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## Echoes from the Past: How the Federal Circuit Continues to Struggle with Patentable Subject Matter Post-Bilski

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## NOTE

# Echoes from the Past: How the Federal Circuit Continues to Struggle with Patentable Subject Matter Post-*Bilski*

*Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011).

JEFF THRUSTON\*

### I. INTRODUCTION

In 2010, the United States Supreme Court levied a decision in *Bilski v. Kappos* that cast further doubt over what exactly constitutes patentable subject matter under 35 U.S.C. § 101 by striking down the Court of Appeals for the Federal Circuit's machine-or-transformation test.<sup>1</sup> As the sole test of what constituted patent-eligible subject matter, the machine-or-transformation test determined patent eligibility based on the claimed subject matter either being implemented by a particular machine specifically tailored for such a purpose or on the claimed matter's ability to transform an article from one form to another.<sup>2</sup> *Bilski* replaced this test with a case-by-case factual inquiry under the patent policy rationale that applying a hard and fast rule, the machine-or-transformation test, was arbitrarily restricting patentable subject matter.<sup>3</sup> Now, courts have been tasked with applying the individual facts of each case challenging 35 U.S.C. § 101 to the patent eligibility trio: *Benson*,<sup>4</sup> *Flook*,<sup>5</sup> and *Diehr*.<sup>6</sup> However, the machine-or-transformation test is still a factor to be considered by the courts.<sup>7</sup> Meaning, if an invention satisfies the machine-or-transformation test, it qualifies as patentable subject matter.

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\* B.S., University of Missouri 2008; J.D. Candidate, University of Missouri School of Law 2012; Associate Member, *Missouri Law Review*, 2011-12. I would like to thank Professor Dennis Crouch for inspiring this Note. I would also like to thank Clayton Thompson, Kyle Gottuso, and Joseph Blumberg, without whose help this Note would never have come to fruition.

1. 130 S. Ct. 3218, 3227 (2010).

2. *In re Bilski*, 545 F.3d 943, 960 (Fed. Cir. 2008) (en banc), *aff'd sub nom. Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

3. *Bilski*, 130 S. Ct. at 3229-30.

4. *Gottschalk v. Benson*, 409 U.S. 63 (1972).

5. *Parker v. Flook*, 437 U.S. 584 (1978).

6. *Diamond v. Diehr*, 450 U.S. 175 (1981).

7. *Bilski*, 130 S. Ct. at 3231.

However, failing the test is not per se dispositive of failing to meet the requirements of 35 U.S.C. § 101.

The recent case of *Classen Immunotherapies, Inc. v. Biogen IDEC*<sup>8</sup> presented the Federal Circuit with one of its first opportunities to apply the new post-*Bilski* patent eligibility standard. Unfortunately, the post-*Bilski* standard appeared difficult to apply – potentially because the cases making up the patent eligibility trio are inherently inconsistent with one another. Regardless, *Classen Immunotherapies* does not bode well for the future of 35 U.S.C. § 101 cases, as it showcased the continued difficulties the Federal Circuit is having with patent-eligible subject matter and, surprisingly, showed the frustrations that Chief Judge Randall Rader feels toward 35 U.S.C. § 101 challenges in general.<sup>9</sup> Writing separately, Chief Judge Rader made a point of stressing the pitfalls of the Federal Circuit entertaining subject matter eligibility challenges and forewarned of the implications this and all 35 U.S.C. § 101 challenges have on the future of claim drafting.<sup>10</sup>

This Note will examine whether the cases comprising the eligible subject matter trio are inherently inconsistent. In looking at this issue, this Note will ask if *Classen Immunotherapies* can be reconciled with the patent eligibility trio, or if both the case and Judge Rader's concerns could have been dealt with more effectively by applying 35 U.S.C. § 101 as a last resort, and instead determining patent eligibility via 35 U.S.C. §§ 102, 103, and 112. It is fundamentally more difficult, expensive, and time consuming to ascertain which category of patentable subject matter a claimed invention falls into, or if the claimed matter satisfies the patent eligibility trio, than it is to determine whether the requirements of novelty, obviousness, and enablement have been satisfied. This is especially so given the creative means with which practitioners will draft claims to "satisfy" the requirements.

## II. FACTS & HOLDING

*Classen Immunotherapies, Inc. v. Biogen IDEC* involved three patents covering inventions created by Dr. John Barthelow Classen and assigned to his company, Classen Immunotherapies, Inc. (Plaintiff).<sup>11</sup> Specifically, the patents included United States Patent Nos. 6,638,739 ('739), 6,420,139 ('139), and 5,723,283 ('283).<sup>12</sup> Dr. Classen determined that the schedule used to immunize infants against infectious diseases could affect the later onset of chronic immune-mediated disorders such as cancer and diabetes.<sup>13</sup>

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8. 659 F.3d 1057 (Fed. Cir. 2011).

9. *Id.* at 1073-75 (Rader, C.J., offering additional views).

10. *Id.*

11. *Id.* at 1060 (majority opinion).

12. *Id.*

13. *Id.*

The three patents state that . . . when one or more immunogens . . . is first administered at an early age (typically prior to 42 days of age), it can substantially decrease the incidence, frequency, prevalence or severity of, or prevent, at least one chronic immune mediated disorder, and/or a surrogate marker thereof.<sup>14</sup>

As a result, the scope of Dr. Classen's three assigned patents claimed that possible immunization schedules were to be screened and compared, the lowest risk schedule identified, and the vaccine administered on the schedule that offered the lowest occurrence of chronic disease.<sup>15</sup>

Plaintiff alleged that its patents, specifically '139 and '739, were infringed when a healthcare provider reviewed the "relevant literature" and selected a particular immunization schedule that was of lower risk regarding the onset of immune mediated disorders and followed said schedule when performing immunizations.<sup>16</sup> Plaintiff also claimed that even if no change to the schedule was made, both '139 and '739 were infringed when the relevant literature was reviewed.<sup>17</sup> Finally, Plaintiff claimed that the '283 patent was infringed when the relevant literature was reviewed, regardless of whether the one reviewing the literature is "a producer of vaccines, a health care provider, or a concerned parent," and in spite of the fact that no immunizations were performed in accordance with the relevant literature.<sup>18</sup>

The alleged infringers, Biogen IDEC, GlaxoSmithkline, Merck & Co., Inc., et al. (Defendants), moved for summary judgment at the district court level, claiming, among other defenses, that Plaintiff's patents failed to meet the requirements of statutory patentable subject matter under 35 U.S.C. § 101.<sup>19</sup> Because Plaintiff's patents claimed a correlation between vaccination schedules and the incidence of immune mediated disorders, the patents claimed a natural phenomenon; Defendants asserted that Plaintiff's patents merely covered an abstract idea.<sup>20</sup> The court determined that Plaintiff's three patents were claiming merely abstract ideas, as "thinking about" the risk of potential vaccinations was a mental process and thus not patentable.<sup>21</sup> Plaintiff appealed the decision to the Court of Appeals for the Federal Circuit, and the Federal Circuit affirmed, applying the holding of *In re Bilski* that without a machine or transformation of matter, the patents covered ineligible subject matter.<sup>22</sup>

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14. *Id.*

15. *Id.* at 1060-61.

