup>102</sup> The Federal Circuit cited two cases to support its claim that the subject-matter-eligibility inquiry could contain underlying issues of fact. *Accenture Global Services, GmbH v Guidewire Software, Inc*, 728 F3d 1336, 1341 (Fed Cir 2013); *Mortgage Grader, Inc v First Choice Loan Services Inc*, 811 F3d 1314, 1325 (Fed Cir 2016). To support the claim, *Accenture* cited only one case that was vacated without comment by the Supreme Court. *Ultramercial, Inc v Hulu, LLC*, 722 F3d 1335, 1339 (Fed Cir 2013), vacd *WildTangent, Inc v Ultramercial, LLC*, 134 S Ct 2870 (2014). *Mortgage Grader* relied on *Accenture* and *Arrhythmia Research Technology, Inc v Corazonix Corp*, 958 F2d 1053, 1055–56 (Fed Cir 1992). *Arrhythmia* lacked any citations for the assertion that subject-matter eligibility “may require findings of underlying facts.” *Arrhythmia*, 958 F2d at 1056. For pushback against this characterization of subject-matter eligibility, see *Aatrix Software*, 882 F3d at 1130 (Reyna dissenting) (“I respectfully disagree with the majority’s broad statements on the role of factual evidence in a § 101 inquiry. Our precedent is clear that the § 101 inquiry is a legal question.”).

<sup>103</sup> See *Berkheimer*, 881 F3d at 1369–70.

<sup>104</sup> *Id* at 1369.

<sup>105</sup> Michael Borella, *Berkheimer v. HP Inc. (Fed. Cir. 2018)* (JD Supra, Feb 9, 2018), archived at <http://perma.cc/9DTH-N8MG>. See also Dennis Crouch, *Patent Eligibility: Underlying Questions of Fact* (Patently-O, Feb 8, 2018), archived at <http://perma.cc/T62C-26DX> (arguing that the decision is “in substantial tension with prior treatment of eligibility analysis”).

<sup>106</sup> See note 102.

<sup>107</sup> See, for example, Gregory H. Lantier and Richard A. Crudo, *Can Juries Decide Patent Eligibility under 35 U.S.C. § 101?*, 27 Fed Cir Bar J 45, 50 (2017).

matter eligibility was endorsed again by the Federal Circuit when it rejected Hewlett-Packard's en banc request.<sup>108</sup>

The *Berkheimer* court maintained that subject-matter-eligibility challenges could be resolved as a matter of law on the pleadings, stating that “[n]othing in this decision should be viewed as casting doubt on the propriety” of past cases doing just that.<sup>109</sup> Therefore, *Berkheimer* clearly leaves open the possibility of subject-matter-eligibility challenges being treated as pure issues of law.

But by stating that subject-matter eligibility can involve questions of fact and actually identifying them in *Berkheimer*, the Federal Circuit may have made it more difficult to determine a patent's validity on a motion to dismiss.<sup>110</sup> Based on *Berkheimer*, these factual disputes can be expected to emerge at *Alice* step two in determining whether the patent contains a legitimate “inventive concept” or is simply a ruse to cover a law of nature, natural phenomenon, or abstract idea. Step one, however, is not immune from factual disputes. A plausible dispute might emerge from a patent in biotechnology like the one covering a synthetic strand of DNA in *Association for Molecular Pathology v Myriad Genetics, Inc.*<sup>111</sup> The parties argued over whether the patent was invalid for covering naturally occurring DNA or whether it was valid for creating “something new” through the manipulation of messenger RNA.<sup>112</sup> It is possible for a similar dispute in a future case to turn on facts outside the patent at *Alice* step one.

## II. THE DISCORD AMONG THE DISTRICT COURTS

Despite the apparent clarity of *i4i*'s holding—the presumption of validity “requires an invalidity defense to be proved by clear and convincing evidence”<sup>113</sup>—district courts have divided over whether the holding applies to subject-matter-eligibility challenges. The Federal Circuit specified in *Berkheimer* that the clear and convincing standard applies to any issues of fact pertaining to the subject-matter-eligibility determination but

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<sup>108</sup> *Berkheimer v HP Inc*, 890 F3d 1369, 1370 (Fed Cir 2018).

<sup>109</sup> *Berkheimer*, 881 F3d at 1368.

<sup>110</sup> See Scott Graham, *Skilled in the Art: The 5 Stages of 'Berkheimer.'* Plus, *Patent Man and the Flying Foam* (Law.com, Mar 9, 2018), archived at <http://perma.cc/436P-C4MC>.

<sup>111</sup> 569 US 576 (2013).

<sup>112</sup> *Id* at 595.

<sup>113</sup> *i4i*, 564 US at 95.

failed to resolve the fundamental disagreement over the heightened standard's applicability to the legal issue posed by subject-matter-eligibility challenges.<sup>114</sup> District court judges still must decide this question for themselves. This Part begins by tracing the sources of the ambiguity and disagreement that gave rise to this dispute. It then outlines the three camps into which the district courts have divided.

#### A. The Sources of the Dispute

The disagreement among the district courts originated in Justice Breyer's *i4i* concurrence.<sup>115</sup> The controversy sparked by the concurrence was not necessarily inevitable. The controlling majority opinion garnered the approval of seven justices and declined to distinguish between issues of law and fact when applying the clear and convincing standard to patent validity challenges generally.<sup>116</sup> District courts could have followed only the majority opinion and ignored Breyer's nonbinding concurrence. Instead, some courts accepted Breyer's premise that he was "emphasizing" an element of the Court's opinion<sup>117</sup> and incorporated it into their understanding of *i4i*.

Breyer's concurrence invited fragmentation, possibly because subject-matter-eligibility challenges were previously understood to present pure issues of law.<sup>118</sup> Unlike other patent validity challenges that present mixed issues of fact and law, such as on-sale bar<sup>119</sup> and nonobviousness,<sup>120</sup> subject-matter-eligibility challenges can be resolved through a motion to dismiss,<sup>121</sup> a possibility *Berkheimer* did not eliminate.<sup>122</sup> To judges who do not apply *i4i* to subject-matter eligibility, Breyer's concurrence

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<sup>114</sup> See *Berkheimer*, 881 F3d at 1367.

<sup>115</sup> See *In re TLI Communications LLC Patent Litigation*, 87 F Supp 3d 773, 797 (ED Va 2015) ("This dispute stems in large measure from Justice Breyer's concurrence.").

<sup>116</sup> See *i4i*, 564 US at 103.

<sup>117</sup> *Id.* at 114 (Breyer concurring).

<sup>118</sup> See, for example, *Trading Technologies International, Inc v CQG, Inc*, 2015 WL 774655, \*3 (ND Ill) (calling subject-matter eligibility "purely a question of law" and applying the clear and convincing standard); *Berkheimer v Hewlett-Packard Co*, 224 F Supp 3d 635, 639 (ND Ill 2016) (calling subject-matter eligibility "a question of law" and declining to apply the clear and convincing standard).

<sup>119</sup> See Part III.A.1.

<sup>120</sup> See Part III.A.2.

<sup>121</sup> See *Berkheimer*, 224 F Supp 3d at 642 (collecting cases).

<sup>122</sup> *Berkheimer*, 881 F3d at 1368 ("Patent eligibility has in many cases been resolved on motions to dismiss or summary judgment. Nothing in this decision should be viewed as casting doubt on the propriety of those cases.").



seems uncontroversial, as they do not think a standard of proof can apply to a pure issue of law. They may think that judges simply “decide” matters of law, whereas juries are tasked with applying a standard of proof while sorting through issues of fact. The Supreme Court has declined to clarify the appropriate standard of proof in its three subject-matter-eligibility cases since *i4i*.<sup>123</sup> The combination of subject-matter eligibility’s legal nature, Breyer’s concurrence, and Supreme Court silence has been enough for some courts to hesitate before applying *i4i*’s otherwise straightforward holding regarding patent invalidity challenges to subject-matter-eligibility challenges.<sup>124</sup>

To make matters more confusing for district courts, the Federal Circuit has sent mixed signals about the answer to this subject-matter-eligibility question without resolving it. The Federal Circuit first endorsed the use of the clear and convincing standard for subject-matter invalidity in two concurring opinions. Both were issued out of the en banc hearing reviewed by the Supreme Court in *Alice*. The Federal Circuit’s one-paragraph per curiam decision was accompanied by five other opinions. Judge Alan Lourie was joined by four other judges—the most of the five opinions—and applied *i4i* to subject-matter invalidity challenges.<sup>125</sup> Another opinion by Chief Judge Randall Rader, joined by three other judges, did the same.<sup>126</sup> Nine out of the ten presiding judges thus endorsed the heightened standard for subject-matter validity challenges. The Supreme Court did not address the issue in *Alice*.<sup>127</sup>

Following this case, the Federal Circuit continued to impose the clear and convincing evidence standard on subject-matter challenges. In *Ultramercial, Inc v Hulu, LLC*<sup>128</sup> (“Ultramercial

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<sup>123</sup> See generally *Mayo Collaborative Services v Prometheus Laboratories, Inc*, 566 US 66 (2012); *Myriad*, 569 US 576; *Alice*, 134 S Ct 2347.

<sup>124</sup> Consider *Trading Technologies International*, 2015 WL 774655 at \*3 (“This Court recognizes the persuasiveness of Justice Breyer’s reasoning . . . [but] this Court concludes that, until the Federal Circuit or the United [States] Supreme Court mandates otherwise, [the movant] must show by clear and convincing evidence that the patents-in-suit claim patent-ineligible subject matter.”).

<sup>125</sup> See *CLS Bank International v Alice Corp*, 717 F3d 1269, 1284 (Fed Cir 2013) (Lourie concurring).

<sup>126</sup> *Id* at 1304–05 (Rader concurring).

<sup>127</sup> See generally *Alice*, 134 S Ct 2347.

<sup>128</sup> 722 F3d 1335 (Fed Cir 2013). This was the case’s second appearance before the Federal Circuit after the initial ruling was vacated by the Supreme Court without comment for reconsideration in light of *Alice*. *WildTangent, Inc v Ultramercial, LLC*, 566 US 1007, 1007 (2012).

