

# “SHALL” WE DANCE? INTERPRETING THE BPCIA’S PATENT PROVISIONS

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Since the Food and Drug Administration (FDA) first approved a biologic in 1982, biologics, a type of therapeutic drug, have become an increasingly significant percentage of the pharmaceutical market. Hundreds of biologics have been approved to treat a wide array of diseases.<sup>1</sup> However, due to their large development costs, biologics have remained much more expensive than other pharmaceutical products.

In an attempt to address the high cost of biologics, Congress passed the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated FDA approval pathway for biosimilars, the equivalent of generic drugs for biologics. The BPCIA aimed to balance innovation with consumer interest by allowing the biosimilar maker to partially benefit from an approved reference product’s clinical trial data, while giving the innovator twelve years of exclusivity and a means for efficiently resolving patent disputes. The patent dispute resolution process included an exchange of information—the biosimilar maker’s application and manufacturing information for the reference product sponsor’s list of potentially infringed patents—termed the “patent dance.”

In the Federal Circuit’s first decision interpreting the BPCIA, *Amgen Inc. v. Sandoz Inc.*,<sup>2</sup> a split court found that the patent dance was not mandatory, and a biosimilar maker could decline to engage in the information exchange. However, the language, statutory structure, and legislative history of the patent dispute resolution provisions in the BPCIA show that Congress intended the patent dance to be mandatory. In the short run, the Federal Circuit’s *Amgen* decision may lead to a greater number of cheaper biosimilar products getting to market more quickly. Overall, the decision may make resolving biosimilar patent disputes a lengthier, costlier,

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DOI: <http://dx.doi.org/10.15779/Z383S0S>

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1. FDA, PURPLE BOOK: LISTS OF LICENSED BIOLOGICAL PRODUCTS WITH REFERENCE PRODUCT EXCLUSIVITY AND BIOSIMILARITY OR INTERCHANGEABILITY EVALUATIONS, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm> [<http://perma.cc/F342-LK8B>] (last visited Jan. 26, 2016).

2. 794 F.3d 1347, 1348 (Fed. Cir. 2015).

and more inefficient process, as well as create additional uncertainty in biosimilar patents, ultimately hurting incentives to innovate.

Part I of this Note sets up background information for understanding the current state of biosimilars and biosimilar regulation. Next, Part II sets forth the Federal Circuit's decision in *Amgen Inc. v. Sandoz Inc.* Part III goes through a statutory interpretation analysis of the BPCIA. Finally, Part IV suggests that the Federal Circuit's decision may be beneficial for consumers in the short run, but harmful in the long term.

## I. BACKGROUND

In part, the science behind biologics created particular issues for any biosimilar regulation to address. Moreover, the growing importance of biologics in the pharmaceutical industry increased the pertinence of passing legislation to regulate biosimilars. Responding to this specific need for biologics and biosimilar regulation, congressional representatives introduced multiple bills proposing different schemes of biosimilar regulation over the course of five years. Ultimately, Congress passed the BPCIA, which contained the particular patent dispute resolution provisions at issue in *Amgen*.

### A. THE SCIENCE OF BIOLOGICS & BIOSIMILARS

Pharmaceutical drugs can be roughly divided into two categories: chemical compounds and biologics. Biologics are protein-based drugs typically made by utilizing cell lines with recombinant DNA technology to synthesize the biologic molecule.<sup>3</sup>

Biologic drugs can consist of millions of atoms, as opposed to small-molecule chemical compounds which comprise no more than a few dozen atoms.<sup>4</sup> Because biologics are created using living systems and not simply chemically synthesized, there is some heterogeneity in the structure of biologics.<sup>5</sup> Small variations in manufacturing conditions can lead to minor structural differences in "identical" biologics.<sup>6</sup> Owing both to the large,

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3. Joyce Wing Yan Tam, *Biologics Revolution: The Intersection of Biotechnology, Patent Law, and Pharmaceutical Regulation*, 98 GEO. L.J. 535, 535 (2010).

4. Linfong Tzeng, *Follow-On Biologics, Data Exclusivity, and the FDA*, 25 BERKELEY TECH. L.J. 135, 138 (2010).

5. *Id.*

6. *Id.*

complex nature and structural variations of biologics, the composition of biologics can be difficult to fully characterize.<sup>7</sup>

The nature of biologics presents unique difficulties in assessing follow-on products that do not apply to small molecules. As minute changes in the manufacturing conditions can result in differences, follow-on biologics can only achieve structural similarity, and not structural identity, with the original product.<sup>8</sup> Moreover, current analytical techniques cannot fully resolve the differences between the original and follow-on product for direct comparison.<sup>9</sup> Not every protein structure may be resolved with current techniques, and using these techniques to identify protein structure is costly and time-intensive,<sup>10</sup> making it infeasible to structurally resolve every batch of biologic. Thus, the possibility exists that these small differences in structure and manufacture may lead to tangible differences in product efficacy, safety, and purity.<sup>11</sup> Unfortunately, the only way to know whether those changes will result in reduced efficacy or safety is through clinical trials.<sup>12</sup>

#### B. THE INCREASING BIOLOGICS & BIOSIMILARS MARKET

The market and market share for biologics has increased significantly since the turn of the century. In 2014, biologics accounted for 29% (\$159 billion) of global pharmaceutical sales, up from just 10% in 2000.<sup>13</sup> And the market is projected to continue to grow.<sup>14</sup> In part, the high percentage of sales is due to the extraordinary cost of biologics. In 2013, the average daily cost in the United States of a biologic drug was \$45, compared to \$2 for a small-molecule drug.<sup>15</sup>

The increasing market for biologics makes them ripe for competition. Moreover, many biologics are no longer covered by intellectual property rights, as patent protection for many lucrative biologics either already has

7. Arthur J. Chirino & Anthony Mire-Sluis, *Characterizing Biological Products and Assessing Comparability Following Manufacturing Changes*, 22 NATURE BIOTECHNOLOGY 1383, 1383 (2004).