16. *Id.* at 1061-62.

17. *Id.*

18. *Id.* at 1061.

19. *Id.* at 1062.

20. *See id.* at 1063.

21. *Id.* at 1062-63.

22. *Id.*

Plaintiff applied for a writ of certiorari, which was granted by the United States Supreme Court.<sup>23</sup> However, after the outcome in *Bilski v. Kappos*, in 2010 the Supreme Court remanded the case to the Court of Appeals for the Federal Circuit, as the decision in *Bilski v. Kappos* eliminated the strict machine-or-transformation test as the exclusive test for patentability.<sup>24</sup> On remand, Defendants argued that Plaintiff's patents encompassed merely reading already published materials, that the comparing of immunization schedules and selecting the lowest risk schedule was something performed exclusively in the mind, and, citing *Parker v. Flook*, that the immunization itself, no matter how conventional, cannot turn an unpatentable principle into a patentable process.<sup>25</sup> Plaintiff rebutted Defendants' contentions and argued that Dr. Classen had discovered a new method of immunizing infants that lowered the risk of future immune mediated disease and that even though particular claims, perhaps, were overbroad, others were directed specifically toward "specific immunogens, specific immunization schedules, and specific immune-mediated disorders."<sup>26</sup> Thus, Plaintiff argued, the methods were not "abstract."<sup>27</sup>

The Federal Circuit, on remand, referenced several cases in making its final determination. Citing to *Bilski v. Kappos*, the Federal Circuit relied on the reiteration of the Supreme Court that barring patent eligibility under 35 U.S.C. § 101 should be done sparingly, as § 101 is only a threshold test.<sup>28</sup> However, the Federal Circuit was careful to note Justice Stevens' concurrence in *Bilski* that "[t]he Court, in sum, never provides a satisfying account of what constitutes an unpatentable abstract idea."<sup>29</sup> Also, relying upon *In re Prater*, the court recognized that the mere inclusion of a mental process within a patent was not, itself, fatal.<sup>30</sup> But, the Court in *Bilski* reaffirmed "the prohibition against patenting abstract ideas," and that merely "attempting to limit the use of a formula to a particular technological" field or "adding insignificant post-solution activity" cannot circumvent the bar of patenting abstract ideas.<sup>31</sup>

Citing to *Association for Molecular Pathology v. United States Patent and Trademark Office*, the Federal Circuit distinguished '283 from '139 and '739, in that the '283 patent failed to contain a claimed immunization step.<sup>32</sup>

23. *Classen Immunotherapies, Inc. v. Biogen IDEC*, 130 S. Ct. 3541 (2010).

24. *Classen Immunotherapies, Inc.*, 659 F.3d at 1063.

25. *Id.* (citing *Parker v. Flook*, 467 U.S. 584, 590 (1978)).

26. *Id.*

27. *Id.*

28. *Id.* at 1064.

29. *Id.* at 1065 (alteration in original) (quoting *Bilski v. Kappos*, 130 S. Ct. 3218, 3236 (2010) (Stevens, J., concurring)).

30. *Id.*

31. *Id.* at 1067 (internal quotation marks omitted).

32. *Id.* (citing *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1359 (Fed. Cir. 2011)).

“[M]ethods that simply collect and compare data, without applying the data in a step of the overall method, may fail to traverse the §101 filter.”<sup>33</sup> Although admitting the lack of a tangible definition of an “abstract idea,” the Federal Circuit held that ‘283 merely invited a reader to think that the immunization step of ‘139 and ‘739 necessarily pulled the claims of those patents “through the coarse filter” of 35 U.S.C. § 101.<sup>34</sup> Thus, post-*Bilski*, the rigid machine-or-transformation test has been replaced by a necessary case-by-case inquiry into whether a patent contains 35 U.S.C. § 101 patentable subject matter. The Federal Circuit, relying on *Bilski*, agreed that a blanket ban of certain, non-codified subject matter was a great disservice to the patent world.<sup>35</sup>

### III. LEGAL BACKGROUND

The United States Constitution provides Congress with the power to establish and regulate a national patent system through the patent clause, which states that Congress shall have the power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”<sup>36</sup> Passed pursuant to the Patent Act of 1952, 35 U.S.C. § 101 states “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”<sup>37</sup> Congress intended these terms to be expansive in order to ensure ingenuity had “liberal encouragement.”<sup>38</sup> Not included within the statutory construction are three judicially created exclusions to patentable subject matter: “laws of nature, physical phenomena, and abstract ideas.”<sup>39</sup> The exclusion of this matter exists because it has always been the parlance of all men and cannot be excluded from them.<sup>40</sup> However, with such broad statutory wording, the courts had to quickly get to work fleshing out what exactly qualified or did not qualify as patentable subject matter under 35 U.S.C. § 101. As this Note will show, the approaches of the various courts are quite divergent.

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33. *Id.*

34. *Id.* at 1067-68.

35. *See id.*

36. U.S. CONST. art. I, § 8, cl. 8.

37. 35 U.S.C. § 101 (2006).

38. *Diamond v. Chakrabarty*, 447 U.S. 303, 308-09 (1980) (quoting Thomas Jefferson) (internal quotation marks omitted). The language of 35 U.S.C. §101 has roots dating back to the original Patent Act of 1793. *See id.*

39. *Id.* at 309.

40. *See Parker v. Flook*, 437 U.S. 584, 589 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *O’Reilly v. Morse*, 56 U.S. 62, 111 (1853); *Le Roy v. Tatham*, 55 U.S. 156, 174-75 (1852).