II”), Rader wrote the court’s opinion, finding that the “high level of proof applies to eligibility as it does to the separate patentability determinations.”<sup>129</sup> He noted that “it will be rare that a patent infringement suit can be dismissed at the pleading stage for lack of patentable subject matter.”<sup>130</sup> However, the Supreme Court vacated Rader’s opinion without comment for reconsideration in light of *Alice*.<sup>131</sup>

As a result, *Ultramercial, Inc v Hulu, LLC*<sup>132</sup> (“Ultramercial III”) returned to the Federal Circuit for a third appearance. This time, the court declined to require clear and convincing evidence and chose not to address the standard of proof question. By the time the case was reheard, Rader had retired and was replaced on the panel by Judge Haldane Robert Mayer.<sup>133</sup> While the court’s opinion did not address the clear and convincing standard, Mayer wrote separately to oppose its use in subject-matter-eligibility challenges.<sup>134</sup> Pointing to the Supreme Court’s silence, Mayer distinguished the presumption of validity from a “presumption of eligibility,” which he asserted left subject-matter eligibility outside the scope of the presumption of validity and *i4i*.<sup>135</sup> He portrayed subject-matter eligibility as the “gateway to the Patent Act” that should be addressed early in litigation to “conserve scarce judicial resources,” deter “vexatious infringement suits,” and “protect[] the public.”<sup>136</sup> Additionally, he claimed that the PTO’s process for vetting patent subject matter was “insufficiently rigorous” to merit deference via the heightened standard of proof.<sup>137</sup>

Since Mayer’s concurrence, the Federal Circuit has provided no further guidance. The Federal Circuit has affirmed cases from district courts on both sides of the debate while avoiding the standard of proof issue.<sup>138</sup> While the Federal Circuit engaged

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<sup>129</sup> *Ultramercial II*, 722 F3d at 1342.

<sup>130</sup> *Id* at 1338.

<sup>131</sup> See *WildTangent, Inc v Ultramercial, Inc*, 134 S Ct 2870, 2870 (2014).

<sup>132</sup> 772 F3d 709 (Fed Cir 2014).

<sup>133</sup> See David Swetnam-Burland and Stacy O. Stitham, *Alice’s Adventures in Oz: Revealing the Man Behind the Curtain*, 9 Akron Intel Prop J 29, 43 (2015).

<sup>134</sup> See *Ultramercial III*, 772 F3d at 717–23 (Mayer concurring).

<sup>135</sup> *Id* at 720–21 (Mayer concurring).

<sup>136</sup> *Id* at 718–19 (Mayer concurring).

<sup>137</sup> *Id* at 720 (Mayer concurring).

<sup>138</sup> Compare, for example, *Trading Technologies International, Inc v CQG, Inc*, 675 Fed Appx 1001, 1004 n 2 (Fed Cir 2017) (affirming district court decision requiring clear and convincing evidence), with *Tranxition, Inc v Lenovo (United States) Inc*, 664 Fed

with the clear and convincing standard in *Berkheimer*, it did so only through its reclassification of subject-matter eligibility as an issue of law that could involve underlying issues of fact.<sup>139</sup> It then stated that facts “pertinent to the invalidity conclusion must be proven by clear and convincing evidence.”<sup>140</sup> Although this holding addresses the clear and convincing standard in the context of a subject-matter-eligibility challenge, it does not address the issue that has divided the district courts. All courts agree that the heightened standard applies to issues of fact. The question is whether the standard applies to the issue of law raised by subject-matter eligibility, which *Berkheimer* fails to answer. The Federal Circuit does not discuss a standard of proof—heightened or otherwise—for the legal questions presented or for cases in which no disputed facts exist. In fact, the court seems to continue to dodge the dispute. *Berkheimer* does not mention the Breyer concurrence or the controversy surrounding its conclusions. It cites only the brief introductory paragraph of *i4i* in applying the clear and convincing standard to issues of fact without saying whether or not the standard is limited to issues of fact.<sup>141</sup>

As a result, district courts must reach their own conclusions after consulting the various available persuasive authorities, such as Breyer’s *i4i* concurrence, the nonbinding and vacated opinions of the Federal Circuit, and the opinions of sister courts. There are three possible approaches, each of which has been adopted by some district court judges.

#### B. Approach One: *i4i* Is Incompatible with Subject-Matter Eligibility

The first, or “strict Breyer,” approach does not require clear and convincing evidence to sustain a subject-matter-eligibility challenge. In one respect, this approach may no longer be good law because some strict Breyer courts maintain that the subject-matter-eligibility inquiry does not involve facts, a claim rejected by *Berkheimer*. These courts rely on two main reasons to support their position.

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Appx 968, 972 n 1 (Fed Cir 2016) (affirming district court decision that did not require clear and convincing evidence).

<sup>139</sup> *Berkheimer*, 881 F3d at 1367. See notes 101–12 and accompanying text.

<sup>140</sup> *Berkheimer*, 881 F3d at 1368, citing *i4i*, 564 US at 95.

<sup>141</sup> See *Berkheimer*, 881 F3d at 1368, citing *i4i*, 564 US at 95.

First, these district courts find the Supreme Court's failure to discuss the heightened standard of proof in its three post-*i4i* subject-matter-eligibility cases telling.<sup>142</sup> If the Supreme Court intended for *i4i* to cover subject-matter challenges, it surely would have said so by now.<sup>143</sup>

Second, *i4i* does not apply because subject-matter eligibility presents an issue of law. Some of the strict Breyer courts read Breyer's concurrence as limiting the Court's *i4i* opinion to questions of fact, and subject-matter eligibility appears to be the quintessential legal issue not covered by the presumption of validity.<sup>144</sup> These courts read the Breyer concurrence alongside the *i4i* majority opinion to determine the scope of the *i4i* holding and conclude that *i4i* does not extend the clear and convincing standard to issues of law like subject-matter eligibility. Others focus on the availability of resolution on the pleadings without discussing Breyer but still maintain that the standard of proof can apply only to issues of fact. Because questions of patentable subject matter can be decided on the pleadings when no factual record yet exists, these courts find nothing to which the standard of proof could apply.<sup>145</sup> One court stated that "it makes little sense" to apply a standard of proof to a motion to dismiss because no evidence outside the pleadings is considered at that stage.<sup>146</sup> Without citing Breyer's concurrence, this court reached the same conclusion: the standard of proof can apply only to disputed issues of fact.<sup>147</sup> Because the court was resolving the subject-matter challenge on a motion to dismiss as a matter of law, there was no need to consider the standard of proof. Whether relying on Breyer or not, all courts taking this approach have made basically the same observation as Judge John Z. Lee,

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<sup>142</sup> See, for example, *Berkheimer*, 224 F Supp 3d at 641; *American Needle, Inc v Café Press Inc*, 2016 WL 232438, \*3 (ND Ill); *Modern Telecom Systems LLC v Earthlink, Inc*, 2015 WL 1239992, \*7 (CD Cal).

<sup>143</sup> See, for example, *Berkheimer*, 224 F Supp 3d at 642 ("[T]he fact that the Supreme Court has made no mention of the clear-and-convincing standard in any of its patent-eligibility decisions since *i4i* suggests that the standard was not meant to extend to the § 101 inquiry.").

<sup>144</sup> See, for example, *id* at 640–42; *California Institute of Technology v Hughes Communications Inc*, 59 F Supp 3d 974, 978 n 6 (2014); *American Needle*, 2016 WL 232438 at \*3.

<sup>145</sup> See, for example, *Modern Telecom Systems*, 2015 WL 1239992 at \*7 (collecting cases disposing of subject-matter-eligibility cases at the pleading stage); *Shortridge v Foundation Construction Payroll Service, LLC*, 2015 WL 1739256, \*7 (ND Cal) (following *Modern Telecom Systems*).

<sup>146</sup> *Modern Telecom Systems*, 2015 WL 1239992 at \*7.

<sup>147</sup> *Id.*

writing for the Northern District of Illinois: “[A]t least as [the subject-matter-eligibility] inquiry has been structured under *Alice*, there are no factual issues to which the clear-and-convincing evidentiary standard might be pertinent.”<sup>148</sup>

In *Berkheimer*, the Federal Circuit rejected strict Breyer courts’ observation that the subject-matter-eligibility inquiry cannot possibly contain underlying factual questions.<sup>149</sup> But the Federal Circuit failed to address the more important claim made by these courts: the clear and convincing standard cannot apply to issues of law. The strict Breyer courts’ claim that the clear and convincing standard cannot apply when the dispute before the court is entirely legal survives *Berkheimer*. These courts would likely maintain that the clear and convincing standard does not apply when no issues of fact are implicated. *Berkheimer* left this possibility open, as it explicitly noted that previous cases disposing of subject-matter-eligibility challenges as a matter of law remain good law.<sup>150</sup>

Several of these courts found Mayer’s concurrence compelling because of both its separation of patent validity and patent eligibility<sup>151</sup> as well as the policy reasons he offered to justify a searching eligibility analysis at the beginning of litigation.<sup>152</sup> These courts find that the policy justifications tilt the balance toward rejecting the clear and convincing standard in subject-matter-eligibility cases.

### C. Approach Two: Splitting the Baby

The second, or “intermediate,” approach resembles the first in its faithfulness to Breyer’s *i4i* concurrence but diverges in its belief that subject-matter eligibility can present underlying issues of fact to which the clear and convincing hurdle would apply.<sup>153</sup> In that respect, these courts anticipated *Berkheimer*.

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<sup>148</sup> *Berkheimer*, 224 F Supp 3d at 642.

<sup>149</sup> See *Berkheimer*, 881 F3d at 1369–70.

<sup>150</sup> *Id.*

<sup>151</sup> See *American Needle*, 2016 WL 232438 at \*3.

<sup>152</sup> See, for example, *Wireless Media Innovations, LLC v Maher Terminals, LLC*, 100 F Supp 3d 405, 411 (D NJ 2015) (noting that use of a clear and convincing standard would “create a near impossible threshold for a defendant to clear when assessing a patent’s subject matter”).

<sup>153</sup> See, for example, *Affinity Labs of Texas, LLC v Amazon.com, Inc.*, 2015 WL 3757497, \*5 (WD Tex) (“[T]o the extent legal questions bear on the ultimate question of subject matter eligibility, the Court will decide those questions as a matter of law. . . . To the extent that questions of fact exist, the Court will apply the clear and convincing evidence standard.”).

They claim that the clear and convincing standard applies only to the issues of fact raised by a subject-matter-eligibility challenge.

