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## The Biologics Price Competition and Innovation Act: Is a Generic Market for Biologics Attainable?

Kasey E. Koballa

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# THE BIOLOGICS PRICE COMPETITION AND INNOVATION ACT: IS A GENERIC MARKET FOR BIOLOGICS ATTAINABLE?

KASEY E. KOBALLA\*

## ABSTRACT

*The Biologics Price Competition and Innovation Act of 2009 (BPCIA) provides an abbreviated approval pathway for biological therapeutic products shown to be biosimilar to an FDA-approved biological reference product. The BPCIA purported to reduce the price of biologics while promoting innovation. In two recent cases, the Federal Circuit interpreted a key provision of the BPCIA requiring an applicant to provide the reference product sponsor with notice 180 days before marketing the product. The Federal Circuit's interpretation extends the exclusivity period already provided for the reference product sponsor, deterring innovation and price reduction. Thus, the Supreme Court granted certiorari in one of the cases.*

*This Note will examine provisions of the BPCIA, discuss the two recent Federal Circuit decisions, offer an interpretation of the relevant BPCIA provisions and a proposed stance on the issues before the Supreme Court, and explain how the current interpretation impairs the potential for a generic market for biologics.*

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## INTRODUCTION

Biopharmaceuticals, which may be referred to as biologics,<sup>1</sup> are a form of medical treatment manufactured in living systems, including plants, animals, and microorganisms—differing from drugs manufactured through chemical processes.<sup>2</sup> In chemical drug manufacturing, the manufacturing process is ordered and resistant to change; however, with biologics, “the product is the process.”<sup>3</sup> The processes are sensitive to minor changes.<sup>4</sup> Due to this, “[m]any [biopharmaceuticals] are produced using recombinant DNA technology” and process controls are specific to manufacturers, increasing the difficulty for a second manufacturer to replicate the product without knowing the exact process used.<sup>5</sup> Combined with the complexity of biologics, these processes make it difficult to ensure that a follow-on product is as safe and effective as the reference product.<sup>6</sup> While the “bioequivalence of a generic drug” can be established through blood level testing or other analyses, the therapeutic equivalence of a biologic can only be proven through clinical trials, and therapeutic equivalence is required for biological products.<sup>7</sup>

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<sup>1</sup> See Ronald A. Rader, *What Is a Biopharmaceutical?*, BIOEXECUTIVE INT’L 60, 64 (Mar. 2005), [http://www.biopharma.com/bioexecutive\\_article\\_pt1.pdf](http://www.biopharma.com/bioexecutive_article_pt1.pdf) [<https://perma.cc/SV37-7YQW>].

<sup>2</sup> *How Do Drugs and Biologics Differ?*, BIOTECHNOLOGY INNOVATION ORGANIZATION, <https://www.bio.org/articles/how-do-drugs-and-biologics-differ> [<https://perma.cc/USE7-WHAZ>] (last visited Feb. 19, 2018).

<sup>3</sup> *Id.* The “product is the process” because the biologics are made through a live system. *Id.* The product can be a living entity such as a cell or tissue and is composed of nucleic acids, proteins, or other natural components. *Id.* (referring to the process of making biologics).

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

<sup>5</sup> *Id.*

<sup>6</sup> *Id.* This differs from chemical drugs where it is easy for manufacturers to reverse engineer a chemical compound to make a generic product. *See generally id.*

<sup>7</sup> *Id.* To be therapeutically equivalent, the drug must be both bioequivalent and pharmaceutically equivalent. *Id.* Drugs are bioequivalent if “the rate and extent of absorption of the test drug do not show a significant difference from the rate and extent of absorption of the reference drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses.” *Nomenclature (as excerpted from the Orange Book)*, U.S. FOOD & DRUG ADMIN., 2, <https://www.fda.gov/ohrms>

Biologics have proven effective in treating chronic conditions, such as multiple sclerosis, rheumatoid arthritis, and cancer.<sup>8</sup> However, the production processes make biologic some of the most expensive drugs available.<sup>9</sup> “In 2013, biologics comprised 28 percent (roughly \$92 billion) of U.S. drug spending, an increase of nearly 10 percent since 2012 ...,”<sup>10</sup> and based on past trends, this percentage will likely continue to increase.<sup>11</sup>

In an effort to reduce the costs of biologics and provide pharmaceutical manufacturers with initiatives to strive continuously for innovation in biological therapies, President Barack Obama signed into law the Biologics Price Competition and Innovation Act of 2009 [hereinafter referred to as the BPCIA] as part of the Patient Protection and Affordable Care Act.<sup>12</sup> To balance innovation and inventor interests, the BPCIA provides a twelve-year exclusivity period for a reference biologic product, preventing follow-on biologics (or biosimilars) from entering the market during this period.<sup>13</sup> Conversely, the BPCIA stimulates accessibility by delineating an abbreviated pathway for biosimilar manufacturers to obtain a license for marketability after the exclusivity period ends.<sup>14</sup>

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/dockets/ac/05/briefing/2005-4137B1\_07\_Nomenclature.pdf [https://perma.cc/E8B6-LZKQ]. Further, “[d]rug products are considered to be therapeutic equivalents only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.” *Id.* at 1. “Drug products are considered pharmaceutical equivalents if they contain the same active ingredient(s), are of the same dosage form, route of administration and are identical in strength or concentration ....” *Id.*

<sup>8</sup> Donna M. Gitter, *Innovators and Imitators: An Analysis of Proposed Legislation Implementing an Abbreviated Approval Pathway for Follow-On Biologics in the United States*, 35 FLA. ST. U.L. REV. 555, 557 (2008).

<sup>9</sup> See Alex Brill, *The Economic Viability of a U.S. Biosimilars Industry*, MATRIX GLOBAL ADVISORS 4 (Feb. 2015), [http://static1.1.sqspcdn.com/static/f/460582/25983845/1424796699187/MGA\\_biosimilars\\_2015\\_web.pdf?token=lc7oFKdV%2Bh2Y1RuuLiIHvc%2BQETc%3D](http://static1.1.sqspcdn.com/static/f/460582/25983845/1424796699187/MGA_biosimilars_2015_web.pdf?token=lc7oFKdV%2Bh2Y1RuuLiIHvc%2BQETc%3D) [https://perma.cc/Q26X-J4X6].

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> See generally Ude Lu, *Biologics Price Competition and Innovation Act: Striking a Delicate Balance Between Innovation and Accessibility*, 15 MINN. J.L. SCI. & TECH. 613 (2014).

<sup>13</sup> *Id.* at 613.

<sup>14</sup> *Id.* at 614. A biological product is biosimilar to a reference product if it is “highly similar to the reference product notwithstanding minor differences in

However, many provisions of the BPCIA remain unclear as to whom the requirements apply.<sup>15</sup>

In 2015, the Federal Circuit decided *Amgen Inc. v. Sandoz Inc.* [hereinafter referred to as *Amgen v. Sandoz*],<sup>16</sup> interpreting a provision of the BPCIA that requires an applicant seeking a license for a biosimilar to give the reference product sponsor at least 180 days advance notice of the first commercial marketing of its biosimilar.<sup>17</sup> The Court held that the applicant must provide notice *after* the biosimilar is approved for marketing by the FDA when the 180-day clock will start to run.<sup>18</sup> In another recent decision, *Amgen Inc. v. Apotex Inc.* [hereinafter referred to as *Amgen v. Apotex*], the Federal Circuit interpreted the 180-day requirement under a different factual basis, and further, limited the rights of the applicant by requiring notice 180 days before marketing, despite that the applicant provided the reference sponsor with manufacturing information to streamline any necessary patent disputes.<sup>19</sup> This Note discusses how the 180-day notice requirement should be interpreted and applied since the requirement is central to both Federal Circuit decisions and extends the exclusivity period for a reference product.<sup>20</sup>

Part I of this Note provides an overview of the BPCIA.<sup>21</sup> Part II discusses *Amgen v. Sandoz*,<sup>22</sup> and Part III explains the

clinically inactive components,” if both products utilize the same mechanism(s) of action, and if the “route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product.” 42 U.S.C.A. § 262(k)(2)(A)(i)(I)(aa), (IV) (West 2015) (amended 2017).

<sup>15</sup> See generally *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052 (Fed. Cir. 2016); *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015).

<sup>16</sup> See *Sandoz Inc.*, 794 F.3d at 1347.

<sup>17</sup> See *id.* at 1347–48; 42 U.S.C.A. § 262(l)(8)(A) (West 2015) (amended 2017) (referencing a license allowing the biosimilar to enter the market and compete with the reference product).

<sup>18</sup> See *Sandoz Inc.*, 794 F.3d at 1358.

<sup>19</sup> See *Apotex Inc.*, 827 F.3d at 1066 (explaining where the applicant disclosed information pursuant to provisions of the BPCIA, but did not provide notice 180 days before commercial marketing).

<sup>20</sup> See generally *id.*; *Sandoz*, 794 F.3d. at 1347 (Fed. Cir. 2015). See also *infra* Part IV.

<sup>21</sup> See *infra* Part I. See generally 42 U.S.C.A. § 262(k)–(l) (West 2015) (amended 2017).

<sup>22</sup> See *infra* Part II. See generally *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015).

holding in *Amgen v. Apotex*.<sup>23</sup> Part IV provides an interpretation of the 180-day requirement and the most efficient way to apply it while balancing property rights with innovation.<sup>24</sup> More specifically, Part IV will discuss how the Federal Circuit's interpretation of the 180-day notice requirement of the BPCIA is flawed because the BPCIA expressly provides remedies if an applicant does not comply with the requirement.<sup>25</sup> This Part will also discuss the proper remedy when an applicant fails to comply with the BPCIA requirements.<sup>26</sup> Part V will discuss how the Supreme Court should address the issues presented in the cross-petitions for certiorari filed in *Amgen v. Sandoz*<sup>27</sup> and, following the analysis in Part IV, why the Supreme Court should rule in favor of Sandoz and interpret the 180-day requirement in light of other provisions in the BPCIA and the policy concerns behind the Act.<sup>28</sup> Further, Part V will discuss how the suggested interpretation of the issues will affect the holdings in both *Amgen v. Sandoz* and *Amgen v. Apotex*.<sup>29</sup> Lastly, Part VI will discuss the efficacy of the BPCIA.<sup>30</sup> There are many foreseeable problems within the Act<sup>31</sup> and few biologics have entered the market since 2009.<sup>32</sup> The

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<sup>23</sup> See *infra* Part III. See generally *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052 (Fed. Cir. 2016).

<sup>24</sup> See *infra* Part IV. See generally *infra* text accompanying notes 139–80.

<sup>25</sup> See *infra* Part IV; see, e.g., Brief for Mylan Pharmaceuticals Inc. as Amicus Curiae in Support of the Petition for Certiorari, at 11, *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052 (2016) (No. 16-332) [hereinafter Brief for Mylan].

<sup>26</sup> See *infra* Part IV; Brief for Mylan, *supra* note 25, at 7–9.

<sup>27</sup> See *infra* Part V. See generally Brief for the United States as Amicus Curiae, *Sandoz Inc. v. Amgen Inc. and Amgen Inc. v. Sandoz Inc.*, 582 U.S.\_\_\_\_ (2017) (Nos. 15-1039, 15-1195), 2016 U.S. S. Ct. Briefs LEXIS 4470 [hereinafter Brief for the United States].

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

<sup>29</sup> See *infra* text accompanying notes 241–48.

