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# SANDOZ INC. V. AMGEN INC.: REMOVING BARRIERS TO MARKET ACCESS FOR BIOSIMILAR MANUFACTURERS

MOYOSORE O. KOYA\*

In 2017, the United States Supreme Court considered a case of first impression, *Sandoz Inc. v. Amgen Inc.*,<sup>1</sup> a case centered on the patent dispute between a biologics manufacturer and a biosimilar manufacturer. The named corporations, Amgen Inc. and Sandoz Inc., produce biopharmaceuticals and drugs that are similar to those original biopharmaceuticals, respectively.<sup>2</sup> The Court addressed two issues raised by the governing biological patent statute, the Biologics Price Competition and Innovation Act (BPCIA): (1) what remedy is available when a biosimilar applicant fails to engage in the disclosure and negotiation procedures and (2) whether the 180-day notice of commercial marketing is mandatory under the statute.<sup>3</sup>

The Supreme Court held that, under the BPCIA provisions outlining the disclosure and negotiation procedures between biologic and biosimilar manufacturers, a declaratory-judgment action is the only federal remedy available for a biosimilar manufacturer's failure to provide the relevant information.<sup>4</sup> The Supreme Court further held that a biosimilar applicant can provide notice of commercial marketing before FDA approval.<sup>5</sup> For the latter part of its holding, the Court applied a plain meaning construction to correctly read the statute as allowing biosimilar applicants to provide premarketing notice before licensure. This Note will focus primarily on the second prong of the Supreme Court's holding. Specifically, this Note will explore the factual and statutory background preceding *Sandoz Inc. v. Amgen Inc.* to both explain the two prongs of the Supreme Court's decision and then argue that the second half

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\* J.D. Candidate, 2019, University of Maryland School of Law. I would like to thank my family for their endless support and encouragement and dedicate this paper to my grandfather, the late Professor Emeritus Toriola F. Solanke, who first taught me about professionalism and scholarship.

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

2. H. Mellstedt et. al., *The challenge of biosimilars*, 19 ANNALS OF ONCOLOGY 411 (2008).

3. *Sandoz*, 137 S. Ct. at 1669.

4. See *infra* notes 113–119 and accompanying text.

5. *Sandoz*, 137 S. Ct. 1664.

of the Court's holding facilitates the goal of the BPCIA of providing an efficient pathway to promote drug innovation accessibility of biosimilars to patients.

### I. THE CASE

Amgen, Inc. and Amgen Manufacturing, Ltd., collectively referred to as the plaintiffs "Amgen" in *Amgen Inc. v. Sandoz Inc.*, began marketing the biosimilar Filgrastim, a drug used by chemotherapy patients to stimulate blood cell production,<sup>6</sup> under the brand name Neupogen in 1991.<sup>7</sup> In July 2014, the defendants Sandoz, Inc., Sandoz International GMBH, and Sandoz GMBH, collectively named "Sandoz," applied to the Food & Drug Administration (FDA) for approval of a biosimilar product based on Amgen's Neupogen.<sup>8</sup> Afterwards, Amgen filed suit against the defendants, in the United States District Court for the Northern District of California based on two grounds.<sup>9</sup> Amgen alleged first that Sandoz failed to follow the disclosure and negotiation procedures of the BPCIA<sup>10</sup> and second, that Sandoz acted unlawfully by planning to market its biosimilar immediately upon FDA approval of its biosimilar instead of waiting 180 days after approval.<sup>11</sup> Ultimately, Amgen argued that it was entitled to injunctive relief under California's unfair competition law.<sup>12</sup>

The district court was tasked with deciding whether Sandoz violated the BPCIA when it failed to follow the negotiation and disclosure procedures.<sup>13</sup> To resolve this issue, the court compared the statutory interpretation of the BPCIA by both Amgen and Sandoz.<sup>14</sup> Amgen argued that Sandoz violated the BPCIA when the company first, failed to provide Amgen with a copy of its Biologic License Application (BLA) within twenty days after the FDA received the application for review and, second, by choosing not to participate in a disclosure and negotiation process.<sup>15</sup> Amgen asserted that the BPCIA requires BLA

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6. *Filgrastim, Filgrastim-sndz, Tbo-filgrastim Injection*, MEDLINEPLUS (Nov. 15, 2017) <https://medlineplus.gov/druginfo/meds/a692033.html>.

7. *See Amgen Inc. v. Sandoz Inc. (Amgen I)*, No. 14-cv-04741-RS, 2015 U.S. Dist. LEXIS 34537, at \*1 (N.D. Cal. Mar. 19, 2015).

8. *Id.* at \*3.

9. *Id.* at \*10–11.

10. *Id.* at \*14.

11. *Id.* Based on these alleged violations, Amgen stated that it could assert conversion and patent infringement claims under California's Unfair Competition Law (UCL). In response, Sandoz filed counterclaims, contesting the UCL and conversion claims by stating that its conduct of not participating in disclosure and negotiation procedures was permissible and not constituting patent infringement. *Id.* at \*3–4.

12. *Amgen I*, 2015 U.S. Dist. LEXIS 34537, at \*1.

13. *Id.* at \*16.

14. *Id.* at \*16–21.

15. *Id.* at \*14.

applicants to comply with the prescribed disclosure and negotiation procedures.<sup>16</sup> The district court agreed with Amgen that the repeated use of the word “shall” in these subsections of the BPCIA supported its argument.<sup>17</sup> However, the court also determined that “shall” in this context does not imply that an action is mandatory in every context.<sup>18</sup> In this case, it would be permissible to interpret the BPCIA to mean that the disclosure and negotiation steps are required only when both parties elect to participate in the procedures.<sup>19</sup>

The district court further determined that the disclosure and negotiation procedures at issue were optional because of subsections § 262(l)(9)(B) and (C) created by the BPCIA, which outline another available mechanism when the biosimilar applicant fails to participate in the disclosure and negotiation process.<sup>20</sup> In such instances, the manufacturer of the original biologic product, also known as the *reference product sponsor*, is allowed to begin patent litigation immediately.<sup>21</sup> The court found this statutory option for reference product sponsors to be consistent with the congressional intent of the BPCIA, which is to expedite patent litigation.<sup>22</sup> Specifically, if the procedures are optional, the biosimilar applicant would be justified in bypassing potentially lengthy disclosure and negotiation procedures in favor of immediate resolution through litigation.<sup>23</sup> Based on this interpretation, the court held that it was not only permissible for Sandoz to avoid the disclosure and negotiation procedures, but also a more accurate interpretation of the statute.<sup>24</sup>

The second issue the district court examined was whether Sandoz acted unlawfully by informing Amgen of its plans to commercially market its biosimilar product before receiving FDA approval.<sup>25</sup> The court again concluded that Amgen’s statutory interpretation of the negotiation and disclosure provisions of the BPCIA was not persuasive.<sup>26</sup> The quoted language from the statute is that the applicant “shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).”<sup>27</sup> According to the court, Amgen determined that “FDA approval must be a condition precedent to valid notice”

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16. *Id.* at \*16.

17. *Id.*

18. *Id.* at \*17.

19. *Id.*

20. *Id.*

21. *Id.* at \*18.

22. *Id.* at \*20.

23. *Id.* at \*20.

24. *Id.* at 21.