The courts adopting this second approach rely on the same very limited precedent classifying subject-matter eligibility as a “legal conclusion [that] may contain underlying factual issues” that the *Berkheimer* court cited.<sup>154</sup> While pre-*Berkheimer* law was ambiguous about whether subject-matter-eligibility challenges raise any issues of fact, *Berkheimer* endorsed this characterization.<sup>155</sup> Unlike the Federal Circuit in *Berkheimer*, no court adopting this intermediate approach actually identified an issue of fact in a subject-matter-eligibility challenge. In each case, the court determined that the parties failed to raise an issue of fact to which the clear and convincing standard would apply.<sup>156</sup>

Both this intermediate approach and *Berkheimer* conceive of subject-matter challenges as legal issues that may contain underlying issues of fact, and both apply the heightened standard of proof to those factual issues. But the intermediate approach goes one step further than *Berkheimer* in explicitly refusing to apply the standard to the overall legal question. The contrast between the intermediate approach and *Berkheimer* highlights how little *Berkheimer* did to identify a standard of proof to be used for the legal issues presented by subject-matter eligibility. *Berkheimer* maintained that future subject-matter-eligibility cases not raising disputed issues of fact could nonetheless still be resolved as a matter of law. In these situations, the appropriate standard of proof remains a mystery to district court judges. When a subject-matter-eligibility challenge does raise issues of fact, *Berkheimer* still answers only half the question. *Berkheimer* stated only that “[a]ny fact . . . that is pertinent to

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<sup>154</sup> *Listingbook, LLC v Market Leader, Inc*, 144 F Supp 3d 777, 785 (MD NC 2015), quoting *Accenture Global Services, GmbH v Guidewire Software, Inc*, 728 F3d 1336, 1340–41 (Fed Cir 2013). See also, for example, *Affinity Labs of Texas*, 2015 WL 3757497 at \*5.

<sup>155</sup> See notes 102–03 and accompanying text.

<sup>156</sup> See, for example, *Technology Development and Licensing, LLC v Comcast Corp*, 258 F Supp 3d 884, 889 (ND Ill 2017) (finding no factual issue to which the clear and convincing standard could be applied); *Nextpoint, Inc v Hewlett-Packard Co*, 227 F Supp 3d 963, 970 (ND Ill 2016) (finding that “nothing in the parties’ submissions reasonably suggests that in this case, the issue turns on the resolution of any disputed factual issue”); *Listingbook*, 144 F Supp 3d at 785 (“[T]he Court has failed to discern any issue of fact requiring evidentiary support, and [the plaintiff] has not brought any to the Court’s attention.”); *Recognicorp, LLC v Nintendo Co, Ltd*, 2015 WL 11217242, \*3 (WD Wash) (“[T]his Court applies the ‘clear and convincing’ standard to disputed questions of fact—which the Parties do not raise.”); *Affinity Labs of Texas*, 2015 WL 3757497 at \*6–7 (declining to assert that there were relevant issues of fact or explicitly identify issues of fact in the analysis section).

the invalidity conclusion must be proven by clear and convincing evidence.”<sup>157</sup> The Federal Circuit was silent about whether the same or a different standard of proof applies to the ultimate conclusion of law regarding subject-matter eligibility that those issues of fact inform. Thus, at some point during a subject-matter-eligibility case, district court judges will still have to decide what standard of proof to apply to the question of law presented by a subject-matter-eligibility challenge.

#### D. Approach Three: *i4i* Extends to Subject-Matter Eligibility

The third, or “pure *i4i*,” approach treats subject-matter-eligibility challenges like any other patent challenge, requiring clear and convincing evidence of invalidity for the whole challenge, not just issues of fact. Faced with the holding of *i4i* and the subsequent silence of higher courts, some courts feel obligated to apply the holding of *i4i* to subject-matter-eligibility challenges.<sup>158</sup> One court cited *i4i* in applying the clear and convincing standard without demonstrating awareness of the conflict.<sup>159</sup> Other courts apply the presumption of validity and its accompanying requirement of clear and convincing evidence without citing *i4i*.<sup>160</sup> Still others cite *i4i* to apply the heightened standard but dodge the debate about its scope.<sup>161</sup>

The justifications for the pure *i4i* approach vary. One argument is that, Breyer’s nonbinding concurrence notwithstanding, following *i4i* is the path most consistent with both precedent and the patent laws.<sup>162</sup> One court concluded that the holding of *i4i*

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<sup>157</sup> *Berkheimer*, 881 F3d at 1368.

<sup>158</sup> See, for example, *DataTern*, 2015 WL 5190715, \*7 (D Mass) (“Judge Mayer may well be correct that an exception should apply in the area of subject-matter eligibility, but the Supreme Court has not so directed. Nor can such an exception be conclusively read into the Supreme Court’s silence in its four recent opinions under section 101.”).

<sup>159</sup> See *O2 Media, LLC v Narrative Science Inc*, 149 F Supp 3d 984, 988 (ND Ill 2016).

<sup>160</sup> See *Netflix, Inc v Rovi Corp*, 114 F Supp 3d 927, 938 (ND Cal 2015) (citing Federal Circuit precedent, but not *i4i*, to require clear and convincing evidence of ineligibility for the invalidity challenge to prevail); *Data Distribution Technologies, LLC v BRER Affiliates, Inc*, 2014 WL 4162765, \*5, 8 (D NJ) (citing § 282 and *State Contracting & Engineering Corp v Condotte America, Inc*, 346 F3d 1057, 1067 (Fed Cir 2003), but not *i4i*).

<sup>161</sup> See, for example, *Ameritox, Ltd v Millennium Health, LLC*, 88 F Supp 3d 885, 902 (WD Wis 2015) (following *i4i* because it prescribes what a challenger must do to show patent invalidity generally and passing on the controversy by asserting that the same result would be reached regardless of the standard).

<sup>162</sup> See, for example, *CertusView Technologies, LLC v S & N Locating Services, LLC*, 111 F Supp 3d 688, 707 n 6 (ED Va 2015) (“Defendants have not presented any authority indicating that the presumption of validity no longer applies to challenges to a patent’s validity under section 101.”).

was inconsistent with the Breyer and Mayer concurrences and applied the clear and convincing standard to a subject-matter-eligibility challenge.<sup>163</sup> Another court found that the weight of *persuasive* authority favored using the clear and convincing standard.<sup>164</sup>

The pure *i4i* courts evaluate subject-matter eligibility conventionally. They examine the claims raised by the challenge and then decide eligibility based on the two-step *Alice* test, relying on analogous precedent as a guide.<sup>165</sup> Unlike the strict Breyer and intermediate approaches, the pure *i4i* courts require the challengers to demonstrate ineligibility under the *Alice* test by clear and convincing evidence. One court chose to determine whether each step individually satisfied the clear and convincing evidence standard.<sup>166</sup> Another court recognized that one patent clearly embodied an abstract idea, satisfying *Alice* step one, and went straight to *Alice* step two. The court identified an “inventive concept,” rendering the patent subject-matter eligible, and concluded that the challenger had “not demonstrated by clear and convincing evidence that the subject matter of the [ ] patent [was] ineligible for patent protection.”<sup>167</sup> The pure *i4i* courts implement the clear and convincing standard by simply requiring the challenger to more persuasively demonstrate subject-matter ineligibility than would be required under the traditional preponderance of the evidence standard.<sup>168</sup>

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At first glance, *Berkheimer* appears to endorse the second approach. However, *Berkheimer* stops short, finding issues of fact to which the standard could apply but declining to specify whether or not the standard applies to legal issues as well. In that respect, *Berkheimer* is consistent with the Federal Circuit’s approach over the past four years in evading the question at the

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<sup>163</sup> *DataTern*, 2015 WL 5190715 at \*7–8.

<sup>164</sup> See *Wolf v Capstone Photography, Inc*, 2014 WL 7639820, \*5 n 1 (CD Cal). See also *Front Row Technologies, LLC v NBA Media Venture, LLC*, 204 F Supp 3d 1190, 1235–36 (D NM 2016) (collecting Federal Circuit cases in which *i4i* is applied in other contexts and characterizing Mayer’s concurrence as an outlier).

<sup>165</sup> See, for example, *CertusView*, 111 F Supp 3d at 722–24. For an overview of the application of the *Alice* framework, see notes 90–97 and accompanying text.

<sup>166</sup> See *CertusView*, 111 F Supp 3d at 722–24.

<sup>167</sup> *DataTern*, 2015 WL 5190715 at \*9.

<sup>168</sup> See notes 56–59 and accompanying text.



heart of this divide: Does the clear and convincing standard apply to questions of law in subject-matter-eligibility challenges?

The way forward does not lie in weighing the relative persuasive power of concurrences, vacated opinions, and Supreme Court silence. The persuasive authorities, like the district courts, are divided, and it is impossible to decipher the meaning of silence. Instead, settling the dispute requires examining how the standard of proof works in other types of patent challenges and how courts navigate the factual versus legal distinction in other areas of law.

### III. TRANSCENDING THE FACT VERSUS LAW DIVIDE

This Part advocates the pure *i4i* approach, applying the clear and convincing standard to all subject-matter-eligibility challenges in their entirety, not just to issues of fact. District court analyses have myopically focused on Justice Breyer's concurrence at the expense of other insights. This Comment looks to other patent challenges to resolve this conflict.

First, Part III.A compares subject-matter-eligibility analysis to two other grounds for invalidating a patent: the on-sale bar and nonobviousness. Both challenges raise mixed issues of law and fact, which present a prime opportunity for the clear and convincing standard to be applied only to the factual issues. Yet since *i4i*, both the legal and factual issues raised by these challenges have been subjected to the clear and convincing standard. The decision by some courts to either deny applying the clear and convincing standard to subject-matter-eligibility challenges entirely or limit its application to potential factual issues appears arbitrary and misguided by comparison.

Part III.B then considers the heightened standard of proof within the context of the entire patent system. Although there are persuasive arguments against applying a presumption of validity at all, the law clearly provides one. While that remains the reality, it is illogical and impractical to apply the clear and convincing standard to the legal and factual issues raised in all patent challenges except for those that are presumably subject to the preponderance of the evidence standard.

#### A. Comparisons from across Patent Law

This Section examines the on-sale bar and nonobviousness patent validity challenges to demonstrate that the clear and convincing standard is fully compatible with subject-matter-

eligibility challenges. It summarizes the doctrine governing each challenge, with a particular focus on how courts ascertain whether a patent violates the on-sale bar or fails to be nonobvious, and reveals how each challenge features both issues of law and issues of fact. It then recounts how the clear and convincing standard has continuously been applied to each challenge as a whole, not just the issues of fact.