<sup>30</sup> See generally *infra* text accompanying notes 298–325.

<sup>31</sup> Ryan Timmis, *The Biologics Price Competition and Innovation Act: Potential Problems in the Biologic-Drug Regulatory Scheme*, 13 NW. J. TECH. & INTELL. PROP. 215, 215 (2015).

<sup>32</sup> Center for Drug Evaluation and Research, *List of Licensed Biological Products with (1) Reference Product Exclusivity and (2) Biosimilarity or Interchangeability Evaluations to Date*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/downloads/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm549201.pdf>.



BPCIA also raises antitrust concerns,<sup>33</sup> affects areas of intellectual property,<sup>34</sup> and has delayed the entry of generics into the market.<sup>35</sup> Similar to the Hatch-Waxman Act, which has been amended to minimize loopholes or decrease generic drug approval times,<sup>36</sup> the BPCIA needs clarification from the Supreme Court to reduce the costs of biologics and provide pharmaceutical manufacturers with stronger incentives to innovate.<sup>37</sup>

## I. THE BIOLOGICS PRICE COMPETITION AND INNOVATION ACT

The Biologics Price Competition and Innovation Act of 2009 established a pathway for biosimilars to enter the market and compete with reference biological products to balance consumer interests with innovation.<sup>38</sup> The BPCIA provides two pathways for a biological product to compete with a reference product: either as a biosimilar or an interchangeable.<sup>39</sup> As their name indicates, interchangeable products can be used interchangeably with the reference product, and thus have more stringent requirements to be eligible for interchangeability status after their development.<sup>40</sup> The BPCIA provides the reference product with an exclusivity period and contains other provisions that balance competitive interests and inventive concerns, including the 180-day notice requirement.<sup>41</sup>

### A. *Licensure as a Biosimilar or Interchangeable*

The pathway established by the BPCIA allows applicants to submit an application for licensure of biological products as either a

<sup>33</sup> Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 499, 558 (2016).

<sup>34</sup> *Id.*

<sup>35</sup> *See id.* at 559.

<sup>36</sup> Martha M. Rumore, *The Hatch-Waxman Act—25 Years Later: Keeping the Pharmaceutical Scales Balanced*, PHARMACY TIMES (Aug. 15, 2009), <http://www.pharmacytimes.com/publications/supplement/2009/genericsupplement0809/generic-hatchwaxman-0809> [<https://perma.cc/66WC-FHWK>].

<sup>37</sup> *See generally infra* text accompanying notes 265–75.

<sup>38</sup> Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7001(b), 124 Stat. 119, 804 (Mar. 23, 2010).

<sup>39</sup> 42 U.S.C.A. § 262(k)(2) (West 2015) (amended 2017).

<sup>40</sup> *Id.*

<sup>41</sup> *See generally id.* § 262(k)–(l).

biosimilar or an interchangeable product.<sup>42</sup> In the application, the applicant must include information to prove that the biological product is biosimilar to the reference product.<sup>43</sup> This biosimilarity must be based on data derived from animal studies, clinical studies, and analytics studies showing “that the biological product is biosimilar to the reference product.”<sup>44</sup> The applicant must demonstrate that both biological products utilize the same mechanism for the condition(s) of use prescribed in the proposed labeling and that those condition(s) of use have been approved for the reference product.<sup>45</sup> The route of administration, dosage form, and strength must be the same as the reference product.<sup>46</sup> The applicant must also show that the manufacturing facility will be safely maintained.<sup>47</sup>

Demonstrating in lieu of determining eligibility for interchangeability (where a biosimilar product can be used interchangeably with the reference product) as opposed to biosimilarity (where the biosimilar produces the same result in the same way),<sup>48</sup> the applicant must meet higher safety standards.<sup>49</sup> The information submitted must show that the biological product is a biosimilar and can be expected to produce the same result.<sup>50</sup> Additionally, if the product is to be administered multiple times a day, the applicant must show that any risk associated with alternating or switching between the interchangeable biosimilar and the reference product is not greater than any risks associated with using the reference product alone.<sup>51</sup>

Generally, an application for a biological product may only be evaluated against one reference product, and the Food and

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<sup>42</sup> *Id.* § 262(k)(1).

<sup>43</sup> *Id.* § 262(k)(2)(A)(i)(I).

<sup>44</sup> *Id.*

<sup>45</sup> *Id.* § 262(k)(2)(A)(i)(II)–(III).

<sup>46</sup> *Id.* § 262(k)(2)(A)(i)(IV).

<sup>47</sup> *Id.* § 262(k)(2)(A)(i)(V).

<sup>48</sup> Edward Li, *Biologic, Biosimilar, and Interchangeable Biologic Drug Products* 6–7 (2016) (background paper prepared for the Am. Pharmacists Ass’n Poly Committee), <https://www.pharmacist.com/sites/default/files/files/Biosimilar%20Policy%20Background%20Paper%20-%20FINAL.PDF> [<https://perma.cc/TKW4-R6U3>].

<sup>49</sup> 42 U.S.C.A. § 262(k)(4) (West 2015) (amended 2017).

<sup>50</sup> *Id.* § 262(k)(4)(A).

<sup>51</sup> *Id.* § 262(k)(4)(B).

Drug Administration must review the application.<sup>52</sup> Additionally, the risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act, which apply to reference biological products, shall apply to the biosimilars licensed under the BPCIA.<sup>53</sup>

*B. Exclusivity for Interchangeable and Reference Products*

If an application for a biosimilar relies on the same reference product for which a prior biological product has received a determination of interchangeability, the first interchangeable product has exclusivity for at least a year.<sup>54</sup> The Secretary of Health and Human Services (Secretary) cannot make a determination until the earlier of: (i) one year after the first commercial marketing of the first interchangeable product,<sup>55</sup> (ii) eighteen months after either a final court decision on all patents in suit in an action against the applicant of the first interchangeable product or a dismissal of the action,<sup>56</sup> (iii) forty-two months after the approval of the first interchangeable if the applicant was sued under subsection (l)(6) and the litigation is ongoing,<sup>57</sup> or (iv) eighteen months after approval of the first interchangeable product if there has been no action under subsection (l)(6).<sup>58</sup>

In addition to exclusivity for the first interchangeable, the reference product has a substantial exclusivity period.<sup>59</sup> The applicants cannot submit an application for a biosimilar product until four years after the date on which the reference product was first licensed,<sup>60</sup> and the approval of the biosimilar or interchangeable cannot be made effective until twelve years after the date on which the reference product was first licensed.<sup>61</sup>

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<sup>52</sup> *Id.* § 262(k)(5)(A)–(B).

<sup>53</sup> *Id.* § 262(k)(5)(C); *see* 21 U.S.C.A. § 355(p) (West 2015) (amended 2017).

<sup>54</sup> 42 U.S.C.A. § 262(k)(6) (West 2015) (amended 2017).

<sup>55</sup> *Id.* § 262(k)(6)(A). The Secretary makes the decision of whether a biosimilar can be used interchangeably with the reference product. *Id.*

<sup>56</sup> *Id.* § 262(k)(6)(B).

<sup>57</sup> *Id.* § 262(k)(6)(C)(i).

<sup>58</sup> *Id.* § 262(k)(6)(C)(ii).

<sup>59</sup> *Id.* § 262(k)(7).

<sup>60</sup> *Id.* § 262(k)(7)(B).

<sup>61</sup> *Id.* § 262(k)(7)(A).

*C. Provisions Implicated in Amgen v. Sandoz and Amgen v. Apotex*

To allow the reference product sponsor to prepare for litigation (and limit a “race to the court”), the BPCIA provides that the applicant “shall” disclose to the reference sponsor the application submitted for approval and, thereafter, a list of patents by which the applicant believes a claim of infringement could be asserted.<sup>62</sup> This allows the reference product sponsor to bring an action for infringement if necessary, and allows the reference product sponsor to control whether or not there is litigation.<sup>63</sup>

If the applicant discloses under the requirements of (l)(2)(A) [hereinafter referred to as (2)(A)], the reference product sponsor cannot bring an action for a declaration of infringement, validity, or enforceability on any of the patents disclosed by the applicant or the reference product sponsor in the disclosure proceedings prior to FDA-approval.<sup>64</sup> However, if the applicant fails to comply with the disclosure proceedings, the reference product sponsor can bring any of those actions.<sup>65</sup>

Under subsection (l)(8) of the BPCIA, the applicant is required to provide notice to the reference product sponsor no later than 180 days before the date that the biological product will be marketed commercially.<sup>66</sup> If an applicant complies and after the reference product sponsor receives such notice, the sponsor may seek a preliminary injunction before the date of the first commercial marketing of the product.<sup>67</sup> This will prohibit the applicant from “engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement ....”<sup>68</sup> This is applicable to any patent that is or is not included in the list provided by the reference product sponsor or the applicant.<sup>69</sup>

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<sup>62</sup> *Id.* § 262(l)(2)–(3).

<sup>63</sup> *Id.* § 262(l)(2)–(7).

<sup>64</sup> *Id.* § 262(l)(9)(A).

<sup>65</sup> *Id.* § 262(l)(9)(B).

<sup>66</sup> *Id.* § 262(l)(8)(A).

<sup>67</sup> *Id.* § 262(l)(8)(B).

<sup>68</sup> *Id.*

<sup>69</sup> *Id.*

Once the sponsor seeks a preliminary injunction, the parties are expected to reasonably cooperate to expedite any necessary discovery in connection with the preliminary injunction motion.<sup>70</sup> However, if the applicant fails to comply with the notice requirement of subsection (l)(8), subsection (l)(9)(B) [hereinafter referred to as (9)(B)] allows the reference product sponsor to bring an action for a declaration of infringement, validity, or enforceability against any patents the applicant discloses or that the applicant recently received.<sup>71</sup> This furthers the goal of expediting entry of the biosimilar into the market and is central to the two recent Federal Circuit cases discussed in the following two sections of this Note.<sup>72</sup>

## II. *AMGEN V. SANDOZ*: 180-DAY NOTICE REQUIREMENT WITHOUT DISPUTE RESOLUTION

The BPCIA provides an abbreviated pathway to negotiate disputes over biosimilars limiting patent litigation.<sup>73</sup> This creates a “temporary safe harbor from declaratory judgment actions.”<sup>74</sup> If a party fails to participate in negotiation proceedings, the opposing party may commence a patent litigation action.<sup>75</sup> These negotiation proceedings are textually distinct from the 180-day notice requirement in subsection (l)(8)(A) [hereinafter referred to as (8)(A)]; however, this case presents a nexus between the two.<sup>76</sup>

### A. *District Court Decision*

In July 2014, Sandoz GmbH applied to the FDA to receive biosimilar status for its filgrastim product, similar to Amgen’s biologic product under the brand-name Neupogen.<sup>77</sup> Plaintiffs,

<sup>70</sup> *Id.* § 262(l)(8)(C).

<sup>71</sup> *Id.* § 262(l)(9)(B).

<sup>72</sup> See generally *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052 (Fed. Cir. 2016); *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015).

<sup>73</sup> See *Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741-RS, 2015 WL 1264756, at \*1 (N.D. Cal. Mar. 19, 2015).

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

<sup>75</sup> *Id.* at \*1.

<sup>76</sup> *Id.* at \*2.