25. *Id.*

26. *Id.*

27. 42 U.S.C. § 262(l)(8)(A) (2018).

because of the choice to use “licensed” in the past tense.<sup>28</sup> Amgen construed this wording to mean that the applicant can only give the required 180-day notice after the FDA approves the BLA.<sup>29</sup> The court disagreed with Amgen and concluded that the focus of the statute is to ensure that the applicant provide notice before “first commercial marketing” because FDA approval is required before entrance into the market.<sup>30</sup> The court found that the word “before” in the context of the statute did not refer to the timeline of licensure, but to commercial marketing; therefore Sandoz did not act unlawfully by providing notice before FDA approval.<sup>31</sup> Amgen filed a timely appeal on the final judgment.<sup>32</sup>

The United States Court of Appeals for the Federal Circuit also examined Amgen’s statutory interpretation. This court affirmed the district court’s ruling on the disclosure and negotiation issue based on the fact that 42 U.S.C. § 262(l)(9)(C) and 35 U.S.C. § 271(e) collectively provide an option for the reference product sponsor when the applicant fails to disclose.<sup>33</sup> The court found that Sandoz initiated this pathway by not participating in the disclosure and negotiation procedures.<sup>34</sup> Therefore, Amgen was not entitled to an injunction based on California law, which states that where the underlying statute expressly provides a remedy, any other remedy is not available.<sup>35</sup>

However, the court of appeals found Amgen’s interpretation of the contested disclosure and negotiation provisions created by the BPCIA persuasive and ultimately held that these sections require a biosimilar product to be licensed prior to notice of commercial marketing.<sup>36</sup> The court reasoned that Congress intended for the FDA to approve the product before the biosimilar applicant can give notice of commercial marketing to the reference product sponsor.<sup>37</sup> Specifically, the court stated that if Congress meant to allow notice before licensure, the statute would have referred to “the biological product that is the subject of the application” instead of “the biological product licensed” as the statute describes.<sup>38</sup> The court interpreted the notice provision of the BPCIA, § 262(l)(8)(A), as mandatory under all circumstances, unlike other provisions that are triggered by an applicant’s opting into the negotiation and disclosure

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28. *Amgen I*, 2015 U.S. Dist. LEXIS 34537, at \*22.

29. *Id.*

30. *Id.*

31. *Id.* at \*24–25.

32. *Amgen Inc. v. Sandoz Inc. (Amgen II)* 794 F.3d 1347 (Fed. Cir. 2015). Amgen also filed an appeal based on the district court’s denial of a preliminary injunction. *Id.*

33. *Id.* at 1357.

34. *Id.* at 1357.

35. *Id.* at 1356, 1360.

36. *Id.* at 1358.

37. *Id.*

38. *Id.*

procedures.<sup>39</sup> Thus, the court ruled that Sandoz was prohibited from marketing its biosimilar until the 180-day timeframe following FDA approval of the product had lapsed.<sup>40</sup>

In summation, the court of appeals decided the case in favor of Sandoz on whether the procedures were mandatory and in Amgen's favor on whether it was unlawful for a biosimilar applicant to give notice of first commercial marketing before FDA approval. As a result, both Amgen and Sandoz appealed to the United States Supreme Court, which granted certiorari in a consolidated case.<sup>41</sup>

## II. LEGAL BACKGROUND

The statutory background surrounding *Sandoz Inc. v. Amgen Inc.* can be confusing so it is necessary to explore the legislative background of the BPCIA to provide context for the provisions at issue in the litigation. Section II.A examines the development and purpose of the BPCIA. Section II.B focuses on the regulatory procedures governing the patent relationship between biologic and biosimilar manufacturers as outlined in the BPCIA as well as the relevant provisions contributing to the tension between Sandoz and Amgen. Finally, Section II.C. focuses on the two issues Amgen raised in the original litigation that were subsequently presented to the Supreme Court.

### A. The BPCIA: A Legislative Overview

The pharmaceutical industry is very lucrative in the United States. Contributing to this are the high prices of drugs known as biologics, which are drug products derived from living organisms.<sup>42</sup> The Biologics Price Competition and Innovation Act (BPCIA) of 2010 was included in President Obama's comprehensive Patient Protection and Affordable Care Act.<sup>43</sup> The two primary goals of the BPCIA are: (1) promoting the innovation of biologic therapies by providing incentives and (2) promoting the accessibility of biologic therapies by keeping prices affordable.<sup>44</sup> The legislation was drafted as an amendment to the

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39. *Id.* at 1360.

40. *Id.* Sandoz's biosimilar Zarxio was approved by the FDA on March 6, 2015, meaning that in order to comply with the ruling of the Court of Appeals for the Federal Circuit, the company could not place its drug on the market until September 2, 2015. *Id.*

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

42. Geoffrey M Levit, *The Drugs/Biologics Approval Process*, in A PRACTICAL GUIDE TO THE FDA'S FOOD AND DRUG LAW REGULATION 125, 167 (Kenneth R. Piña & Wayne L. Pines eds., 6th ed. 2017).

43. *Implementation of the Biologics Price Competition and Innovation Act of 2009*, FDA, <https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/ucm215089.htm> (last updated Feb. 12, 2016); see also *supra* note 27, at 168.

44. Ude Lu, *Biologics Price Competition and Innovation Act: Striking a Delicate Balance Between Innovation and Accessibility*, 15 MINN. J. L. SCI. & TECH. 613, 613 (2014).

Public Health Service Act (PHSA) to create an expedited approval pathway for biosimilar products, also sometimes referred to as “follow-on biologics (FOBs)”, which are characterized as “highly similar” to biological product that is FDA approved.<sup>45</sup> Specifically, the BPCIA amended § 351 of the PHSA by adding subsections (k)<sup>46</sup> and (l).<sup>47</sup>

The new § 351(k) of the PHSA describes the process of licensing a biosimilar product.<sup>48</sup> Four years after a biologic reference product is licensed, anyone can submit a biosimilar application for approval based on the licensed biologic product. This application must include information in five categories, the first of which, in relevant part, requires demonstrating that “the biological product that is the subject of the application is ‘biosimilar’ to a reference product.”<sup>49</sup> The FDA is required to license a biosimilar if the information in the application is “sufficient to show that the biological product is biosimilar to the reference product.”<sup>50</sup>

Additionally, § 351(k) explains the exclusivity periods that exist for both the biosimilar drug and the reference product.<sup>51</sup> The first drug that is classified by the FDA as a biosimilar of the reference product earns two types of exclusivity. First, the biosimilar is the only product that can be classified as interchangeable with the reference product, and second, that biosimilar is granted at least one year of market exclusivity after the biosimilar first commercially markets its product.<sup>52</sup> The reference product sponsor, on the other hand, enjoys a long period of market exclusivity that lasts for twelve years from the date it was first licensed by the FDA regardless of whether or not its original patent has expired.<sup>53</sup>

The long patent life for biologic products spurred the need for legislation like the BPCIA, particularly during the early 2000s when biologics began to

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45. Lu, *supra* note 44, at 613–14.

46. *Id.*

47. *See infra* notes 64–73 and accompanying text.

48. Levit, *supra* note 42, at 168.

49. Levit, *supra* note 42, at 169. The remaining requirements for the information to be provided in a subsection (k) application are: “2) the biosimilar product and reference product use the same mechanism(s) of action for the condition(s) of use prescribed, recommended, or suggested in the proposed labeling, to the extent the mechanism(s) of action are known for the reference product; 3) the condition(s) of use prescribed, recommended, or suggested in the labeling proposed for the biosimilar product have been previously approved for the reference product; 4) the biosimilar product has the same out of administration, dosage form, and strength as the reference product; and 5) the facility in which the biosimilar product is manufactured, processed, packed, or held meets standards designed to assure that the product continues to be safe, pure, and potent.” *Id.*

50. *Id.*

51. 42 U.S.C. § 262(k)(7)(B) (2018).

52. 42 U.S.C. § 262(k)(6). Under this provision, other periods of the patent activity, including the litigation, can determine when a biosimilar’s period of market exclusivity begins. *Id.*

53. 42 U.S.C. § 262(k)(7).

comprise to a significant portion of the pharmaceutical industry.<sup>54</sup> As a result, the industry recognized that the development of an abbreviated pathway for the approval of biosimilars would result in high savings,<sup>55</sup> similar to what the Hatch-Waxman bill accomplished for small molecule drugs.<sup>56</sup> The fact that big pharmaceutical companies faced little to no market competition as their biologics patents began to expire revealed the need for an abbreviated biosimilar approval pathway.<sup>57</sup>

In response, the BPCIA created the Abbreviated Biologic License Application (aBLA) pathway for biosimilar drugs.<sup>58</sup> The aBLA pathway increases the accessibility of biologic therapies, which are typically expensive, by encouraging market competition as a means of developing cheaper drug therapies for consumers.<sup>59</sup> Once the FDA licenses the biosimilar, the product can begin competing with the reference product.<sup>60</sup> The BPCIA simultaneously encourages innovation by biologics companies by offering the incentive of a twelve-year period of market exclusivity for those biologics.<sup>61</sup> This is a win for biologics companies because the market exclusivity period can potentially last longer than that of an active patent.<sup>62</sup>

Although the BPCIA has resulted in positive outcomes for pharmaceutical companies, there is still tension between biologics and biosimilar manufacturers that fundamentally stems from market control. The two statutory provisions of the BPCIA that are responsible for the most litigation are: (1) the necessity of the information exchange procedure known as the “patent dance” and (2) the

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54. Lu, *supra* note 44, at 618.