8. Tzeng, *supra* note 4, at 138.

9. *Id.* at 139.

10. *See* Chirino & Mire-Sluis, *supra* note 7, at 1389.

11. *Id.* at 1384.

12. Tzeng, *supra* note 4, at 139–40.

13. Ashley Kindergan, *Biosimilars Are Here. Now What?*, FINANCIALIST (Apr. 13, 2015), <https://www.thefinancialist.com/biosimilars-are-here-now-what> [<http://perma.cc/7MRU-2ZG7>].

14. *See* Erwin A. Blackstone & Joseph P. Fuhr, Jr., *The Economics of Biosimilars*, 6 AM. HEALTH & DRUG BENEFITS 469, 470 (Sept.–Oct. 2013).

15. *Id.* at 469.

expired or will expire in the next few years. Between 2009 and 2015, an estimated thirty-two biologics, representing \$51 billion in sales in 2009, lost patent protection.<sup>16</sup> By 2018, biologics worth \$43 billion are projected to lose patent protection.<sup>17</sup>

Even without considering patent exclusivity, there are still significant barriers to enter the biosimilars market. Whereas generic drugs cost between \$1 million and \$4 million to develop and market, biosimilar development takes seven to eight years and costs between \$100 million and \$250 million.<sup>18</sup> Still, the development cost of a biosimilar is significantly lower than the estimated \$1.9 billion in 2012<sup>19</sup> and ten to fifteen years to develop a new pharmaceutical drug.<sup>20</sup> Moreover, due to the significant barriers to entry, biosimilars are likely to be produced by large pharmaceutical companies with significant capital<sup>21</sup> and to be priced much more closely to the original biologic. In Europe, the average biosimilar is 30% less expensive than its reference product.<sup>22</sup> Thus, while introducing biosimilars into the market will help alleviate the high price of biologics, they will remain significantly more expensive than small-molecule drugs.

### C. THE LEGISLATIVE HISTORY OF THE BPCIA

Before the enactment of the BPCIA, overlap between existing regulatory structures caused confusion for the regulation of biologics.<sup>23</sup> Starting in 2006, Congress actively engaged in passing new, unified legislation to regulate biosimilar approval. Between 2006 and 2009, Congress proposed eight different bills and a slew of amendments to create an abbreviated biosimilar approval pathway. Those bills varied substantially in their definitions of biosimilarity and interchangeability and the length of innovator exclusivity.<sup>24</sup>

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16. *Id.* at 470.

17. Kindergan, *supra* note 13.

18. Blackstone & Fuhr, *supra* note 14, at 470–71.

19. *Id.* at 473.

20. Michael S. Montgomery, Note, *Generics and Biosimilars: Mapping the Biosimilars Regulatory Approval Pathway Against the Hatch-Waxman Act and Projecting Future Effects on the Biologics Market and Patent Protection*, 75 U. PITT. L. REV. 387, 388 (2014).

21. Bruno Calo-Fernández & Juan Leonardo Martínez-Hurtado, *Biosimilars: Company Strategies to Capture Value from the Biologics Market*, 5 PHARMS. 1393, 1399 (2012).

22. Blackstone & Fuhr, *supra* note 14, at 471.

23. Krista Hessler Carver et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 FOOD & DRUG L.J. 671, 681–82 (2010).

24. See generally Parker Tresemer, Comment, *Interests in the Balance: FDA Regulations Under the Biologics Price Competition and Innovation Act*, 16 UCLA J.L. & TECH. 1 (2012) (comparing the biosimilarity requirements and exclusivity periods of various bills).

The bills also proposed multiple different schemes to resolve patent disputes between the innovator and the biosimilar applicant. Important differences in these schemes included: (1) whether the patent scheme was mandatory, (2) how the biosimilar applicant disclosed its information, and (3) when and which party could initiate a declaratory judgment action. The specifics of these patent provisions were important to industry actors and carefully considered by Congress.

Representative Henry Waxman introduced three bills between 2006 and 2008: H.R. 6257, H.R. 1038, and H.R. 1427.<sup>25</sup> These bills had largely identical patent provisions, which were more favorable to the biosimilar applicant than any other proposed bill's provisions. These bills proposed a patent resolution process that was much different from the provisions in today's BPCIA.

H.R. 6257 provided that the biosimilar applicant "may send a written request for patent information to the holder of the approved application for the reference product."<sup>26</sup> As such, the patent dispute resolution process as a whole was an option that the biosimilar applicant could decide to take part in. The bill explicitly provided that "[t]he decision as to whether to invoke the procedures set forth in this paragraph is left entirely to the discretion of the applicant."<sup>27</sup> Should the applicant make a request, the patent holder would be required to send a list of all the patents it believed covered the reference product.<sup>28</sup> Notably, there were no provisions which required the biosimilar applicant to disclose any of its own information to the patent holder.

The patent holder could only bring suit if the applicant decided to provide a notice that the patents were invalid, unenforceable, or not infringed.<sup>29</sup> The bill then proposed limitations on the remedies available should the innovator fail to disclose a patent or bring suit in a timely manner. An innovator who fails to disclose a patent entirely would be barred from bringing an infringement action on that patent.<sup>30</sup> And one who fails

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25. H.R. 1427, 111th Cong. (1st Sess. 2008); H.R. 1038, 110th Cong. (1st Sess. 2007); H.R. 6257, 109th Cong. (2d Sess. 2006). Concurrently with H.R. 6257, Senator Schumer introduced an identical bill, S. 4016, to the Senate. Carver et al., *supra* note 23, at 716.

26. H.R. 6257 § 3(a)(2) (proposed Public Health Service Act (PHSA) § 351(k)(16)(A)(i)).

27. *Id.* § 3(a)(2) (proposed PHSA § 351(k)(16)(E)).

28. *Id.* § 3(a)(2) (proposed PHSA § 351(k)(16)(A)(i)).

29. *Id.* § 3(a)(2) (proposed PHSA § 351(k)(16)(B)–(C)).