<sup>77</sup> *Id.* at \*1; see *Neupogen: Uses, Dosage & Side Effects*, DRUGS.COM (July 25, 2016), <https://www.drugs.com/neupogen.html> [<https://perma.cc/TD2W-RC5H>]

collectively “Amgen,” asserted that Sandoz behaved unlawfully for two reasons: 1) under 42 U.S.C. § 262(l) by choosing to not engage in the disclosure and dispute resolution process, and 2) by intending to market its biosimilar immediately upon approval from the FDA, rather than waiting 180 days after providing notice to Amgen.<sup>78</sup> While Sandoz did not dispute that it failed to engage in the resolution process, it asserted that it had the right to do so.<sup>79</sup>

The District Court held that the most reasonable interpretation of (l)(8) favored Sandoz.<sup>80</sup> The BPCIA, under the District Court’s interpretation, provides that “[i]f both parties wish to take advantage of its disclosure procedures, then they ‘shall’ follow the prescribed procedures.”<sup>81</sup> However, Sandoz did not take advantage of the disclosures, which the Court claims would have been to its benefit.<sup>82</sup> These procedures are only “required” when the parties “elect to take advantage of their benefits” and are not required when the party fails to do so.<sup>83</sup>

Therefore, the Court ruled that it was not unlawful for Sandoz to give Amgen notice of commercial marketing 180 days before receiving full FDA-approval.<sup>84</sup> According to Amgen’s interpretation of the statute, an extra six months of exclusivity would have been tacked on to the twelve years Amgen already can enjoy.<sup>85</sup> Furthermore, Amgen requested a preliminary injunction under the belief that Sandoz unlawfully failed to provide notice 180 days before commercial marketing.<sup>86</sup> However, this claim was denied as the Court found Sandoz’s actions lawful, and Amgen’s claims for unfair competition and conversion were dismissed without prejudice.<sup>87</sup>

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(stating Neupogen is a form of protein that stimulates the growth of white blood cells in your body. It is used to treat neutropenia (a lack of certain white blood cells) caused from cancer and by receiving chemotherapy).

<sup>78</sup> *Sandoz Inc.*, 2015 WL 1264756 at \*5.

<sup>79</sup> *Id.* at \*2.

<sup>80</sup> *Id.* at \*7.

<sup>81</sup> *Id.* at \*6.

<sup>82</sup> *Id.* at \*9.

<sup>83</sup> *Amgen Inc. v. Sandoz Inc.*, 2015 WL 1264756, at \*6.

<sup>84</sup> *Id.* at \*8.

<sup>85</sup> *Id.*

<sup>86</sup> *Id.* at \*9.

<sup>87</sup> *Id.*

*B. Federal Circuit Decision*

Amgen appealed the final decision and the denial of the preliminary injunction to the Federal Circuit.<sup>88</sup> When presented with the same arguments as the District Court, the Federal Circuit concluded that, when “read in isolation, the ‘shall’ provision in [sub-subsection] (2)(A) appears to mean that a subsection (k) applicant is required to disclose ...” the information specified in the statute. The Federal Circuit further found that the BPCIA refers to this information as “required” in other sections of the BPCIA.<sup>89</sup> The BPCIA, contemplating that the applicant may fail to disclose, sets forth a consequence allowing the reference product sponsor to commence an infringement action.<sup>90</sup> This bars the applicant from bringing a declaratory action on patents that claim the biological product.<sup>91</sup> However, the Federal Circuit found that Sandoz did not violate the BPCIA because this was expressly contemplated in the BPCIA.<sup>92</sup>

The Federal Circuit further determined that Sandoz may not satisfy its obligation to provide notice to the sponsor before the FDA licenses its product.<sup>93</sup> Rather, the applicant may only give effective notice after the FDA has licensed its product,<sup>94</sup> and Sandoz did not comply with this requirement.<sup>95</sup> The Court determined that the “shall” provision in (8)(A) is required because it “presumptively signals a statutory requirement.”<sup>96</sup> The BPCIA allows noncompliance with the disclosure provisions; however, the Court held that nothing in the BPCIA indicates that the applicant is not obligated to give the sponsor notice of commercial marketing.<sup>97</sup> Therefore, Sandoz may not market the product before 180 days from the date of notice of FDA-approval.<sup>98</sup> The Court

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<sup>88</sup> See *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1354 (Fed. Cir. 2015).

<sup>89</sup> *Id.* at 1355.

<sup>90</sup> *Id.*

<sup>91</sup> *Id.* at 1356.

<sup>92</sup> *Id.* at 1357.

<sup>93</sup> *Id.*

<sup>94</sup> *Id.*

<sup>95</sup> *Id.* at 1358.

<sup>96</sup> *Id.* at 1359.

<sup>97</sup> *Id.*

<sup>98</sup> *Id.* at 1360.

entered an injunction to prevent Sandoz from marketing, selling, or importing the product.<sup>99</sup> Because the District Court had rendered a decision, the Federal Circuit held that the appeal from the denial of the preliminary injunction was moot and dismissed that aspect of the appeal.<sup>100</sup>

### *C. Supreme Court Response*

Following the Federal Circuit decision, Sandoz petitioned for a writ of certiorari.<sup>101</sup> Consequently, Amgen filed a cross-petition for certiorari.<sup>102</sup> The issues presented in Sandoz's petition were whether notice given before FDA-approval of the biosimilar application is legally effective, and if not, whether the notice requirement may be enforced by an injunction that delays the marketing of the biosimilar until 180 days after FDA-approval.<sup>103</sup> The questions presented in Amgen's cross-petition were whether sub-subsection (2)(A) of the BPCIA is a required disclosure obligation that may be enforced by an injunction or whether the only recourse for failure to disclose under (2)(A) is to commence immediate litigation for patent infringement.<sup>104</sup>

In response, the Supreme Court called for the views of the Solicitor General regarding the petitions for certiorari in *Amgen v. Sandoz*.<sup>105</sup> The Solicitor General's brief expressing the views of the United States is intended to help the Supreme Court decide if the lower decision should be reviewed.<sup>106</sup> The Solicitor General recommended granting certiorari and reversing some of the holdings.<sup>107</sup> The Solicitor General did not agree that the premarketing 180-day notice cannot be given until the biosimilar application has been approved by the FDA.<sup>108</sup>

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<sup>99</sup> *Id.* at 1360–61.

<sup>100</sup> *Id.* at 1362.

<sup>101</sup> Petition for Writ of Certiorari, *Sandoz Inc. v. Amgen Inc.*, 2016 U.S. S. Ct. Briefs LEXIS 731 (No. 15-1039), at i–ii.

<sup>102</sup> *Id.* at 859.

<sup>103</sup> *Id.* at 67a.

<sup>104</sup> *Id.* at 77a–79a.

<sup>105</sup> *Amgen Inc. v. Sandoz Inc.*, 136 S. Ct. 2501 (June 20, 2016).

<sup>106</sup> Brief for the United States, *supra* note 27.

<sup>107</sup> *Id.*

<sup>108</sup> *Id.* at 7–8.



*D. District Court Decision on Remand*

Following the issuance from the Federal Circuit, the parties agreed to lift the stay and Amgen asserted a claim of patent infringement, which the lower court faced on remand.<sup>109</sup> The United States District Court for the Northern District of California construed the claims to determine if Sandoz infringed Amgen's asserted patent.<sup>110</sup> The Court then sent the case for further Case Management Strategies.<sup>111</sup>

### III. *AMGEN V. APOTEX*: 180-DAY NOTICE REQUIREMENT WITH THE "PATENT DANCE"

Like the discussion of *Amgen v. Sandoz* in the prior section of this Note, the dispute in *Amgen v. Apotex* arose from conflicting interpretations of the 180-day notice requirement of (8)(A).<sup>112</sup> There are factual distinctions in the two cases, but based on the Federal Circuit's interpretations, the cases are legally the same as the rights of the reference product sponsor are extended.<sup>113</sup> While Sandoz did not disclose its biosimilar application pursuant to the requirement in (2)(A), Apotex participated in the "patent dance"<sup>114</sup> and complied with the disclosure requirements.<sup>115</sup>

<sup>109</sup> *Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741-RS, 2016 WL 4137563, at \*1 (N.D. Cal. Aug. 4, 2016).

<sup>110</sup> *Id.*

<sup>111</sup> *Id.* at \*19. Case Management Strategies allow the parties to meet and decide if they will agree to settle the case, such as through an alternative dispute resolution method, or if they would like to proceed to trial. *See generally* Joint Case Management Statement, *Amgen Inc. v. Sandoz Inc. and Sandoz Inc. v. Amgen Inc.*, No. 3:16-cv-02581-RS (N.D. Cal. Oct. 28, 2016).

<sup>112</sup> *See generally* *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052 (Fed. Cir. 2016); *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015).

<sup>113</sup> *Id.*

<sup>114</sup> The "patent dance" refers to the disclosure requirements outlined in 262(l). *See* Connie Ding, *Biologics and 'patent dance,'* LEXOLOGY, Aug. 23, 2017, <https://www.lexology.com/library/detail.aspx?g=a2acb833-6b80-483c-91fa-63aeb87dd9b9> [<https://perma.cc/Y5S8-E9YH>]. The subsection provides a schedule by which the applicant and reference sponsor exchange information regarding the applicant for the biosimilar to help streamline litigation. *See* 42 U.S.C.A. § 262(l) (West 2015) (amended 2017).

<sup>115</sup> *See generally* *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052 (Fed. Cir. 2016).

### A. District Court Decision

Like Amgen and Sandoz, Apotex manufactures biologic therapies.<sup>116</sup> Amgen asserted patent claims against Apotex based upon Apotex's application for FDA-approval to market a biosimilar version of Amgen's pegylated filgrastim product, Neulasta.<sup>117</sup> The parties disputed terms in the patents asserted, and the Florida Southern District Court construed the claims.<sup>118</sup> The District Court then preliminarily enjoined Apotex from entering the market until it gives Amgen notice *after* receiving the license and waits 180 days, following the holding in *Amgen v. Sandoz*.<sup>119</sup>

### B. Federal Circuit Decision

The appeal to the Federal Circuit did not involve the merits of the infringement allegations at the District Court.<sup>120</sup> Rather, it delved into the action brought under the BPCIA.<sup>121</sup> Amgen alleged that Apotex's proposed marketing would infringe Amgen's patent.<sup>122</sup> Amgen moved for a preliminary injunction to prohibit Apotex from launching the product into the market once it received FDA-approval.<sup>123</sup>

Apotex failed to give notice 180 days before commercially marketing its FDA-licensed product; therefore, Amgen sought a preliminary injunction to enforce the provision.<sup>124</sup> Apotex argued, that unlike Sandoz, it launched the statutory process for exchanging patent information and channeling patent litigation, and thus, a different result was required.<sup>125</sup> However, the Federal Circuit

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<sup>116</sup> *Amgen Inc. v. Apotex Inc.*, No. 15-61631-CIV-COHN/SELTZER, 2016 WL 1375566, at \*1 (S.D. Fla. Apr. 7, 2016).

<sup>117</sup> *Id.* (stating that "Neulasta and Neupogen are, in the simplest of terms, biologic therapies which consist of bacterial proteins that stimulate production of white blood cells in patients undergoing chemotherapy and/or stem cell transplants").

<sup>118</sup> *Id.* at \*5–6.

<sup>119</sup> *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1054 (Fed. Cir. 2016).

<sup>120</sup> *See generally* *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052 (Fed. Cir. 2016).

<sup>121</sup> *Id.*

<sup>122</sup> *See id.* at 1054.