This reality runs counter to Breyer's declaration that the clear and convincing standard can apply only to issues of fact.<sup>169</sup> It also undercuts the argument that the clear and convincing standard could not apply to an issue of law. Furthermore, all three patent challenges require similar types of legal analysis in order for a court to rule on the merits. Taken together, the choice most consistent with the law is also the most practical: subject-matter-eligibility challenges should enjoy the unqualified use of the clear and convincing evidence standard of proof conferred by the presumption of validity.

1. The on-sale bar.

The on-sale bar does not allow patenting when the subject of the patent is offered for sale for over a year before the patent application is filed.<sup>170</sup> This restriction prevents inventors from gaming the patent system. They cannot sell their invention for an extended period of time and then acquire the twenty-year monopoly of a patent after competitors attempt to replicate it and sell their own version.<sup>171</sup> If permitted, an inventor would obtain "an undue advantage over the public" by "preserv[ing] the monopoly to himself for a longer period than is allowed by the policy of the law."<sup>172</sup> The one-year grace period balances this concern with the inventor's legitimate need to gauge the market for her invention.<sup>173</sup> The evaluative time is limited to a year, however, so the inventor must be content "with either secrecy, or legal monopoly."<sup>174</sup>

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<sup>169</sup> See *i4i*, 564 US at 114 (Breyer concurring).

<sup>170</sup> See 35 USC § 102(a)–(b).

<sup>171</sup> See Stephen Bruce Lindholm, Comment, *Revisiting Pfaff and the On-Sale Bar*, 15 Albany L J Sci & Tech 213, 215 (2004).

<sup>172</sup> *Elizabeth v Pavement Co*, 97 US 126, 137 (1877).

<sup>173</sup> See Lindholm, 15 Albany L J Sci & Tech at 215 (cited in note 171).

<sup>174</sup> *Metallizing Engineering Co v Kenyon Bearing & Auto Parts Co*, 153 F2d 516, 520 (2d Cir 1946).

To show that the on-sale bar has been violated, the challenger must demonstrate that the inventor completed the invention and offered it for sale more than a year before she actually filed the patent application for that particular invention. The Supreme Court divided this task into a two-prong test in *Pfaff v Wells Electronics, Inc.*<sup>175</sup> First, the challenger must show that the invention was “the subject of a commercial offer for sale.”<sup>176</sup> This part turns on the classic question of contract law: Was there an offer?<sup>177</sup> Recently, the en banc Federal Circuit directed courts to the Uniform Commercial Code (UCC) to determine whether a party offered the invention for sale in a commercial setting.<sup>178</sup> This determination involves examining the actions of the parties and the context of their interaction, but the final conclusion is a legal one. That makes the on-sale bar a mixed question of law and fact.

Second, the invention must have been “ready for patenting” at the time of sale.<sup>179</sup> This second part basically asks whether the patent-seeker’s act of invention preceded her act of selling. If so, the on-sale bar could potentially deny a patent to prevent the inventor from obtaining a monopoly that runs longer than allowed by the patent system. Determining whether the inventor had previously created this product requires comparing it to previous work, or “prior art,” which is identified by looking to other patents, publications, and materials that were “otherwise available to the public.”<sup>180</sup> If the prior art matches the claims of the patent, then a court will conclude that the invention claimed by the patent was previously invented and “ready for patenting.”<sup>181</sup> If this prior invention that was ready for patenting was offered for sale more than a year before the filing of the patent application, then the inventor has run afoul of the on-sale bar, and the creation is unpatentable.

“Ready for patenting” is not very descriptive, but the Supreme Court has identified two ways the second prong of the *Pfaff* test can be met.<sup>182</sup> An invention can be “reduced to

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<sup>175</sup> 525 US 55 (1998).

<sup>176</sup> *Id.* at 67.

<sup>177</sup> See *Group One, Ltd v Hallmark Cards, Inc.*, 254 F3d 1041, 1047 (Fed Cir 2001) (directing courts to determine if an “offer” occurred pursuant to contract law).

<sup>178</sup> See *Medicines Co v Hospira, Inc.*, 827 F3d 1363, 1373 (Fed Cir 2016) (en banc).

<sup>179</sup> *Pfaff*, 525 US at 67.

<sup>180</sup> 35 USC § 102(a)(1).

<sup>181</sup> *Pfaff*, 525 US at 67–69.

<sup>182</sup> *Id.* at 67.

practice,” meaning, somewhat unhelpfully and circularly, that the invention has been recognizably completed.<sup>183</sup> In response, the Federal Circuit has created a “reduced to practice” test. An invention is “reduced to practice” if it both matches all the claims made in the patent and “work[s] for its intended purpose.”<sup>184</sup> The other way to satisfy the second prong of *Pfaff* is to show that the “inventor ha[s] prepared drawings or other descriptions of the invention that [are] sufficiently specific to enable a person skilled in the art to practice the invention.”<sup>185</sup> To satisfy this “written description” test, the drawings or writings must be “complete,” not merely “substantially complete,” so that the hypothetical “person skilled in the art” could replicate the entire invention.<sup>186</sup>

To rebut the on-sale bar challenge, the patent holder can show that the offer occurred less than a year before the application, that the invention offered differed materially from the claims made in the actual patent, or that the alleged offer did not constitute a legal offer.

*Pfaff* prong one—whether there was a commercial offer—is often satisfied by the presence of a communication between the offeror and offeree, often known as a “Supply and Purchase Agreement.”<sup>187</sup> But when such a smoking gun is absent, the parties have to support their positions with facts suggesting the presence or absence of a commercial offer. The chances of finding an offer are buoyed by the passage of title or evidence of marketing, while their absence or evidence that the transaction was confidential counsel against finding an offer.<sup>188</sup>

A decision on *Pfaff* prong two—whether the invention was ready for patenting—often comes down to what progress had

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<sup>183</sup> *Id.* at 57 n 2, quoting *Corona Cord Tire Co v Dovan Chemical Corp*, 276 US 358, 383 (1928) (quotation marks omitted) (“A process is reduced to practice when it is successfully performed. A machine is reduced to practice when it is assembled, adjusted and used. A manufacture is reduced to practice when it is completely manufactured. A composition of matter is reduced to practice when it is completely composed.”).

<sup>184</sup> *Fox Group, Inc v Cree, Inc*, 700 F3d 1300, 1305 (Fed Cir 2012) (“The test for establishing reduction to practice requires that ‘the prior inventor must have (1) constructed an embodiment or performed a process that met all the claim limitations and (2) determined that the invention would work for its intended purpose.’”), quoting *Teva Pharmaceutical Industries Ltd v AstraZeneca Pharmaceuticals LP*, 661 F3d 1378, 1383 (Fed Cir 2011). See also *Helsinn Healthcare SA v Teva Pharmaceuticals USA, Inc*, 855 F3d 1356, 1371–72 (Fed Cir 2017), cert granted, 138 S Ct 2678 (2018).

<sup>185</sup> *Pfaff*, 525 US at 67–68.

<sup>186</sup> *Id.* at 66, 67.

<sup>187</sup> See, for example, *Helsinn*, 855 F3d at 1364.

<sup>188</sup> See *id.*

been made toward building the invention or what writings existed before the patent filing date. For example, one company defended its slow cooker patent by arguing that the slow cooker was not completed until its engineers finally perfected a lid that would fully seal the cooker.<sup>189</sup> The company's *Pfaff* prong two defense failed under both the reduction to practice test and the written description test. The record showed that the company had developed a successful prototype of the slow cooker—reducing it to practice—and had completed several drawings showing “side clips and [a] lid gasket” that were used “to keep the lid in place and seal the food inside.”<sup>190</sup>

The on-sale bar presents “a question of law based on underlying factual findings,” or a mixed question of law and fact.<sup>191</sup> In part, it turns on certain factual questions: Did the parties exchange a Supply and Purchase Agreement? Had the company developed a slow cooker lid with an effective seal? Breyer identified another question of fact in the on-sale bar context in his *i4i* concurrence: determining “when a product was first sold.”<sup>192</sup> Other possible points of contention in an on-sale bar challenge raise legal questions, such as prong one of the *Pfaff* test. Courts even look to the UCC in determining whether an offer occurred.<sup>193</sup> The UCC does not free the judge from careful legal analysis, as the Federal Circuit has commented that determining “who is the offeror, and what constitutes a definite offer, requires looking closely at the language of the proposal itself.”<sup>194</sup> The first prong thus seems to present both questions of fact (such as, was there a Supply and Purchase Agreement?) and a question of law (was there an offer?).

Similarly, the second prong can rest on both factual and legal determinations. A factual question might ask whether the slow cooker lid was completed or whether the inventor believed the invention went to testing virtually finished.<sup>195</sup> To satisfy prong two, the challenger would be required to show by clear

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<sup>189</sup> See *Hamilton Beach Brands, Inc v Sunbeam Products, Inc*, 726 F3d 1370, 1378 (Fed Cir 2013).

<sup>190</sup> *Id* at 1378–79.

<sup>191</sup> *Id* at 1375.

<sup>192</sup> *i4i*, 564 US at 114 (Breyer concurring).

<sup>193</sup> See *Group One*, 254 F3d at 1047.

<sup>194</sup> *Id* at 1048.

<sup>195</sup> See *id* at 1378–79 (discussing completion of the slow cooker lid); *In re Omeprazole Patent Litigation*, 536 F3d 1361, 1373–75 (Fed Cir 2008) (discussing the inventor's belief about the invention's completion prior to testing).

and convincing evidence that the lid was fully designed or that the inventor believed the invention was finished to demonstrate reduction to practice. Yet once those factual questions are resolved, the issue of readiness for patenting remains a question of law. According to the Federal Circuit, the second prong of the on-sale bar can also be decided as a matter of law when there is “no genuine dispute of material fact.”<sup>196</sup> In fact, the Federal Circuit has described the reduction to practice test—one of the two ways to satisfy *Pfaff* prong two—as a “question[ ] of law . . . based on subsidiary factual findings.”<sup>197</sup> It is clear that *Pfaff* prong two is not purely factual. It depends on facts, but a judge is free to grant judgment as a matter of law when those details are not disputed.

As a question of law with underlying factual findings, the on-sale bar appears to be an example of the scenario anticipated by Breyer in *i4i*, in which the clear and convincing standard would apply to the facts but not to the question of law. For example, on *Pfaff* prong one, a court faithfully adhering to Breyer’s concurrence would require clear and convincing evidence of a warranty’s existence—a question of fact—but not whether that warranty helped constitute a commercial offer, a question of law. If the clear and convincing standard of proof applies only to issues of fact, then there should be on-sale bar challenges that require clear and convincing evidence of relevant facts but require only a preponderance of the evidence to establish the legal conclusions underlying the on-sale bar when no facts are disputed. Breyer’s concurrence suggests a selective, rather than blanket, use of the clear and convincing standard. But that has not been the case.