30. *Id.* § 3(a)(2) (proposed PHSA § 271(e)(5)(B)).

to bring suit within the allotted forty-five days would have a reasonable royalty as a sole remedy for prevailing in an infringement action.<sup>31</sup>

The patent provisions of Waxman's bills were criticized by the makers of original biologic products, referred to as the innovator industry. The Biotechnology Innovation Organization (BIO), a trade association representing the interests of innovator companies, "strongly oppose[d]" H.R. 1038, in part because it "eviscerate[d] incentives to develop new therapies through its one-sided alteration of long-standing patent law in ways that favor follow-on biologics' manufacturers."<sup>32</sup> Additionally, in a 2009 House hearing, Teresa Rea, President of the American Intellectual Property Law Association (AIPLA), criticized Waxman's patent resolution provisions as having the potential to weaken biotechnology patents.<sup>33</sup> Chiefly, Rea was concerned that the bill would limit patent holders' ability to assert their patent rights, as it did not provide the patent holder with "any access to information to determine whether the follow-on product likely infringes any of the reference product holder's patents."<sup>34</sup> And, without allowing for all disputes to be resolved prelaunch, patent disputes "would strain the federal judiciary by requiring—in preliminary injunction proceedings—resolution of the complex legal and scientific questions involved with each biosimilar product launch."<sup>35</sup>

Patent dispute resolution provisions were clearly important to the innovator industry. In 2007, Representative Jay Inslee introduced H.R. 1956.<sup>36</sup> H.R. 1956 had strong support from the innovator industry.<sup>37</sup> However, notably, the Inslee bill did not provide for any mechanism of patent dispute resolution.<sup>38</sup> In a largely supportive letter to Representative Inslee regarding the bill, BIO stressed the importance of adding such a provision to the legislation. As such, BIO encouraged Inslee to add

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31. *Id.* § 3(a)(2) (proposed PHSA § 271(e)(5)(A)).

32. Press Release, Biotechnology Innovation Organization, BIO Restates Opposition to H.R. 1038 (Mar. 26, 2007), <http://www.bio.org/media/press-release/bio-restates-opposition-hr-1038> [<http://perma.cc/GT8C-VB5U>].

33. *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts and Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 21, 197 (2009) [hereinafter *Biologics Hearings*].

34. *Id.* at 208.

35. *Id.* at 201.

36. H.R. 1956, 110th Cong. (1st Sess. 2007).

37. Carver et al., *supra* note 23, at 739.

38. *See* H.R. 1956.

“appropriate mechanisms for the resolution of any patent-related disputes that may occur prior to market entry of a follow-on biologic.”<sup>39</sup>

Also in 2007, Senator Judd Gregg introduced a bill similar to Representative Inslee's.<sup>40</sup> One main difference between Inslee's bill and Gregg's bill was that the latter included patent resolution provisions. Once the biosimilar application was submitted, the reference product sponsor “may request information” from the applicant to determine infringement, provide patent information to the applicant, or indicate licensing preference.<sup>41</sup> Thus, the patent scheme was a nonmandatory scheme which gave the reference product sponsor the ability to decide whether to initiate the process. Finally, the bill provided limitations upon when the biosimilar applicant could bring a declaratory judgment action but not on when the patent holder could.<sup>42</sup>

In 2008, Representative Anna Eshoo introduced H.R. 5629, with yet another distinct patent resolution structure.<sup>43</sup> Upon submission of the application, the biosimilar applicant “shall provide the reference product sponsor” the application and manufacturing information.<sup>44</sup> At the time, interested industry actors seemed to interpret this language to mean the disclosure was mandatory.<sup>45</sup> Unlike any other bill, it allowed “interested third parties” to give notice to the biosimilar applicant and engage in the patent resolution process.<sup>46</sup> The bill also limited the applicant's ability to bring a declaratory judgment action to the later of (1) three years before the expiration of data exclusivity period or (2) 120 days after the applicant provided written explanation of invalidity or noninfringement.<sup>47</sup>

Generic companies and supporters opposed Representative Eshoo's bill.<sup>48</sup> The opposition largely stemmed from what the generics industry

39. Letter from James C. Greenwood, Pres. & CEO, Biotechnology Industry Organization, to Jay Inslee, Representative (Aug. 27, 2007), [https://www.bio.org/sites/default/files/Inslee\\_Support\\_Letter\\_20070827.pdf](https://www.bio.org/sites/default/files/Inslee_Support_Letter_20070827.pdf) [<http://perma.cc/T6UT-G75S>].

40. Carver et al., *supra* note 23, at 739 (citing *GOP Senators Introduce Brand-Friendly Biogenics Bill*, FDA WEEK (June 1, 2007)).

41. S. 1505, 110th Cong. § 2(a)(2) (1st Sess. 2007) (proposed PHSA § 351(k)(8)(B)(i)).

42. *Id.* (proposed PHSA § 351(k)(8)(E)).

43. Carver et al., *supra* note 23, at 771.

44. H.R. 5629, 110th Cong. § 101(a)(2) (2d Sess. 2008) (proposed PHSA § 351(l)(4)(A)(i)).

45. *Biologics Hearings*, *supra* note 33, at 204 (“Eshoo-Barton mandates disclosure,” “the reference product sponsor would be entitled to access to the follow-on product's abbreviated application”).

46. H.R. 5629, 110th Cong. § 101(a)(2) (proposed PHSA § 351(l)(1)(D)).

47. *Id.* (proposed PHSA § 351(l)(6)).