<sup>123</sup> *Id.*

<sup>124</sup> *Id.*

<sup>125</sup> Apotex engaged in the "patent dance." *Id.*

affirmed the decision from the District Court, holding that “the (8)(A) requirement of 180 days’ post-licensure notice before commercial marketing ... is a mandatory [requirement] enforceable by [an] injunction whether or not (2)(A) notice was given.”<sup>126</sup> The Federal Circuit interpreted the word “shall” in (8)(A) to mean that the directive is mandatory and concluded that there is no language indicating the notice is dependent on whether the applicant took the earlier step of giving notice under (2)(A).<sup>127</sup>

Apotex further believes that, under this interpretation, the (8)(A) requirement would effectively extend the twelve-year exclusivity period by six months.<sup>128</sup> However, the Federal Circuit held that this is consistent with the exclusivity period in § 262(k)(7).<sup>129</sup> Section 262(k)(7) establishes the twelve-year date as a minimum, and as the earliest date on which a biosimilar license can take effect.<sup>130</sup> Therefore, the court held that even when entry is delayed under (8)(A), it is consistent with the exclusivity period, and as time goes, this will become less of an issue.<sup>131</sup>

Apotex further argued that the exclusive remedy for violations of (8)(A) should be a declaratory judgment under (9)(B).<sup>132</sup> (9)(B) permits a declaratory judgment action on a patent if the applicant “fails to complete” any of the several steps required by the statute, including (8)(A) notice.<sup>133</sup> However, the court concluded that this is not the exclusive remedy because (9)(B) states “that, in certain circumstances, the reference product sponsor ‘may bring’ such an action,” and there is no language excluding

<sup>126</sup> *Id.* at 1060–61 ((2)(A) notice is the notice requirement to launch the information-exchange process to expedite a patent infringement suit) (alteration in quotation).

<sup>127</sup> *Id.* at 1061.

<sup>128</sup> If the applicant cannot enter the market until 180 days after market approval, despite that the reference product sponsor has knowledge of the product, the exclusivity period is extended. *Id.*

<sup>129</sup> *Id.*

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

<sup>131</sup> *Id.* at 1061–62 (stating “[b]ut as time passes, more and more of the reference products will be newer, and a biosimilar-product applicant, entitled to file an application a mere four years after licensure of the reference product, § 262(k)(7)(B), can seek approval long before the 12-year exclusivity period is up”).

<sup>132</sup> *Id.* at 1063.

<sup>133</sup> *Id.* at 1064.

other remedies.<sup>134</sup> The District Court's grant of a preliminary injunction was affirmed.<sup>135</sup>

### *C. District Court on Remand*

On remand to the District Court, Amgen's infringement claims against Apotex's Neulasta biosimilar failed.<sup>136</sup> The District Court found that Apotex did not infringe on Amgen's patents.<sup>137</sup> However, the products have yet to be approved by the FDA.<sup>138</sup>

## IV. STATUTORY ANALYSIS OF THE 180-DAY NOTICE REQUIREMENT

The 180-day notice requirement of (8)(A) is central to these decisions since both turned on the statutory interpretation of this requirement.<sup>139</sup> However, the Federal Circuit's reasoning in these decisions is flawed and disregards the Congressional intent behind the BPCIA.<sup>140</sup> The notice requirement should not apply to subsection (k) applicants who launch the "patent dance," and the notice requirement should not extend the twelve-year exclusivity period.<sup>141</sup>

### *A. 180-Day Notice Provision Applicability*

These two Federal Circuit decisions revolve around statutory interpretations of the BPCIA, which could have larger implications on the biologics market and potentially deter the primary goal behind the BPCIA—to drive down the cost of biologic therapies.<sup>142</sup> The Federal Circuit held that the applicant is not required

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<sup>134</sup> *Id.*

<sup>135</sup> *Id.* at 1066.

<sup>136</sup> *See* Amgen Inc. v. Apotex Inc., Nos. 15-61631-CIV-COHN/SELTZER; 15-62081-CIV-COHN/SELTZER, 2017 U.S. Dist. LEXIS 13919, at \*6 (S.D. Fla., Jan. 31, 2017).

<sup>137</sup> *Id.* at \*11.

<sup>138</sup> *See* Center for Drug Evaluation and Research, *supra* note 32.

<sup>139</sup> *Contra* Amgen Inc. v. Apotex Inc., 827 F.3d 1052, 1064 (Fed. Cir. 2016); Amgen Inc. v. Sandoz Inc., 794 F.3d 1347, 1358 (Fed. Cir. 2015).

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

<sup>141</sup> *Id.*

<sup>142</sup> *See generally* Amgen Inc. v. Apotex Inc., 827 F.3d 1052 (Fed. Cir. 2016); Amgen Inc. v. Sandoz Inc., 794 F.3d 1347 (Fed. Cir. 2015).

to launch the “patent dance” and dispute resolution proceedings; however, regardless of whether the disclosure process was launched, the applicant is required to give notice of FDA-approval 180 days before marketing the product.<sup>143</sup> The Federal Circuit’s interpretation of the 180-day notice provision in *Amgen v. Apotex* is flawed.<sup>144</sup>

The Federal Circuit reviewed the District Court’s interpretation of the statute de novo and reached the holding after looking at both the language of the statute and legislative history.<sup>145</sup> However, the court overemphasized the usual meaning of “shall” in (8)(A).<sup>146</sup> Sub-subsection (8)(A) provides that “[t]he subsection (k) 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>147</sup>

Typically, the word “shall” does indicate that the directive is mandatory.<sup>148</sup> However, as the Federal Circuit explained in *Amgen v. Sandoz*, other language can force “shall” to not be a term of “enforceable compulsory obligation.”<sup>149</sup>

In *Amgen v. Sandoz*, the Federal Circuit interpreted the provision in (2)(A), which provides that “the subsection (k) applicant *shall provide* to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k) ...”<sup>150</sup> The court found that, when read in isolation, the “shall” provision appears to mean that the applicant is required to disclose and go through the “patent dance.”<sup>151</sup> However, the court held that the provision “cannot be read in isolation.”<sup>152</sup> Because other sections of the BPCIA contemplate that the applicant might choose

<sup>143</sup> *Sandoz Inc.*, 794 F.3d at 1358.

<sup>144</sup> *Contra Apotex Inc.*, 827 F.3d 1052, 1054 (Fed. Cir. 2016).

<sup>145</sup> *See Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1060–61, 1063 (Fed. Cir. 2016).

<sup>146</sup> *Contra id.* at 1060–61.

<sup>147</sup> 42 U.S.C.A § 262(l)(8)(A) (West 2015) (amended 2017) (emphasis added).

<sup>148</sup> *See Barnhart v. Peabody Coal Co.*, 123 S. Ct. 748, 769 (2003) (citing AMERICAN HERITAGE DICTIONARY 1598 (4th ed. 2000)).

<sup>149</sup> *Contra Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1061 (Fed. Cir. 2016).

<sup>150</sup> *See Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1354 (Fed. Cir. 2015) (emphasis added).

<sup>151</sup> *Id.* at 1355.

<sup>152</sup> *Id.*

to withhold the information and, because it sets forth consequences for such actions, “shall’ ... does not mean ‘must.’”<sup>153</sup>

Similarly, “shall” in (8)(A) does not mean “must.”<sup>154</sup> The Federal Circuit held that there was no statutory language that effectively compelled a nonmandatory treatment of (8)(A) to dispose of Apotex’s argument; thus, (8)(A) was given its plain meaning to extend the exclusivity period.<sup>155</sup> However, this interpretation is incorrect and would thwart the purpose of the BPCIA as a whole.<sup>156</sup> A principle of statutory interpretation is that the plain language enjoys a robust presumption in its favor.<sup>157</sup> However, precedent in case law states that “[i]t is a ‘fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.’”<sup>158</sup> Other parts of the statute indicate that “shall” is not mandatory in (8)(A).<sup>159</sup>

Similar to the Federal Circuit’s holding in *Amgen v. Sandoz*, another provision of the BPCIA anticipates and provides a remedy for failing to provide (8)(A) notice when the applicant followed disclosure procedures.<sup>160</sup> Sub-subsection (9)(B) provides a remedy to the reference product sponsor in the event that the applicant chooses not to provide notice of commercial marketing.<sup>161</sup> This remedy would be unnecessary if (8)(A) was mandatory for applicants who are in compliance with (2)(A) and the subsequent disclosure requirements in subsections (l)(3) through (5).<sup>162</sup> A

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<sup>153</sup> *Id.*

<sup>154</sup> See 42 U.S.C.A. § 262(l)(8)(A) (West 2015) (amended 2017).

<sup>155</sup> See *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1061 (Fed. Cir. 2016).

<sup>156</sup> Interpreting (8)(A) by its plain meaning and a literal interpretation is incorrect. *Contra id.*

<sup>157</sup> See *FBI v. Abramson*, 456 U.S. 615, 638 (1982).

<sup>158</sup> *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 576 F.3d 1348, 1363 (Fed. Cir. 2009) (quoting *Davis v. Mich. Dept. of Treas.*, 489 U.S. 803, 809 (1989)).

<sup>159</sup> See 42 U.S.C.A. § 262(l)(9)(B) (West 2015) (amended 2017).

<sup>160</sup> See *id.*

<sup>161</sup> *Id.* (stating “[i]f a subsection (k) applicant fails to complete an action required for the subsection (k) applicant under ... paragraph (8)(A), the reference product sponsor ... may bring action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A) ...”).

<sup>162</sup> See 42 U.S.C.A. § 262(l)(2)–(8) (West 2015) (amended 2017).

statute should not be construed so that a clause is superfluous, void, or insignificant.<sup>163</sup> Therefore, the applicant may choose to not provide notice under (8)(A).<sup>164</sup>

Further, the Federal Circuit in *Amgen v. Apotex* held that the possibility of extending the exclusivity period would not counteract the purpose of the statutory scheme.<sup>165</sup> Thus, the statute should not be interpreted in light of the facts at hand,<sup>166</sup> but this creates an exclusivity windfall for the reference product sponsor, more specifically for Amgen in both of these cases.<sup>167</sup> The twelve-year period was established as a “middle ground between innovator and generic interests.”<sup>168</sup> The purpose of the BPCIA was not to preserve the market for reference product sponsors but, instead, to balance the interests of innovation and cost competition.<sup>169</sup> This period was intended to be similar in scope and duration to the exclusivity afforded to innovative drugs by patent protection.<sup>170</sup>

Requiring 180 days of notice before commercial marketing, even when applicants launch the “patent dance,” would not promote the introduction of biosimilars and the interests of innovation.<sup>171</sup> This would deter the resolution of patent disputes, for which the requirement in (2)(A) was specifically included to expedite.<sup>172</sup>

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<sup>163</sup> See *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001).

<sup>164</sup> *Contra Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1061–63 (Fed. Cir. 2016).

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

<sup>166</sup> See *id.* at 1062.

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

<sup>168</sup> Krista H. Carver et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 FOOD & DRUG L.J. 671, 817 (2010), <https://www.cov.com/-/media/files/corporate/publications/2010/01/an-unofficial-legislative-history-of-the-biologics-price-competition-and-innovation-act-of-2009.pdf> [<https://perma.cc/FJ2C-NM4B>].

<sup>169</sup> Lu, *supra* note 12, at 614.

<sup>170</sup> See *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the H. Comm. on the Judiciary*, 111th Cong. 8–9 (2009) (statement of the Honorable Anna G. Eshoo, a Representative in Congress from the State of California, sponsor of the Pathway for Biosimilars Act H.R. 1548, 111th Cong. 2009). For biologics, Representative Eshoo’s bill would have maintained an exclusivity period equivalent to the protections for small molecules under the Hatch-Waxman Act. *Id.*

<sup>171</sup> See generally Lu, *supra* note 12, at 629.