55. *Biogenerics: Not Yet a Reality in the U.S.*, TRADER THOUGHTS 1 (Dec. 24, 2011), <https://seekingalpha.com/article/58230-biogenerics-not-yet-a-reality-in-the-u-s>.

56. Similar to the BPCIA, the Hatch-Waxman Act focuses on promoting innovation and accessibility by providing a patent term extension (PTE) incentive for innovators and establishing the abbreviated new drug application (ANDA) to help generic drugs enter the market. Lu, *supra* note 44, at 615.

57. *Id.* at 619–20.

58. *Id.* at 614.

59. *Id.* 633–34.

60. Gregory S. Ascioia & Matthew J. Perez, “*Shall We Dance?*” – *Biologic-Biosimilar Competition Under the Biologics Price Competition and Innovation Act*, CPI ANTITRUST CHRONICLE 1, 2 (2015).

61. Lu, *supra* note 44, at 623–24 (describing this exclusivity period as one of the major tools outlined in the BPCIA to encourage innovation). *See also* 42 U.S.C. § 262(k)(7)(A) (2018).

62. Lu, *supra* note 44, at 623–24. Other benefits to this exclusivity period: it covers more than one patent because FDA approval on each biological entity coverage on average 2.7 patents; FDA exclusivity is independent from patent exclusivity even if the patent for a biologic expires, the FDA exclusivity is still applicable; FDA exclusivity eliminates design around issues because it applies to the final product so a generic company can’t get FDA approval on that basis that it manufactured the final product differently. *Id.* at 623–24. *See also* Felix Shin, *Leaping from the Patent Cliff into the Global Drug Gap: Overcoming Exclusivity to Provide Affordable Biosimilars*, 37 LOY. L.A. INT’L & COMP. L. REV. 419, 429 (2016) (stating that the 12 year exclusivity period runs parallel to any patents already held by the reference product sponsor which offers greater security for the reference product sponsor in the drug market).



necessity of getting FDA approval prior to issuing the 180-notice of commercial marketing.<sup>63</sup>

*B. The New § 262(l) and The “Patent Dance”*

The BPCIA created a series of private information exchanges between the biosimilar applicant and the reference product sponsor known as the “patent dance” in an effort to try and avoid patent litigation.<sup>64</sup> This information exchange is divided into five steps called the “patent dance” which are further split into two stages of litigation.<sup>65</sup> The first stage of litigation begins after the FDA informs a biosimilar applicant that its subsection (k) application has been accepted for review.<sup>66</sup> Within twenty days of that notice, the biosimilar applicant must submit to the reference product sponsor a copy of its application and any information concerning the processes used to manufacture the biosimilar.<sup>67</sup> The next step requires the reference product sponsor to provide a list of patents that cover the biologic product to the subsection (k) applicant within sixty days of the application being submitted.<sup>68</sup> This list also includes “patents that the reference product sponsor would be prepared to license to the applicant.”<sup>69</sup> These steps outlined in the statute also suggests that the subsection (k) applicant can within sixty days provide a list of patents to which the applicant reasonably believes the reference product sponsor could assert a claim of patent infringement.<sup>70</sup>

Next, the applicant and the reference product sponsor participate in “good faith negotiations” to determine which of the patents listed by the applicant from the preceding step “shall be the subject of an action for patent infringement.”<sup>71</sup> If the parties agree on which patents may be subject to patent infringement actions, the reference product sponsor must bring the infringement action within 30 days.<sup>72</sup> A biosimilar applicant’s failure to adhere to these procedures entitles the reference product sponsor to a declaratory patent infringement action.<sup>73</sup> This marks the end of the first phase of the litigation process.

During the second phase of litigation, the biosimilar applicant needs to provide notice to the reference product sponsor at least 180 days before it begins

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63. Gregory S. Ascioffa & Matthew J. Perez, “*Shall We Dance?*” – *Biologic-Biosimilar Competition Under the Biologics Price Competition and Innovation Act*, CPI ANTITRUST CHRONICLE 3 (2015).

64. Levit, *supra* note 42, at 171.

65. 42 U.S.C. § 262(l)(2)–(6) (2018).

66. Levit, *supra* note 42, at 171.

67. 42 U.S.C. § 262(l)(2).

68. 42 U.S.C. § 262(l)(3)(A)(i)–(ii).

69. *Id.*

70. 42 U.S.C. § 262(l)(3)(B)(i).

71. 42 U.S.C. § 262(l)(4).

72. 42 U.S.C. § 262(l)(6).

73. 42 U.S.C. § 262(l)(9)(B).

commercially marketing its biosimilar product.<sup>74</sup> Once the reference product sponsor receives notice, they can move for a preliminary injunction on any patents previously identified in the lists of patents held by the reference product sponsor that did not move past the first stage of the patent litigation.<sup>75</sup>

It can be challenging to keep track of the different patent negotiation and litigation steps and one question the “patent dance” raises is whether or not the information exchange between the applicant and reference product sponsor is mandatory or optional.<sup>76</sup> Proponents of a mandatory patent dance argue that the framework provides certainty and protection for both the reference product sponsor and the biosimilar applicant because each party can concurrently prepare for litigation under an establishing process following the approval of a biosimilar application.<sup>77</sup> On the other hand, if the “patent dance” is optional, biosimilar applicants gain the advantage of being in a position to dictate the nature of its interaction with the reference product sponsor from the point of biosimilar application approval.<sup>78</sup>

*C. Two Issues on Point: Identifying The Appropriate Federal Remedy and The Notice of Commercial Marketing timing Requirement*

As the Supreme Court recognized, the patent scheme responsible for the litigation between Sandoz and Amgen is a complicated one. First, this section will examine the congressional intent behind supplying a federal remedy for a § 262(l)(2)(A) violation and, second, this section will highlight the treatment of the notice requirement under § 262(l)(2)(A).

*1. What is the federal remedy?*

The BPCIA created § 262(l)(2)(A), which states that a subsection (k)<sup>79</sup> applicant “shall provide to the reference product sponsor a copy of the application” and “such other information that describes the process or processes used to manufacture the biological product that is the subject of such application.”<sup>80</sup> This language suggests that a biosimilar applicant must provide

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74. 42 U.S.C. § 262(l)(8)(A).

75. 42 U.S.C. § 262(l)(8)(B).

76. Dov Hirsch, *The Riddle of the Mysterious Patent Dance Wrapped in an Enigma: Is the Patent Dance of the BPCIA Optional or Mandatory*, 27 *FORDHAM INTELL. PROP. MEDIA & ENT. L.J.* 645, iv (2017) (describing that whether the “patent dance” is mandatory or optional has implications for the pharmaceutical industry, specifically because a designation of mandatory or optional changes which party, the biologic manufacturer or the biosimilar applicant, has a greater advantage and bargaining position during the stages of negotiation outlined in the BPCIA).

77. Hirsch, *supra* note 76, at 670.

78. *Id.*

79. *See supra* notes 48–49 and accompanying text.