### A. *No Patents for Abstract Ideas?*

One of the first cases to address the issue of whether abstract ideas fell within the patent purview was in 1852 in *Le Roy v. Tatham*.<sup>41</sup> The Tathams (Defendants on appeal) were the assignees of a patent for “improvements upon, and additions to, the machinery used for manufacturing pipes and tubes from lead or tin, or an alloy of soft metals capable of being forced, by great pressure, from out of a receiver, through or between apertures, dies, and cores, when in a set or solid state.”<sup>42</sup> Defendants brought a patent infringement case in the Southern District of New York, basing their claim upon Le Roy (Plaintiff on appeal) manufacturing two thousand tons of lead pipe.<sup>43</sup> The Southern District found for the Tathams, stating that Le Roy manufactured 711,551 pounds of infringing pipe and that the Tathams were entitled to money damages.<sup>44</sup>

On appeal, Plaintiffs argued the jury instruction, “that the originality of the invention did not consist in the novelty of the machinery, but in bringing a newly discovered principle into practical application” was clearly erroneous.<sup>45</sup> The Supreme Court agreed, stating: “We think there was error in the above instruction, that the novelty of the combination of the machinery, specifically claimed by the patentees as their invention, was not a material fact for the jury, and that on that ground, the judgment must be reversed.”<sup>46</sup> In defining “principle” the Supreme Court noted

[t]he word *principle* is used . . . in adjudications of courts, with such a want of precision in its application, as to mislead. It is admitted, that a principle is not patentable. A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.<sup>47</sup>

The Court held that the invention, in itself, was not in discovering the abstract principle, which is open to all, but in applying the principle to a useful object.<sup>48</sup>

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41. 55 U.S. 156.

42. *Id.* at 172.

43. *Id.* at 171-72.

44. *Tatham v. Le Roy*, 23 F. Cas. 709, 716 (S.D.N.Y. 1852), *rev'd*, 55 U.S. 156.

45. *Tatham*, 55 U.S. at 176-77.

46. *Id.* at 177.

47. *Id.* at 174-75.

48. *Id.* at 175.

B. Chakrabarty & State Street: *The Pre-Bilski  
Standard Applied by the Federal Circuit*

In *Diamond v. Chakrabarty*, the Supreme Court confronted the issue of whether a man-made, genetically engineered bacterium (*Pseudomonas*) capable of breaking down crude oil was patentable subject matter under 35 U.S.C. § 101.<sup>49</sup> The patent examiner rejected Chakrabarty's claims relating to the bacterium itself on the grounds that micro organisms are a product of nature and that living things are not patentable subject matter.<sup>50</sup> Chakrabarty appealed to the Patent Office Board of Appeals which affirmed the patent examiner on the ground that 35 U.S.C. § 101 was not meant to cover living things.<sup>51</sup> The Court of Customs and Patent Appeals reversed, citing the holding in *In re Bergy*, which stated, "the fact that microorganisms . . . are alive . . . [is] without legal significance' for purposes of the patent law."<sup>52</sup>

The Supreme Court granted certiorari to determine whether Chakrabarty's bacterium constituted a "manufacture" or "composition of matter" within 35 U.S.C. § 101.<sup>53</sup> Looking at the plain meaning of the statute and a lack of contrary legislative history, the Court determined that "[i]n choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope."<sup>54</sup> Ultimately, the Court held that "Congress intended statutory subject matter to 'include anything under the sun that is made by man,'"<sup>55</sup> and since Chakrabarty's bacterium was not naturally occurring, but was instead altered by man, it fell plainly within patentable subject matter.<sup>56</sup>

Eighteen years later, in 1998, the Court of Appeals for the Federal Circuit further refined the standard to be applied when evaluating 35 U.S.C. § 101 patentable subject matter in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*<sup>57</sup> In *State Street*, the Federal Circuit was tasked with determining whether a claimed invention, which allowed its operator "to monitor and record the financial information flow and make all calculations necessary for maintaining a partner fund financial services configuration," satisfied 35 U.S.C. § 101 patentable subject matter.<sup>58</sup> The Federal Circuit

49. *Diamond v. Chakrabarty*, 447 U.S. 303, 305-06 (1980).

50. *Id.* at 306.

51. *Id.*

52. *Id.* (alteration in original) (quoting *In re Bergy*, 563 F.2d 1031, 1038 (1977)).

53. *Id.* at 307.

54. *Id.* at 308.

55. *Id.* at 309 (citing S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952)).

56. *See id.*

57. 149 F.3d 1368 (Fed. Cir. 1998), *abrogated by In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), *aff'd sub nom. Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

58. *Id.* at 1371.



determined that Signature Financial Group's patent, as claimed, consisted of "a machine, namely, a data processing system for managing a financial services configuration of a portfolio established as a partnership."<sup>59</sup>

The Federal Circuit again noted that the plain and unambiguous language of 35 U.S.C. § 101 provides that any "process, machine, manufacture, or composition of matter . . . may obtain a patent."<sup>60</sup> Since the patent in question claimed a machine, or at the very least a process implemented by a machine, the court determined it was patentable subject matter.<sup>61</sup> However, the analysis did not stop there because, although the patent fell within 35 U.S.C. § 101, it could still fail under the judicial exceptions to patentable subject matter: laws of nature, physical phenomena, and abstract ideas.<sup>62</sup> The question then became whether the claimed invention, specifically its mathematical algorithm component, was unpatentable due to being an abstract idea.<sup>63</sup> Mathematical algorithms are not patentable when "they are merely abstract ideas constituting disembodied concepts or truths that are not 'useful.'"<sup>64</sup> However, "the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces 'a useful, concrete and tangible result.'"<sup>65</sup> The pre-*Bilski* standard applied by the Federal Circuit was quite expansive in its statutory interpretation, allowing for anything under the sun made by man to fall within patentable subject matter, provided that the claimed matter created some tangible result.

### C. *The Machine or Transformation Test*: In re *Bilski*

*In re Bilski* was an appeal from the Board of Patent Appeals and Interferences' rejection of all eleven claims of Bernard Bilski and Rand Warsaw's (*Bilski*) patent application.<sup>66</sup> Bilski appealed the Board's decision that the patent application failed to fall within 35 U.S.C. § 101 patentable subject matter.<sup>67</sup> The Board summarized the claims of the invention as embodying "a method of hedging risk in the field of commodities trading."<sup>68</sup> Ultimately, the Board held that because Bilski's claimed invention "did not produce a 'useful, concrete and tangible result,'" the process necessarily was an abstract

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59. *Id.* at 1372.

60. *Id.*

61. *Id.*

62. *Id.* at 1373 (citing *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)).

63. *Id.*

64. *Id.*

65. *Id.*

66. 545 F.3d 943, 949 (Fed. Cir. 2008) (en banc), *aff'd sub nom.* *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

67. *Id.*

68. *Id.*

idea that would remove risk hedging from being performed by any person or machine in any field.<sup>69</sup>

The Federal Circuit reviewed the issue of whether Bilski's claimed invention encompassed a fundamental process (abstract idea) or a mental process.<sup>70</sup> In looking to the Supreme Court's decision in *Diamond v. Diehr*, the Federal Circuit noted that "while a claim drawn to a fundamental principle is unpatentable, 'an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.'"<sup>71</sup> But in order to determine whether Bilski's claimed process was narrowly tailored enough to encompass only one application, the Federal Circuit looked to the Supreme Court's definitive test: (1) is the claimed subject matter "tied to a particular machine or apparatus," or (2) does it "transform[] a particular article into a different state or thing?"<sup>72</sup>

The Federal Circuit viewed the machine-or-transformation test as a clue to determining whether a claimed invention was narrowly tailored enough such that, as claimed, it would not preempt substantially all uses of a fundamental principle, rendering it unpatentable.<sup>73</sup> In essence, the use of a machine-or-transformation must limit the claim's scope in a meaningful way and not merely act as post-solution activity in order to qualify as patentable subject matter.<sup>74</sup> Also, the transformation of an article "must be central to the purpose of the claimed process" in order to qualify for patent eligibility.<sup>75</sup> However, although *In re Bilski* was paramount in reiterating the machine-or-transformation test, as distilled from prior Supreme Court jurisprudence, it was equally important with regard to the patent eligibility tests it rejected.<sup>76</sup>

First, the Federal Circuit rejected the Freeman-Walter-Abele test.<sup>77</sup> Second, the Federal Circuit struck down portions of the *State Street* decision;<sup>78</sup>

69. *See id.* at 950.