<sup>172</sup> Carver et al., *supra* note 168, at 813.

Further, it would not provide any benefit to the public or to the biosimilar market.<sup>173</sup>

This is not particular to the facts of this case as the Federal Circuit speculates.<sup>174</sup> Rather, other biosimilar applicants may face this same situation.<sup>175</sup> In *Amgen Inc. v. Hospira Inc.*, Amgen asserted two patents involving Hospira's biosimilar and both expired.<sup>176</sup> This decision in *Amgen v. Apotex* will force Hospira to delay the commercial marketing by 180 days, even though the patents expired and Amgen has no exclusivity rights.<sup>177</sup> This could continue to happen as more biosimilar applicants receive FDA-approval and attempt to enter the market.<sup>178</sup> This decision will harm the public and produce anticompetitive effects.<sup>179</sup> Thus, a windfall is created for the reference product sponsors, which is not supported by the plain language of the statute or the Congressional intent.<sup>180</sup>

### *B. Purpose of the 180-Day Notice Requirement*

The BPCIA parallels the Hatch-Waxman Act and its amendments, which provided a statutory generic drug approval process and established the abbreviated new drug application (ANDA) approval process by balancing public interests.<sup>181</sup> The Hatch-Waxman Act was amended to include a 180-day exclusivity period, but not for the same interests as the provision in the BPCIA.<sup>182</sup> The Hatch-Waxman Act was amended to incentivize challenging patents or designing around them;<sup>183</sup> however, the 180-day requirement

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<sup>173</sup> See generally Lu, *supra* note 12, at 633.

<sup>174</sup> Brief for Mylan, *supra* note 25, at 4.

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

<sup>176</sup> *Id.* at 4.

<sup>177</sup> See *id.*

<sup>178</sup> See *id.*

<sup>179</sup> Brief for Mylan, *supra* note 25, at 5.

<sup>180</sup> Opening Brief for Defendants-Appellants Apotex Inc. and Apotex Corp., *Amgen Inc. v. Apotex Inc.*, 2016 U.S. S. Ct. Briefs LEXIS 4225 (No. 16-1308), at 18.

<sup>181</sup> See generally 21 U.S.C.A. § 355(j) (West 2015) (amended 2017).

<sup>182</sup> Carver et al., *supra* note 168, at 816.

<sup>183</sup> The exclusivity period in the Hatch-Waxman Act will encourage manufacturers to design around the drugs, rather than filing for an ANDA, because they can avoid the exclusivity period. *Id.*



was implemented in the BPCIA to ensure that the “decision-making regarding further patent litigation is not conducted under time pressure that will impair its fairness and accuracy.”<sup>184</sup>

As opposed to the Hatch-Waxman Act, the reference product sponsor is already incentivized to challenge the patents when they receive (2)(A) notice, and the notice of applying for FDA-approval under (2)(A) should provide the reference product sponsor with adequate notice to prepare for litigation.<sup>185</sup> The Federal Circuit rested the decision on theoretical concerns over a “race to [the] court”; however, a “race to [the] court” is unlikely to occur as this case shows.<sup>186</sup>

Amgen became aware of Apotex’s intention to market its biosimilar when Apotex provided both pre-licensure notice of commercial marketing and disclosure information pursuant to the requirement in (2)(A), and as a result, Amgen was able to take the steps to protect its legal rights.<sup>187</sup> All the information Amgen needed to protect the rights held in its patents was disclosed under (2)(A).<sup>188</sup> After disclosure under (2)(A), the reference sponsor should be able to generate a list of patents for which it believes a claim of infringement could be asserted under subsection (l)(3)(A).<sup>189</sup> Here, Amgen had eleven months to review the bio-similar application and manufacturing information.<sup>190</sup> No statutory purpose would be served by delaying the launch of the biosimilar product by another six months.<sup>191</sup>

The Federal Circuit asserted that this will become less of a problem as time goes by, but this reasoning is flawed as well.<sup>192</sup>

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<sup>184</sup> *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1062 (Fed. Cir. 2016) (citing *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1358, 1360 (Fed. Cir. 2015)).

<sup>185</sup> *Contra id.*

<sup>186</sup> *See id.* at 1065.

<sup>187</sup> *Id.* at 1059.

<sup>188</sup> *Id.*

<sup>189</sup> 42 U.S.C.A. § 262(l)(3)(A) (West 2015) (amended 2017) (stating that subject to this subsection, “the reference product sponsor shall provide ... a list of patents for which the reference product sponsor believes a claim of patent infringement reasonably could be asserted ...”).

<sup>190</sup> Opening Brief for Defendants-Appellants Apotex Inc. and Apotex Corp., *Amgen Inc. v. Apotex Inc.*, 2016 U.S. S. Ct. Briefs LEXIS 4225 (No. 16-1308), at 29.

<sup>191</sup> *Id.* at 29–30.

<sup>192</sup> *Contra Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1061–62 (Fed. Cir. 2016).

The Federal Circuit stated that they “have been pointed to no reason that the FDA may not issue a license before the 11.5-year mark and deem the license to take effect on the 12-year date”<sup>193</sup> but there is no basis for this statement.<sup>194</sup> There is no policy by which the FDA could provide a license for the applicants prior to exhaustion of the exclusivity period.<sup>195</sup> Rather, the BPCIA expressly states that an “approval of an application ... may not be made effective ... until the date that is [twelve] years after the date on which the reference product was first licensed ....”<sup>196</sup>

The BPCIA was drafted to allow biosimilar applicants to control the timing of the two stages of patent litigation.<sup>197</sup> Therefore, the applicants could choose to resolve any patent conflicts prior to the expiration of the twelve-year statutory period.<sup>198</sup> However, the Federal Circuit’s interpretation requires any second-stage patent litigation to occur after licensure by the FDA.<sup>199</sup> The dispute resolution proceeding allows the applicant to choose to litigate the proceeding in either one or two stages.<sup>200</sup> If all patents are not litigated immediately, notice under (8)(A) triggers the second litigation, and again, the applicant can control the timing.<sup>201</sup> Therefore, the law allows the parties to litigate at the second stage post-licensure, but that is not required.<sup>202</sup> If the Federal Circuit’s interpretation holds, the applicant would be required to delay the potential second-stage litigation, which conflicts with the policy Congress intended to implement in the BPCIA.<sup>203</sup>

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<sup>193</sup> *Id.* at 1062.

<sup>194</sup> *Contra id.*

<sup>195</sup> *See generally* 42 U.S.C.A. § 262(k) (West 2015) (amended 2017).

<sup>196</sup> 42 U.S.C.A. § 262(k)(7)(A) (West 2015) (amended 2017) (alteration in quotation).

<sup>197</sup> Brief for Mylan, *supra* note 25, at 8.

<sup>198</sup> *Id.*

<sup>199</sup> *Id.* at 9 (illustrating that under the statute, the Applicant can choose to litigate all listed patents in (3)–(5) at one stage, or may choose to narrow the initial dispute and resolve the remaining patents in a second stage of litigation).

<sup>200</sup> *Id.* at 8.

<sup>201</sup> *Id.*

<sup>202</sup> *Id.* at 9.

<sup>203</sup> The BPCIA intended for the applicant to control the timing of the litigation. If the applicant is required to delay the litigation because of the notice requirement, the applicant loses that control. *Id.* at 8–9.

*C. Preliminary Injunction as a Remedy*

In both *Amgen v. Sandoz* and *Amgen v. Apotex*, Amgen sought injunctive remedies to enforce the 180-day notice requirement of (8)(A).<sup>204</sup> However, a preliminary injunction cannot enforce (8)(A) in either case.<sup>205</sup> When an applicant fails to undergo the disclosure procedures of (2)(A) and fails to provide notice under (8)(A), injunctive relief is not available for a failure to furnish notice under (2)(A).<sup>206</sup> When the applicant fails to provide the information required by (2)(A), (9)(C) provides that the sponsor may bring suit on any relevant patent.<sup>207</sup> That is the exclusive remedy.<sup>208</sup>

Instead, Amgen argued that it should be afforded the monetary and injunctive infringement remedies under the Patent Act.<sup>209</sup> However, failing to provide notice under (8)(A) does not constitute an act of infringement, which is necessary to trigger the injunctive remedies under the Patent Act.<sup>210</sup> The BPCIA does provide for injunctive relief, but only if confidentiality rules are violated.<sup>211</sup> The exclusive remedy for non-compliance is to immediately initiate an action for patent infringement.<sup>212</sup>

While Sandoz did not disclose as sub-subsection (2)(A) provides, Apotex followed the BPCIA provisions, but still failed to provide notice 180 days before commercial marketing.<sup>213</sup> Amgen then sought a preliminary injunction seeking to force Apotex to comply, and the Federal Circuit granted this remedy.<sup>214</sup> However, this holding is incorrect.<sup>215</sup> If an applicant like Apotex participated

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<sup>204</sup> See *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1054 (Fed. Cir. 2016); *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1350–51 (Fed. Cir. 2015).

<sup>205</sup> Brief for the United States, *supra* note 27, at 13.

<sup>206</sup> *Id.* at 12–13.

<sup>207</sup> *Id.* at 17.

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

<sup>209</sup> *Amgen Inc. v. Sandoz Inc.*, 794 F.3d at 1354–57.

<sup>210</sup> Brief for the United States, *supra* note 27, at 19.

<sup>211</sup> 42 U.S.C.A. § 262(l)(1)(H) (West 2015) (amended 2017).

<sup>212</sup> Brief for the United States, *supra* note 27, at 15.

<sup>213</sup> *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1059 (Fed. Cir. 2016).

<sup>214</sup> *Id.* at 1054.

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

in the “patent dance,” but chose to not provide notice under (8)(A), the statute allows the sponsor to bring a *declaratory* injunction, not a preliminary injunction.<sup>216</sup> If the applicant provided notice, the sponsor could bring a preliminary injunction under (8)(B), but those are not the facts here.<sup>217</sup>

A declaratory judgment is the express remedy Congress provides for failing to provide premarket notice.<sup>218</sup> However, the Federal Circuit granted Amgen an “extra-statutory” remedy when it upheld the preliminary injunction to compel premarketing notice.<sup>219</sup> Congress did not expressly forbid any “extra-statutory” remedies, but “where a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies.”<sup>220</sup> Section 262(l)(8)(B) allows the sponsor to “seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product’ based on any patent listed in the initial exchanges during the ‘patent dance’ but not selected for litigation.”<sup>221</sup> Therefore, Congress did not intend for the preliminary injunction remedy to always be available since (8)(B) applies when the applicant provided notice.<sup>222</sup> Rather, (9)(B) provides the remedy for failure to comply with the notice requirement, and Amgen should have sought a declaratory judgment action.<sup>223</sup>

#### V. SUPREME COURT REVIEW OF CROSS-PETITIONS FOR CERTIORARI IN *AMGEN V. SANDOZ*

On December 12, 2016, the Supreme Court denied certiorari in *Amgen v. Apotex*, which clarified the Federal Circuit’s earlier

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<sup>216</sup> Brief for Mylan, *supra* note 25, at 15.

<sup>217</sup> *Id.* at 15–16.

<sup>218</sup> 42 U.S.C.A. § 262(l)(8)(A) (West 2015) (amended 2017).