80. 42 U.S.C. § 262(l)(2)(A).

the aforementioned information and it follows that there is a remedy available when the biosimilar applicant fails to do so. The BPCIA acknowledges this by stating that when a subsection (k) applicant does not provide the information listed in § 262(l)(2)(A), the reference product sponsor can bring an action for “a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.”<sup>81</sup>

Understanding how the BPCIA works to identify violations, like a failure to disclose, and the associated remedies, requires careful statutory interpretation. One principle of statutory construction is that where a statute identifies a certain remedy, courts should uphold enforcement of that remedy and avoid reading more remedies under the statute.<sup>82</sup> This means that the strongest evidence for the remedy Congress intended to provide is within the language of the statute,<sup>83</sup> in this case, the BPCIA. Another pillar of statutory construction helpful in understanding the BPCIA is relying on the legislative history of the congressional measure to infer intent.<sup>84</sup> In 2007 the U.S. Senate Committee on Health, Education, Labor & Pensions engaged in discussions to make amendments to the PHSA.<sup>85</sup> The committee drafted the S.1695 bill to include provisions for both patent litigation and remedies “available to the innovator upon a finding that the patent was valid and infringed.”<sup>86</sup>

The proposed amendments also included declaratory judgment provisions to § 351(l) of the PHSA. One amended provision indicates that where a biosimilar applicant has failed to provide its application and manufacturing information, the reference product sponsor could bring a declaratory judgment in reference to the “patent that claimed the biological product or a use of the biological product.”<sup>87</sup> This language survived for the next three years and

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81. 42 U.S.C. § 262(l)(9)(C).

82. *Transamerica Mortgage Advisers, Inc. v. Lewis*, 444 U.S. 11, 19 (acknowledging that whether or not a statute “creates a cause of action either expressly or by implication, [it] is basically a matter of statutory construction.”).

83. For a discussion on the weight of evidence the statute provides in revealing congressional intent, see *Middlesex County Sewerage Authority v. Sea Clammers*, 453 U.S. 1, 14 (1981), stating that “[i]n the absence of strong indicia of a contrary congressional intent, we are compelled to conclude that Congress provided precisely the remedies it considered appropriate.”

84. *Sea Clammers*, 453 U.S. at 13.

85. 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, 755 (2010). It is important to note that the PHSA is an important legislative ancestor of the BPCIA because the Biologics Act of 1902 was incorporated as § 351 of the PHSA, which subsequently became the provision amended by the BPCIA. *Id.* For a recent discussion on the legislative history leading up to the enactment of both the Biologics Act and the PHSA, see Terry S. Coleman, *Early Developments in the Regulation of Biologics*, 71 FOOD & DRUG L. J. 544 (2016).

86. Hessler, *supra* note 85, at 755.

87. *Id.* (citing S. 1695 2(a)(2), proposed PHSA § 351(l)(9)(C)).

through the BPCIA was incorporated as § 262(l)(9)(C).<sup>88</sup> Therefore, both the language of this provision and its legislative history suggest that Congress intended to provide a declaratory judgment action as the remedy for the reference product sponsor when the applicant fails to disclose as outlined under § 262(l)(2)(A).

### 2.. *The Requirement of Notice of First Commercial Marketing*

The BPCIA established a notice requirement under § 262(l)(8)(A), which had the unfortunate effect of fostering tension between biologics and biosimilar manufacturers. This subsection of the statute states that the biosimilar applicant needs to provide notice to the reference product sponsor of its plans to market a biosimilar product “not later than 180 days before the date of first commercial marketing.”<sup>89</sup> *Amgen Inc. v. Sandoz Inc.* presented the question of whether a biosimilar applicant can only provide premarketing notice *after* the FDA approves its biosimilar product.<sup>90</sup> Treatment of § 262(l)(8)(A) indicates that the consensus among lower courts is to interpret the provision as requiring FDA approval of a biosimilar before the applicant can give notice to the reference product sponsor. For example, in *Amgen Inc. v. Apotex Inc.*,<sup>91</sup> the Court of Appeals for the Federal Circuit embraced this consensus by holding that the subsection (k) applicant must wait for FDA approval before it can give notice of commercial marketing.<sup>92</sup>

The following year in *Janssen Biotech v. Celltrion Healthcare*,<sup>93</sup> the United States District Court for the District of Massachusetts relied on the holding in *Amgen, Inc. v. Apotex, Inc.* to interpret that the negotiation and disclosure section of the BPCIA to mean that biosimilar applicants could only give post-approval notice of first commercial marketing.<sup>94</sup> In its complaint, plaintiff Janssen argued that because the defendants (Celltrion and Hospira) provided notice before FDA approval of their biosimilar version of Janssen’s Remicade, the defendants acted in contrast to the purpose of the BPCIA’s statutory timeline.<sup>95</sup> According to Janssen, requiring the applicant to wait for FDA approval allows the parties to adjudicate patent disputes and affords the biologics innovator time to seek a preliminary injunction to prevent the biosimilar from entering the market.<sup>96</sup> The

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88. 42 U.S.C. § 262(l)(2)(C) (2018).

89. 42 U.S.C. § 262 (l)(8)(A).

90. *See supra* Part II.

91. *Amgen Inc. v. Apotex Inc. (Amgen III)*, 827 F.3d 1052 (Fed. Cir. 2016).

92. *Amgen III*, 827 F.3d at 1054.

93. *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, 210 F. Supp. 3d 244 (D. Mass. 2016).

94. *Janssen*, 210 F. Supp. at 246–47.

95. Complaint of Petitioner at 3, No. 1:15-v-10698-MLW, *Janssen Biotech Inc. v. Celltrion Healthcare Co.*, 210 F. Supp. 3d 244 (D. Mass. 2016).

96. *Id.*

district court found these arguments persuasive and the opinion further implied that FDA licensure was a prerequisite to premarketing notice.<sup>97</sup>

Janssen's arguments acknowledge the policy concerns surrounding the BPCIA's commercial marketing provision. Innovators of biologics, like Janssen, prefer to support a requirement for licensure prior to notice because it allows them fully exercise their power in the patent litigation and resolution process as outlined in the BPCIA. On the other hand, biosimilar applicants prefer a flexible interpretation that allows notice prior to licensure. This is because as a strategic move, an applicant who gives notice before FDA approval could attempt to bypass the second phase of patent litigation by informing the reference product sponsor that their product is ready for market.<sup>98</sup>

Primarily, the BPCIA provides the framework for reference product sponsors like Amgen and biosimilar manufacturers like Sandoz to interact with one another. Within this framework, the patent dance and notice of first commercial marketing by the biosimilar applicant are just two such interactions that can result in litigation between pharmaceutical companies. It then becomes the role of a court to determine what remedy, if any, is available, and whether certain provisions of the BPCIA, such as the disclosure and notice of commercial marketing provisions, are optional or mandatory for the parties in the suit.

### III. THE COURT'S REASONING

In *Sandoz Inc. v. Amgen Inc.*, the United States Supreme Court's decision included two holdings. The Court examined the BPCIA and held first that injunctive relief was unavailable as a federal remedy under § 262(l)(2)(A).<sup>99</sup> Second, the Court held that a biosimilar applicant is allowed to give notice of first commercial marketing prior to FDA approval under § 262(l)(8)(A) of the statute.<sup>100</sup> This section will explore how the Supreme Court came to both conclusions by (1) examining the Court's interpretation of the relevant statutory provisions and (2) identifying how the Court differentiated from the analysis of the United States Court of Appeals for the Federal Circuit.

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97. *Janssen*, 210 F. Supp. at 246. The district judge opined that although the FDA approved defendant Cellitron's biosimilar product in April 2016, the company could not begin selling its product until October 2016. *Id.*

98. John L Marquardt & Stephen R Auten, *Strategic Considerations under the Biologics Price Competition and Innovation Act*, 23 EXPERT OPINION ON THERAPEUTIC PATS. 915, 918 (2013), <https://www.tandfonline.com/doi/full/10.1517/13543776.2013.813935>.

99. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1674 (2017).

100. *Id.* at 1677.