70. *Id.* at 952.

71. *Id.* at 953 (quoting *Diamond v. Diehr*, 450 U.S. 175, 187 (1981)). The Court in *Diehr* thus drew a distinction between those claims that "seek to pre-empt the use of" a fundamental principle, on the one hand, and claims that seek only to foreclose others from using a particular "application" of that fundamental principle, on the other. *Diehr*, 450 U.S. at 187.

72. *In re Bilski*, 545 F.3d at 954 (citing *Diehr*, 450 U.S. at 182; *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 788 (1876)).

73. *Id.*

74. *Id.* at 961-62.

75. *Id.* at 962.

76. *Id.* at 958-59.

77. *Id.* ("[The test] appears to conflict with the Supreme Court's proscription against dissecting a claim and evaluating patent-eligibility on the basis of individual limitations."). The Freeman-Walter-Abele test allowed process and method claims for inventions that were implemented by software, provided that the claims did not preempt unpatentable subject matter such as laws of nature or pure mathematical algorithms. *See In re Abele*, 684 F.2d 902, 907-08 (C.C.P.A. 1982), *abrogated by In*

specifically, it rejected the useful, concrete, and tangible result test.<sup>79</sup> Further, the Federal Circuit stated that any of its prior decisions that relied upon either the Freeman-Walter-Abele test<sup>80</sup> or the useful, concrete, and tangible result test should no longer be followed.<sup>81</sup> Next, the Federal Circuit struck down the technological arts test<sup>82</sup> and physical steps test.<sup>83</sup> Finally, the Federal Circuit upheld part of its decision in *State Street* – the rejection of a blanket exclusion for business method patents.<sup>84</sup> Although this was a major shift in patent eligibility, the machine-or-transformation test would not last long.

#### D. The Patent Eligibility Trio: Benson, Flook, and Diehr

The most recent shift in patent-eligible subject matter came in the case of *Bilski v. Kappos*.<sup>85</sup> The Court in *Bilski* faced three questions on appeal from the Federal Circuit's case of *In re Bilski*: may an invention meet the criteria of 35 U.S.C. § 101 if “(1) it is not tied to a machine and does not transform an article; (2) it involves a method of conducting business; and (3) it is merely an abstract idea?”<sup>86</sup> The Federal Circuit rejected its prior test for determining whether a claimed invention was a patentable process under 35 U.S.C. § 101 – whether it produces a “useful, concrete and tangible re-

*re Bilski*, 545 F.3d 943 (Fed. Cir. 2010); *In re Walter*, 618 F.2d 758, 765-67 (C.C.P.A. 1980), *abrogated by In re Bilski*, 545 F.3d 943; *In re Freeman*, 573 F.2d 1237, 1245-47 (C.C.P.A. 1978), *abrogated by In re Bilski*, 545 F.3d 94..

78. *In re Bilski*, 545 F.3d at 959-60.

79. *Id.* (“[W]hile looking for ‘a useful, concrete and tangible result’ may in many instances provide useful indications of whether a claim is drawn to a fundamental principle or a practical application of such a principle, that inquiry is insufficient to determine whether a claim is patent-eligible under [35 U.S.C. § 101]. And it was certainly never intended to supplant the Supreme Court’s test.”).

80. *Id.* at 959 n.17.

81. *Id.* at 960 n.19.

82. *Id.* (The technological arts test was noted as having never been adopted by the Supreme Court, Federal Circuit, or any other court); *see Ex parte Lundgren*, No. 2003-2088, 76 U.S.P.Q.2d 1385, 1387-88 (B.P.A.I. Sept. 28, 2005) (noting that the technological arts test should not act as a bar to patentability under 35 U.S.C. § 101).

83. *In re Bilski*, 545 F.3d at 960-61 (“[A] claim that recites ‘physical steps’ but neither recites a particular machine or apparatus, nor transforms any article into a different state or thing, is not drawn to patent-eligible subject matter. Conversely, a claim that purportedly lacks any ‘physical steps’ but is still tied to a machine or achieves an eligible transformation passes muster under [35 U.S.C. § 101].”).

84. *Id.* at 960 (The Federal Circuit noted that all process claims (including business method claims) are to be evaluated as any other process or method claim would be.).

85. 130 S. Ct. 3218 (2010).

86. *Id.* at 3223.

sult.”<sup>87</sup> The Supreme Court granted certiorari to address those questions and to evaluate the new test handed down by the Federal Circuit.<sup>88</sup>

At issue in *Bilski* was a method patent for hedging risk in the commodities trading industry.<sup>89</sup> However, petitioner’s main claims, claims 1 and 4, merely defined the theory of hedging loss and implemented the theory into an algorithm.<sup>90</sup> Justice Kennedy, writing for the majority, noted that the petitioner was attempting “to patent both the concept of hedging risk and the application” of hedging risk to the energy market.<sup>91</sup> Justice Kennedy stressed the importance of not “adopting categorical rules that might have wide-ranging and unforeseen impacts.”<sup>92</sup> As such, the Court struck down the machine-or-transformation test as the sole test for patent-eligible subject matter<sup>93</sup> and instituted a case-by-case analysis in light of the Court’s previous decisions: *Benson*,<sup>94</sup> *Flook*,<sup>95</sup> and *Diehr*.<sup>96</sup>

The Court in *Gottschalk v. Benson* was faced with determining whether an algorithm, the purpose of which was to convert binary-coded decimal numerals into pure binary code, was patentable subject matter under 35 U.S.C. § 101.<sup>97</sup> Claim 8 of the patent in question required, as the Court noted, an operative device (reentrant shift register) to perform the algorithm, but said algorithm was found to be able to be performed on existing digital computers or even by humans without a computer.<sup>98</sup> The Court found that although claim 8 required a reentrant shift register, it was not limited solely to that piece of hardware and as a result was not patentable subject matter.<sup>99</sup> From a public policy standpoint, that would have allowed for the patenting of a mathematical algorithm, which is an abstract idea barred by 35 U.S.C. § 101.<sup>100</sup>

The Supreme Court in *Parker v. Flook* was faced with a claimed mathematical equation that was alleged to be an improvement in calculating alarm limit values.<sup>101</sup> In much the same vein as the Court in *Benson*, the Court in *Flook* noted that the claimed mathematical equation could be performed

87. *In re Bilski*, 545 F.3d at 959-60 & n.19.