<sup>219</sup> Brief for Mylan, *supra* note 25, at 16.

<sup>220</sup> *Id.* at 16 (quoting *Karahalios v. Nat’l Fed’n of Fed. Emps., Local 1263*, 489 U.S. 527, 533 (1989) (citing *Transamerica Mortg. Advisors, Inc. v. Lewis*, 444 U.S. 11, 19 (1979)) (internal quotations omitted)).

<sup>221</sup> *Id.* at 18–19.

<sup>222</sup> *Id.*

<sup>223</sup> *Id.* at 15.

decision in *Amgen v. Sandoz*.<sup>224</sup> However, on January 13, 2017, the Supreme Court granted certiorari in the earlier decision and will decide on the issues presented in the cross-petitions.<sup>225</sup>

#### A. Issues Presented in *Sandoz's* Petition

Sandoz presented two issues in the petition for certiorari:

(a) whether notice of commercial marketing under Subsection (l)(8)(A) is legally effective if it is given before Food and Drug Administration (FDA) approval of the biosimilar application, and, if not, (b) whether Subsection (l)(8)(A) is a stand-alone requirement that may be enforced by means of an injunction that delays the marketing of the biosimilar until 180 days after FDA approval.<sup>226</sup>

The Federal Circuit's interpretation in the case is incorrect.<sup>227</sup> Section 262(l)(8)(B) allows the applicant to provide the reference product sponsor with notice of commercial marketing 180 days before FDA-approval.<sup>228</sup> It merely requires that notice is given "not later than 180 days before th[at] date."<sup>229</sup> The Federal Circuit overemphasized the word "licensed" in the phrase requiring that the notice must be given 180 days before "the date of the first commercial marketing of the biological product *licensed* under [subsection] (k)."<sup>230</sup> Therefore, the Supreme Court should overturn the current interpretation of the notice requirement.<sup>231</sup>

Further, as discussed in Section IV.C of this Note, there is no private right of action for injunctive relief to enforce the requirement in (8)(A).<sup>232</sup> Rather, if proper notice is not given, the course contemplated by the BPCIA is to commence an action for

<sup>224</sup> *Apotex Inc. v. Amgen Inc.*, 2016 U.S. LEXIS 7478 (No. 16-332) (Dec. 12, 2016).

<sup>225</sup> *Sandoz Inc. v. Amgen Inc.*, 2017 U.S. LEXIS 692 (No. 15-1039) (Jan. 13, 2017).

<sup>226</sup> Brief for the United States, *supra* note 27, at (I).

<sup>227</sup> *See generally id.*

<sup>228</sup> *Id.* at 13.

<sup>229</sup> *Id.* at 14 (alteration in quotation).

<sup>230</sup> *Id.* (emphasis added) (alteration in quotation).

<sup>231</sup> *Id.*

<sup>232</sup> *Id.* at 20.

patent infringement.<sup>233</sup> However, this issue would not affect the case on appeal because Sandoz has begun to market the product.<sup>234</sup>

### *B. Issues Presented in Amgen's Petition*

Following Sandoz's petition, Amgen filed a conditional cross-petition presenting the question of "[a)] whether Subsection (l)(2)(A) creates a binding disclosure obligation that a court may enforce by injunction, or [(b)] whether the sponsor's sole recourse for the applicant's failure to disclose the information is the right, prescribed elsewhere in the BPCIA, to commence an intermediate action for patent infringement."<sup>235</sup>

Like the argument in response to Sandoz's petition, the BPCIA contemplates a course of action if the applicant chooses to forego the disclosure procedures in sub-subsection (2)(A).<sup>236</sup> (2)(A) poses a mandatory condition to invoke subsection 262(l)'s patent-dispute proceedings.<sup>237</sup> An injunction is not available to compel compliance with the conditions set forth in the BPCIA.<sup>238</sup> Rather, the sponsor can file an infringement suit.<sup>239</sup> Thus, information the reference product sponsor seeks may only be obtained during discovery, not through a preliminary injunction.<sup>240</sup>

### *C. Effect on Amgen v. Apotex*

If the Supreme Court adopts the proposed stance on the issues in the cross-petitions, the holding in *Amgen v. Apotex* will be affected.<sup>241</sup> Despite that Apotex has not given Amgen 180

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<sup>233</sup> See *supra* text accompanying notes 208–12.

<sup>234</sup> Elaine Schattner, *Why The FDA Panel's Nod To Sandoz's Filgrastim (Zarzio) Is Good News For Patients*, FORBES, <http://www.forbes.com/sites/elaine-schattner/2015/01/07/the-fdas-approval-of-zarzio-is-good-news-for-patients/#2425b8224797> [<https://perma.cc/7DPG-TWSN>] (last updated Mar. 8, 2015).

<sup>235</sup> Brief for the United States, *supra* note 27, at (I).

<sup>236</sup> *Id.* at 21.

<sup>237</sup> *Id.* (“[T]he only consequences for failing to satisfy th[e] conditions are those expressly set forth by Congress in the BPCIA.”)

<sup>238</sup> *Id.*

<sup>239</sup> *Id.*

<sup>240</sup> *Id.* at 20–21.

<sup>241</sup> See *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1053 (Fed. Cir. 2016).

days of notice before commercial marketing, Apotex effectively provided Amgen with notice of commercial marketing.<sup>242</sup> Amgen would argue that Apotex has not provided Amgen with any “legally effective” notice; however, the disclosure procedures in (2)(A) effectively provide notice to Amgen.<sup>243</sup> This is notice that Apotex is seeking FDA-approval and, hence, that Apotex will soon begin to market the product.<sup>244</sup>

Further, the policy reasons for allowing notice pre-FDA-approval would support this stance.<sup>245</sup> The BPCIA addressed “[t]he timing of biosimilars’ entry onto the market ....”<sup>246</sup> Because the BPCIA provides “exclusivity periods, it is particularly unlikely that Congress would have further delayed biosimilars’ marketing in such an indirect manner.”<sup>247</sup> Apotex and Amgen completed the “patent dance,” and Apotex should not face the anti-competitive effects of the Federal Circuit decision.<sup>248</sup>

In the decision, the Federal Circuit affirmed the District Court’s grant of a preliminary injunction for failing to provide 180 days of notice before commercial marketing.<sup>249</sup> Under the interpretation proposed above, the injunction is invalid. There is no cause of action “under which a sponsor could obtain injunctive relief if the applicant fails to give notice” under (8)(A) if the applicant does not provide the information required by subsection (l)(2)(A).<sup>250</sup>

If the applicant discloses the information required by (l)(2)(A), (9)(B) permits a *declaratory judgment* action on a patent if the applicant “fails to complete” any of the several steps required by the statute, including (8)(A) notice.<sup>251</sup> The Federal Circuit concluded that this is not the exclusive remedy because

<sup>242</sup> See *supra* text accompanying notes 185–91.

<sup>243</sup> See *supra* text accompanying notes 185–91.

<sup>244</sup> See *supra* text accompanying notes 185–91.

<sup>245</sup> Brief for the United States, *supra* note 27, at 15.

<sup>246</sup> *Id.* at 14–15.

<sup>247</sup> *Id.* at 15.

<sup>248</sup> Petition for Writ of Certiorari, *Apotex Inc. v. Amgen Inc.*, 137 S. Ct. 591 (2016) (No. 16-332), 2016 WL 4921167, at 2.

<sup>249</sup> *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1066 (Fed. Cir. 2016).

<sup>250</sup> Brief for the United States, *supra* note 27, at 14.

<sup>251</sup> *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1064 (Fed. Cir. 2016).

(9)(B) states “that, in certain circumstances, the reference product sponsor ‘may bring’ such an action,” and there is no language excluding other remedies.<sup>252</sup> This holding is incorrect<sup>253</sup> because the BPCIA expressly provides for an exclusive remedy, a declaratory judgment.<sup>254</sup> Similar to the analysis of *Amgen v. Sandoz* where patent-litigation is the sole remedy for failure to comply with (l)(2)(A), a declaratory judgment is the sole remedy for failing to provide premarketing notice.<sup>255</sup> Because the biosimilar product has yet to gain FDA-approval, the pending suit will not likely deter market entry if Apotex complies with the 180-day notice requirement after FDA-approval.<sup>256</sup>

## VI. EFFICACY OF THE BIOLOGICS PRICE COMPETITION AND INNOVATION ACT

As stated above, the BPCIA was enacted to decrease the price of biologics while still promoting innovation and research.<sup>257</sup> However, like the Hatch-Waxman Act, the legislation the BPCIA was modeled after, there are problems within the BPCIA that need to be addressed to avoid unnecessary litigation, which has already occurred.<sup>258</sup>

### A. Foreseeable Problems Within the Statute

As discussed in Section I.B of this Note, the BPCIA creates a twelve-year exclusivity period for the reference drug and an exclusivity period for the first interchangeable biosimilar.<sup>259</sup> These long exclusivity periods will likely inhibit the development of

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<sup>252</sup> *Id.*

<sup>253</sup> *Contra id.*

<sup>254</sup> See 42 U.S.C.A. § 262(l)(9)(B) (West 2015) (amended 2017).

<sup>255</sup> See *supra* text accompanying notes 218–23.

<sup>256</sup> See Jenny Shmuel & Tasha M. Francis, *Amgen Loses BPCIA Suit Against Apotex’s Neulasta® and Neupogen® Biosimilars*, FISH LITIGATION BLOG (Sept. 8, 2016), <http://www.fr.com/fish-litigation/amgen-apotex-neulasta-neupogen-biosimilars/> [<https://perma.cc/69MH-67T3>].

<sup>257</sup> Timmis, *supra* note 31, at 226.

<sup>258</sup> See *id.*

<sup>259</sup> 42 U.S.C.A. § 262(k)(6)–(7) (West 2015) (amended 2017).



biosimilars and interchangeables alike.<sup>260</sup> The twelve-year exclusivity period for the reference drug (before the first biosimilar can be approved) includes a four-year period of data exclusivity, which prohibits the filing of biosimilar applications.<sup>261</sup> Similarly, the exclusivity period for the first interchangeable can range from twelve to forty-two months, again posing a barrier to market entry for a biosimilar.<sup>262</sup> In contrast to the BPCIA, the Hatch-Waxman Act provides only a five-year exclusivity period for new chemical drugs and a three-year exclusivity period for new chemical investigations of small-molecule drugs.<sup>263</sup> These longer exclusivity periods will cause prices of both biosimilars and interchangeables to remain higher for a longer period of time, countering the goals behind the expedited process.<sup>264</sup>

The Hatch-Waxman Act provides exclusivity for a period of only 180 days following the first commercial marketing efforts from an applicant for the generic drug.<sup>265</sup> This exclusivity period is half of the duration of the minimal exclusivity period for interchangeables under the BPCIA. Some may believe that this difference will “provide a ... catalyst for competition, hastening the entry of additional [biologic] drugs to the market”<sup>266</sup> because the Hatch-Waxman Act contained loopholes which allowed applicants to prevent additional generics from entering the market.<sup>267</sup> The FDA implemented the exclusivity periods on a first-to-file

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<sup>260</sup> See Timmis, *supra* note 31, at 228.

<sup>261</sup> *Id.*

<sup>262</sup> *Id.*

<sup>263</sup> *Id.* Under the Hatch-Waxman Act, full new drug applications receive five years of exclusivity for a new chemical entity drug product that has never been approved by the FDA. However, only a three-year exclusivity period is granted for a drug product that contains an active molecule that has been previously approved. *Emerging Health Care Issues: Follow-On Biologic Drug Competition*, FED. TRADE COMM’N at 27 (2009), <https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf> [<https://perma.cc/6G62-8WUP>].