*A.. Identifying the Appropriate Remedy for Negotiation and Disclosure Violations*

The Supreme Court began its analysis by combing through the relevant statutory provisions to determine whether the information exchange between the applicant and reference product sponsor described by the BPCIA is enforceable by injunction.<sup>101</sup> The Court identified 42 U.S.C. § 262(l)(9)(C) and 35 U.S.C. § 271(e), the statutory scheme for patent infringement, as outlining what remedies are available when an applicant does not comply with the disclosure requirements.<sup>102</sup>

The Court focused closely on two clauses within 35 U.S.C. § 271(e)(2)(C). Clauses (i) and (ii) recognize that an act of artificial infringement can result in either of two pathways after the applicant receives notice from the FDA that its application is under review.<sup>103</sup> Clause (i) states that artificial infringement occurs when the biosimilar applicant submits an application regarding the patents potentially subject to suit, which were identified by each party in the § 262(l)(3) lists created previously.<sup>104</sup> In the alternative, clause (ii) states that artificial infringement occurs when the applicant submits an application without first sharing the application and manufacturing information with the reference product sponsor so the parties never reach the stage of assembling § 262(l)(3) lists to identify what patents might be subject to suit.<sup>105</sup> Therefore, under this section, submission of the application represents an act of artificial infringement “with respect to any patent that *could* have been included on the lists.”<sup>106</sup>

Based on this, the Court determined that the two provisions of § 271(e)(2)(C) worked together to identify that the act of infringement for which a remedy is available under § 271(e) is the act of submitting the biosimilar application.<sup>107</sup> The Supreme Court then reasoned that Sandoz’s failure to provide its application or manufacturing information is not the sort of action identified as an act of artificial infringement within the statute.<sup>108</sup> The Court stressed this point in an attempt to clarify why the lower court’s reasoning, despite reaching the correct conclusion on this issue, was flawed. According to the Supreme Court, the lower court focused on the following language in § 271(e)(2)(C)(ii): “if the applicant for the application fails to provide the application and information

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101. *Id.* at 1674.

102. *Id.*

103. *Id.*

104. *Id.*

105. *Id.*

106. *Id.*

107. *Id.*

108. *Id.*

required under [262(l)(2)(A)]”<sup>109</sup> to determine that Sandoz committed artificial infringement.<sup>110</sup> By concluding that Sandoz was guilty of artificial infringement, the court of appeals concluded that the only remedy available to Amgen was that prescribed by § 271(e)(4).<sup>111</sup> However, the Supreme Court’s focus on the structure of § 271(e)(2)(C) allowed it to conclude that neither clause describes an “applicant’s failure to provide its application and manufacturing information an element of the act of artificial infringement” and furthermore that in neither clause does “271(e)(4) provide a remedy for that failure.”<sup>112</sup>

Next, the Supreme Court moved its discussion to the remedy available when an applicant fails to provide its application and manufacturing information.<sup>113</sup> As enacted by the BPCIA, § 262(l)(9)(C) a sponsor is authorized to immediately file an action for a declaratory judgment based on an act of artificial infringement as defined by § 271(e)(2)(C)(ii).<sup>114</sup> In this case, Sandoz’s submission of its application to the FDA without first providing the application and manufacturing information to Amgen constituted an act of artificial infringement,<sup>115</sup> entitling Amgen to a remedy under § 262(l)(9)(C).<sup>116</sup> The Court determined that § 262(l)(9)(C) was meant to provide the only federal remedy for an applicant’s failure to comply with the disclosure requirements under § 262(l)(2)(A).<sup>117</sup> Writing for the Court, Justice Thomas, relying on *Great-West Life & Annuity v. Ins. Co. v. Knudson*, argued that the best evidence of what remedy Congress intended to provide for such a failure was the language and structure of the BPCIA itself.<sup>118</sup> Based on the language of this provision, it was clear to the Court that “Congress did not intend to authorize other remedies that it simply forgot to incorporate expressly.”<sup>119</sup>

The Supreme Court relied on additional text within the BPCIA to support the position that Congress intended to make available to a reference product

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109. *Id.*

110. *Id.*

111. *Id.*

112. *Id.* at 1675.

113. *Id.*

114. *Id.*

115. Neither party was in dispute that Sandoz failed to comply with the disclosure procedures outlined in § 262(l)(2)(A). *Id.* at 1676.

116. *Id.* at 1675.

117. *Id.*

118. *Id.* (citing *Great-West Life & Annuity v. Ins. Co. v. Knudson*, 534 U.S. 204, 209 (2002) (demonstrating that where there exists an extensive and comprehensive piece of legislation, in the context of what equitable remedies are available under Employment Retirement Income Security Act (ERISA) in a state action brought to enforce a reimbursement provision by a health plan to recover from a beneficiary any proceeds paid by a third party, the Supreme Court is reluctant to extend the scope of a statute so as to infer remedies that are not already outlined in the statute itself)).

119. *Id.* at 1675 (quoting *Great-West Life & Annuity v. Ins. Co. v. Knudson* 534 U.S. 204, 209 (2002)).

sponsor only a declarative judgment action only when a biosimilar applicant fails to disclose its application and manufacturing information. For example, § 262(l)(1)(H) states that a court can consider injunctive relief as an available remedy for a violation, or threatened violation, of the rules of confidentiality as they relate to any information disclosed under § 262(l).<sup>120</sup> According to the Court, because Congress explicitly attached injunctive relief as a remedy for a confidentiality violation, an applicant's failure to disclose is not a violation that Congress intended to attach injunctive relief as the remedy.<sup>121</sup> Therefore, the Supreme Court affirmed the Federal Circuit's holding that enforcing compliance with § 262(l)(2)(A) via an injunction was not the appropriate remedy for Amgen under federal law.<sup>122</sup>

*B. Identifying the Timeline for Notice of First Commercial Marketing Under the BPCIA*

The second prong of the Supreme Court's holding addressed whether or not, the BPCIA allows a biosimilar applicant to provide notice of first commercial marketing to the reference product sponsor only after FDA approval.<sup>123</sup> Specifically, the Court examined whether Sandoz complied with the law when it informed Amgen of plans to start marketing its biosimilar immediately after receiving FDA approval of its drug.<sup>124</sup>

The BPCIA adopted § 262(l)(8)(A) as the statutory text that refers to the timeline concerning when a biosimilar applicant is to provide notice of first commercial marketing. The Court again focused on the structure of the provision itself to interpret its meaning<sup>125</sup> The Supreme Court concentrated on the exact language of the statute, which states that the applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of first commercial marketing of the biological product licensed under subsection (k)."<sup>126</sup> The Court interpreted this as requiring the applicant to provide notice at least 180 days before the date of first commercial marketing.<sup>127</sup>

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120. *Id.*

121. *Id.*

122. *Id.* The Court declined to review the Federal Circuit's holding that Sandoz's failure to disclose its application and manufacturing information was not "unlawful under California's unfair competition law" both because this did not present a question of federal law and whether the BPCIA's negotiation and disclosure procedures are relevant matters only insofar as to determine whether there was unlawful conduct under the state law. *Id.*

123. *Id.* at 1677.

124. *Id.* at 1672.

125. *Id.* at 1677.

126. *Id.* (quoting 42 U.S.C. § 262(l)(8)(A) (2018)).

127. *Id.*



Next, the Court evaluated the strength of Amgen's main argument that the statute requires a biosimilar product to be approved by the FDA before the applicant can inform the reference product sponsor of first commercial marketing.<sup>128</sup> Amgen argued that because § 262(l)(8)(A) referred to "the biological product licensed" instead of just "the biological product that is the subject of the application" like in other BPCIA provisions, that meant that notice of first commercial marketing can only come after FDA approval.<sup>129</sup> The Supreme Court was not persuaded by this argument because the provision that Amgen relied on, § 262(l)(3)(B)(ii)(I),<sup>130</sup> inherently needs to reference the biological product that the subsection (k) application is based on, otherwise referring to a licensed product in this provision would not have made sense.<sup>131</sup>

Accordingly, the Supreme Court held that an applicant could provide notice of commercial marketing prior to FDA licensure and thus Sandoz was in full compliance with § 262(l)(8)(A).<sup>132</sup> Ultimately, the Court felt that the lower appellate court erred in granting an injunction to prevent Sandoz from marketing its filgrastim product until 180 days after licensure.<sup>133</sup> The two courts differed on this issue because each relied on different interpretations for the number of timing requirements for notice of commercial marketing imposed by the BPCIA. The Supreme Court interpreted § 262(l)(8)(A) as imposing only the requirement that the applicant needed to provide notice at least 180 days prior to marketing, but not necessarily prior to licensure.<sup>134</sup> The federal circuit, however, interpreted this same provision as imposing two timing requirements such that the biosimilar applicant would be providing notice of commercial marketing both after the FDA approves the product and at least 180 days before the applicant begins marketing its biosimilar.<sup>135</sup> The Supreme Court reasoned that the lower court incorrectly interpreted the statute, and supported its argument with the fact that the adjacent provision, § 262(l)(8)(B), expressly outlined two timing requirements.<sup>136</sup>

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128. *Id.*

129. *Id.* (referencing Brief for Amgen Inc. et al.).