88. *See Bilski*, 130 S. Ct. at 3224-25.

89. *Id.* at 3223.

90. *Id.*

91. *Id.* at 3229.

92. *Id.*

93. *Id.* at 3226 (“The Court of Appeals incorrectly concluded that this Court has endorsed the machine-or-transformation test as the exclusive test.”).

94. *Gottschalk v. Benson*, 409 U.S. 63 (1972).

95. *Parker v. Flook*, 437 U.S. 584 (1978).

96. *Diamond v. Diehr*, 450 U.S. 175 (1981).

97. *Benson*, 409 U.S. at 64.

98. *See id.* at 67, app. at 73.

99. *Id.* at 71-72, app. at 73.

100. *Id.* at 71-72.

101. 437 U.S. 584, 586 (1978).

without an apparatus in the human mind.<sup>102</sup> Further, the patent specification at issue failed to disclose any apparatus or means for adjusting an alarm system.<sup>103</sup> The Court in *Flook* stated that “[w]hile a scientific truth, or the mathematical expression of it, is not [a] patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be[.]”<sup>104</sup> However, the Court warned that insignificant post-solution activity to an otherwise unpatentable process cannot transform the unpatentable process into a patentable process.<sup>105</sup>

The Supreme Court granted certiorari in *Diamond v. Diehr* in order to clarify its prior precedent regarding process patents under 35 U.S.C. § 101.<sup>106</sup> The patent application at issue in *Diehr* contained – as did the aforementioned patent applications – an algorithm which was to be performed via a computer.<sup>107</sup> However, the algorithm in *Diehr* was tied specifically to a method for molding raw rubber into precision products via a molding press, which was temperature-controlled by said algorithm.<sup>108</sup> The Court ultimately upheld the patent under two rationales: first, processes that involve transformation of an article into a different state or thing are patentable under 35 U.S.C. § 101;<sup>109</sup> second, because claims that are drawn to otherwise statutory subject matter do not become non-statutory simply by using a mathematical formula or computers to perform several of the steps.<sup>110</sup> The Court emphasized the need to consider the claimed invention as a whole: “an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.”<sup>111</sup> Therefore, under *Diehr*, a claimed process may fall within patentable subject matter provided that the claimed steps, when performed on an object, elicit a change. But, under *Benson*, if a process is not tied to a particular machine, then the claimed process will fail to fall within patentable subject matter. And, if the claimed process contains a mathematical algorithm, then the algorithm must be integrated to such a degree that removing it would destroy the process’s functionality.

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102. *Id.*

103. *Id.*

104. *Id.* at 591 (quoting *Mackay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 U.S. 86, 94 (1939)).

105. *Id.* at 590.

106. *Diamond v. Diehr*, 450 U.S. 175 (1981).

107. *Id.* at 177.

108. *Id.* at 178-79.

109. *Id.* at 184.

110. *Id.* at 187.

111. *Id.*

## IV. INSTANT DECISION

In the instant case, the court found that the '283 patent failed to meet or exceed the threshold of patentable subject matter under 35 U.S.C. § 101, as it failed to claim more than the mental processes of reading the relevant literature and ascertaining the lowest risk immunization schedule thereafter.<sup>112</sup> According to the court, patents '139 and '739 were upheld as containing patentable subject matter, even though they required the same mental process as patent '283.<sup>113</sup> The Federal Circuit held them patentable because, in light of *Bilski*, both patents required the additional step of performing the immunization.<sup>114</sup>

The court noted that after *Diamond v. Diehr*, “[i]t is now commonplace that an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.”<sup>115</sup> This principle went on to influence the Supreme Court in *Bilski v. Kappos*, where the Court reiterated that 35 U.S.C. § 101 was only a threshold test for patent-eligibility.<sup>116</sup> The Federal Circuit took that into account in *In re Prater*, which noted the precedent that, under 35 U.S.C. § 101, there could be no rigid rule of ineligibility for a mental step, but that such steps had to be evaluated on a spectrum from purely mental to purely physical and evaluated case-by-case.<sup>117</sup>

The majority in the instant case also noted that Justice Stevens in concurrence found that the Supreme Court in *Bilski* “never provides a satisfying account of what constitutes an unpatentable abstract idea.”<sup>118</sup> The difficulty of defining what exactly constituted an abstract idea was wrestled with previously in *Research Corp. Technologies, Inc. v. Microsoft Corp.*, where the Federal Circuit stated “this court also will not presume to define ‘abstract’ beyond the recognition that this disqualifying characteristic should exhibit itself so manifestly as to override the broad statutory categories of eligible subject matter.”<sup>119</sup> The Federal Circuit went on to explain in *Research Corp.* that the claims in a patent must be considered in their totality when determining patent eligibility, and again the court reiterated that 35 U.S.C. § 101 is a threshold test and not the ultimate test of patentability.<sup>120</sup>

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112. See *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1067 (Fed. Cir. 2011).

113. *Id.* at 1067-68.

114. *Id.* at 1068.

115. *Id.* at 1064 (quoting *Diehr*, 450 U.S. at 187).

116. See 130 S. Ct. 3218, 3225 (2010).

117. *Classen Immunotherapies, Inc.*, 659 F.3d at 1065 (citing *In re Prater*, 415 F.2d 1393, 1402 n.22 (C.C.P.A. 1969)).

118. *Id.* (quoting *Bilski*, 130 S. Ct. at 3236 (Stevens, J., concurring)).

119. *Id.* (quoting *Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 868 (Fed. Cir. 2010)).

120. *Id.* at 1065-66.