Before *i4i*, the Federal Circuit required clear and convincing evidence to satisfy the on-sale bar challenge as a whole, not just the issues of fact.<sup>198</sup> The Federal Circuit called this approach “well-settled” in 2005<sup>199</sup> and reiterated it in 2008.<sup>200</sup> In one case,

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<sup>196</sup> *Hamilton Beach Brands*, 726 F3d at 1379.

<sup>197</sup> *Cooper v Goldfarb*, 154 F3d 1321, 1327 (Fed Cir 1998).

<sup>198</sup> See, for example, *Abbott Laboratories v Geneva Pharmaceuticals, Inc*, 182 F3d 1315, 1318 (Fed Cir 1999) (“As the parties challenging the validity of a presumptively valid patent . . . the defendants bore the burden of proving the existence of an on-sale bar by clear and convincing evidence.”); *Juicy Whip, Inc v Orange Bang, Inc*, 292 F3d 728, 736 (Fed Cir 2002) (“Because a patent is presumed valid, the quantum of proof required at trial was clear and convincing evidence.”).

<sup>199</sup> *Electromotive Division of General Motors Corp v Transportation Systems Division of General Electric Co*, 417 F3d 1203, 1212 n 2 (Fed Cir 2005).

it explicitly called the “[a]pplication of the on-sale bar” a “question of law” and required the challenger to “demonstrate by clear and convincing evidence that ‘there was a definite sale or offer to sell.’”<sup>201</sup> In that case, the relevant documents, a series of communications between the two parties, were available and undisputed.<sup>202</sup> No sale had occurred, so the on-sale bar question turned on whether “the correspondence and other interactions” between the parties “add[ed] up to a commercial offer to sell.”<sup>203</sup> The question whether an offer existed thus turned on the meaning of the correspondence, a question of law that the court resolved at summary judgment.<sup>204</sup> District courts followed suit.<sup>205</sup>

Since *i4i*, courts have continued to impose the clear and convincing evidence standard of proof on parties bringing on-sale bar challenges.<sup>206</sup> They have applied the standard to the entire challenge, not just issues of fact. The standard has even been applied at summary judgment, which is granted “when there is no genuine issue of material fact and the moving party is entitled to a judgment as a matter of law.”<sup>207</sup> In some instances at summary judgment, the court is comparing the evidence that each side has presented. When considering if there is a genuine issue of material fact, the Supreme Court has instructed judges to “be guided by the substantive evidentiary standards that apply to the case.”<sup>208</sup> The Court reached that conclusion in *Anderson v Liberty Lobby, Inc.*<sup>209</sup> in the course of addressing a circuit split over whether the clear and convincing

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<sup>200</sup> See *In re Omeprazole*, 536 F3d at 1373.

<sup>201</sup> *Group One*, 254 F3d at 1045, quoting *UMC Electronics Co v United States*, 816 F2d 647, 656 (Fed Cir 1987).

<sup>202</sup> *Group One*, 254 F3d at 1044.

<sup>203</sup> *Id* at 1048.

<sup>204</sup> *Id* at 1049.

<sup>205</sup> See, for example, *Dey, LP v Teva Parenteral Medicines, Inc.*, 6 F Supp 3d 651, 663 (ND W Va 2014); *Tang v Northpole, Ltd.*, 2012 WL 12846984, \*2 (WD Ark).

<sup>206</sup> The Federal Circuit has done so without citing *i4i*. See *Leader Technologies, Inc v Facebook, Inc.*, 678 F3d 1300, 1305 (Fed Cir 2012), citing *Juicy Whip*, 292 F3d at 736–37, 738. Several district courts, however, have cited *i4i* for the same proposition. See *Dey*, 6 F Supp 3d at 663; *Orbis Corp v Rehrig Pacific Co.*, 970 F Supp 2d 875, 879 (ED Wis 2013); *Tang*, 2012 WL 12846984 at \*2; *Tesco Corp v Weatherford International, Inc.*, 904 F Supp 2d 622, 627 (SD Tex 2012); *Medtronic, Inc v Edwards Lifesciences Corp.*, 2013 WL 12113417, \*9 (CD Cal); *Helsinn Healthcare S.A. v Dr. Reddy’s Laboratories Ltd.*, 2016 WL 832089, \*52 (D NJ), *revd* on other grounds, *Helsinn Healthcare*, 855 F3d 1356.

<sup>207</sup> *Abbott Laboratories*, 182 F3d at 1317–18, citing FRCP 56(c). See also *Group One*, 254 F3d at 1045–46; *Orbis Corp*, 970 F Supp 2d at 879.

<sup>208</sup> *Anderson v Liberty Lobby, Inc.*, 477 US 242, 255 (1986).

<sup>209</sup> 477 US 242 (1986).

standard applies at summary judgment.<sup>210</sup> The Court's holding that it does continues to apply today.<sup>211</sup> But in determining whether there is a disputed material fact that could conceivably prevent a jury from finding for the movant by clear and convincing evidence, the judge is arguably considering whether the *facts* satisfy the clear and convincing standard. That would be compatible with Breyer's concurrence.

Although not all on-sale bar challenges involve disputed facts, the clear and convincing standard has nonetheless been deployed. The Federal Circuit imposed the standard on a patent challenger at summary judgment when "there [were] no facts in dispute, leaving only the legal issue whether the § 102(b) on-sale bar invalidates the patent."<sup>212</sup> A district court applied the standard at summary judgment, when the parties disputed whether two presentations and a quote from a manufacturer constituted legal offers but not whether they existed.<sup>213</sup> The Federal Circuit has also applied the standard directly to a legal issue when reviewing the denial of a motion for judgment as a matter of law after a jury verdict.<sup>214</sup> In this posture, the record is final, and the question of reversing the district court's denial is a legal one.<sup>215</sup> The Federal Circuit evaluated the evidence submitted to the jury to see if the challenger "failed as a matter of law to prove invalidity by clear and convincing evidence."<sup>216</sup>

Courts do not appear to have ever imposed two standards of proof—one for issues of law and another for issues of fact—when considering on-sale bar challenges. Most notably, they have continued to require clear and convincing evidence of the on-sale bar even when confronted only with an issue of law. These two realities reveal that courts have routinely imposed the clear and convincing standard on the entire on-sale bar violation, including both issues of fact and issues of law. Despite presenting a mixed question of law and fact, the standard of proof for on-sale bar challenges has remained the clear and convincing standard.

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<sup>210</sup> See *id.* at 244.

<sup>211</sup> See *id.*

<sup>212</sup> *Abbott Laboratories*, 182 F3d at 1318.

<sup>213</sup> See *Orbis Corp.*, 970 F Supp 2d at 879, 881.

<sup>214</sup> *Leader Technologies*, 678 F3d at 1305.

<sup>215</sup> See *id.*

<sup>216</sup> *Id.* at 1306.



## 2. Nonobviousness.

The nonobviousness requirement prevents patenting an invention “if the differences between the claimed invention and the prior art . . . would have been obvious . . . to a person having ordinary skill in the art to which the claimed invention pertains.”<sup>217</sup> In other words, an invention is unpatentable if it merely combines “familiar elements according to known methods . . . do[ing] no more than yield[ing] predictable results”<sup>218</sup> that would have been “obvious to a person reasonably skilled in that art.”<sup>219</sup> Nonobviousness effectively establishes an innovation minimum for patents.<sup>220</sup> Without nonobviousness, basic improvements to existing technology that might inevitably be adopted by an entire industry could be monopolized by a single company or individual.<sup>221</sup> The patent system strives to reward ingenuity, not basic inferences anyone could make.

*Graham v John Deere Co of Kansas City*<sup>222</sup> continues to guide courts in determining whether a patent is invalid for obviousness. Courts consider primary factors, such as the “scope and content of the prior art,” “differences between the prior art and the claims at issue,” and the “level of ordinary skill in the pertinent art” to decide what innovations would be obvious to a person of ordinary skill in the profession.<sup>223</sup> If these are not determinative, “secondary considerations,” including “commercial success, long felt but unsolved needs, failure of others, etc.,” can help a court ascertain whether the inventor’s innovation is sufficiently innovative.<sup>224</sup> Together, these primary and secondary factors compose the “indicia of obviousness or nonobviousness.”<sup>225</sup> In the most recent Supreme Court decision on nonobviousness, *KSR International Co v Teleflex Inc.*,<sup>226</sup> the Court endorsed the

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<sup>217</sup> 35 USC § 103.

<sup>218</sup> *KSR International Co v Teleflex Inc.*, 550 US 398, 416 (2007).

<sup>219</sup> *Graham v John Deere Co of Kansas City*, 383 US 1, 37 (1966).

<sup>220</sup> See *KSR*, 550 US at 427 (“[A]s progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws.”).

<sup>221</sup> See *id.* at 416.

<sup>222</sup> 383 US 1 (1966).

<sup>223</sup> *Id.* at 17.

<sup>224</sup> *Id.*

<sup>225</sup> *Id.* at 18.

<sup>226</sup> 550 US 398 (2007).

*Graham* framework and supplemented the indicia of obviousness with additional factors to consider.<sup>227</sup>

Like the on-sale bar, nonobviousness presents “a question of law based on underlying facts.”<sup>228</sup> The factual issues are the indicia of obviousness, and courts often explicitly identify the factors laid out in *Graham* and *KSR* as factual questions.<sup>229</sup> For example, parties may agree on what the prior art is but disagree about what it actually shows. The parties in one case disputed whether the prior art really portrayed the use of “negative pressure”<sup>230</sup> to treat wounds.<sup>231</sup> As one of the *Graham* factors, the difference between the claims of the patent and the prior art represents an underlying factual finding.<sup>232</sup> Yet the ultimate determination of nonobviousness is a legal conclusion. The negative pressure case came to the Federal Circuit on review of the district court judge’s decision to grant a motion for judgment as a matter of law, reversing a jury’s nonobviousness verdict.<sup>233</sup> The Federal Circuit reversed the district court judge, holding that the judge had improperly substituted his own witness credibility judgments for the jury’s in regard to three pieces of prior art.<sup>234</sup> The credibility of witnesses is an issue of fact, and the judge was not permitted to override the jury’s factual determinations at the postverdict stage as long as they were supported by “substantial evidence.”<sup>235</sup> However, the district court judge still possessed the authority to overturn the jury’s nonobviousness decision as long as he relied on the jury’s legitimate factual findings because nonobviousness is a “legal conclusion.”<sup>236</sup> In essence, the relevant indicia of obviousness raise issues of fact to be

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<sup>227</sup> See *id.* at 418 (noting factors like the “interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art”).