130. This section "requires the applicant to explain why the sponsor's patents are 'invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application.'" *Id.* (quoting 42 U.S.C. § 262(l)(3)(B)(ii)(I) (2018)).

131. *Id.* Section 262(l)(3)(B)(ii)(I) references the product that is the subject of the (k) application because the applicant would be unable to make the evaluation identified in the section after licensure "because the biosimilar's specifications may change during the application process." The Supreme Court also found Amgen's policy arguments unpersuasive. *Id.*

132. *Id.* at 1678.

133. *Id.*

134. *Id.* at 1677.

135. *Id.*

136. *Id.*

The Supreme Court relied on *Russello v. United States*<sup>137</sup> to strengthen its assertion that if Congress meant to impose two timing requirements in § 262(l)(8)(A), “it presumably would have done so expressly as it did in the immediately following subparagraph.”<sup>138</sup> For these reasons, the Supreme Court reversed the federal circuit’s holding that a biosimilar applicant can only provide notice to the reference product sponsor of commercial marketing following FDA approval. Instead, the Supreme Court held that a biosimilar applicant is permitted to provide notice of first commercial marketing before FDA approval of the biosimilar drug product.<sup>139</sup>

#### IV. ANALYSIS

In *Sandoz Inc. v. Amgen Inc.*, the Supreme Court’s holding is two-fold. This Analysis focuses on the second part of the Court’s opinion, which articulated the correct holding that a biosimilar applicant could provide premarketing notice prior to FDA licensure.<sup>140</sup> The holding is significant for the following reasons: (1) it is consistent with the innovation and drug accessibility goals of the BPCIA; and (2) it both creates a new incentive for biosimilar manufacturers and acts as a mechanism that ensures the exclusivity period for the original biologic product of the reference sponsor is limited to exactly twelve years.

##### *A. Permitting Pre-approval Notice of Commercial Marketing is Consistent With the Goals of the BPCIA*

At its basic level, the BPCIA provides an accelerated approval pathway for biosimilars, which incentivizes competition between biologics manufacturers and biosimilar manufacturers while reducing overall costs to patients.<sup>141</sup> The Supreme Court’s unanimous 9–0 decision in *Sandoz* of allowing biosimilar applicants to provide premarketing notice before FDA approval is consistent with these goals.

Additionally, the BPCIA provides a solution to the unique challenge biosimilar manufacturers experience when entering the drug market.<sup>142</sup> This challenge is due in part to the manufacturing process associated with creating

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137. *Russello v. United States*, 464 U.S. 1, 16 (1983).

138. *Sandoz*, 137 S. Ct. at 1677 (2017) (quoting *Russello*, 464 U.S. at 23).

139. *Id.*

140. *Id.* at 1678.

141. See *supra* note 44 and accompanying text.

142. Erwin A. Blackstone and Joseph P. Fuhr, *The Economics of Biosimilars*, 6 AM. HEALTH & DRUG BENEFITS 469, 471 (2013) (describing that biosimilar market entry is first delayed by the barriers imposed in needing to overcome the unique hurdles “associated with manufacturing, marketing, storage (cold) and other distribution issues, delivery devices, immunogenicity (i.e., patient adverse reactions because of live organisms), and special requirements for pharmacovigilance (ie, postsale monitoring)).

biologic drugs, which are known for their structural complexity.<sup>143</sup> Biologics are developed from living cells<sup>144</sup> and because individual cells are often not perfect copies of each other, this leads to slight variations in the development of the biosimilars based on those biologic products.<sup>145</sup> This prevents biosimilars from being marketed as perfect or identical substitutes for biologic products, thereby requiring creative marketing strategies that demonstrate why biosimilars are still beneficial to patients in order to assuage any skepticism from stakeholders.<sup>146</sup>

The challenge of creating biosimilars results in fewer biosimilar entrants to the drug market,<sup>147</sup> making it difficult to boost innovation among biosimilar manufacturers. Thus, biologics manufacturers are in a position to significantly monopolize the drug market by requiring biosimilar applicants to wait 180 days after FDA approval to provide commercial marketing notice.<sup>148</sup> For example, Amgen produces a substantial fraction of the biologic products for common medical conditions and in 2016, benefitted from about \$16.7 billion in U.S. sales.<sup>149</sup> Therefore, it does little to foster innovation when the same companies like Amgen, Hoffman-la Roche,<sup>150</sup> and Johnson & Johnson<sup>151</sup> produce a bulk of biologic pharmaceuticals for common medical conditions.<sup>152</sup>

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143. Bhupinder Singh Sekhon & Vikrant Saluja, *Biosimilars: An Overview*, DOVE PRESS J.: BIOSIMILARS 1, 2–3 (2011) (describing that some of the difficulty associated with manufacturing biologic products is that they are much bigger molecules than small molecule drugs, adding considerably to the molecular weight of biologic products).

144. Bruno Calo Fernandez & Juan Leonardo Martinez-Hurtado, *Biosimilars: Company Strategies to Capture Value from the Biologics Market*, 5 PHARMACEUTICALS 1393, 1397 (2012).

145. *Id.*

146. John Carlsen, MHA & Kristi Skorija, *Biosimilars: The Commercial Challenge*, COVANCE BLOG (Sept. 2, 2014), <http://blog.covance.com/2014/09/biosimilars-commercial-challenge/>.

147. Henry Grabowski et al, *Biosimilar Pathway*, 41 SETON L. REV., 511, 538 (2011).

148. One way that exclusivity periods for biologics manufacturers exists is in the way that these companies are able to sell their products at “monopoly rates,” meaning that biologics innovators become more incentivized to maintain these monopolies as long as possible, to the detriment of biosimilar manufacturers. Yaniv Heled, *Patents v. Statutory Exclusivities in Biological Pharmaceuticals – Do We Really Need Both?*, 18 MICH. TELECOM. TECH. L. REV. 419 (2012).

149. Fiona Scott Morton & Lysle T. Boller, *Enabling Competition in Pharmaceutical Markets*, HUTCHINS CTR. 1, 4 (2011) (depicting as Table 1: Top 30 biologics by sales, which breaks down the amount in U.S. dollars of sales in 2016 for pharmaceutical companies producing biologics for particular medical indications and that Amgen Corporation’s sales in 2016 resulted from products treating rheumatoid arthritis, cancer, anemia, renal failure, osteoporosis, bone cancer, and HIV/AIDS.).

150. *Id.* (indicating \$14 billion in total sales in 2016 for Hoffmann la-Roche resulting from biologics targeting cancer, rheumatoid arthritis, macular degeneration, breast cancer, asthma, anemia and renal failure).

151. *Id.* (indicating \$8.3 billion in total sales in 2016 for Johnson & Johnson resulting from biologics treating rheumatoid arthritis, Crohn’s disease, psoriasis, and ulcerative colitis).

152. A related problem acknowledged by commentators in the pharmaceutical industry is the overall decline in the past few years within the Big Pharma sector in research and development productivity, which at least for brand-name companies resulted in defensive strategies to keep generics from threatening the market. Ajay Gautam, *The Changing Model of Big Pharma: Impacts of Key Trends*, 21 DRUG

Against this backdrop, the Supreme Court's holding in *Sandoz* facilitates the BPCIA's goal of innovation because a biosimilar applicant's product need not be licensed before the applicant provides notice of commercial marketing, resulting in quicker drug dissemination once the biosimilar product is approved.<sup>153</sup> This incentivizes biosimilar development because an applicant does not need to wait until licensure to start developing a successful marketing strategy and could conceivably plan to enter the market almost immediately following FDA approval.<sup>154</sup> The steady influx of new biosimilars approved by the FDA will weaken the monopolies held by biologic drug manufacturers,<sup>155</sup> which in turn will foster industry competition.