<sup>264</sup> Timmis, *supra* note 31, at 228.

<sup>265</sup> *Id.* (stating “[i]n other words, the first person to complete an ANDA gets 180 days of exclusivity dating from when she first begins marketing”).

<sup>266</sup> *Id.*

<sup>267</sup> *Id.*

basis and, therefore, first applicants could toll this period by choosing to delay marketing of the product.<sup>268</sup> In contrast, this “anticompetitive behavior” seems impossible under the BPCIA because the first interchangeable can either choose to not enter the market for eighteen months and accept payment or, in the alternative, not enter the market for forty-two months while patent litigation ensues.<sup>269</sup>

However, the Federal Circuit’s current interpretation of the 180-day exclusivity period for biosimilars under the BPCIA allows this type of anticompetitive behavior.<sup>270</sup> The twelve-year exclusivity period can be extended as the FDA cannot approve a biosimilar until the twelve-year exclusivity period is exhausted, extending the exclusivity period for six months.<sup>271</sup> Because the notice provision triggers second-stage litigation and the applicant cannot begin second-stage litigation until the applicant receives FDA-approval, the reference sponsor will not compete with the biosimilar until the litigation has commenced.<sup>272</sup>

This anticompetitive behavior counters the purpose of the BPCIA.<sup>273</sup> Biosimilars will enter the market later and the reference product sponsor will not have more time to adjudicate patent rights without rushing to court.<sup>274</sup> This effect will lessen the emergence of multiple biosimilars on top of the long exclusivity periods.<sup>275</sup>

### *B. Biosimilar vs. Interchangeable*

As discussed in Section I.A of this Note, a biosimilar product can be used interchangeably with the reference product, as an interchangeable, rather than biosimilar,<sup>276</sup> if more safety standards are met.<sup>277</sup> This means that the interchangeable product “can be

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<sup>268</sup> *Id.* at 229.

<sup>269</sup> *Id.*

<sup>270</sup> *See* Amgen Inc. v. Apotex Inc., 827 F.3d 1052, 1062–64 (Fed. Cir. 2016).

<sup>271</sup> *See supra* text accompanying notes 185–91.

<sup>272</sup> *See supra* text accompanying notes 185–91.

<sup>273</sup> Timmis, *supra* note 31, at 229.

<sup>274</sup> *Id.*

<sup>275</sup> *Id.* at 231.

<sup>276</sup> Li, *supra* note 48.

<sup>277</sup> 42 U.S.C.A. § 262(k)(2)(B) (West 2015) (amended 2017).

expected to produce the same clinical result as the reference product in any given patient ....”<sup>278</sup> Additionally,

if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and reference product is not greater than the risk of using the reference product without such alteration or switch.<sup>279</sup>

This is a very “difficult” classification to obtain in comparison to biosimilarity.<sup>280</sup> The FDA has not yet adopted regulations for determining interchangeability; however, it has distributed a guidance document as notice with opportunity to comment.<sup>281</sup> The guidance document expressly states that the data and information needed to support interchangeability are “beyond that needed to demonstrate biosimilarity.”<sup>282</sup> The document lists factors which determine the amount of data and information needed to support interchangeability as there are multiple influences which vary with the product.<sup>283</sup> Additionally, the document concedes that current analytical methodologies may not even determine or characterize the relevant differences between the reference product and the interchangeable.<sup>284</sup>

This document alone shows that interchangeability will not be utilized by most biosimilar manufacturers.<sup>285</sup> The trials and analyses would likely be unduly burdensome and costly,<sup>286</sup> intensifying the delayed emergence of biosimilars.<sup>287</sup> Studies from other countries “with analogous biosimilar-interchangeable regulatory

<sup>278</sup> Li, *supra* note 48.

<sup>279</sup> *Id.*

<sup>280</sup> *Id.*

<sup>281</sup> See generally Center for Biologics Evaluation and Research, *Considerations in Determining Interchangeability With a Reference Product: Guidance for Industry*, U.S. FOOD & DRUG ADMIN. (Jan. 12, 2017), <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537135.pdf>.

<sup>282</sup> *Id.* at 5.

<sup>283</sup> *Id.* at 5–9.

<sup>284</sup> *Id.* at 6.

<sup>285</sup> See generally *id.*

<sup>286</sup> Timmis, *supra* note 31, at 230.

<sup>287</sup> *Id.*

systems further indicate that those seeking interchangeable approval are likely facing an uphill battle.”<sup>288</sup> As of 2012, the European Medicines Agency, serving a similar role as the FDA in the European Union, had approved six biosimilars, but no interchangeables.<sup>289</sup>

With chemical drugs, generic drugs can automatically be substituted by a pharmacist without physician approval, which allows the generic to gain market share more quickly.<sup>290</sup> This trend continues as more generics enter the market, further promoting competition and lowering the cost of pharmaceuticals.<sup>291</sup> However, biosimilars need to qualify as an interchangeable to receive this same automatic substitution.<sup>292</sup> Therefore, the biosimilar manufacturers cannot bypass the physician without undergoing the additional burden of reaching interchangeable status.<sup>293</sup> Uncertainties about the interchangeables, in addition to increased marketing expenditures, would pose a greater burden on manufacturers.<sup>294</sup> Few incentives would exist for the physicians to prescribe a new drug if there is a fear the patients may react differently to a critical method of treatment.<sup>295</sup> Furthermore, state substitution laws for the interchangeables may not be as favorable as they are for pharmaceutical generics.<sup>296</sup> In addition to the stricter standards, this would further discourage biosimilar manufacturers from utilizing interchangeability.<sup>297</sup>

### *C. Market Effects of the Abbreviated Approval Pathway*

As explained above, provisions of the BPCIA detract from its statutory purposes.<sup>298</sup> Few biosimilars will achieve interchangeability status and few biosimilars will enter the market

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<sup>288</sup> *Id.*

<sup>289</sup> *Id.*

<sup>290</sup> *Id.*

<sup>291</sup> *Id.*

<sup>292</sup> *Id.*

<sup>293</sup> *Id.* at 231.

<sup>294</sup> *Id.*

<sup>295</sup> *Id.*

<sup>296</sup> Darren S. Tucker & Gregory F. Wells, *Emerging Competition Issues Involving Follow-On Biologics*, 29 ANTITRUST 100, 102 (2014).

<sup>297</sup> *See id.*

<sup>298</sup> *See supra* text accompanying notes 259–75.

quickly to drive the cost of biologic therapies down.<sup>299</sup> Statistics from the FDA support these conclusions.<sup>300</sup> Since the implementation of the BPCIA, only four biosimilars have entered the market, and no biosimilars have achieved interchangeability.<sup>301</sup> Notwithstanding, the purposes of the BPCIA have been promoted by the few biosimilars that have entered the market.<sup>302</sup>

For example, Zarxio, a biosimilar to Amgen's Neupogen product, subject of the litigation in *Amgen v. Sandoz*, received market approval on March 6, 2015.<sup>303</sup> Less than a year later, Amgen reported that its year-on-year worldwide sales of Neupogen dropped 4 percent and full-year sales dropped 9 percent because of competition in the United States and unfavorable changes in foreign exchange rates.<sup>304</sup> The revenue from Neupogen in the United States fell 11 percent in 2015.<sup>305</sup> However, Zarxio was only sold at a 15 percent discount when it was first marketed.<sup>306</sup> Some doctors may not feel that this saving is worth the risk, but as time goes on, this could "subside as biosimilar drugs become more commonplace."<sup>307</sup>

After Zarxio kick-started the biosimilar movement, sales for Inflectra, the second biosimilar approved for sale in the United States, launched in November 2016<sup>308</sup> at a 15 percent discount of

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<sup>299</sup> See *supra* text accompanying notes 285–89.

<sup>300</sup> See Center for Drug Evaluation and Research, *supra* note 32.

<sup>301</sup> *Id.* (showing those are Inflectra, Zarxio, Erelzi, Amjevita).

<sup>302</sup> Dan Stanton, *First U.S. biosimilar gradually eroding Amgen's market share*, Sandoz, BIOPHARMA-REPORTER.COM (Jan. 29, 2016, 3:14 PM), <http://www.biopharma-reporter.com/Markets-Regulations/Sandoz-s-biosimilar-Zarxio-gradually-eroding-Amgen-s-Neupogen-sales> [<https://perma.cc/3XPX-GBPN>].

<sup>303</sup> Schattner, *supra* note 234.

<sup>304</sup> Dan Stanton, *U.S. biosimilars in 2016: Where we're at following Zarxio's breakthrough*, BIOPHARMA-REPORTER.COM (Jan. 6, 2016), <http://www.biopharma-reporter.com/Markets-Regulations/US-biosimilars-in-2016-Where-we-re-at-following-Zarxio-s-breakthrough> [<https://perma.cc/KMJ9-QRQ4>].

<sup>305</sup> *Id.*

<sup>306</sup> *Id.*

<sup>307</sup> *Id.*

<sup>308</sup> Beth Snyder Bulik, *For Inflectra Launch, Pfizer Uses 'Hybrid Model' to Home in on HCPs*, FIERCEPHARMA (Dec. 19, 2016, 8:21 AM), <http://www.fiercepharma.com/marketing/pfizer-s-inflectra-biosimilar-launch-marks-new-go-to-market-strategy> [<https://perma.cc/5WYT-JF3S>].

the reference product,<sup>309</sup> hoping for the same success as Zarxio. However, the nature of this biologic could deter market growth.<sup>310</sup>

Oncologists in Europe had used the reference product for Zarxio for almost a decade before Zarxio was approved as a biosimilar.<sup>311</sup> The reference product for Inflectra has only been used for a couple of years.<sup>312</sup> Rheumatologists and gastroenterologists may be more hesitant to uptake the product.<sup>313</sup> Additionally, Inflectra was not tested in gastroenterology patients, but rheumatologists have much more clinical data to depend on, and thus, sales may not be curtailed.<sup>314</sup> This puts Johnson & Johnson's \$5.9 billion in projected sales of the reference product in 2017 at risk.<sup>315</sup>

Both Zarxio and Inflectra have entered the market despite ongoing patent disputes.<sup>316</sup> Launching the products before dispute resolution puts the manufacturers at risk for triple damages if they are found in violation of the patents.<sup>317</sup> Manufacturers of the other two biosimilars have been hesitant to take this same risk.<sup>318</sup>

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<sup>309</sup> Eric Sagonowsky, *Pfizer loads up for Remicade biosim launch, with \$4.5B J&J brand in its sights*, FIERCEPHARMA (last updated on Oct. 18, 2016, 11:00 AM), <http://www.fiercepharma.com/pharma/despite-ongoing-patent-dispute-pfizer-announces-inflectra-u-s-launch> [<https://perma.cc/W9LV-HXXV>].

<sup>310</sup> Nicole Gray, *Why Inflectra may face greater challenges than Zarxio in winning over U.S. docs*, BIOPHARMADIVE (Apr. 16, 2016), <http://www.biopharmadive.com/news/why-inflectra-may-face-greater-challenges-than-zarxio-in-winning-over-us-do/418206/> [<https://perma.cc/N3NC-V8GU>].

<sup>311</sup> *Id.* (noting that the product is prescribed by oncologists).