<sup>228</sup> *Apple Inc v Samsung Electronics Co*, 839 F3d 1034, 1047 (Fed Cir 2016) (en banc).

<sup>229</sup> See, for example, *Santarus, Inc v PAR Pharmaceutical, Inc*, 694 F3d 1344, 1351, 1352 (Fed Cir 2012); *Kinetic Concepts, Inc v Smith & Nephew, Inc*, 688 F3d 1342, 1360 (Fed Cir 2012).

<sup>230</sup> “Negative Pressure Wound Therapy . . . uses controlled negative pressure using [a] Vacuum-Assisted Closure device [ ] to help promote wound healing by removing fluid from open wounds through a sealed dressing and tubing which is connected to a collection container.” Prabhdeep Singh Nain, et al, *Role of Negative Pressure Wound Therapy in Healing of Diabetic Foot Ulcers*, 3 J Surgical Technique & Case Report 17, 17 (2011).

<sup>231</sup> See *Kinetic Concepts*, 688 F3d at 1361.

<sup>232</sup> See *id.* at 1360.

<sup>233</sup> *Id.* at 1346.

<sup>234</sup> *Id.* at 1362, 1364, 1365.

<sup>235</sup> *Kinetic Concepts*, 688 F3d at 1356–57.

<sup>236</sup> *Id.* at 1357.

addressed exclusively by the trier of fact, but whether those facts demonstrate obviousness or nonobviousness is an issue of law that is always supervised by the judge regardless whether a decision is reached at summary judgment or by a jury.

According to Breyer's *i4i* concurrence, the factual issues ought to be determined according to the clear and convincing standard, but the overall question of law should not. Nonobviousness, as a mixed issue of law and fact, would be evaluated according to two standards of proof—clear and convincing for the issues of fact and, presumably, preponderance of the evidence for issues of law.<sup>237</sup> As with the on-sale bar, however, the case law does not reflect that approach. Most prominently in *Procter & Gamble Co v Teva Pharmaceuticals USA, Inc.*,<sup>238</sup> the Federal Circuit stated that “[t]he evidentiary burden to show facts supporting a conclusion of invalidity is one of clear and convincing evidence.”<sup>239</sup> Strict Breyer courts might claim that this statement supports their position: the clear and convincing evidence standard is a “burden to show *facts*,” not law.<sup>240</sup>

However, that reading of *Procter & Gamble* is too simplistic. Right before stating the standard of proof, the court specified the applicable level of appellate deference. Whether the patent was obvious was identified as “a question of law . . . reviewed de novo,” while the “[f]actual determinations underlying the obviousness issue are reviewed for clear error.”<sup>241</sup> The Federal Circuit managed to disentangle issues of fact from issues of law in order to recognize the different levels of deference each merited, but it did not make the same distinction for the standard of proof. The fact that the Federal Circuit treated appellate deference differently from the standard of proof suggests that “clear and convincing evidence” is actually modifying “evidentiary burden,” not “facts.”<sup>242</sup> The court was clearly capable of applying different standards of proof to questions of fact and questions of law but chose not to.

In fact, *Procter & Gamble* provides a fine example of how not to elide the distinction between the level of appellate deference and the standard of proof. The appellate standard of

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<sup>237</sup> See notes 65–73 and accompanying text.

<sup>238</sup> 566 F3d 989 (Fed Cir 2009).

<sup>239</sup> *Id.* at 993–94.

<sup>240</sup> *Id.* at 993 (emphasis added).

<sup>241</sup> *Id.*

<sup>242</sup> *Procter & Gamble*, 566 F3d at 993–94.

review indicates the deference an appellate court must afford “decisions made by a district court judge, a jury, or an administrative agency.”<sup>243</sup> In accordance with the Federal Rules of Civil Procedure, appellate courts apply the most deferential standard of “clear error” to findings of fact developed at the trial level.<sup>244</sup> De novo review of a legal issue, on the other hand, “means the court of appeals owes no deference to the district court.”<sup>245</sup> Mixed issues of law and fact, such as the on-sale bar and nonobviousness, present a standard of review conundrum that courts have not dealt with uniformly.<sup>246</sup> The Federal Circuit’s treatment of the on-sale bar and nonobviousness—for which the underlying issues of fact are reviewed for clear error but the ultimate question of law is reviewed de novo—is one possible approach to mixed questions.<sup>247</sup>

In contrast, the standard of proof—whether it is preponderance of the evidence, clear and convincing evidence, or beyond a reasonable doubt—instructs the party bearing the burden of persuasion, not an appellate court. In particular, it specifies to what extent the party must persuade the factfinder of its argument.<sup>248</sup> As discussed in Part I.B, this does not mean, however, that judges always act independently of standards of proof.<sup>249</sup> The standard of proof does not apply to each premise advanced by the party that bears the burden of proof, but rather has been understood to encompass that party’s entire proposed legal conclusion.<sup>250</sup> The standard of review, therefore, does not stipulate the patent challenger’s standard of proof on a particular issue, whether legal or factual.

With this in mind, the Federal Circuit appears quite deliberate in *Procter & Gamble*. The court did not neglect the difference between fact and law but found it relevant only to appellate review, not the standard of proof. Later in the opinion, the Federal Circuit again implied that the clear and convincing

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<sup>243</sup> Robert E. Larsen, *Navigating the Federal Trial* § 16:1 (West 2017 ed).

<sup>244</sup> See FRCP 52(a).

<sup>245</sup> David G. Knibb, *Federal Court of Appeals Manual* § 31:3 (West 6th ed 2017)

<sup>246</sup> See *id.* at § 31:6 (collecting different ways in which courts have approached mixed issues of law and fact).

<sup>247</sup> *Id.*

<sup>248</sup> See notes 54–59 and accompanying text.

<sup>249</sup> See notes 65–73 and accompanying text.

<sup>250</sup> See Charles Alan Wright and Kenneth W. Graham Jr, 21B *Federal Practice & Procedure: Evidence* § 5122 at 405–10 (West 2d ed 2005) (describing the standards of proof in relation to legal conclusions, such as criminal guilt, deportation proceedings, and common law fraud).

standard applies to the entire nonobviousness challenge rather than just underlying factual questions about the indicia of obviousness. It required the challenger to “demonstrate ‘by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.’”<sup>251</sup> That sentence contains the entire nonobviousness challenge. It encompasses any specific factual questions related to the indicia of obviousness and also the conclusion of law that the ultimate determination of nonobviousness reflects.

*Procter & Gamble* has not been an outlier, either, as the Federal Circuit has consistently imposed the clear and convincing standard on nonobviousness challenges, both before<sup>252</sup> and after *i4i*.<sup>253</sup> In some cases, courts required clear and convincing evidence without citing *i4i*.<sup>254</sup> Many others did attribute the standard to *i4i*, sometimes also citing *Procter & Gamble*.<sup>255</sup> The clear and convincing standard is the unquestioned standard of proof in nonobviousness disputes.

In these cases, courts have indicated that the clear and convincing standard applies to nonobviousness challenges as a whole, not just to the factual questions. Sometimes this reality emerges in the same manner as in *Procter & Gamble*, in which the distinction between law and fact informs the proper level of appellate deference but not the use of the standard of proof.<sup>256</sup> In one post-*i4i* case, the Federal Circuit considered a nonobviousness challenge in the context of a preliminary injunction. The court measured the movant’s likelihood of succeeding on the entire nonobviousness claim—one of the four factors in the

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<sup>251</sup> *Procter & Gamble*, 566 F3d at 994, quoting *Pfizer, Inc v Apotex, Inc*, 480 F3d 1348, 1361 (Fed Cir 2007).

<sup>252</sup> See *Para-Ordnance Manufacturing, Inc v SGS Importers International, Inc*, 73 F3d 1085, 1088 (Fed Cir 1995).

<sup>253</sup> See *Sciele Pharma Inc v Lupid Ltd*, 684 F3d 1253, 1260 (Fed Cir 2012).

<sup>254</sup> See, for example, *Kinetic Concepts*, 688 F3d at 1360 (citing *Procter & Gamble* instead of *i4i*); *InTouch Technologies, Inc v VGo Communications, Inc*, 751 F3d 1327, 1347 (Fed Cir 2014) (same).

<sup>255</sup> See, for example, *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation*, 676 F3d 1063, 1069 (Fed Cir 2012) (citing *i4i* as reaffirming *Procter & Gamble*); *Santarus*, 694 F3d at 1352, 1363–64 (applying *i4i* in general to patent validity challenges pursuant to § 282 and specifically to nonobviousness in conjunction with *Procter & Gamble*); *Sciele Pharma*, 684 F3d at 1259–61 (citing *i4i* to require clear and convincing evidence).

<sup>256</sup> See, for example, *Para-Ordnance Manufacturing*, 73 F3d at 1088.

preliminary injunction consideration—according to the clear and convincing standard.<sup>257</sup> Indeed, the Federal Circuit claimed to be evaluating how likely the patent holder was to “withstand the accused infringer’s challenges to the validity and enforceability of the patent.”<sup>258</sup>

Applying the clear and convincing standard broadly to validity challenges necessarily encompasses any underlying factual questions and the ultimate question of law of nonobviousness. And as with the on-sale bar, the Federal Circuit has reviewed posttrial nonobviousness verdicts on motions for judgment as a matter of law according to the clear and convincing standard. At that stage, the court presumes the same factual findings as the jury as long as “they are supported by substantial evidence” and then considers the “[ultimate] legal conclusion [of obviousness] de novo to see whether it is correct in light of the presumed jury fact findings.”<sup>259</sup> This procedural posture offered the Federal Circuit an opportunity to use a lesser standard of proof for the issue of law presented by the nonobviousness conclusion. Instead, it has imposed the heightened standard in this situation twice since *i4i*.<sup>260</sup> As if to further emphasize this point, the Federal Circuit stated, “At all times, the burden is on the defendant to establish by clear and convincing evidence that the patent is obvious.”<sup>261</sup>

Like the on-sale bar, nonobviousness provides a concrete example of courts applying the clear and convincing standard without distinguishing between legal and factual issues. The next Section demonstrates that district courts hearing subject-matter-eligibility challenges should follow suit in applying a uniform clear and convincing standard of proof to the entire challenge.