Furthermore, the holding in *Sandoz*, by encouraging competition between biologics and biosimilars, does even more to facilitate the second goal of the BPCIA of promoting accessibility to patients by reducing drug costs.<sup>156</sup> A 2009 Federal Trade Commission (FTC) report estimated that biosimilar products would be about ten to thirty percent cheaper than brand-name biologics.<sup>157</sup> Although the report argued that the long-term benefits of an abbreviated biosimilar pathway would not be as immediately apparent as with the generic drug pathway under the Hatch-Waxman Act, the Commission nonetheless recognized that the ten to thirty percent decrease in price still represented significant consumer savings.<sup>158</sup> A statement from the Congressional Budget Office in 2010 reiterated this point by suggesting that a biosimilar pathway would lead to a \$7 billion reduction in the federal deficit between 2010 and 2019.<sup>159</sup>

Unlike their cheaper biosimilar counterparts, most biologics are secured by patents, which contributes to higher costs for patients who may have few other

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DISCOVERY TODAY 379, 380 (Mar. 2016); *see also* Mannching Sherry Ku, *Recent Trends in Specialty Pharma Business Model*, 23 J. FOOD & DRUG ANALYSIS 595, 598 (2015).

153. Aron Fischer, *Supreme Court Decides Amgen v. Sandoz: Patent Dance Cannot Be Enforced by Federal Injunction, Notice of Commercial Marketing Can Be Given at Any Time*, BIOLOGICSBLOG (June 14, 2017), <https://www.biologicsblog.com/supreme-court-decides-amgen-v-sandoz-patent-dance-cannot-be-enforced-by-federal-injunction-notice-of-commercial-marketing-can-be-given-at-any-time> (emphasizing that the *Sandoz*'s interpretation of the notice timeline in the BPCIA will allow biosimilar entry into the drug market sooner).

154. *Id.*

155. *See supra* note 148 and accompanying text.

156. Christine Blank, *Supreme Court Ruling Raises Biosimilars' Access*, MODERNMEDICINE NETWORK (June 19, 2017), <http://www.drugtopics.com/latest/supreme-court-ruling-raises-biosimilars-access>.

157. FEDERAL TRADE COMM'N, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION 47 (2009) (outlining an analysis of the effects of the creation of an abbreviated pathway for the development of biosimilars).

158. *Id.* at v.

159. Grabowski, *supra* note 147, at 544–545.

options.<sup>160</sup> Against this backdrop, it is crucial to encourage biosimilar manufacturers to enter these drug markets as soon as the patents for biologics products expire. As more biosimilars entering the market, competition will increase among manufacturers of biologics and biosimilars, resulting in lower prices for consumers because of the desire of pharmaceutical companies to ensure that their products stay competitive.<sup>161</sup> Added biosimilar presence in the drug market can increase the availability of marketing assessment and implementation strategies that are primarily used by biologics manufacturers.<sup>162</sup>

The Supreme Court's decision in *Sandoz* further promotes market accessibility for biosimilars by creating a mechanism for biosimilar manufacturers to begin implementing commercial marketing strategies, such as outreach to doctors and other forms of targeted advertising,<sup>163</sup> as soon as the company obtains FDA approval.<sup>164</sup> Faster marketing for biosimilars results in patients, physicians, and pharmacists, being made aware of the existence of quality-of-life improving therapies sooner.<sup>165</sup> This is significant in light of the research demonstrating that drug marketing strategies, particularly direct-to-consumer marketing campaigns, result in significant information dissemination of new products.<sup>166</sup> This facilitates having a shorter period between FDA approval and commercial marketing, which is significant considering the existing barriers to cheaper drug alternatives, like high copays.<sup>167</sup> Consequently,

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160. See THE AM. CONSUMER INST. CTR. FOR CITIZEN RESEARCH, LIFE SAVING DRUGS AT LOWER COSTS, <https://www.theamericanconsumer.org/wp-content/uploads/2014/07/Biosimilars-ConsumerGram-Final.pdf> (describing that prices per year per patient for certain conditions like blood diseases, Crohn's and Hunter's syndrome can cost \$400,000; \$50,000; and \$375,00 respectively).

161. *Id.* at 2.

162. Carlsen, *supra* note 146, at 3.

163. Mary Ebeling, 'Get with the Program!': *Pharmaceutical marketing, symptom checklists and self-diagnosis*, 73 SOC. SCI. & MED. 825, 826 (2011) (identifying other forms of marketing strategies for pharmaceuticals, such as targeting other health care professionals, promotional educational events, and direct-to-consumer advertising).

164. Christine Blank, *Supreme Court Ruling Raises Biosimilars' Access*, MODERNMEDICINE NETWORK (June 19, 2017), <http://www.drugtopics.com/latest/supreme-court-ruling-raises-biosimilars-access>.

165. An analysis of marketing strategies among pharmaceutical companies by McKinsey & Company suggests that companies can mitigate losses following drug launches by capturing the momentum associated with early consumer exposure to the product. Hemant Ahlawat, et. al., *The Secret of Successful Drug Launches*, MCKINSEY & CO. (Mar. 2014) <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-secret-of-successful-drug-launches>.

166. Ebeling, *supra* note 163, at 826 (citing a 2008 survey conducted to gauge direct-to-consumer advertising in which 91 percent of people who completed the survey indicated that they "had seen or heard at least one drug advertisement").

167. HUTCHINS POLICY BRIEF, TEN CHALLENGES IN THE PRESCRIPTION DRUG MARKET – AND TEN SOLUTIONS 1, 4 (2017). Insurers create these high co-pays to encourage patients to find cheaper alternatives but, when drug companies engage in the practice of distributing coupons to consumers to cover high co-pay prices, this has the effect of decreasing the likelihood of patients exploring low-cost alternatives. *Id.*

biosimilar manufacturers can begin benefitting from a lucrative drug market,<sup>168</sup> which will contribute to the positive patient outcomes of cheaper prices and increased accessibility to alternative treatments.

*B.. Allowing Pre-Approval Notice of Commercial Marketing Levels the Playing Field Between Biologic and Biosimilar Manufacturers*

The second prong of the holding in *Sandoz* underscores the leveling of the playing field between biologics and biosimilars manufacturers in an arena where the former typically has the upper hand. For example, the steps of the “patent dance” are advantageous to biologics manufacturers because of the exclusivity period that follows the licensure for a biologic.<sup>169</sup> The BPCIA’s amendments to subsection (k) of the PHSA create two types of exclusivity for the reference product sponsor.<sup>170</sup> First, an applicant is not allowed to file its aBLA with the FDA for review until four years after the date that the reference product was first licensed.<sup>171</sup> Second, under § 351(k)(7)(C) of the PHSA, the FDA cannot approve a biosimilar product sooner than twelve years after licensure of the original biologic product.<sup>172</sup> Thus, the statute creates a security mechanism for biologics manufacturers by delaying both the applicant’s filing and as well as the applicant’s hope for approval of its own product for another eight years after submitting its aBLA.

Biologics manufacturers receive added protection because subsection (k) requires applicants to wait 180 days after licensure before sending notice of commercial marketing.<sup>173</sup> The twelve-year exclusivity period incentivizes biologics manufacturers because they stand to benefit from even more market security than that guaranteed by the patents originally associated with their products.<sup>174</sup> Therefore, strict adherence to a 180-day period before premarketing notice limits market opportunities for biosimilar manufacturers. Requiring biosimilar manufacturers to wait another six months to give notice of commercial marketing extends the exclusivity period to twelve years and six months. Apotex

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168. Ester Bloom, *Here’s how much the average American spends on health care*, CNBC (June 23 2017, 5:15 PM), <https://www.cnbc.com/2017/06/23/heres-how-much-the-average-american-spends-on-health-care.html> (citing the Centers for Medicare and Medicaid Services statistics that show that “the average American spent \$9,596 on healthcare’ in 2012, which was ‘up significantly from \$7,700 in 2007’” and that the average spending per person on healthcare is expected to increase to \$14,944 in 2023).

169. *See infra* notes 170–172 and accompanying text.

170. FDA, GUIDANCE FOR INDUSTRY: REFERENCE PRODUCT EXCLUSIVITY FILED UNDER 351(A) OF THE PHS ACT 1 (2014).

171. *Id.*

172. *Id.*

173. *See supra* note 92 and accompanying text.