The majority, in the instant case, thus found that the claims of patent '139 and '739 included a physical step of performing an immunization on a determined schedule and as such were directed to a specific, tangible application in accordance with its prior decision in *Research Corp.* and the guidance set forth in *Bilski v. Kappos* that “[r]ather than adopting categorical rules that might have wide-ranging and unforeseen impacts,” exclusions from patent-eligibility should be applied narrowly.<sup>121</sup> The court ultimately held that the subject matter of patents '139 and '739 traversed the coarse eligibility filter of 35 U.S.C. § 101.<sup>122</sup> The court also distinguished patent '283 from '139 and '739 by analogizing it to *Association for Molecular Pathology v. United States Patent and Trademark Office*, which determined that methods that merely collect data and compare data, without applying the data in a step of the method itself, may fail to meet 35 U.S.C. § 101.<sup>123</sup> This court, when taking *Association for Molecular Pathology* into account, determined that without a specific application, patent '283 claimed only a purely mental process and was thus an unpatentable abstract idea.<sup>124</sup>

## V. COMMENT

Both the Federal Circuit and the Supreme Court have struggled with 35 U.S.C. § 101. Both courts have gone back and forth establishing and overruling tests to determine patent-eligible subject matter. Not surprisingly, the jurisprudence surrounding patent-eligible subject matter is scattered and contradictory, and as a result, it is quite possible that the patent eligibility trio is inherently contradictory. This Note will next address the inherent contradiction of the patent eligibility trio in isolation and as applied to *Classen Immunotherapies, Inc. v. Biogen IDEC*, discuss the pitfalls of the current system, and then offer a potentially better way of evaluating patent eligibility with other statutes already in place.

### A. *The Inherent Conflict of the Patent Eligibility Trio*

It is difficult to understand why the Supreme Court would choose to revert back to thirty-plus-year-old case law in order to evaluate patentable subject matter in light of the fact that the chosen case law dealt with incredibly outdated technology. Further, in order to qualify as eligible subject matter, one's claimed invention must be reconciled with the inherently inconsistent trio of *Benson*, *Flook*, and *Diehr*. Commentators have argued that the lack of rationality and predictability in what constitutes patent-eligible subject matter

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121. *Id.* at 1066 (alteration in original) (quoting *Bilski*, 130 S. Ct. at 3229).

122. *Id.*

123. *Id.* at 1067 (citing *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1356 (Fed. Cir. 2011)).

124. *See id.* at 1067-68.

stems from the ambiguous holding in *Benson*.<sup>125</sup> *Flook* and *Diehr* were the two most influential cases that followed the confusion handed down by *Benson*.<sup>126</sup>

*Parker v. Flook* incorrectly framed the issue of patentable subject matter because of the poor analysis in *Benson*.<sup>127</sup> The claimed subject matter in *Flook* involved an algorithm, but the Court confused the subject matter as a method with post-solution applications.<sup>128</sup> In light of *Benson*'s confusing holding, the Court reasoned that the claimed algorithm was prior art and not patentable, as it was a well known mathematical principle.<sup>129</sup> Because of *Benson*, the Court in *Flook* focused almost exclusively on a single claim – the claimed algorithm.<sup>130</sup> *Benson*'s broad equation of an algorithm to a mathematical formula brought *Flook*'s mathematical formula within the categorical restriction of algorithms.<sup>131</sup> Ironically, the claimed formula was merely one step in an algorithm.<sup>132</sup> Instead of choosing to part with *Benson*, the Court followed it – even though what constituted an algorithm was less than clear.<sup>133</sup>

The next case to deal with *Benson*'s confusion was *Diamond v. Diehr*. *Diehr* also dealt with a claimed mathematical formula – a formula necessary in evaluating temperatures for rubber curing.<sup>134</sup> The majority held that the claimed subject matter was for a typical industrial process and thus clearly fell within patentable subject matter.<sup>135</sup> However, *Benson* and *Flook* had created so much confusion regarding what constituted a patentable process that coming to a reasoned decision was not possible.<sup>136</sup> The Court chose to avoid *Flook*'s “prior art” language and yet purported to confirm its holding.<sup>137</sup> Justice Stevens, who authored the *Flook* opinion, even had a difficult time reconciling the trio – rather than following Supreme Court jurisprudence

125. See, e.g., Donald S. Chisum, *The Patentability of Algorithms*, 47 U. PITT. L. REV. 959, 992 (1986).

126. See *id.*

127. *Id.* at 993 (“The Court treated the claimed subject matter as though it were a method, one step of which was an ‘algorithm or mathematical formula’ and other steps of which were ‘conventional post-solution applications’ of the formula.”).

128. *Id.*

129. *Id.*

130. *Id.* at 994.

131. *Id.*

132. *Id.*

133. *Id.* at 994-95 (“[T]he Court left matters in confusion – what is an ‘algorithm’? how do algorithms differ from other, patentable processes? It also added an aberrational corollary – treatment of what an inventor had discovered as though it were known prior art. That aberration was so basically antithetical to patent law principles that it would have to be purged.”).

134. *Id.* at 995.

135. *Id.* at 997.

136. *Id.*

137. *Id.*



alone, he chose to follow lower court decisions regarding mental steps in his *Diehr* dissent.<sup>138</sup>

### B. Pitfalls of the Current System for Determining Patent Eligibility

In its decision in *Classen Immunotherapies, Inc. v. Biogen IDEC*, the Federal Circuit was tasked with applying the test handed down in *Bilski v. Kappos* to the under-theorized doctrine of excluding abstract ideas from the scope of patentable subject matter.<sup>139</sup> Though the court's ultimate conclusion in the instant case is not all that surprising, namely that a purely mental process, without more, is an abstract idea,<sup>140</sup> the case still has far-reaching implications. First, this case is one of the most recent in a line of 35 U.S.C. § 101 challenges passing through the Supreme Court, and it was specifically remanded to the Federal Circuit to be decided in light of *Bilski v. Kappos*.<sup>141</sup> Second, and most notably, this is one of the rare cases in which Federal Circuit Chief Judge Randall Rader chose to write separately from the majority about his frustrations with subject matter challenges and their ultimate impact upon the patent system as a whole.<sup>142</sup>

Challenges to patentability under 35 U.S.C. § 101 have a long and storied past. As early as 1839, Justice Story referred to patents as securing the free flow of secrets into the community but warned against granting a patent for a principle in the abstract.<sup>143</sup> Just as Justice Story wrestled with the notion of granting an exclusive right in an abstract idea, courts in the more modern era have wrestled with the advancements in biological sciences and 35 U.S.C. § 101 challenges. For example, in *Diamond v. Diehr*, the Supreme Court stated that “[i]t is now commonplace that an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.”<sup>144</sup> Out of the same line of cases grew *Bilski v. Kappos*, which ultimately held that the machine-or-transformation test should no longer be the sole 35 U.S.C. § 101 filter and replaced it with a case-by-case factual analysis.<sup>145</sup>

The court in *Classen Immunotherapies*, relying on *Bilski*, was left without any tangible definition of “abstract.” Similarly, the court was left without a black-and-white test to apply to 35 U.S.C. § 101 challenge cases. Thus, as

138. *Id.* at 999 (Stevens' dissent in *Diamond v. Diehr* was in stark contrast to the majority opinions in *Flook* and *Benson*, as well as the majority in *Diehr* which relied on authority established in prior Supreme Court opinions.).

139. *See Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1059 (Fed. Cir. 2011).

140. *See id.* at 1067-68.

141. *Id.* at 1059.

142. *See id.* at 1073-75 (Rader, C.J., offering additional views).