### 3. The legal case for treating subject-matter eligibility like the on-sale bar and nonobviousness.

Because the on-sale bar and nonobviousness present mixed questions of law and fact,<sup>262</sup> the blanket imposition of the clear and convincing standard on those challenges means the

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<sup>257</sup> *Sciele Pharma*, 684 F3d at 1259–60.

<sup>258</sup> *Id.* at 1259.

<sup>259</sup> *Kinetic Concepts*, 688 F3d at 1356–57, quoting *Jurgens v McKasy*, 927 F2d 1552, 1557 (Fed Cir 1991).

<sup>260</sup> See *Kinetic Concepts*, 688 F3d at 1360; *InTouch Technologies*, 751 F3d at 1347.

<sup>261</sup> *Kinetic Concepts*, 688 F3d at 1360 (emphasis added).

<sup>262</sup> See *Hamilton Beach Brands*, 726 F3d at 1375. See also text accompanying notes 191 and 237.

standard covers both legal and factual issues. If the clear and convincing standard is compatible with the legal questions presented by these two challenges, then it ought to also be compatible with the legal question presented by the subject-matter-eligibility challenge. Refusing to apply the clear and convincing standard to a mixed-question subject-matter-eligibility challenge sows inconsistency in patentability doctrine. It defers to the PTO's legal judgment in regard to the on-sale bar and non-obviousness, but not patentable subject matter, without adequate justification for the divergent treatment. Additionally, this inconsistency may lead to uncertainty regarding the appropriate evaluation of all patent validity challenges.

A unified approach works regardless of whether a court identifies a disputed issue of fact or not. If a court does, then subject-matter eligibility operates like on-sale bar and nonobviousness challenges. Yet even if no factual dispute arises, the on-sale bar and nonobviousness doctrines show that the clear and convincing standard is not confined to factual questions. The standard is compatible with subject-matter eligibility in all its permutations.

The procedural posture the Federal Circuit adopts when hearing appeals may confuse some courts into thinking that issues of law and issues of fact receive different standards of proof. Courts should look to cases like *Procter & Gamble* to see how the shifting levels of appellate deference for legal and factual issues can coexist with a constant standard of proof. Courts do not need to neglect the difference between fact and law; they only need to act on the difference in regards to appellate deference, not the standard of proof. *Procter & Gamble* shows that the Federal Circuit is equipped to differentiate the standard of proof from the standard of review. It must continue to do so in all patent validity challenges, including subject-matter-eligibility challenges.

The on-sale bar and nonobviousness show that the clear and convincing standard should apply to the challenger's entire persuasive burden, not just her factual assertions. If the subject-matter-eligibility inquiry turns on a factual determination at *Alice* step two—whether the patent possesses an “inventive concept” that makes it more than a patent of an ineligible concept<sup>263</sup>—as in

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<sup>263</sup> *Alice*, 134 S Ct at 2355.

*Berkheimer*,<sup>264</sup> the on-sale bar and nonobviousness examples apply directly. Challengers seeking to invalidate patents based on one of these two mixed questions of law and fact are required to demonstrate invalidity by clear and convincing evidence. A subject-matter-eligibility challenge that raises a mixed question of law and fact should be no different.

Strict Breyer courts may maintain that *i4i* is inapplicable to issues of law and argue that the clear and convincing standard cannot apply to a subject-matter-eligibility challenge that fails to raise a factual question. After all, *Berkheimer* maintained that some subject-matter-eligibility challenges will continue to offer pure questions of law that can be resolved on the pleadings.<sup>265</sup>

This argument also falls short because it overlooks the fact that the defendant still carries a persuasive burden when moving to dismiss a complaint. The *Alice* test can be conducted solely by examining the patent, a legal document included with the pleadings.<sup>266</sup> The accused infringer seeking to dismiss the case on the basis of subject-matter invalidity relies on an affirmative defense. At the pleading stage, the defendant must show the affirmative defense through allegations in the complaint,<sup>267</sup> which includes the patent. The defendant infringer already carries a persuasive burden. The advent of plausibility pleading in *Ashcroft v Iqbal*<sup>268</sup> made clear that reality.<sup>269</sup> Although somewhat ambiguous and not phrased as a familiar standard of proof, the Supreme Court sketched the contours of the plausibility standard governing the motion to dismiss stage: “Where a complaint pleads facts that are merely consistent with a defendant’s liability, it stops short of the line between possibility and plausibility of entitlement of relief.”<sup>270</sup> Surely when

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<sup>264</sup> See *Berkheimer*, 881 F3d at 1368.

<sup>265</sup> See *id.*

<sup>266</sup> See *Alice*, 134 S Ct at 2355.

<sup>267</sup> See *Jones v Bock*, 549 US 199, 215 (2007) (“If the allegations, for example, show that relief is barred by the applicable statute of limitations, the complaint is subject to dismissal for failure to state a claim.”).

<sup>268</sup> 556 US 662 (2009).

<sup>269</sup> See Damon C. Andrews, Note, *Iqbal-ing* Seagate: *Plausibility Pleading of Willful Patent Infringement*, 25 Berkeley Tech L J 1955, 1967–68 (2010).

<sup>270</sup> *Iqbal*, 556 US at 678 (quotation marks omitted), quoting *Bell Atlantic Corp v Twombly*, 550 US 544, 557 (2007).



already subject to a standard of proof, a defendant can also carry a heightened persuasive burden.<sup>271</sup>

Believing that the motion to dismiss stage cannot involve a standard of proof risks contradiction. For example, one district court said both that “it makes little sense to apply a ‘clear and convincing evidence’ standard—a burden of *proof*—to such motions” and that “[d]efendants . . . still bear the burden of establishing that the claims are patent-ineligible.”<sup>272</sup> The court did not explain why the defendant could bear a burden—perhaps the plausibility standard of *Iqbal* or civil litigation’s default preponderance of the evidence standard—but not a heightened one in accordance with *i4i*’s requirement that patent challengers demonstrate invalidity by clear and convincing evidence.

The examples of the on-sale bar and nonobviousness raise another reason to be skeptical about claims that the clear and convincing standard applies only to issues of law in patent validity challenges: Breyer overlooks the fact that the on-sale bar and nonobviousness are mixed questions of law and fact. He refers to one element of the on-sale bar (when the product was first sold) as an issue of fact and to nonobviousness as an issue of law.<sup>273</sup> Both statements oversimplify two mixed questions of law and fact. As a result, Breyer misrepresents the ease with which a judge could apply one standard of proof to issues of law and another to issues of fact. The questions of law and fact are often entangled and defy individual treatment. Furthermore, the case law on the on-sale bar and nonobviousness challenges reveals that the clear and convincing standard has consistently encompassed those challenges as a whole, not just the issues of fact. Breyer’s concurrence assumes the difference between issues of fact and issues of law to be far more acute than it is in practice, and fails to account for the historical use of the clear and convincing standard in other patent validity challenges. It consequently lacks usefulness.

Beyond the question of fact versus question of law issue, the clear and convincing standard ought to be compatible with the subject-matter-eligibility inquiry because it is already deployed for the analytically similar inquiries necessitated by the on-sale

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<sup>271</sup> See *Ultramercial II*, 722 F3d at 1339 (requiring clear and convincing evidence of invalidity to satisfy the affirmative defense at the pleading stage). See also notes 65–73 and accompanying text.

<sup>272</sup> *Modern Telecom Systems*, 2015 WL 1239992 at \*7, 8.

<sup>273</sup> See *i4i*, 564 US at 114.

bar and nonobviousness requirements. At *Alice* step one, courts ask if the patent is intended for an abstract concept.<sup>274</sup> The second prong of the on-sale bar test—whether the “invention was ready for patenting”—asks a similarly opaque question.<sup>275</sup> Both inquiries task the court with determining whether a patent or invention amounted to a hazy but recognizable concept—abstract for subject-matter eligibility and complete for the on-sale bar. Similarly, *Alice* step two—whether the invention “transform[s] the nature of the claim’ into a patent-eligible application”<sup>276</sup>—resembles the nonobviousness requirement that the invention represent a transformation that would not be “obvious to a person reasonably skilled in that art.”<sup>277</sup> Both tests seek to identify a sufficient transformation. If the clear and convincing standard does not impede judges from making on-sale bar and nonobviousness determinations, it can surely work with the similarly constructed subject-matter-eligibility inquiry.

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When compared to the on-sale bar and nonobviousness, the treatment of subject-matter eligibility seems exceptional. The clear and convincing standard has consistently been applied to on-sale bar and nonobviousness challenges. Courts have not narrowed the standard’s scope to factual issues in those two challenges, as Breyer’s *i4i* concurrence urges, even though they both involve a question of law with underlying factual findings. Breyer’s concurrence has impacted only subject-matter-eligibility challenges. The heart of the argument against extending the clear and convincing standard to subject-matter-eligibility challenges rests on the Breyer concurrence’s distinction between law and fact, but that line is not significant to determining the appropriate standard of proof in patent validity challenges. Applying the clear and convincing standard to subject-matter-eligibility challenges harmonizes the standard of proof across patent validity suits in a way that is consistent with precedent and the holding of *i4i*. Seeking consistency with the law is preferable to relying on specious dichotomies.

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<sup>274</sup> See *Alice*, 134 S Ct at 2355.

<sup>275</sup> *Medicines*, 827 F3d at 1368.

<sup>276</sup> *Alice*, 134 S Ct at 2355, quoting *Mayo Collaborative Services v Prometheus Laboratories, Inc.*, 566 US 66, 78 (2012).

<sup>277</sup> *Graham*, 383 US at 37 (1966). See also 35 USC § 103.

The next Section considers this question from another perspective. It examines how failing to apply the clear and convincing standard to subject-matter eligibility will sow inconsistencies and contradiction relative to other patent validity challenges and within the patent system as a whole.