174. *See supra* note 62.

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unsuccessfully raised this argument against Amgen in 2015.<sup>175</sup> The Court of Appeals for the Federal Circuit interpreted the relevant provision to imply that FDA approval can occur at the earliest date of twelve years following the licensure of the reference product.<sup>176</sup> Therefore it was not unfair to allow only post-licensure notice under § 262(l)(8)(A). In its discussion, the court of appeals expressed that there was nothing preventing the FDA from issuing a license to a biosimilar product after eleven and a half years with the caveat that it will not be official until the twelve-year mark.<sup>177</sup>

However, this argument ignores that a biosimilar applicant with a provisional license after 11.5 years has to wait another full year from that point just to give notice to the reference product sponsor about future commercial marketing. The Court of Appeals for the Federal Circuit's analysis in *Amgen Inc. v. Apotex Inc.* appears to minimize this burden to biosimilar manufacturers simply because they still benefit from eventual FDA approval. The reality is that a further delay of six months following approval risks imposing a financial burden on a biosimilar manufacturer who has already spent millions<sup>178</sup> developing a product and an effective marketing strategy, only to be required to wait six another months before it can benefit from its innovation and enter the market. The Supreme Court's holding in *Sandoz* erodes this impediment to market access by sticking close to the language of § 262(l)(8)(A)<sup>179</sup> and providing only the period of exclusivity proscribed for reference product sponsors and nothing more. This spells good news for biosimilar applicants, who now have a way to fight against industry preference of post-licensure notice of commercial marketing.

Companies, like Amgen, that prefer reading the statute to require applicants to wait the 180 days insist that period is necessary to give the reference product sponsor "a period of time to assess and act upon its patent."<sup>180</sup> This argument loses persuasiveness in light of the premarket litigation scheme already outlined in the BPCIA, which protects the patent rights of the biologic manufacturer. For example, under § 262(l)(3)(A) of the BPCIA, the reference product sponsor can develop a list of patents associated with the reference product and then if the biosimilar applicant chooses to engage in negotiations, both parties can decide

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175. *Amgen III*, 827 F.3d 1052, 1061 (Fed. Cir. 2016).

176. *Id.*

177. *Id.* at 1062.

178. Developing a biosimilar drug costs between \$100 and \$250 million, making these products more expensive to manufacture than generic drugs, which typically cost between \$1 and \$4 million to produce. Erwin A. Blackstone & Joseph P. Fuhr, *The Economics of Biosimilars*, 6 AM. HEALTH & DRUG BENEFITS 469, 471 (2013).

179. 42 U.S.C. § 262(l)(8)(A) (2018).

180. *Amgen II*, 794 F.3d at 1360.

which patents will result in litigation.<sup>181</sup> If the biosimilar applicant elects not to participate in these negotiations, the BPCIA makes available preliminary injunction and declaratory judgment actions to enforce the patents held by the reference product sponsor.<sup>182</sup> These forms of relief empower the reference product sponsor to delay the FDA's approval of a biosimilar, which is a significant statutory grant of authority.

The effect of the BPCIA in granting biologics manufacturers the ability to potentially stall biosimilar approval is a powerful deterrent to biosimilar applicants, especially when compounded with the fact that big biologics manufacturers have already adopted one strategy of delaying the market entry of biosimilars. This strategy involves the reference product sponsor giving money, or other consideration, to the biosimilar applicant in exchange for the applicant not entering the market immediately.<sup>183</sup> These arrangements are known *pay-for-delay*<sup>184</sup> agreements and they ultimately benefit the biologic manufacturer because a biologic manufacturer that can secure the market delay of a biosimilar can control higher prices of its product.<sup>185</sup> Even the FTC has acknowledged the inherent danger of these agreements in hindering consumer access to critical and low-cost generic alternatives.<sup>186</sup> As a result, consumers are dramatically limited in their drug options because the only available products are often biologics, which are more expensive<sup>187</sup> than “traditional drugs of the pharmaceutical industry.”<sup>188</sup>

The Supreme Court's acceptance of the pre-approval notice under § 262(l)(8)(A) of the BPCIA<sup>189</sup> limits a biologic manufacturer's ability to delay a

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181. See *supra* notes 69–71 and accompanying text.

182. See *supra* note 75 and accompanying text.

183. Erwin A. Blackstone & Joseph P. Fuhr Jr., *Biologics and Biosimilars: The Possibility of Encouraging Innovation and Competition*, 11 THE SCITECH L. AM BAR ASS'N 1, 3 (2015).

184. *Id.*

185. *Id.*

186. See Press Release, Fed. Trade Comm'n, FTC Sues Endo Pharmaceuticals Inc. and Others for Illegally Blocking Lower-Cost Generic Versions of the Branded Drugs Opana ER and Lidoderm (Mar. 31, 2016), <https://www.ftc.gov/news-events/press-releases/2016/03/ftc-sues-endo-pharmaceuticals-inc-others-illegally-blocking-lower> (describing the FTC's most recent 2016 suit in a ten year battle against drug companies in violation of antitrust laws by using pay-for-delay agreements, which make low-cost generics less accessible to consumers); see also *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2230 (2013) (indicating that in the settlement between the parties, Actavis Inc. agreed not to enter its generic product into the drug market with until 2015, and this agreement was subsequently followed by the FTC suing the settling parties on the basis that such agreements were in violation of the Federal Trade Commission Act).

187. See *supra* note 160.

188. Felix Shin, *Leaping from the Patent Cliff into the Global Drug Gap: Overcoming Exclusivity to Provide Affordable Biosimilars*, 37 LOY. L.A. INT'L & COMP. L. REV. 419, 423 (2016) (differentiating between traditional drugs, which are small molecule drugs typically produced via five to ten chemical reactions, and biologic products that are typically manufactured using living organisms and may require between 5,000 and 10,000 chemical reactions).

189. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1678 (2017).



biosimilar applicant's market entry. Biologics manufacturers could still try to enter pay-for-delay agreements, but now that biosimilar applicants can provide pre-approval notice of commercial marketing without risking a statutory violation, these arrangements will be less enticing to biosimilar applicants because they can now market and launch products sooner.<sup>190</sup> In fact, the end result of the Supreme Court's holding may be in deterring biologics manufacturers from encouraging pay-for-delay agreements once those companies realize that biosimilars now have greater incentive to push for earlier market entry, which is good news for consumers.

Ultimately, the Supreme Court's holding is a substantial win for biosimilar manufacturers because these companies now have an opportunity to challenge the tight market exclusivity that biologics manufacturers hold.<sup>191</sup> Biosimilar manufacturers now have a more streamlined route to the drug market because they can provide pre-approval notice of first commercial marketing to reference product sponsors without violating the BPCIA. The positive effect of this decision is that it improves access to cost effective therapies so patients no longer have to rely only on biologic drugs for a wide variety of common medical conditions.<sup>192</sup>

#### V. CONCLUSION

In *Sandoz Inc. v. Amgen Inc.*, the Supreme Court's plain language interpretation and focus on the structure of the BPCIA resulted in the correct holding that biosimilar applicants can provide the reference product sponsor with notice of commercial marketing prior to FDA approval. This part of the Court's holding reflects the ultimate goals of the BPCIA to promote innovation and drug accessibility for patients while also recognizing that biosimilar products already face inherent challenges to gaining market access. Therefore, the BPCIA should not be interpreted to impose additional barriers to biosimilar manufacturers whose products act as a cheaper alternative to patients.

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190. Christine Blank, *Supreme Court Ruling Raises Biosimilars' Access*, MODERNMEDICINE NETWORK (June 19, 2017), <http://www.drugtopics.com/latest/supreme-court-ruling-raises-biosimilars-access> (describing that companies seeking approval for biosimilar products may be able to launch their products sooner without any unnecessary delay).

191. See *supra* notes 148–152 and accompanying text.

192. Gene Quinn, *Industry Reaction to SCOTUS decision in Sandoz v. Amgen*, IPWATCHDOG (June 14, 2017), <http://www.ipwatchdog.com/2017/06/14/industry-reaction-scotus-sandoz-v-amgen/id=84473/>.