<sup>312</sup> *Id.*

<sup>313</sup> *Id.* (noting that the product is prescribed by rheumatologists and gastroenterologists).

<sup>314</sup> *Id.*

<sup>315</sup> Tracy Staton, *Top of 2017's pharma heap? Pfizer, Novartis, Roche—and 7 drugs headed for biosim attack*, FIERCEPHARMA (Dec. 8, 2016, 10:16 AM), <http://www.fiercepharma.com/pharma/biosim-threats-coming-fast-for-world-s-top-2017-drugs> [<https://perma.cc/Z7SJ-KL4X>].

<sup>316</sup> Kevin E. Noonan, *Sandoz' NEUPOGEN® Biosimilar Now on the Market*, PATENT DOCS (Sept. 7, 2015), <http://www.patentdocs.org/2015/09/Sandoz-neupogen-biosimilar-now-on-the-market.html> [<https://perma.cc/PL78-GSAP>]; Sagonowsky, *supra* note 309.

<sup>317</sup> Sagonowsky, *supra* note 309.

<sup>318</sup> *Amgen: Unlikely to Launch AMJEVITA® Biosimilar Before 2018*, GOODWIN: BIG MOLECULE WATCH (Oct. 28, 2016), <http://www.bigmoleculewatch.com/2016/10/28/amgen-unlikely-to-launch-amjevita-biosimilar-before-2018/> [<https://perma.cc/2PX4-W5ZQ>].

Sandoz's Erelzi, a biosimilar for Enbrel, received FDA-approval in August 2016, but sales will not likely launch until mid-2017.<sup>319</sup> Amjevita, Amgen's biosimilar to AbbVie's Humira product, received FDA-approval in September 2016; however, sales will not likely launch until 2018.<sup>320</sup> These two products demonstrate that the need for innovation at a lower cost will not be met under the current judicial interpretation of the BPCIA.<sup>321</sup>

As indicated over the past four years and by the market data above, fewer biologics are expected to enter the market as biosimilars due to the significant development costs.<sup>322</sup> Biosimilars take around eight to ten years and \$100–\$250 million to develop, while generic small-molecule pharmaceuticals only cost around \$5 million.<sup>323</sup> If manufacturers will have to face extended periods of litigation due to the Federal Circuit decision in *Amgen v. Sandoz* and delayed market entry after FDA-approval (and potentially triple damages if the products are found to be infringing), there are few incentives to pursue biosimilarity.<sup>324</sup> The Supreme Court's upcoming decision could potentially increase these incentives.<sup>325</sup>

#### CONCLUSION

This Note disagrees with the Federal Circuit's holdings in both *Amgen v. Sandoz* and *Amgen v. Apotex*.<sup>326</sup> The BPCIA anticipates that applicants will not go through the disclosure and information sharing process to minimize litigation and streamline disputes since the BPCIA provides a remedy to the reference product sponsor if the applicant fails to comply.<sup>327</sup> However, if

<sup>319</sup> John Miller, *Novartis Bid to Sell New Biosimilar Crimped by U.S. Court Battles*, REUTERS (Aug. 31, 2016, 6:40 AM), <http://www.reuters.com/article/us-novartis-fda-biosimilars-idUSKCN11619F> [<https://perma.cc/282R-9H6Y>].

<sup>320</sup> See GOODWIN: BIG MOLECULE WATCH, *supra* note 318.

<sup>321</sup> See, e.g., *id.*

<sup>322</sup> Tucker & Wells, *supra* note 296, at 101–02.

<sup>323</sup> *Id.* at 102.

<sup>324</sup> See *supra* text accompanying notes 270–75.

<sup>325</sup> See *supra* text accompanying notes 226–40.

<sup>326</sup> *Contra Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1066 (Fed. Cir. 2016); *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1362 (Fed. Cir. 2015).

<sup>327</sup> See *supra* text accompanying notes 241–50 for a discussion of the remedy for failing to comply with the disclosure requirements.

applicants streamline this process, and do comply, the reference product sponsor effectively has notice of the potential marketability of the product.<sup>328</sup> The 180-day notice provision should not apply to applicants who have disclosed pursuant to (2)(A).<sup>329</sup>

Furthermore, the BPCIA contemplates a course of action if the applicant chooses to forego the disclosure procedures in (2)(A).<sup>330</sup> An injunction is not available to compel compliance with the procedures.<sup>331</sup> Rather, the sponsor can file an infringement suit.<sup>332</sup> Thus, information the reference product sponsor seeks may only be obtained during discovery, not through a preliminary injunction.<sup>333</sup>

Additionally, (8)(A) allows the applicant to provide the reference product sponsor with notice of commercial marketing 180 days *before* FDA-approval.<sup>334</sup> Section (8)(A) only requires that notice is given no later than 180 days before the date of commercial marketing.<sup>335</sup> Requiring the applicant to provide notice *after* FDA-approval would unnecessarily extend the exclusivity period for the reference product sponsor for six months,<sup>336</sup> and the applicant would face anticompetitive effects.<sup>337</sup>

There is no private right of action for injunctive relief to enforce this requirement in (8)(A).<sup>338</sup> If proper notice is not given, the course contemplated by the BPCIA is to commence an action for a declaration of infringement, validity, or enforceability.<sup>339</sup> Therefore, the Supreme Court should overturn the current interpretation of the notice requirement and the remedies for non-compliance in answering the cross-petitions for certiorari in *Amgen v. Sandoz*.<sup>340</sup>

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<sup>328</sup> See *supra* text accompanying notes 185–91.

<sup>329</sup> See *supra* text accompanying notes 185–91.

<sup>330</sup> See *supra* text accompanying notes 205–08.

<sup>331</sup> See *supra* text accompanying notes 205–08.

<sup>332</sup> See *supra* text accompanying notes 205–08.

<sup>333</sup> See *supra* text accompanying notes 205–08.

<sup>334</sup> See *supra* text accompanying notes 228–31.

<sup>335</sup> See *supra* text accompanying notes 228–31.

<sup>336</sup> See *supra* text accompanying notes 228–31.

<sup>337</sup> See *supra* text accompanying notes 270–71.

<sup>338</sup> See 42 U.S.C.A. § 262(l)(9)(A) (West 2015) (amended 2017).

<sup>339</sup> *Id.*

<sup>340</sup> See *supra* text accompanying notes 226–40.



Like the Hatch-Waxman Act, there are imperfections that need to be resolved in the BPCIA.<sup>341</sup> The 180-day notice requirement is just one problem.<sup>342</sup> This can extend the exclusivity period and delay generic entry into the market.<sup>343</sup> Only four biosimilars have been approved by the FDA and no interchangeable biologics have.<sup>344</sup> Few manufacturers are likely to pursue interchangeability due to the higher safety requirements.<sup>345</sup> However, biosimilars need to qualify as an interchangeable to receive the automatic substitutability as generic small-molecule drugs.<sup>346</sup> Few incentives exist for the physicians to prescribe a new drug if there is a fear the patients may react differently to a critical method of treatment that is only slightly less expensive.<sup>347</sup>

The market data of the two biosimilars that have entered the market indicate that biosimilars can reduce the cost of biologic therapies.<sup>348</sup> Under the current interpretation of the 180-day notice requirement and injunctive remedies, this will not happen quickly.<sup>349</sup> Biosimilars are very costly to develop, and if manufacturers will have to face extended periods of litigation, delayed market entry, and potentially treble damages due to the Federal Circuit decision in *Amgen v. Sandoz*, there are few incentives to pursue biosimilarity.<sup>350</sup> This decision is delaying litigation and the process of biosimilars.<sup>351</sup> The case before the Supreme Court could increase these incentives and achieve the purpose behind the BPCIA, creating a market for generic biological therapies.<sup>352</sup>

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<sup>341</sup> See Timmis, *supra* note 31, at 227.

<sup>342</sup> See, e.g., *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1066 (Fed. Cir. 2016); *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1348 (Fed. Cir. 2015).

<sup>343</sup> See *supra* text accompanying notes 270–76.

<sup>344</sup> See Center for Drug Evaluation and Research, *supra* note 32.

<sup>345</sup> See Li, *supra* note 48.

<sup>346</sup> See Timmis, *supra* note 31, at 230–31.

<sup>347</sup> *Id.* at 231.

<sup>348</sup> See *supra* text accompanying notes 308–15.

<sup>349</sup> See Miller, *supra* note 319.

<sup>350</sup> See *supra* text accompanying notes 322–25.

<sup>351</sup> See *supra* text accompanying notes 322–25.

<sup>352</sup> See *supra* text accompanying notes 322–25.

EPILOGUE—THE SUPREME COURT’S DECISION IN  
*AMGEN V. SANDOZ*

The Supreme Court announced its decision after the completion of this Note on June 12, 2017.<sup>353</sup> As the Note argued, the Court held that section 262(l)(8)(A) allows the applicant to provide notice before receiving FDA approval, since “the phrase ‘of the biological product licensed under subsection (k)’ modifies ‘commercial marketing’ rather than ‘notice ...’”<sup>354</sup> Thus, the “biosimilar must be ‘licensed’” when the product is marketed, not when notice is given.<sup>355</sup>

The Court further held that the requirement under (l)(2)(A) “is not enforceable by an injunction.”<sup>356</sup> Rather, (l)(9)(C) provides the remedy when the applicant does not provide the application and manufacturing information required under (l)(2)(A).<sup>357</sup> An “immediate declaratory-judgment action for artificial infringement” may be brought by “the sponsor, [ ] not the applicant.”<sup>358</sup>

However, the Supreme Court directed the Federal Circuit on remand to determine “whether an injunction is available under state law to enforce” these requirements.<sup>359</sup> Yet, Sandoz filed a statement at the Federal Circuit to remand the case to the district court, since the court would be faced with a question of state law.<sup>360</sup> The case is still pending before the Federal Circuit.<sup>361</sup>

Nonetheless, this Supreme Court decision gives hope for a biosimilar market since it limits the exclusion period for the reference product.<sup>362</sup> However, as the Note argues, this purpose

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<sup>353</sup> *Sandoz Inc. v. Amgen, Inc.*, 137 S. Ct. 1664, 1664 (2017).

<sup>354</sup> *Id.* at 1668.

<sup>355</sup> *Id.* at 1667.

<sup>356</sup> *Id.*

<sup>357</sup> *Id.* at 1668.

<sup>358</sup> *Id.* at 1667–68.

<sup>359</sup> *Id.* at 1668.

<sup>360</sup> *Amgen v. Sandoz: Sandoz Requests Remand to District Court*, BIG MOLECULE WATCH (June 30, 2017), <https://www.bigmoleculewatch.com/2017/06/30/sandoz-requests-remand/> [<https://perma.cc/ZF7Q-MCR8>].

<sup>361</sup> *See, e.g., The Biosimilars Council Supports Sandoz’s Preemption Position in Federal Circuit Amicus Brief*, BIG MOLECULE WATCH (Sept. 15, 2017), <https://www.bigmoleculewatch.com/2017/09/15/biosimilars-council-supports-sandozs-preemption-position-federal-circuit-amicus-brief/> [<https://perma.cc/6LW5-9DNS>].

<sup>362</sup> *See Sandoz Inc.*, 137 S. Ct. at 1670.

could be furthered if applicants in compliance with (l)(2)(A) do not need to comply with the 180-day requirement at all, since the reference sponsor effectively has notice, but that holding is inconsistent with the current interpretation of the statute and the current state of the law.<sup>363</sup>

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<sup>363</sup> See *supra* text accompanying notes 185–91.