## B. Functional Considerations

This Section considers the functional logic of the presumption of validity and how that logic informs the use of the clear and convincing standard. As noted above, the clear and convincing standard arose from nineteenth-century judges implementing the presumption of validity.<sup>278</sup> The Supreme Court incorporated that common law doctrine into the statutory presumption of validity in *i4i*.<sup>279</sup> Underlying the presumption of validity at common law was “the basic proposition that a government agency . . . was presumed to do its job.”<sup>280</sup> In *i4i*, the Supreme Court distanced the presumption of validity from PTO expertise by emphasizing that the statute incorporated a “fixture of the common law.”<sup>281</sup>

The presumption of validity and the clear and convincing standard have been maligned by some scholars. Criticism has focused on reasons why it is a mistake to assume the PTO’s initial decision is correct. For example, some maintain that PTO examiners cannot possibly review each patent application thoroughly when they are flooded with hundreds of thousands of applications each year.<sup>282</sup> The lack of adversarial process is also considered a deficiency in PTO review.<sup>283</sup> One district court judge claimed that, in his experience, “at least one-third of patent claims asserted in litigation should never have issued.”<sup>284</sup>

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<sup>278</sup> See note 80 and accompanying text. See also *American Hoist & Derrick Co v Sowa & Sons, Inc*, 725 F2d 1350, 1358 (Fed Cir 1984) (“The presumption was, originally, the creation of the courts.”); *i4i*, 564 US at 101–02.

<sup>279</sup> *i4i*, 564 US at 102–03.

<sup>280</sup> *American Hoist*, 725 F2d at 1359.

<sup>281</sup> *i4i*, 564 US at 102.

<sup>282</sup> See Doug Lichtman and Mark A. Lemley, *Rethinking Patent Law’s Presumption of Validity*, 60 Stan L Rev 45, 53–56 (2007). See also Kristen Dietly, Note, *Lightening the Load: Whether the Burden of Proof for Overcoming a Patent’s Presumption of Validity Should Be Lowered*, 78 Fordham L Rev 2615, 2654–57 (2010) (arguing in favor of lowering the standard to a preponderance of the evidence).

<sup>283</sup> See Lichtman and Lemley, 60 Stan L Rev at 55–56 (cited in note 282).

<sup>284</sup> William Alsup, *Memo to Congress: A District Judge’s Proposal for Patent Reform: Revisiting the Clear and Convincing Standard and Calibrating Deference to the Strength of the Examination*, 24 Berkeley Tech L J 1647, 1648 (2009).

Similarly, one of Judge Mayer's arguments against applying the clear and convincing standard to subject-matter-eligibility challenges arose from what he viewed as insufficient subject-matter screening by the PTO.<sup>285</sup>

In addition to concerns about PTO effectiveness, some fear that applying the clear and convincing standard to subject-matter-eligibility challenges will prove a boon to "nonpracticing entities," or patent trolls.<sup>286</sup> Patent trolls sit on previously unenforced patents and then spring upon unsuspecting infringers, seeking damages or hefty settlements negotiated in the shadow of an injunction against the unwitting infringer.<sup>287</sup> The Supreme Court is aware of the pernicious effects of trolls. In *eBay, Inc v MercExchange, LLC*,<sup>288</sup> Justice Anthony Kennedy wrote a concurring opinion joined by three other justices, including Breyer, expressing concern that firms "use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees."<sup>289</sup> Mayer explicitly argued that the heightened standard of proof should not apply to subject-matter-eligibility challenges so that subject-matter eligibility could serve as the "bulwark against vexatious infringement suits" seeking "to extract nuisance value settlements from accused infringers."<sup>290</sup> At least one district court has shared the same concern.<sup>291</sup> Mayer seems to view subject-matter eligibility as troll repellent. Because subject-matter eligibility can be dealt with early in litigation, it presents defendants with an important opportunity to eliminate the suit at minimal cost before they face the costs of litigation and especially of discovery.<sup>292</sup> Because patent trolls are likely to wield "vague and overbroad" patents, the patents could realistically run afoul of subject-matter eligibility.<sup>293</sup> Requiring

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<sup>285</sup> See *Ultramercial III*, 772 F3d at 720 (Mayer concurring).

<sup>286</sup> See Gerard N. Magliocca, *Blackberries and Barnyards: Patent Trolls and the Perils of Innovation*, 82 Notre Dame L Rev 1809, 1810 n 3 (2007).

<sup>287</sup> See *id.* at 1814.

<sup>288</sup> 547 US 388 (2006).

<sup>289</sup> *Id.* at 396 (Kennedy concurring).

<sup>290</sup> *Ultramercial III*, 772 F3d at 719 (Mayer concurring) (citation and quotation marks omitted).

<sup>291</sup> See *Wireless Media Innovations, LLC v Maher Terminals, LLC*, 100 F Supp 3d 405, 412 (D NJ 2015).

<sup>292</sup> See *Ultramercial III*, 772 F3d at 719 (Mayer concurring) ("From a practical perspective, addressing section 101 at the outset of litigation will . . . conserve scarce judicial resources.").

<sup>293</sup> *Id.*

clear and convincing evidence of subject-matter eligibility thus risks weakening the effectiveness of this repellent.

Given the doubt surrounding the effectiveness of PTO review and concerns over patent trolls,<sup>294</sup> some might be uneasy at the thought of lengthier litigation or greater protection for undeserving patents. This concern clearly motivated Mayer.<sup>295</sup> Whether subject-matter-eligibility questions deserve deference, however, is not the question raised by this dispute. This debate arises over whether subject-matter-invalidity challenges, as a matter of law, should be subject to the clear and convincing standard of proof. As Part III.A made clear, the weight of legal authority favors applying the clear and convincing standard to subject-matter-eligibility challenges. On this basis alone, judges ought to set aside their own policy preferences and adhere to the current state of the law. But even when standing on their own, these policy arguments are incompatible with the reality of PTO review and with the application of the clear and convincing standard to other validity challenges.

First, it seems misguided to be selectively skeptical about legal conclusions reached by PTO examiners. As shown by the on-sale bar and nonobviousness, the clear and convincing standard applies to legal questions in other challenges, even when tied up with facts.<sup>296</sup> Before one of those legal questions became the subject of patent litigation, a PTO examiner had definitively answered it. If the PTO's review merits the clear and convincing standard on the ultimate conclusion of law in a mixed issue of law and fact, then there is no reason for not also trusting its judgment on the legal question presented by subject-matter eligibility. The clear and convincing standard has historically recognized the PTO's expertise on both issues of law and issues of fact.

Second, the policy considerations against the clear and convincing standard apply with equal force to all patent validity challenges, not just subject-matter eligibility. The policy arguments may even be right. Mayer's concurrence provides several reasons why his approach is advisable.<sup>297</sup> But these arguments

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<sup>294</sup> See Magliocca, 82 *Notre Dame L Rev* at 1814–17 (cited in note 286) (providing background on common definitions and characteristics of patent trolls).

<sup>295</sup> See *Ultramercial III*, 772 F3d at 719 (Mayer concurring). See also text accompanying note 136.

<sup>296</sup> See Part III.A.1–2.

<sup>297</sup> See *Ultramercial III*, 772 F3d at 718–20 (Mayer concurring).

prove too much. They fail to explain why subject-matter eligibility should be singled out for special treatment. The same policy arguments against the clear and convincing standard apply to other patent validity challenges. The only distinguishing feature of subject-matter eligibility identified by courts following the strict Breyer approach is the untenable and artificial distinction between issues of law and fact.<sup>298</sup> Furthermore, despite possessing the opportunity to curb or eliminate the presumption of validity, all three branches of government have recently affirmed it. The America Invents Act<sup>299</sup>—passed by Congress and signed by the President in 2011—reshaped the American patent system in significant ways but retained the presumption of validity.<sup>300</sup> That same year, the *i4i* Supreme Court incorporated the common law’s clear and convincing standard of proof into the presumption of validity. The result in *i4i* indicates quite clearly the Supreme Court’s intention to maintain the presumption. Between Kennedy’s *eBay* concurrence and the “numerous amici” who urged the Supreme Court to limit the presumption of validity in *i4i*, the Supreme Court knew the risk posed by trolls.<sup>301</sup> It still reiterated the clear and convincing standard unanimously.

Although grounded in the law, the argument this Comment advances may support frivolous infringement cases and limit the capacity of subject-matter eligibility to act as a patent gatekeeper. This fear, however, should not trump the well-established practice of applying the clear and convincing standard to patent validity challenges writ large, not just their factual issues. Those who believe the presumption of validity should be scaled back should focus their efforts on Congress rather than carving out a legally dubious subject-matter-eligibility exception. If the doomsday scenario feared by Mayer comes to fruition, lawmakers may be

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<sup>298</sup> See text accompanying note 154.

<sup>299</sup> Pub L No 112-29, 125 Stat 284, codified as amended in various sections of Title 35.

<sup>300</sup> See note 28.

<sup>301</sup> See Benjamin J. Bradford and Sandra J. Durkin, *A Proposal for Mandatory Patent Reexaminations*, 52 *Intell Prop L Rev* 135, 136 (2012). Not all academic literature views the clear and convincing standard as the primary scourge afflicting the patent system. Consider Jonathan Masur, *Patent Inflation*, 121 *Yale L J* 470, 474 (2011) (arguing that the PTO as an institution, independent of its other shortcomings, is incentivized to approve patents in order to avoid appeal and reversal by the Federal Circuit); Sean B. Seymore, *The Presumption of Patentability*, 97 *Minn L Rev* 990, 1015 (2013) (arguing that procedural and substantive mechanisms that give patent applications a presumption of patentability create a “predilection toward patent issuance [that] counteracts efforts to both improve patent examination quality and to reduce overall application volume”).

spurred to action. Until then, a subject-matter-eligibility exception only masks the alleged underlying problem.

#### CONCLUSION

The question whether to apply the clear and convincing standard of proof to purely legal subject-matter-eligibility challenges will not dissipate over time. Accused infringers will continue to utilize invalidity challenges, and subject-matter eligibility may grow more popular if clear and convincing evidence is not required. Until the Supreme Court or the Federal Circuit addresses this issue, district court judges must rely on their own wits.

To that end, they should look to the examples of the on-sale bar and nonobviousness. These examples show that the factual versus legal divide has not been and continues not to be relevant in applying the clear and convincing standard. Just because an issue is legal in nature does not mean a heightened standard of proof is inapplicable. Furthermore, the legal and policy arguments for imposing a different standard of proof on subject-matter-eligibility challenges fall apart after the implications of all other patent invalidity challenges are considered. The standard of proof should be understood as the overall burden borne by the challenger, regardless of whether the challenger raises a pure issue of law or a mixed issue of law and fact. In both this spirit and in accordance with *i4i*, district courts should extend the clear and convincing standard to subject-matter-eligibility challenges.