143. *See Blanchard v. Sprague*, 3 F. Cas. 648, 650 (C.C.D. Mass. 1839).

144. *Diamond v. Diehr*, 450 U.S. 175, 187 (1981).

145. *See Bilski v. Kappos*, 130 S. Ct. 3218, 3231 (2010).

*Bilski* predicted, the court was forced to go through the patent eligibility trio to determine whether Plaintiff's patents claimed more than an abstract idea.<sup>146</sup> First, from *Bilski* itself, the court was well aware that 35 U.S.C. § 101 was merely a threshold question<sup>147</sup> – namely because subsequent statutes (§§ 102, 103, and 112) deal with the substantive nature of the claimed invention and are more than adequate to parse out inventions that fail to be unanticipated, novel, and fully disclosed.<sup>148</sup> In applying the trio of cases, the *Classen Immunotherapies* court found that patent '283 was invalid as claiming an abstract idea.<sup>149</sup>

The court noted the reliance of the Supreme Court in *Bilski* upon *Diamond v. Diehr*, in which it was stated that a mathematical formula or law of nature could be patented if it is incorporated such as to apply its properties.<sup>150</sup> The court in *Classen Immunotherapies*, also relying upon that language, justified allowing patents '139 and '739 because, although they claimed a natural phenomena (infant inoculations resulting in adult onset immune mediated health problems), they were applied to the physical act of performing an immunization.<sup>151</sup> Thus, because '139 and '739 were tailored to a specific act of immunization, they were determined to move past the 35 U.S.C. § 101 barrier.<sup>152</sup> Similarly, because '283 completely omitted the immunization step and only claimed to be performing research in the relevant literature and ascertaining the safest immunization schedule, it was determined to have failed to meet the requirements of 35 U.S.C. § 101.<sup>153</sup>

What is troubling, however, is the court's failure to follow *Flook*. The Supreme Court in *Flook* made it clear that applying a scientific truth, or the mathematical expression of it, is not a patentable invention unless the claimed invention also contains a novel and useful structure.<sup>154</sup> However, the Court in *Flook* warned that insignificant post-solution activity to an otherwise unpatentable process cannot transform the unpatentable process into a patentable one.<sup>155</sup> Merely reading relevant literature and ascertaining the safest immunization schedule cannot be resurrected into patentable subject matter by attaching the insignificant post-solution activity of performing the immunization. However, the court in *Classen* found that the physical act of performing an immunization was sufficient to lift an abstract concept into the realm of patentable subject matter.<sup>156</sup>

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146. See *Classen Immunotherapies, Inc.*, 659 F.3d 1057.

147. *Id.* at 1064.

148. *Id.* at 1064-65; *id.* at 1073-75 (Rader, C.J., offering additional views).

149. See *id.* at 1067-68 (majority opinion).

150. *Id.* at 1067.

151. *Id.* at 1067-68.

152. *Id.*

153. *Id.*

154. *Parker v. Flook*, 437 U.S. 584, 590-91 (1978).

155. *Id.* at 590.

156. See *Classen Immunotherapies, Inc.*, 659 F.3d at 1067-68.

*Benson*, although mentioned, was not analyzed appropriately. *Benson* stood for the idea that pure algorithms could not be patented, for to do so would preempt the algorithm from all markets – thus allowing for the patenting of an abstract idea.<sup>157</sup> The policy behind granting a patent is rather simple. You give an inventor a monopoly over a method, process, or composition of matter in a very limited field, and in exchange society receives the knowledge. Without the “invention” being tailored to a specific implementation, the idea behind the invention is being taken from all facets of society. Although the court in *Classen Immunotherapies* struck down ‘283 as failing to be more than a purely mental process, it failed to surmise that ‘139 and ‘739 were both merely the mental processes for reading literature and thinking about the literature.<sup>158</sup> Thus, in theory, reading relevant medical literature and thinking about it are now preempted from society as a whole because the addition of post-solution activity (the actual act of performing immunizations) is sufficient to allow an abstract idea to become patentable.

An obviously frustrated Chief Judge Rader surprisingly concurred with the majority that ‘139 and ‘739 were both patentable in light of *Bilski*, *Flook*, *Diehr*, and *Benson*.<sup>159</sup> However, he was quick to condemn the court’s desire to entertain so many 35 U.S.C. § 101 challenges.<sup>160</sup> Rader fears, and rightfully so, that by constantly rewriting the rule as to what qualifies as 35 U.S.C. § 101 patentable subject matter, more claim drafters will be drawn into customizing claim construction to usurp the system.<sup>161</sup> In doing so, the already clogged United States Patent and Trademark Office<sup>162</sup> will be forced to ascertain whether the claims they are examining are being custom tailored to defeat the system rather than looking for actual invention, novelty, and anticipation.

By encouraging claim drafters to draft their claims in a more clever fashion, Rader feels that the already very expensive patent process will become even more expensive.<sup>163</sup> The more expensive it becomes, the fewer inventors there will be who can ultimately afford the process.<sup>164</sup> By barring

157. *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972).

158. *See Classen Immunotherapies, Inc.*, 659 F.3d at 1067-68.

159. *See id.* at 1058.

160. *See id.* at 1073-74 (Rader, C.J., offering additional views).

161. *See id.* at 1074-75.

162. More than “1.2 million non-provisional patent applications are pending examination at the USPTO. Of those, more than 700,000 have not received even a preliminary examination. The backlog is the source of a tremendous amount of bad publicity for the USPTO.” Dennis Crouch & Jason Rantanen, *Unreasonable Patent Applicant Delay and the USPTO Backlog*, PATENTLY-O (July 9, 2010, 3:11 PM), <http://www.patentlyo.com/patent/2010/07/unreasonable-patent-applicant-delay-and-the-uspto-backlog.html>.

163. *See Classen Immunotherapies, Inc.*, 659 F.3d at 1074-75 (Rader, C.J., offering additional views).

164. *See id.*

the majority of inventors, at least financially, from the process, the calculus breaks down. Meaning that incentivizing ingenuity with the monopoly that a patent creates will no longer have the effect it currently does because most inventors will not be able to afford the process in the first place, and even if they can, there is no guarantee that the application will be granted a patent – especially given the nature of the patentable subject matter test, i.e., the case-by-case analysis.<sup>165</sup>

As evident in *Classen Immunotherapies*, the court is still having extreme difficulty in light of the new test. It shows that even the Federal Circuit, a court specifically created to harmonize the regional circuits' patent cases,<sup>166</sup> is unable to apply the standard handed down from the Supreme Court with any kind of convincing rationale. In fact, the court here left its overall analysis vague and couched in weak, pseudo-application of the patent eligibility trio.

### C. An Alternative Solution

As the conflicting case law shows, 35 U.S.C. § 101 is controversial. The interesting part of the dilemma surrounding 35 U.S.C. § 101 is that it does not need to be applied prior to 35 U.S.C. §§ 102, 103, and 112, yet nearly every court chooses to apply the statutes in that order.<sup>167</sup> Why apply the most difficult statute first?

Avoiding 35 U.S.C. § 101 whenever possible makes sense for several reasons. First, 35 U.S.C. §§ 102, 103, and 112 all have extensive bodies of case law – “[a]ny validity requirement that has generated an extensive body of case law will in general be a firmer and less controversial basis for invalidating a patent than the philosophical post-*Bilski* inquiry under § 101.”<sup>168</sup> Also, applying 35 U.S.C. § 101 becomes more and more convoluted because its text has remained largely unchanged for 200 years, and yet the Supreme

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165. “Only 54 percent of patent applications receive approval, according to the patent office.” Julia Feldmeier, *Any Bright Ideas?: How Local Inventors Try to Capitalize on that ‘Aha!’ Moment*, WASH. POST, Mar. 4, 2007, at M01; Gene Quinn, *The Cost of Obtaining a Patent in the US*, IPWATCHDOG (Jan. 28, 2011, 1:14 PM), <http://www.ipwatchdog.com/2011/01/28/the-cost-of-obtaining-patent/id=14668/> (stating that the average cost of filing and ultimately obtaining a patent ranges from \$5000 to more than \$15,000 based on complexity).

166. FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 10 (2003) (“Congress created the Federal Circuit to bring about uniformity of decisions in certain critical areas of the law . . . . To this end, the Federal Circuit was given exclusive jurisdiction over appeals from all district courts in cases which arise under the patent laws.”).

167. Dennis Crouch & Robert P. Merges, *Operating Efficiently Post-Bilski by Ordering Patent Doctrine Decision-Making*, 25 BERKELEY TECH. L.J. 1673, 1679-82 (2010).

168. *Id.* at 1682.

Court continues to read in restrictions that are not within the wording of the statute, but which are based on policy.<sup>169</sup> Second, the patent validity statutes contain a substantial amount of overlap, meaning that a claimed invention could and often does fail under multiple statutory restrictions.<sup>170</sup>

In a study of 1500 recently issued U.S. patents, 84% of the applications that were rejected on patentable subject matter grounds were also rejected on anticipation or obviousness grounds, under 35 U.S.C. §§ 102 and 103.<sup>171</sup> Similarly, in a recent study of 117 published opinions of the Board of Patent Appeals and Interferences, 94% of the claims questioned on patentable subject matter grounds were also rejected on at least one other ground.<sup>172</sup> “This data appears to show an exceptionally high rate of doctrinal overlap and lends credence to the idea that, by initially avoiding subject-matter-eligibility questions, many of those potential issues will be avoided.”<sup>173</sup> Meaning, if you were to apply 35 U.S.C. §§ 102, 103, and 112 prior to 101, 94% of patents that would have failed under 101 would still fail, but the process would be much easier. For example, *Bilski v. Kappos* – which as it stands has created a great deal of controversy<sup>174</sup> – could have been decided under other patent validity doctrines, which would not have had such far reaching consequences. The concept of hedging risk is quite old and more likely than not would have been unpatentable on obviousness or anticipation grounds. Thus the Court could have invalidated *Bilski*’s patent without ever having to invoke the controversial 35 U.S.C. § 101. By avoiding the most vague patent eligibility doctrines, courts will save invaluable time and resources.<sup>175</sup>

## VI. CONCLUSION

The patent world is still adjusting to *Bilski v. Kappos*, in which the machine-or-transformation test was scrapped for a less tangible, and more difficult to apply, case-by-case factual analysis. Even though the Supreme Court in *Bilski* claimed a public policy rationale for dropping the machine-or-

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169. *Id.*

170. *Id.* at 1686.

171. *Id.* (citing Christopher A. Cotropia, Mark Lemley & Bhaven Sampat, *Do Applicant Patent Citations Matter? Implications for the Presumption of Validity* (Stanford Law & Econ., Working Paper No. 401, 2010), available at <http://ssrn.com/abstract=1656568>).

172. *Id.*

173. *Id.* at 1686-87.

174. See John F. Duffy, *Why Business Method Patents*, 63 STAN. L. REV. 1247, 1248 (2011) (“The Supreme Court’s decision in *Bilski* seems unlikely to end all controversy over business method patents. Rather, the debate over business method patents will now turn from the question whether any business methods are patentable to the question how broad the scope of patentable subject matter should be for business methods.”).

175. See Crouch & Merges, *supra* note 167, at 1691.

transformation test,<sup>176</sup> it has made the already difficult task of determining patent eligibility even less clear. The difficulty of the new test hardly makes the public policy rationale worthwhile, as time will show with more and more 35 U.S.C. § 101 litigation.

Without the machine-or-transformation test acting as the sole filter for 35 U.S.C. § 101 patent eligibility, courts are now to apply a trio of patent eligibility cases. Invariably, allowing a plethora of federal district courts to apply a trio of cases will lead to splits in what constitutes patentable subject matter. Thus, more 35 U.S.C. § 101 cases will be awaiting determination in the Federal Circuit. The Supreme Court will then be called on, again, to hand down yet another test with which the Federal Circuit and district courts will be obligated to apply. Obviously fearing that, Judge Rader wrote about his personal frustrations with entertaining 35 U.S.C. § 101 challenges.

By entertaining 35 U.S.C. § 101 challenges, Rader warned, those tasked with drafting patent applications will seek unique ways to usurp the system in order to obtain patents on subject matter outside the scope of 35 U.S.C. § 101.<sup>177</sup> In doing so, more § 101 challenges will be filed – those challenges, coupled with the inevitable challenges filed as a result of the Supreme Court's case-by-case analysis creating divergences across the district courts, will result in an even more expensive, time consuming, and arduous patent system. Until the Supreme Court hands down a rigid test of patentability that can be applied even handedly across the courts, the patent system will continue to fail, miserably.

However, until then, a more pragmatic approach to patent-eligible subject matter needs to be applied. By avoiding a rigid application of the patent validity statutes, namely 35 U.S.C. § 101 prior to §§ 102, 103, and 112, all courts can avoid the problem the Chief Judge Rader fears – clever claim drafting to satisfy § 101.<sup>178</sup> By placing § 101 at the end of the patent validity inquiry, more than 84% of claimed subject matter would fail anyway. Therefore, applying 35 U.S.C. § 101 first is not only a waste of time and money but also breeds additional § 101 challenges and clever claim drafting – problems that commentators and judges alike fear.

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176. See *Bilski v. Kappos*, 130 S. Ct. 3218, 3227 (2010).

177. See *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1074-75 (Fed. Cir. 2011) (Rader, C.J., offering additional views).

178. *Id.*