48. *Reps. Eshoo, Barton Introduce Bill on FDA Approval of Bigeneric Drugs*, 6 PHARM. L. & IND. R. 330 (Mar. 21, 2008), [http://news.bna.com/piln/PILNWB/split\\_display](http://news.bna.com/piln/PILNWB/split_display)

perceived as a lengthy data exclusivity period and needless roadblocks to access.<sup>49</sup> On the other hand, BIO praised the bill and specifically called the patent dispute resolution process a “balanced procedure” that would make it “likely that such disputes can fairly be resolved prior to the market-entry of a follow-on biologic.”<sup>50</sup>

When Representative Eshoo reintroduced her bill, H.R. 1548,<sup>51</sup> in 2009 at a House hearing<sup>52</sup> she emphasized that an important goal of her bill was the resolution of patent disputes before the commercial marketing of biosimilars, as well as the ability for third-party patent holders to defend their patent rights.<sup>53</sup> Bruce A. Leicher, Senior Vice President of Momenta Pharmaceuticals, criticized Eshoo’s bill as (1) creating a “complex, lengthy, patent clearance process that only begins 3 years before the end of a lengthy data exclusivity period,” which would lead to litigation delaying the commercial marketing of a biosimilar and (2) increasing the cost and time of litigation by allowing third parties to enter.<sup>54</sup>

By contrast, Teresa Rea praised the bill. Rea said the information exchange provisions were “reasonable” and “balanced,” as they “entitled” the reference product sponsor to access the follow-on maker’s application and manufacturing information.<sup>55</sup> In general, Rea described the patent resolution provisions as an “efficient, streamlined prelaunch patent litigation” method.<sup>56</sup>

Finally, four members of the Senate Committee on Health, Education, Labor, and Pensions (HELP) worked with the generic and innovator industries to introduce a bipartisan bill that they hoped would represent a compromise.<sup>57</sup> S. 1695, the bill proposed by the HELP committee and that which would eventually be passed as the BPCIA, included most of the ultimate language regarding patent dispute resolution. It provided that the biosimilar applicant “shall” provide a copy of the biosimilar application and

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.adp?fedfid=7147825&cvname=plirnotallissues&cjd=plir\_6\_330&split=0 [http://perma.cc/9YZN-L8M4].

49. *Id.*

50. Letter from James C. Greenwood, Pres. & CEO, Biotechnology Industry Organization, to Anna Eshoo & Joe Barton, Representatives (May 9, 2008), [http://www3.bio.org/healthcare/followonbkg/20080509\\_Eshoo\\_Barton\\_support\\_letter.pdf](http://www3.bio.org/healthcare/followonbkg/20080509_Eshoo_Barton_support_letter.pdf) [http://perma.cc/ND8E-43CK].

51. H.R. 1548, 111th Cong. (1st Sess. 2009).

52. *Biologics Hearings*, *supra* note 33.

53. *Id.* at 9.

54. *Id.* at 21.

55. *Id.* at 204.

56. *Id.* at 197.

57. Carver et al., *supra* note 23, at 724.



other information regarding the process used to manufacture the biological product.<sup>58</sup> It then required the reference product sponsor to give the applicant a list of patents, provided for a process to narrow it down, and created an act of infringement, allowing the patent holder to bring suit.<sup>59</sup> The bill also included a notice provision for commercial marketing<sup>60</sup> and limits upon when the reference product sponsor and applicant could bring declaratory judgment actions.<sup>61</sup> The specifics of these provisions are discussed in Section I.D, *infra*.

A press release from Senator Orrin Hatch, one of the four committee members who introduced the bill to the Senate, summarized the bill's patent resolution provisions.<sup>62</sup> With respect to the initial information disclosure, the press release summarized that “[t]he biosimilar applicant *must* provide its application and information about its manufacturing process to the brand company.”<sup>63</sup> The press release also characterized the limits on when parties could bring suit, in part, as resulting from the biosimilar applicant's failure to do “what it is required to do.”<sup>64</sup>

#### D. THE BPCIA'S PATENT PROVISIONS

The BPCIA serves three primary functions. It sets forth a regulatory pathway for follow-on biologic approval, provides an exclusivity period to biologics, and creates a mechanism for identifying and resolving patent disputes.

The BPCIA provides a detailed structure for resolution of patent disputes, briefly outlined in Figure 1.

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58. S. 1695, 110th Cong. § 2(a)(2) (2d Sess. 2007) (proposed PHSA § 351(l)(2)(A)).

59. *Id.* (proposed PHSA § 351(l)(3)–(7)).

60. *Id.* (proposed PHSA § 351(l)(8)).

61. *Id.* (proposed PHSA § 351(l)(9)).

62. Press Release, United States Senator Orrin Hatch, Hatch, Enzi: Biosimilar Bill Will Reduce Prescription Drug Costs (June 26, 2008), <http://www.hatch.senate.gov/public/index.cfm/2008/6/hatch-enzi:-biosimilar-bill-will-reduce-prescription-drug-costs> [<http://perma.cc/C9MJ-3XST>].

63. *Id.* (emphasis added).

64. *Id.*

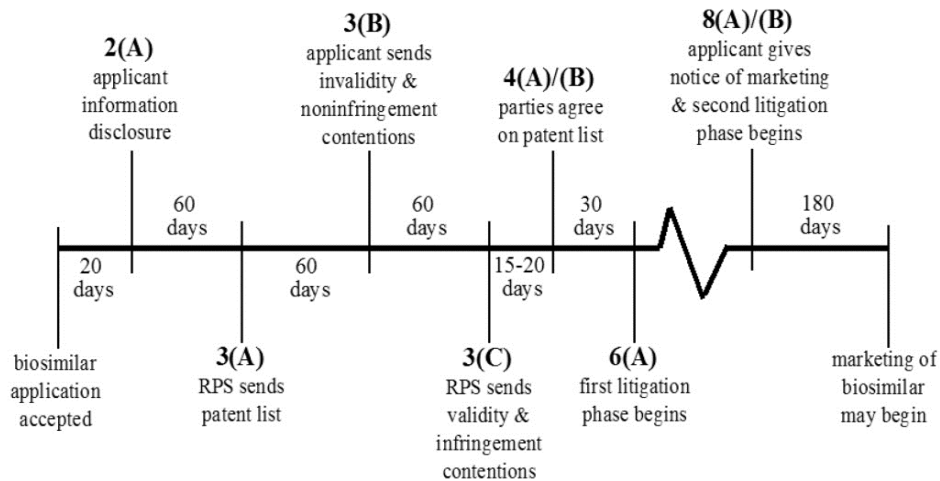


Fig. 1: Timeline of the BPCIA's patent resolution structure.

Initially, the BPCIA states that a biosimilar applicant, known as a subsection (k) applicant, within twenty days of being accepted for review, “shall provide to the reference product sponsor a copy of the application . . . and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application.”<sup>65</sup> The applicant also “may provide to the reference product sponsor additional information requested.”<sup>66</sup> This initial disclosure triggers a chain of disclosures and negotiations aimed at clarifying patent issues.

Within sixty days of receiving application information, the reference product sponsor (RPS) then must provide a list of patents it believes support an infringement claim and any patents it would be willing to license.<sup>67</sup> Then, within sixty days of receiving the patent list, the applicant must respond to each patent, either with an acknowledgement of infringement, a statement that it will not market until the patent has expired, or a “detailed statement that describes, on a claim by claim basis, the factual and legal basis” for noninfringement or invalidity.<sup>68</sup> The RPS must then respond to that detailed statement with its own detailed statement of validity and infringement.<sup>69</sup> Thus, no later than 180 days after the RPS receives the

65. 42 U.S.C. § 262(1)(2)(A) (2012).

66. *Id.* § 262(1)(2)(B).

67. *Id.* § 262(1)(3)(A).

68. *Id.* § 262(1)(3)(B).

69. *Id.* § 262(1)(3)(C).

applicant's information, both parties have formed detailed patent infringement positions.

The BPCIA then requires that both parties engage in good faith negotiations to agree on which patents the RPS shall pursue in a patent infringement action.<sup>70</sup> Should the parties fail to reach an agreement in fifteen days, the parties exchange lists of patents that they believe should be the subject of a patent infringement action, with the requirement that the RPS may not list more patents than the applicant.<sup>71</sup>

After the list of patents has been decided, the BPCIA provides for a first phase of patent litigation. Within thirty days of either agreement or exchange of patent lists, the RPS can bring an action for patent infringement with respect to those patents.<sup>72</sup>

The applicant must provide notice of marketing to the RPS at least "180 days before the date of the first commercial marketing" of the licensed biological product.<sup>73</sup> This sets up the second phase of litigation. Upon notification, the RPS may then also seek a preliminary injunction with respect to any patent included in its first list of patents but not included in the first phase of litigation.<sup>74</sup> This includes any patents that issued after the first disclosure of patents, where the RPS notified the applicant within thirty days of issuance or licensing.<sup>75</sup> The applicant then must reasonably cooperate to expedite discovery in conjunction with these preliminary injunction motions.<sup>76</sup>

Finally, the BPCIA provides "limitations on declaratory judgment action."<sup>77</sup> If the applicant provides the RPS with its application and manufacturing information, neither party may bring a declaratory judgment action for any patent not included in the first phase of litigation.<sup>78</sup> However, if the applicant fails to provide such information, the RPS may bring a declaratory judgment action for "any patent that claims the biological product or a use of the biological product."<sup>79</sup> Further, if the applicant provides the initial information but then fails to comply with a later

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70. *Id.* § 262(1)(4)(A).

71. *Id.* §§ 262(1)(4)(B), (5).

72. *Id.* § 262(1)(6)(A)–(B).

73. *Id.* § 262(1)(8)(A).

74. *Id.* § 262(1)(8)(B).

75. *Id.* § 262(1)(7).

76. *Id.* § 262(1)(8)(C).

77. *Id.* § 262(1)(9).

78. *Id.* § 262(1)(9)(A).

79. *Id.* § 262(1)(9)(C).

provision, the RPS may bring a declaratory judgment action for any patent it included in its initial list of patents.<sup>80</sup>

## II. AMGEN V. SANDOZ

*Amgen* represents the first time that the Federal Circuit issued a decision interpreting the BPCIA. In doing so, the court set forth the framework that all future biosimilar applicants and reference product sponsors will use to litigate patent disputes.

### A. FACTS & PROCEDURAL HISTORY

In May 2014, Sandoz filed an abbreviated application for Zarxio, a biosimilar product for which Amgen's Neupogen is the reference product.<sup>81</sup> The FDA notified Sandoz that it had accepted its application for review on July 7, 2014.<sup>82</sup> Sandoz notified Amgen of the pending application review and that it intended to launch Zarxio immediately upon FDA approval, around "Q1/2 of 2015," but explicitly opted out of providing Zarxio's product and manufacturing information as detailed in § 262(l)(2)(A).<sup>83</sup> The FDA approved Zarxio on March 6, 2015, at which time Sandoz gave "further notice of commercial marketing."<sup>84</sup>

Amgen sued Sandoz in the Northern District of California in October 2014 for (1) unfair competition for unlawful business practices, (2) conversion for wrongful use of Amgen's Neupogen license, and (3) infringement of U.S. Patent No. 6,162,427, a patent claiming the method for using the biologic.<sup>85</sup> At the heart of the unfair competition and conversion claims, Amgen alleged that Sandoz's failure to disclose product information within twenty days of the FDA accepting its application, as contemplated in § 262(l)(2)(A), violated the BPCIA.<sup>86</sup> Additionally, Amgen argued that Sandoz's notice of commercial marketing was premature and ineffective because it was given before the FDA approved Zarxio.<sup>87</sup> Sandoz counterclaimed for a declaratory judgment that it had accurately interpreted the BPCIA.<sup>88</sup>

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80. *Id.* § 262(l)(9)(B).

81. *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1352–53 (Fed. Cir. 2015).

82. *Id.* at 1352.

83. *Id.* at 1353.

84. *Id.*

85. *Id.*

86. *Id.*

87. *Id.*

88. *Id.*

The parties filed cross motions for summary judgment on these issues.<sup>89</sup> The district court granted summary judgment to Sandoz on both interpretations, finding that (1) the exchange of information in § 262(l)(2)(A) is not mandatory, and (2) an abbreviated Biologic License Application applicant may give notice of commercial marketing before the biosimilar is FDA approved.<sup>90</sup> Because Sandoz did not violate the BPCIA, the court dismissed Amgen's unfair competition and conversion claims. Amgen appealed the decision to the Federal Circuit.<sup>91</sup>

#### B. THE FEDERAL CIRCUIT'S DECISION

In its decision, the Federal Circuit answered two questions of statutory interpretation regarding the BPCIA: (1) Is it mandatory under § 262(l)(2)(A)<sup>92</sup> for a subsection (k) applicant to provide the RPS with its application and product manufacturing information?, and (2) Does the biosimilar product need to be FDA approved before an applicant can give effective notice of commercial marketing under § 262(l)(8)(A)? The Federal Circuit split 2–1, with a different judge dissenting on each question. The majority held that (1) the initiation of the “patent dance” was not mandatory,<sup>93</sup> relying heavily on § 262(l)(9)(C), which explicitly contemplates noncompliance, but (2) a biosimilar product must be approved by the FDA before the biosimilar maker is capable of giving effective notice of commercial marketing.<sup>94</sup> This Note only addresses the first question.<sup>95</sup>

In holding that it was permissible for a subsection (k) applicant to opt out of supplying the RPS with its application and product information, the court considered both textual and statutory organization arguments. The court found that the language of the relevant subsection favored a reading that the information exchange was mandatory. Section 262(l)(2)(A) states that an applicant “shall” provide information to the RPS, as opposed to § 262(l)(2)(B), which states additional information “may” be provided.

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89. *Id.*

90. *Id.*

91. *Id.* at 1354.

92. “[T]he subsection (k) applicant shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application.” 42 U.S.C. § 262(l)(2)(A).

93. *Amgen*, 794 F.3d at 1357.

94. *Id.* at 1358.

95. On the second question, the dissenting opinion depends in part on an inconsistency that arises from interpreting § 262(l)(2)(A) as nonmandatory. *Id.* at 1367 (Chen, J., dissenting). As this Note argues that § 262(l)(2)(A) is mandatory, this inconsistency would be remedied.

Additionally, the court recognized that other provisions refer to “information *required* to be produced pursuant to paragraph (2).”<sup>96</sup> The court found that, in isolation, these textual arguments would tend to support an understanding that “shall” should be interpreted as mandatory.<sup>97</sup>

However, reading the statute as a whole, the court found that it was permissible for a subsection (k) applicant to opt out of providing information. Section 271(e)(2)(C)(ii) of the Patent Act states that it is an act of infringement to file a subsection (k) application and then fail to disclose the information discussed in paragraph (1)(2)(A).<sup>98</sup> Moreover, § 262(l)(9)(C) allows the RPS to bring a declaratory judgment action on a patent claim when “a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A).”<sup>99</sup> The court found that both of these provisions establish remedies for the RPS in the event that the applicant does not provide information under paragraph (2)(A), indicating that providing the information is not mandatory.<sup>100</sup> Moreover, the court looked to § 271(e)(4), which provides the “*only* remedies which may be granted by a court for an act of infringement,” and found that failing to provide information under paragraph (1)(2)(A) was such an act of infringement.<sup>101</sup> Thus, not providing the information under paragraph (1)(2)(A) is simply a different pathway contemplated by the BPCIA, rather than a violation of it.

In dissent, Judge Newman emphasized the textual arguments contemplated by the majority to find that “shall” should be interpreted to mean “must.” Unlike the majority, Judge Newman considered these statutory provisions in light of the purpose of the BPCIA. Judge Newman looked to the legislative record and found that the purpose of expediting and averting litigation “pervades” it.<sup>102</sup> Judge Newman noted that the purpose of the BPCIA was to effectuate the “efficient resolution of patent issues” and that the information exchange triggered by paragraph (2)(A) was “fundamental” to that purpose.<sup>103</sup>

Judge Newman then found that the remedy of a declaratory action provided by paragraph (9)(C) is not an exclusive remedy under the BPCIA. It only extends to “any patent that claims the biological product or a use of

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96. *Id.* at 1355 (citing 42 U.S.C. § 262(l)(1)(B)(i)).

97. *Id.*

98. 35 U.S.C. § 271(e)(2)(C)(ii).

99. 42 U.S.C. § 262(l)(9)(C).

100. *Amgen*, 794 F.3d at 1355–56.

101. *Id.* at 1356.

102. *Id.* at 1365 (Newman, J., dissenting).

103. *Id.* at 1364 (Newman, J., dissenting).

the biological product” and not manufacturing process patents, which may be “highly material” in biosimilar infringement actions.<sup>104</sup> Instead, Judge Newman found that paragraph 9(C)'s main function is to prevent a noncompliant party from getting relief through a declaratory judgment.<sup>105</sup> As such, the provisions the majority uses as alternative pathways to initiating the patent dance are instead just “continuing prohibition[s]” on parties who fail to comply with the mandatory obligations of paragraph (2)(A).<sup>106</sup> Thus, to maintain the balance between innovation and consumer interest, the information exchange must be mandatory to protect the patent rights of innovators.

### III. *AMGEN* ANALYSIS: A MANDATORY PATENT DANCE

The Federal Circuit described its task in *Amgen* as doing its best to “unravel the riddle, solve the mystery, and comprehend the enigma” of the BPCIA.<sup>107</sup> Judge Chen echoed that sentiment in dissent, writing that in deciding *Amgen*, the Federal Circuit “must choose from a series of imperfect choices.”<sup>108</sup> Indeed, as evidenced by the fractured opinion, the patent provisions in the BPCIA could reasonably be interpreted in multiple ways. However, examining the drafting decisions and statutory purpose as laid out in the statutory structure and legislative history, there is a most reasonable interpretation of the BPCIA. As a whole, the statute makes clear that Congress intended the information exchange provisions of the BPCIA to be mandatory.

#### A. STATUTORY LANGUAGE

“[I]n interpreting a statute a court should always turn first to one, cardinal canon before all others. . . . [C]ourts must presume that a legislature says in a statute what it means and means in a statute what it says there.”<sup>109</sup> Thus, the statutory interpretation inquiry begins with the language of the statute. As both the majority and Judge Newman agreed, the BPCIA's language alone supports an interpretation that the patent dance is mandatory.

Namely, paragraph (1)(2)(A) (the “information disclosure provision”) states that the biosimilar maker “*shall* provide to the reference product

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104. *Id.* (Newman, J., dissenting).

105. *Id.* at 1366 (Newman, J., dissenting).

106. *Id.* (Newman, J., dissenting).

107. *Id.* at 1351 n.1.

108. *Id.* at 1371 (Chen, J., dissenting).

109. *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253–54 (1992) (citations omitted).

sponsor a copy of the application . . . and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application.”<sup>110</sup> As “the mandatory ‘shall’ . . . normally creates an obligation impervious to judicial discretion,”<sup>111</sup> the usage of shall here strongly lends itself to be interpreted as mandatory. And, in the very next paragraph, the statute goes on to state that the biosimilar applicant “*may* provide to the reference product sponsor additional information requested.”<sup>112</sup> As the Supreme Court has explained, “Congress’ use of the permissive ‘may’ . . . contrasts with the legislators’ use of a mandatory ‘shall’ in the very same section,” which supports a finding that “shall” indicates statutory obligation.<sup>113</sup> Thus, paragraph (l)(2)(B)’s use of “may” lends even stronger support that Congress meant the initial information disclosure to be mandatory.

Such an interpretation is further reinforced by the language in other provisions of the BPCIA. Section 262(l)(1)(B)(i) states that the biosimilar applicant “shall provide . . . confidential access to the information *required to be produced* pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate.”<sup>114</sup> Not only does this section refer to the information as “required to be produced,” but it also contrasts that with other information that the applicant has “sole discretion” to deem appropriate. Sections 262(9)(A) and (9)(C) both refer to “information required under paragraph 2(A).”<sup>115</sup> Finally, § 271(e)(2)(C)(ii) once again refers to “information required under section 351(l)(2)(A) of [the Public Health Service Act].”<sup>116</sup>

On textual analysis in isolation, the court agreed that the use of “shall” in the information disclosure provision “appears to mean that a subsection (k) applicant is *required* to disclose its [abbreviated application] and manufacturing information.”<sup>117</sup>

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110. 42 U.S.C. § 262(l)(2)(A) (2012) (emphasis added).

111. *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998); *accord Alabama v. Bozeman*, 533 U.S. 146, 153 (2001) (“The word ‘shall’ is ordinarily the language of command.”) (citing *Anderson v. Yungkau*, 329 U.S. 482, 485 (1947)).

112. 42 U.S.C. § 262(l)(2)(B) (emphasis added).

113. *See Lopez v. Davis*, 531 U.S. 230, 241 (2001).

114. 42 U.S.C. § 262(l)(1)(B)(i) (emphasis added).

115. *Id.* § 262(l)(9)(A), (C).

116. 35 U.S.C. § 271(e)(2)(C)(ii) (2012).

117. *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1355 (2015) (emphasis added).



## B. STATUTORY STRUCTURE

The statutory structure of the BPCIA is consistent with a mandatory information disclosure provision. The *Amgen* majority, despite recognizing textual arguments, found that examination of the greater context of the statute resulted in a nonmandatory interpretation of the initial information disclosure provision. A close look at the statutory structure is a necessary exercise of statutory interpretation. Indeed, statutory construction is a “holistic endeavor” and provisions that may seem “ambiguous in isolation” can be clarified by the statutory scheme, as one interpretation may be more consistent with the substantive effect of the law.<sup>118</sup> However, while the majority discerned context by looking to “the provisions of the whole law,” it neglected to consider “its object and policy.”<sup>119</sup> In doing so, the court settled upon an interpretation that disregarded the very purpose behind the provisions it was construing.

The court placed great weight in the two provisions of the BPCIA that reference noncompliance of the information disclosure provision in reaching its interpretation. It reasoned that these provisions of the BPCIA set out an alternative pathway for biosimilar applicants and defined the remedies available to the patent holder. However, Congress intended neither of these provisions as exclusive remedies for a failure to disclose information under paragraph (1)(2)(A). Section 262(1)(9)(C) must be understood in the context of subsection 9 as a whole, which merely places limits on when parties can bring declaratory judgment actions. And, §§ 271(e)(2)–(4) provide remedies for infringement actions but do not provide limitations on causes of action.

### 1. *Section 262(1)(9)(C) Defines Limits, Not Remedies*

In order to properly understand the function of § 262(1)(9)(C), the two-phase litigation structure of the patent provisions as a whole must be understood. The first phase of patent litigation occurs after the parties have narrowed down the list of patents at issue.<sup>120</sup> At the latest, this litigation begins 230 days after the biosimilar applicant’s initial disclosure of information.<sup>121</sup> Thus, the BPCIA is structured such that the parties begin

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118. *United Sav. Ass’n of Texas v. Timbers of Inwood Forest Assocs.*, 484 U.S. 365, 371 (1988).

119. *See* *United States v. Heirs of Boisdoré*, 49 U.S. 113, 122 (1850).

120. *See* 42 U.S.C. § 262(1)(6) (2012).

121. After the initial information disclosure, the RPS has sixty days to respond with a list of potentially infringed patents. 42 U.S.C. § 262(1)(3)(A). Then, the biosimilar applicant has sixty days to respond to that patent list with its invalidity and noninfringement contentions. *Id.* § 262(1)(3)(B). The RPS then has another sixty days to

informed litigation on the most pertinent patent infringement issues at a relatively early stage in the biosimilar approval process.

The second phase of patent litigation is triggered by the biosimilar applicant's notice of commercial marketing, which occurs 180 days before the launch of the biosimilar product. In this stage of litigation, the RPS may seek a preliminary injunction on any patent it has previously listed but did not get to litigate in the first phase.<sup>122</sup> Thus, this phase of litigation settles any lingering patent disputes that would impede the marketing of the biosimilar.

The provisions of subsection 9 of the BPCIA reinforce this two-phase litigation structure. As an initial matter, subsection 9 is titled "Limitation on declaratory judgment action."<sup>123</sup> The headings of a statute may aid the court in resolving any ambiguity of the statute's text.<sup>124</sup> Specifically, headings may be helpful in determining the general purview of section.<sup>125</sup> Here, the heading specifically states that the section will deal with "limitations" on declaratory judgment actions. This title indicates that Congress primarily viewed subsection 9 as providing limitations on when the parties could bring infringement actions and not as providing remedies.

A closer look at the individual provisions in subsection 9 supports such an understanding. As 35 U.S.C. § 271(e)(2)(C) creates an artificial act of infringement upon submission of an application seeking approval for a biosimilar, some internal limitations on when parties can bring infringement actions are necessary to enforce the two-phase litigation structure. Accordingly, paragraph (l)(9)(A) (the "declaratory judgment prohibition provision") broadly prohibits both parties from bringing declaratory judgment actions.<sup>126</sup> Specifically, it sets up the second phase of

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respond with its own validity and infringement contentions. *Id.* § 262(l)(3)(C). After the validity and infringement contentions have been exchanged, the parties have fifteen days to agree on which patents will be part of the first phase of litigation. *Id.* § 262(l)(4)(B). If the parties do not come to an agreement, they have five days to exchange patent lists. *Id.* § 262(l)(5)(B)(i). Finally, the RPS has thirty days to bring a patent infringement suit. *Id.* § 262(l)(6).

122. *Id.* § 262(l)(8)(B).

123. *Id.* § 262(l)(9).

124. *INS v. Nat'l Ctr. for Immigrants' Rights, Inc.*, 502 U.S. 183, 189–90 (1991) (citing *Mead Corp. v. Tilley*, 490 U.S. 714, 723 (1989); *FTC v. Mandel Bros., Inc.*, 359 U.S. 385, 388–89 (1959)).

125. *See Almendarez-Torres v. United States*, 523 U.S. 224, 234 (1998) (finding a section titled "Criminal penalties for reentry of certain deported aliens" indicates that the provisions of the section were intended to discuss penalties and not create a new substantive crime).

126. *See* 42 U.S.C. § 262(l)(9)(A) (2012).

litigation by explicitly prohibiting either party from bringing suit on any patent not included in the first phase of litigation before the biosimilar applicant gives notice of commercial marketing. Then, paragraph (l)(9)(B) lifts this limitation for the RPS should the biosimilar applicant fail to give notice of commercial marketing or participate in the narrowing of patents.<sup>127</sup> If the biosimilar applicant neglects to comply with any of the steps after the initial disclosure of information, the RPS may bring an infringement suit on any of the patents it has listed.

Similarly, paragraph (l)(9)(C) lifts the limitation on bringing declaratory judgment actions when the biosimilar applicant fails to comply with the initial disclosure.<sup>128</sup> If the biosimilar applicant fails to follow the information disclosure provision, then the RPS may bring a declaratory judgment action on any product or use claims that cover the biosimilar. In context of the rest of the subsection 9, 9(C) only contemplates noncompliance for the specific purpose of these limitations on declaratory judgment. The limitations in the declaratory judgment prohibition provision are required to effectuate the two-phase litigation structure, explicitly prohibiting either party from prematurely bringing suit on any phase two litigation patent.

However, if the biosimilar applicant fails to comply with any of the patent resolution process provisions, the BPCIA recognizes that it would be inequitable to continue to bar the RPS from bringing an infringement action. As such, 9(B) and 9(C) simply lift the declaratory judgment prohibition provision. The difference between 9(B) and 9(C) is in the patents that the RPS is allowed to bring an infringement action on. In 9(B), those patents are any of the patents the RPS has previously listed. In 9(C), because the RPS will not have given a list of potentially infringed patents to the biosimilar applicant yet, those patents are any patents covering the biological product or use. Thus, 9(C) is not a unique remedy for noncompliance with the information disclosure provision; instead, such noncompliance necessitates a separate paragraph only because no patent list will have been generated yet.

Thus, the court's reading of 9(C) as primarily laying out remedies to the RPS for the biosimilar applicant's noncompliance with the information disclosure provision is misguided. The *Amgen* court found that "[a]s a direct consequence of failing to comply with paragraph (l)(2)(A), paragraph (l)(9)(C) bars the subsection (k) applicant from bringing a declaratory judgment action on patents that claim the biological product or its use."<sup>129</sup>

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127. *See id.* § 262(l)(9)(B).

128. *See id.* § 262(l)(9)(C).

129. *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1356 (2015).

However, this ignores the fact that even if a biosimilar applicant does comply with the information disclosure provision, the declaratory judgment prohibition provision still bars it from bringing a declaratory judgment action. The only difference between the two, in terms of the biosimilar applicant, is that the declaratory judgment prohibition provision refers to the list of patents produced in the BPCIA's disclosure provisions, whereas 9(C) cannot refer to that list of patents because it will not have been produced. The bar on bringing declaratory judgment actions should be understood, then, not as a specific consequence of failing to comply with the information disclosure provision but as furthering the two-phase litigation structure. None of the language in subsection 9 indicates that it is intended to grant exclusive remedies for the biosimilar applicant's failure to comply with the BPCIA's provisions.

2. *Section 271(e) Does Not Define Exclusive Remedies*

Neither does 35 U.S.C. § 271(e), the other provision the court looked to, grant exclusive remedy for such failures of compliance. Specifically, § 271(e)(2)(C) creates artificial acts of infringement when the biosimilar applicant submits its application for approval of its product. Much like paragraphs (l)(9)(B) and (l)(9)(C), § 271(e)(2)(C) is split up into two parts, depending on which patents may be subjects of the infringement actions. