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## Is the Federal Circuit Learning its Lessons? A Case Study of BPCIA Preemption

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IS THE FEDERAL CIRCUIT LEARNING  
ITS LESSONS?  
A CASE STUDY OF BPCIA PREEMPTION  
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## I. INTRODUCTION

When Congress created the Federal Circuit, its central purpose was to promote uniformity and certainty of legal doctrines in patent law.<sup>1</sup> However, since its creation in 1982, the Federal Circuit has been the subject of many criticisms.<sup>2</sup> Recently, the Supreme Court has joined in this criticism. In the Federal Circuit's first fifteen years, the Supreme Court stayed largely out of its way and only heard eight cases involving patent issues.<sup>3</sup> However, according to a 2013 study, the Supreme Court has since heard twenty-eight patent cases, and in 80 percent of them has "reversed, vacated, modified, or otherwise seriously questioned the Federal Circuit's approach."<sup>4</sup> This recent Supreme Court involvement in patent law leaves critics to believe the Federal Circuit needs some sort of reform.<sup>5</sup> Specifically, critics, including the Supreme Court, believe that the Federal Circuit adopts specific patent rules that deviate from traditional general legal principles.<sup>6</sup> Additionally, critics believe the Federal Circuit has a pro-patent bias, which would favor patent holders' policy considerations over those of non-patent holders.<sup>7</sup> Lastly, critics also believe the Federal Circuit fails to adequately address policy considerations.<sup>8</sup>

After the increased Supreme Court involvement in patent law in recent years, has the Federal Circuit learned from the Supreme Court's guidance and become more consistent with traditional legal principles and Congress' intended policy objectives? This article will explore this issue in light of the Federal Circuit's recent holding in *Sandoz v. Amgen* on remand.

The Supreme Court recently issued its landmark decision in *Sandoz v. Amgen*, primarily interpreting the meaning of 42 U.S.C. § 262(l)(2)(A) of the Biologics Price Competition and Innovation Act ("BPCIA").<sup>9</sup> Section 262(l)(2)(A) provides that when an applicant submits an application to the FDA for approval of a biosimilar product, the applicant must provide certain

1. NEW YORK CITY BAR ASSOCIATION, SHOULD PATENT JURISDICTION BE REMOVED FROM THE JURISDICTION OF THE FEDERAL CIRCUIT AND RETURNED TO REGIONAL COURTS OF APPEAL? REPORTS OF THE COMMITTEE ON PATENTS AND COMMITTEE ON FEDERAL COURTS 2 (2015) [hereinafter "NY Bar Report"].

2. *Id.* at 3.

3. *Id.* at 4 (citing Rochelle C. Dreyfuss, *Percolation, Uniformity, and Coherent Adjudication: The Federal Circuit Experience*, 66 SMU L. REV. 505, 509–10 (2013)).

4. *Id.* (citing Dreyfuss, *supra* note 4, at 509–10).

5. *Id.*

6. *Id.* at 8.

7. *Id.* at 7–8.

8. Rochelle C. Dreyfuss, *In Search of Institutional Identity: The Federal Circuit Comes of Age*, 23 BERKELEY TECH. L.J. 787, 809 (2008).

9. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664 (2017). See Biologics Price Competition and Innovation Act, 42 U.S.C. § 262(l)(2)(A) (2010) [hereinafter "BPCIA"].

initial disclosures to the sponsor of the reference product.<sup>10</sup> The Supreme Court held that noncompliance under § 262(l)(2)(A) was not enforceable by injunction under *federal* law and ordered the Court of Appeals for the Federal Circuit (“Federal Circuit”) to determine on remand whether noncompliance under § 262(l)(2)(A) of the BPCIA was enforceable by injunction under *state* law.<sup>11</sup> On December 14, 2017, the Federal Circuit issued its decision on remand and held that noncompliance under § 262(l)(2)(A) of the BPCIA was also not enforceable by injunction under state law.<sup>12</sup> However, did the Federal Circuit get it right?

This article begins by providing a background describing the BPCIA generally, the Supreme Court’s decision in *Sandoz v. Amgen*, and the Federal Circuit’s decision on remand. The article then evaluates the Federal Circuit’s decision on remand and discusses whether the Federal Circuit correctly found BPCIA preemption. Specifically, this article will discuss whether the Federal Circuit’s finding of BPCIA preemption remained consistent with traditional legal principles of preemption and with Congress’ underlying policy concerns behind the BPCIA.

After this analysis, this article will conclude that the Federal Circuit did stay consistent with traditional legal principles of preemption. To support these conclusions, this article will discuss how the Federal Circuit correctly applied the law from traditional field and conflict preemption cases to find that the field of patent law is generally a federal matter and that state law remedies would conflict with the federal objectives in the BPCIA. Finally, this article will conclude that the Federal Circuit also stayed consistent with Congress’ underlying policy concerns in the BPCIA. In reaching this conclusion, the article will discuss how the Federal Circuit considered Congress’ underlying policy concerns in the BPCIA, to balance the interests of pioneer biologics companies and biosimilar applicants, and ruled in a way so as to maintain this balance. Thus, it appears that, at least in *Sandoz v. Amgen*, the Federal Circuit is “learning its lessons” and considering traditional legal principles and policy concerns.

## II. BACKGROUND

### Brief Introduction of the BPCIA

In the 1980s, Congress was challenged with addressing the opposing concerns raised by the pharmaceutical industry and the general public that

10. *Sandoz Inc.*, 137 S. Ct. at 1670–71.

11. *Id.* at 1675–76.

12. *Amgen Inc. v. Sandoz Inc.*, 877 F.3d 1315, 1329 (Fed. Cir. 2017).

needed cheaper drugs. As further explained later in this article, Congress needed to find a way to “encourage innovation in pharmaceutical research” while also helping provide the general public with access to “lower-cost” or “generic” drugs.<sup>13</sup> In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act (commonly known as the “Hatch-Waxman Act”) to address these conflicting concerns.<sup>14</sup> Even though the Hatch-Waxman Act only applied to non-biologic<sup>15</sup> drugs, it provided Congress with a model to adopt for biologic drugs.<sup>16</sup> In the 1990s, Congress began their efforts to harmonize the non-biologic and biologic drug laws.<sup>17</sup> After years of work, in 2010, Congress passed the BPCIA to establish a “biosimilars pathway balancing innovation and consumer interests.”<sup>18</sup> Like the Hatch-Waxman Act before it, the BPCIA was a compromise between the competing interests of the pioneer biologics companies and the general public. To encourage innovation, the BPCIA gave pioneer biologic companies a 12-year period of exclusivity on their drugs in order to recoup costs and make a profit.<sup>19</sup> To lower consumer drug prices, the BPCIA created an abbreviated pathway for FDA approval of biosimilars.<sup>20</sup> Thus, in passing the BPCIA, Congress reached yet another compromise, this time between the competing interests of the pioneer biologics companies and the general public.

As previously stated, the BPCIA provides an abbreviated pathway for obtaining FDA approval of a biosimilar drug. A biosimilar drug is a “biologic product that is highly similar to a biologic product that has already been approved by the [FDA].”<sup>21</sup> The already approved biologic product is referred to as the “reference product.”<sup>22</sup> The pioneer biologic company that created the reference product is referred to as the “sponsor” company.<sup>23</sup>

13. Allen M. Sokal & Bart A. Gerstenblith, *The Hatch-Waxman Act: Encouraging Innovation and Generic Drug Competition*, FINNEGAN (2010), <https://www.finnegan.com/en/insights/the-hatch-waxman-act-encouraging-innovation-and-generic-drug.html>.

14. *Id.*

15. A non-biologic drug is a traditional drug that is “typically synthesized from chemicals,” whereas a biologic drug is a type of drug “derived from natural, biological sources such as animals or microorganisms.” *Sandoz Inc.*, 137 S. Ct. at 1669–70.

16. Krista Hessler Carver, et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 FOOD & DRUG L.J. 671, 672 (2010).

17. *Id.* at 687.

18. BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. 119, 804 (2010).

19. Richard Epstein, *The Constitutional Protection of Trade Secrets and Patents under the Biologics Price Competition and Innovation Act of 2009*, N.Y.U. LAW AND ECONOMICS WORKING PAPERS 285, 286 (2011).

20. *Id.*

21. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1669 (2017).

22. *Id.* at 1666.

23. *Id.*

To obtain FDA approval of a biosimilar drug, the applicant must follow the pathway provided in § 262(k) of the BPCIA.<sup>24</sup> Additionally, the applicant must follow § 262(l)(2)(A) and § 262(l)(8)(A) of the BPCIA, which are at issue in this case and explained further below.<sup>25</sup> If the applicant fails to follow these requirements, then the sponsor may immediately bring an action for declaratory judgment of infringement, validity, or enforceability of a patent.<sup>26</sup>

### Sandoz & Amgen Dispute Background

Turning to the *Sandoz v. Amgen* case, Neupogen, a filgrastim product used to stimulate the production of white blood cells, is the reference product marketed by Amgen.<sup>27</sup> Amgen is the pioneer sponsor and patent holder for patents on methods of manufacturing and using filgrastim.<sup>28</sup> Sandoz is a competitor that sought FDA approval to market a biosimilar filgrastim product named Zarxio.<sup>29</sup> The FDA notified Sandoz that its application had been accepted for review, and the following day Sandoz notified Amgen of the submitted application and its intent to market Zarxio immediately after receiving FDA approval.<sup>30</sup> Later, Sandoz notified Amgen that it did not intend to provide the application materials and manufacturing information required by § 262(l)(2)(A) of the BPCIA.<sup>31</sup> Amgen sued Sandoz for patent infringement and “unlawful” conduct in violation of California’s unfair competition law based on the following two BPCIA violations: (1) for not providing the application materials and manufacturing information as required by § 262(l)(2)(A), and (2) for violating the notice of commercial marketing requirement under § 262(l)(8)(A).<sup>32</sup> Amgen sought injunctions to enforce both BPCIA requirements.<sup>33</sup> While the case was pending, the FDA licensed Zarxio and Sandoz provided Amgen further notice of commercial marketing.<sup>34</sup>

The District Court granted partial judgment on the pleadings to Sandoz on the BPCIA counterclaims and dismissed Amgen’s state-law unfair

24. *Id.*

25. *Id.*

26. *Id.*

27. *Id.* at 1672–73.

28. *Id.* at 1673.

29. *Id.*

30. *Id.*

31. *Id.*

32. *Id.*

33. *Id.*

34. *Id.*

competition claims.<sup>35</sup> The Federal Circuit affirmed the dismissal of Amgen’s state-law claim based on § 262(l)(2)(A), holding that “Sandoz did not violate the BPCIA in failing to disclose its application and manufacturing information” and that the BPCIA provides the exclusive remedies for failure to comply with this requirement.<sup>36</sup> The court also held that under § 262(l)(8)(A), an applicant must provide notice of commercial marketing *after* obtaining licensure, and that this requirement is mandatory.<sup>37</sup> The court then enjoined Sandoz from marketing Zarxio until 180 days after it provided its second notice.<sup>38</sup> Both parties petitioned for a rehearing en banc, which the Federal Circuit denied.<sup>39</sup> Sandoz then filed a petition for a writ of certiorari in the Supreme Court regarding the § 262(l)(8)(A) requirement.<sup>40</sup> Amgen then filed a conditional cross-petition for writ of certiorari regarding the § 262(l)(2)(A) requirement and whether the sole remedy was that provided under § 262(l)(9)(C).<sup>41</sup> The Supreme Court subsequently granted both petitions and consolidated the cases in *Sandoz v. Amgen*.<sup>42</sup>

#### The Supreme Court’s Decision in *Sandoz v. Amgen*

The first portion of the BPCIA at issue in this case is § 262(l)(2)(A), which provides that, when an applicant submits an application to the FDA for approval of a biosimilar product, the applicant must provide its application materials and manufacturing information to the sponsor of the reference product within 20 days of notification from the FDA that the application has been accepted for review.<sup>43</sup> The Supreme Court addressed whether the requirement under § 262(l)(2)(A) is enforceable by injunction under federal law. In answering this question, the Supreme Court focused solely on the text of § 262. Specifically, the Court looked to the provisions in § 262 that provided remedies.<sup>44</sup> First, the Court looked to § 262(l)(9)(C), which provided a remedy for when an applicant failed to comply with the § 262(l)(2)(A) application and manufacturing information disclosure requirements.<sup>45</sup> Section 262(l)(9)(C) authorizes the sponsor to bring an immediate declaratory judgment action for infringement when an applicant

35. *Id.*

36. *Id.*

37. *Id.*

38. *Id.*

39. *Amgen Inc. v. Sandoz Inc.*, 877 F.3d 1315, 1319 (Fed. Cir. 2017).

40. *Id.*

41. *Id.*

42. *Id.* at 1319–20.

43. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1669 (2017). *See* BPCIA, 42 U.S.C. § 262(l)(2)(A).

44. *Sandoz Inc.*, 137 S. Ct. at 1675.

45. *Id.*

fails to comply with § 262(l)(2)(A).<sup>46</sup> The Court concluded that by explicitly providing the remedy in § 262(l)(9)(C), Congress implicitly excluded all other federal remedies, including injunctive relief.<sup>47</sup> In holding this, the Court found, “when Congress wished to provide a private damage remedy, it knew how to do so and did so expressly.”<sup>48</sup> Thus, the Court inferred from the text that Congress only intended to provide the declaratory judgment remedy in § 262(l)(9)(C) for failure to comply with § 262(l)(2)(A), and if Congress wanted to provide injunctive relief, then it would have done so expressly. In holding this, the Court found § 262(l)(2)(A) was not enforceable by injunction under federal law.

The Supreme Court also addressed whether the requirement under § 262(l)(2)(A) is enforceable by injunction under state law. In answering this question, the Court looked to the parties’ briefs, which “frame this issue as whether the § 262(l)(2)(A) requirement is mandatory in all circumstances . . . or merely a condition precedent to the information exchange process.”<sup>49</sup> The Court reasoned that if this requirement was only a “condition precedent,” then the applicant can withhold this information without committing an “unlawful” act.<sup>50</sup> The Court then concluded that this issue did not present a question of federal law because there was no dispute over how the federal scheme worked.<sup>51</sup> Rather, the Court concluded that whether this requirement was mandatory or conditional “*only* mattered for the purposes of California’s unfair competition law, which penalizes ‘unlawful’ conduct.”<sup>52</sup> Thus, the Court held this was a state-law question and that the Federal Circuit, on remand, should decide if this conduct was “unlawful” under California law.<sup>53</sup> Lastly, the Court held the Federal Circuit should also decide whether the BPCIA preempts any additional state law remedies for failure to comply with § 262(l)(2)(A).<sup>54</sup> The Federal Circuit’s holdings on remand will be discussed in the following section of this article.

The second portion of the BPCIA at issue in this case was § 262(l)(8)(A), which provides that the applicant must provide a 180-day notice to the sponsor of the reference product before the date of the first commercial marketing of the biosimilar product.<sup>55</sup> The Supreme Court

46. *Id.*

47. *Id.*

48. *Id.* (quoting *Touche Ross & Co. v. Redington*, 442 U.S. 560, 572 (1979)).

49. *Id.* at 1676.

50. *Id.*

51. *Id.*

52. *Id.* (emphasis in original).

53. *Id.*

54. *Id.*

55. *Id.* at 1666. *See* BPCIA, 42 U.S.C. § 262(l)(8)(A).

addressed whether the applicant must give notice to the sponsor after, rather than before, obtaining a license from the FDA for its biosimilar. The Court found that the applicant may provide notice to the sponsor either before or after receiving FDA approval.<sup>56</sup> This means the applicant can give notice before FDA approval, starting the 180-day clock, and begin commercial marketing immediately after FDA approval so long as the 180 days has run. Essentially, this means the sponsor's commercial marketing exclusivity period could be cut 180-days shorter than it would have been if notice was required after FDA approval.

However, as previously stated, the Supreme Court's decision in *Sandoz v. Amgen* did not answer all the issues raised. One question, whether the requirement under § 262(l)(2)(A) that an applicant provide its application and manufacturing information to the sponsor of the reference product is enforceable by injunction under *state* law, was not answered by the Court and was sent back to the Federal Circuit to answer on remand. This question necessarily raised an issue for the Federal Circuit to answer on remand: whether the BPCIA preempts any additional state law remedies for failure to comply with § 262(l)(2)(A). This issue is the main focus of the remaining sections of this article.

#### The Federal Circuit's Decision on Remand

The main issue the Federal Circuit addressed on remand was whether the BPCIA preempts state law remedies for failure to comply with § 262(l)(2)(A). Before deciding this issue, the Federal Circuit addressed whether Sandoz waived its preemption defense. The court decided to exercise its discretion and to address preemption, even though Sandoz did not argue the preemption defense before the District Court, reasoning that preemption in this case was "a significant question [] of general impact or of great public concern."<sup>57</sup> Lastly, in deciding this preemption issue, the Federal Circuit applied its own law.<sup>58</sup>

In addressing preemption, the Federal Circuit first looked to the Supremacy Clause, which states that federal law "shall be the supreme Law of the Land."<sup>59</sup> Under the Supremacy Clause, state law can be preempted through express preemption, field preemption, or conflict preemption.<sup>60</sup>

56. *Sandoz Inc.*, 137 S. Ct. at 1677.

57. *Amgen Inc. v. Sandoz Inc.*, 877 F.3d 1315, 1325 (Fed. Cir. 2017) (quoting *Hall v. Bed Bath & Beyond, Inc.*, 705 F.3d 1357, 1371 (Fed. Cir. 2013)).

58. *Id.* at 1325–26.

59. *Id.* at 1326 (quoting U.S. CONST. art. VI, cl. 2).

60. *Id.*

Express preemption is “a question of congressional intent and when Congress has made its intent known through explicit statutory language.”<sup>61</sup> However, express preemption was not the issue in this appeal since the BPCIA does not explicitly state Congress’ intent to preempt state law.<sup>62</sup> Field preemption occurs when state law is preempted because “it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively.”<sup>63</sup> This congressional intent for field preemption can be inferred from a “scheme of federal regulation . . . so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it,” or where an Act of Congress “touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.”<sup>64</sup> If field preemption applies because Congress intended federal law to occupy an entire field, then “even complementary state regulation is impermissible.”<sup>65</sup> Conflict preemption occurs when state laws conflict with federal law.<sup>66</sup> This happens when “it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”<sup>67</sup> The Federal Circuit then concluded that both field and conflict preemption were present in this case.<sup>68</sup>

In finding that field preemption was present, the Federal Circuit noted that patent litigation is not a field in which the States have traditionally occupied.<sup>69</sup> In finding this, the court reasoned that “patents are ‘inherently federal in character’ because a patent ‘originates from, is governed by, and terminates according to federal law.’”<sup>70</sup> Further, the court noted that Congress granted federal courts exclusive jurisdiction over cases relating to patents.<sup>71</sup> The court also noted that the FDA has “exclusive authority to license biosimilars.”<sup>72</sup> Comparing this case to the field preemption found in *Arizona v. United States*, the court found that “the scheme here is

61. *Id.* (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 78–79 (1990)).

62. *Id.*

63. *Id.* (quoting *English*, 496 U.S. at 79).

64. *Id.* (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

65. *Id.* (quoting *Arizona v. United States*, 567 U.S. 387, 401 (2012)).

66. *Id.*

67. *Id.* (quoting *English*, 496 U.S. at 79).

68. *Id.*

69. *Id.* at 1327.

70. *Id.* (citing *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 347 (2001) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947))).

71. *Id.* (citing *Gunn v. Minton*, 568 U.S. 251, 253 (2013) (quoting 28 U.S.C. § 1338(a) (2011))).

72. *Id.*

‘comprehensive’ and ‘provide[s] a full set of standards governing’ the exchange of information in biosimilar patent litigation, ‘including the punishment for noncompliance.’<sup>73</sup> Further, the court found that “BPCIA’s comprehensive, carefully calibrated ‘scheme of federal regulation . . . [is] so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it.’”<sup>74</sup> Thus, in so finding this, the court found field preemption applied.

The Federal Circuit also found that conflict preemption was present. The court noted that Amgen sought state law injunctive relief, even though injunctive relief was not present in federal law through the BPCIA, and cited the Supreme Court’s holding that “[b]ecause § 262(l)(9)(C) provides the exclusive federal remedy for failure to comply with § 262(l)(2)(A), federal law does not permit injunctive relief or damages for such failure.”<sup>75</sup> The court then cited *Arizona* again in finding that “[p]ermitting the State to impose its own penalties for the [alleged violation of federal law] here would conflict with the careful framework Congress adopted.”<sup>76</sup> Thus, the court held that there was also conflict preemption because there was no federal injunctive relief under the BPCIA. To allow state law to provide injunctive relief would “clash” with Congress’ intent behind the BPCIA.<sup>77</sup>

### III. EVALUATING THE FEDERAL CIRCUIT’S FINDING OF BPCIA PREEMPTION

#### Consistency with Traditional Preemption Principles

Looking to the Federal Circuit’s decision, I will now discuss whether the Federal Circuit correctly decided this issue in terms of traditional preemption principles. Specifically, I will discuss whether the Federal Circuit appears to remain consistent with the general legal principles regarding preemption, or rather, is making the type of specialized rules for patent law for which it is often criticized. Since the Federal Circuit decided the case on field and conflict preemption grounds, I will focus on those two grounds.

As described above, Article VI of the Constitution contains the Supremacy Clause, which provides that the “[l]aws of the United States . . .”

73. *Id.* (quoting *Arizona v. United States*, 567 U.S. 387, 401 (2012)).

74. *Id.* at 1328 (citing *Rice*, 331 U.S. at 230).

75. *Id.* (citing *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1675 (2017)).

76. *Id.* at 1328 (citing *Arizona*, 567 U.S. at 402).

77. *Id.* at 1329.

(i.e. federal law) “shall be the Supreme Law of the Land.”<sup>78</sup> As a result of this federal supremacy, “States have no power . . . to retard, impede, burden, or in any manner control the operations of the Constitutional laws enacted by Congress to carry into execution the powers vested in the [Federal] Government.”<sup>79</sup> Further, “[A]cts of the State Legislatures . . . [that] interfere with, or are contrary to the laws of the Congress [are to be invalidated because] [i]n every such case, the act of Congress . . . is supreme; and the law of the State, though enacted in the exercise of powers not controverted, must yield to it.”<sup>80</sup> So, when there is a conflict between federal and state law, the federal law controls and invalidates the state law because federal law is supreme.

The difficulty, however, is in deciding whether a particular state or local law conflicts with federal law and requires preemption. The Supreme Court gave some guidance to this inquiry in *Gade v. National Solid Wastes Management Association*:

Preemption may be either express or implied and is compelled whether Congress’ command is explicitly stated in the statute’s language or implicitly contained in its structure and purpose. Absent explicit preemptive language, we have recognized at least two types of implied preemption: field preemption, where the scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it, and conflict preemption, where compliance with both federal and state regulations is a physical impossibility, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.<sup>81</sup>

Unfortunately, Congress is rarely clear about its intent for preemption to apply or the scope of what is preempted.<sup>82</sup> As a result, courts must interpret Congress’ intent and decide what is preempted as “[t]he purpose of Congress is the ‘ultimate touchstone’ in every preemptive case.”<sup>83</sup> However, “although the Court purports to be finding congressional intent, it often is left to make guesses about purpose based on fragments of statutory language,

78. U.S. CONST. art. VI, cl. 2.

79. *McCulloch v. Maryland*, 17 U.S. 316, 436 (1819).

80. *Gibbons v. Ogden*, 22 U.S. 1, 211 (1824).

81. *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 98 (1992) (internal citations omitted).

82. ERWIN CHERMERINSKY, *CONSTITUTIONAL LAW* 453 (Wolters Kluwer, 5th ed. 2017).

83. *Id.* (citing *Medtronic Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Retain Clerks v. Schermerhorn*, 373 U.S. 96, 103 (1963))).

random statements in the legislative history, and the degree of detail of the federal regulation.”<sup>84</sup>

Applying the Court’s guidance in *Gade* to this case, the Federal Circuit was correct in concluding only field and conflict preemption apply here.<sup>85</sup> First, looking at the BPCIA, there is no express preemption language; thus, implied preemption is the only possibility.

Looking first at field preemption, the Federal Circuit appeared to follow the correct general legal principles. Field preemption is a type of implied preemption where the federal regulation is “so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it.”<sup>86</sup> In other words, “the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.”<sup>87</sup> Field preemption has been found in a number of situations. For example, in *Hines v. Davidowitz* and *Arizona v. United States*, the Supreme Court found field preemption in the immigration law context.<sup>88</sup> In *Hines*, the Court found the alien registration system was enacted by Congress to create one uniform national registration system, and state law could not be enforced when it interfered with this federal regulation.<sup>89</sup> The Court emphasized that alien registration “is in a field which affects international relations,” so it “demand[ed] broad national authority.”<sup>90</sup> The Court also emphasized the “extensive federal regulation in immigration, including a ‘broad and comprehensive plan describing the terms and conditions upon which aliens may enter this country’” and the fact that aliens were required to register with the federal government.<sup>91</sup>

Like immigration, patents are usually a matter of federal law, not state law.<sup>92</sup> The United States pointed out in its Amicus brief that “[w]hile Congress has not occupied the field of patent law or intellectual property law more generally . . . Congress has occupied the field of federal patent litigation.”<sup>93</sup> Federal courts have exclusive jurisdiction over patent law

84. *Id.*

85. *Amgen Inc. v. Sandoz Inc.*, 877 F.3d 1315, 1326 (Fed. Cir. 2017).

86. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

87. *Id.*

88. *Hines v. Davidowitz*, 312 U.S. 5272–74 (1941); *Arizona v. United States*, 567 U.S. 387, 402–03 (2012).

89. *Hines*, 312 U.S. at 73–74.

90. *Id.* at 68.

91. CHEMERINSKY, *supra* note 82, at 467 (quoting *Hines*, 312 U.S. at 69).

92. Paul R. Gugliuzza, *Patent Law Federalism*, 2014 WIS. L. REV. 11, 12 (2014).

93. Brief for the United States as Amicus Curiae at 3, *Amgen Inc. v. Sandoz Inc.*, 877 F.3d 1315 (Fed. Cir. 2017) (No. 2015-1499) [hereinafter “US Amicus Brief”].

claims, and state courts are expressly barred from hearing these claims.<sup>94</sup> Additionally, federal laws and the Federal Rules of Civil Procedure govern the “presentation of patent claims and defenses.”<sup>95</sup> For these reasons, it appears the “federal interest is so dominant” in federal patent litigation so as to “preclude enforcement of state laws on the same subject,” and the scheme of federal patent litigation regulation is “so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it.”<sup>96</sup> Congress’ occupation of federal patent litigation is the an important consideration supporting a finding that patent law is usually within the field of federal law.

Also, like obtaining citizenship and alien registration in immigration law, patents can only be obtained and registered by the federal government. Further, Congress created many patent laws that provide a “broad and comprehensive plan describing the terms and conditions” upon which one may obtain a patent.<sup>97</sup> Congress’ rules and regulations for obtaining patents is another factor supporting a finding that patent law is usually within the field of federal law.

So, it appears that, in general, patent law is usually within the field of federal law. However, this case is about biosimilars and the BPCIA specifically. Like the regulation in *Hines*, the BPCIA appears to be an “extensive federal regulation” with a “broad and comprehensive plan” for obtaining FDA approval of biosimilars.<sup>98</sup> The Supreme Court expressly recognized this and also found that the BPCIA created a “carefully calibrated scheme” for adjudicating patent infringement claims between sponsors and applicants.<sup>99</sup> These reasons support an inference that the “federal interest is so dominant” in biosimilar litigation so as to “preclude enforcement of state laws on the same subject,” and the scheme of biosimilar litigation regulation is “so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it.”<sup>100</sup> Thus, it appears that the BPCIA, like patent law generally, is likely within the field of federal law.

Comparing this analysis to the Federal Circuit’s analysis in this case (as described in the previous section of this article), the analysis looks almost identical. The Federal Circuit first looked to the field preemption principles as described in *Rice v. Santa Fe Elevator Corp.* The Federal Circuit then

94. *Id.* See also Gugliuzza, *supra* note 92, at 12.

95. US Amicus Brief, *supra* note 93, at 3.

96. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

97. *Hines v. Davidowitz*, 312 U.S. 52, 69 (1941).

98. *Id.*

99. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670 (2017).

100. *Rice*, 331 U.S. at 230.

recognized that patent litigation is solely governed by federal law, that patents are solely obtained by the federal government, and that biosimilars are governed by the federal government through the FDA. The Federal Circuit then looked to the BPCIA and found it was “comprehensive” like the schemes in *Arizona* and *Hines*. Thus, the Federal Circuit appears to have stuck strictly to the general legal principles regarding field preemption and has “got it right” in terms of field preemption.

Next, turning to conflict preemption, the Federal Circuit again appears to have followed the correct general legal principles. Conflict preemption is a type of implied preemption where “there is a conflict between federal and state law . . . even if federal law does not expressly preempt state law, preemption will be found where ‘compliance with both federal and state regulations is a physical impossibility.’”<sup>101</sup> In other words, conflict preemption is found where state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”<sup>102</sup> Conflict preemption has been found in a number of situations.

For instance, in *International Paper Co. v. Ouellette*, the Supreme Court found conflict preemption in the environmental law context.<sup>103</sup> In *International Paper Co.*, the plaintiffs filed suit against the defendants for alleged pollution under Vermont’s common law of nuisance.<sup>104</sup> The defendants argued, and the Supreme Court agreed, that the Clean Water Act (“CWA”) preempted the common law nuisance suit.<sup>105</sup> In finding conflict preemption, the Supreme Court stated:

In determining whether Vermont nuisance law “stands as an obstacle” to the full implementation of the CWA, it is not enough to say that the ultimate goal of both federal and state law is to eliminate water pollution. A state law is also preempted if it interferes with the methods by which the federal statute was designed to reach this goal.<sup>106</sup>

The Supreme Court then found conflict preemption because the Vermont law would allow the plaintiffs to circumvent a system under the

101. CHEMERINSKY, *supra* note 82, at 453 (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963)).

102. *Hines*, 312 U.S. at 67.

103. *Int’l Paper Co. v. Ouellette*, 479 U.S. 481, 500 (1987).

104. *Id.* at 484.

105. *Id.* at 500.

106. *Id.* at 494.

CWA, thus, “upsetting the balance of public and private interests so carefully addressed” by the CWA.<sup>107</sup>

Like *International Paper Co.*, allowing state law to apply concurrently with federal law in the biosimilar context would upset the “balance of public and private interests so carefully addressed” by Congress in the BPCIA.<sup>108</sup> Before the case went to the Supreme Court,<sup>109</sup> the Federal Court found that the initial disclosures under § 262(l)(2)(A) of the BPCIA were optional.<sup>110</sup> In other words, Congress provided in the BPCIA a *choice* for applicants.<sup>111</sup> If applicants choose to not make initial disclosures under § 262(l)(2)(A) of the BPCIA, then that does not violate the BPCIA and is, rather, “a path expressly contemplated by the BPCIA.”<sup>112</sup> However, if state law *mandates* these initial disclosures under § 262(l)(2)(A) of the BPCIA, then this would be “an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”<sup>113</sup> Specifically, this state law would be depriving applicants of the option to make initial disclosures under § 262(l)(2)(A) of the BPCIA, which would be obstructing “a path expressly contemplated by [Congress in enacting] the BPCIA.”<sup>114</sup> Thus, “state law would obstruct [one of] the BPCIA’s purposes and objectives.”<sup>115</sup> Further, if state law applied and was able to mandate these disclosures, that adds a burden to applicants, which would upset the “balance of public and private interests so carefully addressed” by Congress in the BPCIA.<sup>116</sup> For these reasons, federal preemption should apply since state law conflicts with federal law in regard to the initial disclosures under § 262(l)(2)(A) of the BPCIA.

Similarly, Congress “imposed short and fixed statutory time limits on each of the prescribed steps in 42 U.S.C. § 262(l)(2) through (l)(6), leading to the commencement of patent litigation no more than roughly 250 days after FDA accepts the applicant’s biosimilar application for review.”<sup>117</sup> If

107. *Id.*

108. *Id.*

109. It should be noted that the Supreme Court criticized the Federal Circuit’s analysis of whether the initial disclosures were optional or mandatory. This is only included to explain another argument for why conflict preemption should apply. Following this criticism, on remand, the Federal Circuit did not rely on these grounds in its decision that conflict preemption applied. Rather, the Federal Circuit found conflict preemption on other grounds, *see Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1676 (2017).

110. US Amicus Brief, *supra* note 93, at 7.

111. *Id.*

112. US Amicus Brief, *supra* note 93, at 7 (citing *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1357 (Fed. Cir. 2015)).

113. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

114. *Amgen Inc.*, 794 F.3d at 1357.

115. US Amicus Brief, *supra* note 93, at 8. *See also Hines*, 312 U.S. at 67.

116. *Int’l Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987).

117. US Amicus Brief, *supra* note 93, at 9.

sponsors were able to also sue under state law, which would likely be long and drawn-out litigation, this would undermine Congress' goal in the BPCIA to "expedit[e] the resolution of biosimilar patent disputes."<sup>118</sup> Thus, state law would obstruct one of the BPCIA's purposes and objectives.<sup>119</sup> Again, this would add another burden on the applicants, which would upset the "balance of public and private interests so carefully addressed" by Congress in the BPCIA.<sup>120</sup> For these reasons, federal preemption should apply since state law conflicts with federal law in regard to the "short and fixed statutory time limits" of the BPCIA, which were designed to quickly resolve biosimilar patent disputes.<sup>121</sup>

Likewise, the Supreme Court in *Sandoz v. Amgen* found that Congress intended the remedies under the BPCIA to be the sole remedies for noncompliance with the initial disclosures under § 262(l)(2)(A).<sup>122</sup> If injunction were allowed in state court, that would constitute an additional remedy not provided by Congress in the BPCIA.<sup>123</sup> If sponsors were able to sue in state court for injunction, this would undermine Congress' goal in the BPCIA to provide the exclusive remedies for noncompliance. Thus, state law would obstruct one of the BPCIA's purposes and objectives.<sup>124</sup> Again, this would add another burden on the applicants, upsetting the balance of interests considered by Congress in the BPCIA.<sup>125</sup> For these reasons, federal preemption should apply since state law conflicts with federal law in regard to the BPCIA's exclusive remedies for noncompliance.<sup>126</sup>

Comparing this analysis to the Federal Circuit's analysis in this case, the Federal Circuit focuses only on the issue of injunction conflicts. However, even though the Federal Circuit did not discuss the initial disclosures conflicts under the BPCIA or the litigation time limits conflicts under the BPCIA, the Federal Circuit's discussion of injunction conflicts appears to be correct. Specifically, like the analysis described above, the Federal Circuit found the BPCIA exclusively provided remedies for noncompliance, so allowing state law injunction would "interfere with the careful balance struck by Congress."<sup>127</sup> Thus, the Federal Circuit appears to

118. *Id.*

119. *See Hines*, 312 U.S. at 67.

120. *Int'l Paper Co.*, 479 U.S. at 494.

121. US Amicus Brief, *supra* note 93, at 9.

122. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1675 (2017).

123. US Amicus Brief, *supra* note 93, at 9–10.

124. *See Hines*, 312 U.S. at 67.

125. *Int'l Paper Co.*, 479 U.S. at 494.

126. US Amicus Brief, *supra* note 93, at 9–10.

127. *Amgen Inc. v. Sandoz Inc.*, 877 F.3d 1315, 1329 (Fed. Cir. 2017) (quoting *Arizona v. United States*, 567 U.S. 387, 405–06 (2012)).

have stuck to the general legal principles regarding conflict preemption and has “got it right” in terms of conflict preemption.

Therefore, the Federal Circuit appears to remain consistent with the general legal principles regarding preemption, rather than making specialized rules for patent law. Perhaps this means that the Federal Circuit, at least in *Sandoz v. Amgen*, has “learned its lesson” that the Supreme Court has been teaching for the past decade and is staying more consistent with general legal principles.

#### Consistency with the BPCIA’s Underlying Policy Concerns

Looking to the Federal Circuit’s decision, I will now discuss whether the Federal Circuit correctly decided this issue in terms of policy concerns. Specifically, I will discuss whether the Federal Circuit appears to remain consistent with Congress’ policy goals behind the BPCIA. To analyze this, I will first provide a background to the policy Congress considered in enacting the BPCIA.

An underlying concern behind the Hatch-Waxman Act and the BPCIA was the pioneer companies’ fear that they do not have enough time for exclusivity on the market because of how long it took to get FDA approval before a drug could go on the market.<sup>128</sup> To ensure ample protection, pioneer companies filed patent applications while the drugs were still in development.<sup>129</sup> This meant the duration of patent protection began to run before the drugs had even completed development and reached the market.<sup>130</sup> Thus, by the time the drugs reached the market, pioneer companies had already lost significant time to sell their products exclusively. In other words, these companies had lost significant time to recoup their development costs and make a profit before their patent protection expired and generics could enter the market. Logically, if pioneer companies could not recoup their costs and make a profit, the incentive to create new drugs would be diminished. This desire to continue to encourage innovative research and development was one of the competing concerns Congress faced in passing the Hatch-Waxman Act and the BPCIA.<sup>131</sup>

However, there also existed the opposing concern to help generic drugs reach the market more quickly, which would provide the public with lower-cost drugs.<sup>132</sup> Before a generic drug could enter the market, the law required

128. Sokal & Gerstenblith, *supra* note 13; Epstein, *supra* note 19, at 285–86.

129. Sokal & Gerstenblith, *supra* note 13.

130. *Id.*

131. Sokal & Gerstenblith, *supra* note 13; Epstein, *supra* note 19, at 286.

132. Sokal & Gerstenblith, *supra* note 13.

proof that the new drug was safe, effective, and accepted by the FDA.<sup>133</sup> Additionally, clinical trials were required to get FDA approval, which took considerable time and money.<sup>134</sup> Yet, in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, the Federal Circuit held that tests for FDA approval of a generic drug infringed the patent on the branded drug.<sup>135</sup> Since the patent had to expire before testing, and testing a drug and getting FDA approval could take years, there was an extended amount of time of exclusivity of the brand drug on the market.<sup>136</sup> As a result, this brand drug enjoyed extended exclusivity on the market allowing the pioneer company to keep the prices high, meaning the public was not able to benefit from lower-cost generic drugs for years. This public need for lower-cost generic drugs was the other competing concern Congress faced in passing the Hatch-Waxman Act and the BPCIA.<sup>137</sup>

The Hatch-Waxman Act and the BPCIA addressed these competing concerns by essentially drafting a compromise. For pioneer companies, the two laws provided various favorable protections, such as patent term extensions to compensate for the delay caused by FDA review and market exclusivities prohibiting the submission and/or approval of a new drug application for a given amount of time.<sup>138</sup> The two laws also provided various favorable protections for generic drug manufacturers, such as abbreviated new drug applications that did not require preclinical and clinical safety and efficacy testing and a “safe harbor” provision overruling *Roche* that allowed generics to test drugs for FDA approval without risk of infringement lawsuits.<sup>139</sup> Therefore, by including these protections in the Hatch-Waxman Act and the BPCIA, Congress was able to balance the competing interests of the pioneer companies and the general public.

In the BPCIA specifically, Congress established many mechanisms in order to maintain the balance of these competing interests. For example, to encourage innovation, Congress provided biologic companies a 12-year period of exclusivity to recoup costs and make a profit.<sup>140</sup> On the other hand, to lower consumer drug prices and help biosimilars quickly reach the market, Congress created an abbreviated pathway for FDA approval of

133. *Id.*

134. *Id.*

135. *Id.* See *Roche Prod., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 861 (Fed. Cir. 1984).

136. Sokal & Gerstenblith, *supra* note 13.

137. *Id.*

138. Sokal & Gerstenblith, *supra* note 13; Epstein, *supra* note 19, at 286.

139. Sokal & Gerstenblith, *supra* note 13.

140. Epstein, *supra* note 19, at 286.

biosimilars.<sup>141</sup> The *Sandoz v. Amgen* case dealt with the particulars of this abbreviated pathway.<sup>142</sup> The remaining focus of this analysis discusses whether the Federal Circuit remained consistent with the particulars of this abbreviated pathway that Congress provided, so as to stay consistent with the overall balance of competing interests behind the BPCIA.

As discussed previously, the Supreme Court in *Sandoz v. Amgen* found Congress provided in the BPCIA the exclusive *federal* remedies that could be taken against biosimilar applicants for noncompliance.<sup>143</sup> Thus, since the BPCIA did not provide for federal injunction, this remedy did not exist for applicants' noncompliance. The Federal Circuit extended this reasoning on remand by finding Congress provided in the BPCIA the exclusive remedies, federal or state, that could be taken against biosimilar applicants for noncompliance.<sup>144</sup> Thus, since the BPCIA did not provide for state injunction, this remedy did not exist for applicants' noncompliance. In finding this, the Federal Circuit appears to have been conscious of the policy considerations of the BPCIA.

First, when finding field preemption, the Federal Circuit considered Congress' intent that federal law exclusively occupy the field of biosimilar litigation.<sup>145</sup> In considering this, the Federal Circuit recognized Congress' overarching intent behind the BPCIA:

The BPCIA is a complex statutory scheme . . . that establishes processes both for obtaining FDA approval of biosimilars and for resolving patent disputes between manufacturers of licensed biologics and manufacturers of biosimilars. It sets forth a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of patent infringement. Congress established this scheme as part of its careful balancing of innovation and consumer interests.<sup>146</sup>

Thus, the Federal Circuit recognized that Congress' purpose behind the BPCIA was to balance the competing interests of pioneer sponsors and biosimilar applicants. After considering this overarching intent, the Federal Circuit went on to hold that the BPCIA was "comprehensive" and "carefully drafted and detailed," so presumptively Congress would have included state law remedy or "left room for the States" if Congress intended biosimilar

141. *Id.*

142. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1669–70 (2017).

143. *Id.* at 1675.

144. *Amgen Inc. v. Sandoz Inc.*, 877 F.3d 1315, 1330 (Fed. Cir. 2017).

145. *Id.* at 1327.

146. *Id.* (internal citations, alterations, and quotation marks omitted).

litigation to not be completely within the federal law field.<sup>147</sup> Thus, in finding field preemption, the Federal Circuit first considered the overarching Congressional intent behind the BPCIA.

Next, when finding conflict preemption, the Federal Circuit considered whether state law remedies would conflict with the BPCIA's ultimate objectives.<sup>148</sup> In considering this, the Federal Circuit reflected on how allowing patent holders to bring state law claims, in addition to federal law claims, would impact biosimilar applicants.<sup>149</sup> The Federal Circuit found "compliance with the BPCIA's 'detailed regulatory regime in the shadow of 50 States' tort regimes,' and unfair competition standards, could 'dramatically increase the burdens' on biosimilar applicants beyond those contemplated by Congress in enacting the BPCIA."<sup>150</sup> So, the Federal Circuit again considered the overarching Congressional intent behind the BPCIA, to balance the competing interests of pioneer sponsors and biosimilar applicants, and how state law remedies would disrupt this balance. The Federal Circuit found there would be disruption to this carefully crafted balance if state law and federal law remedies existed because the biosimilar applicants would have an added burden that Congress did not intend.<sup>151</sup> Thus, the Federal Circuit found conflict preemption because state law remedies would conflict with the objectives of the BPCIA.<sup>152</sup>

So, in finding field and conflict preemption, the Federal Circuit considered Congress' policy concerns behind the BPCIA. Specifically, the Federal Circuit considered the compromise Congress struck between pioneer sponsors and biosimilar applicants. Further, the Federal Circuit did not merely consider these policy concerns, but the Federal Circuit ruled in such a way that maintained the careful balance Congress struck between the pioneer sponsors and the biosimilar applicants. If the Federal Circuit had ruled otherwise, the balance would have been upset in favor of sponsors and against biosimilar applicants who would have had additional burdens.

Thus, it appears that the Federal Circuit has "gotten in right" in terms of the underlying BPCIA policy concerns. Specifically, the Federal Circuit appears to remain consistent with Congress' underlying objective to balance the interests of the pioneer sponsors and the biosimilar applicants. Rather than ignore policy concerns, as critics believe the Federal Circuit has a history of doing, the Federal Circuit here considered these policy concerns

147. *Id.* at 1327–28 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

148. *Id.* at 1329.

149. *Id.*

150. *Id.* (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001)).

151. *Id.*

152. *Id.*

and ruled in a way that maintained Congress' policy objectives. Perhaps this means that the Federal Circuit, at least in *Sandoz v. Amgen* and in the BPCIA context, has "learned its lesson" and is staying more consistent with Congress' underlying policy concerns.

#### IV. CONCLUSION

The Supreme Court's decision makes clear that the requirement under § 262(l)(2)(A) of the BPCIA can only be enforced by the remedy provided in § 262(l)(9)(C) and that no *federal* injunctive remedy exists. The Federal Circuit's decision makes clear that the requirement under § 262(l)(2)(A) of the BPCIA can only be enforced by the remedy provided in § 262(l)(9)(C) and that no *state* law injunctive remedy exists because of field and conflict preemption. After analyzing the traditional preemption principles, it appears the Federal Circuit correctly decided this issue. The Federal Circuit correctly applied the law from traditional field and conflict preemption cases to find that the field of patent law is generally a federal matter and that state law remedies would conflict with the federal objectives in the BPCIA. Lastly, after analyzing Congress' underlying policy concerns in the BPCIA, it appears that the Federal Circuit correctly decided this issue. The Federal Circuit expressly considered these policy concerns in its opinion and ruled in a way that supported Congress' objectives. Thus, it appears that, at least in *Sandoz v. Amgen* and in the BPCIA context, the Federal Circuit is "learning its lessons" and is considering traditional legal principles and policy concerns.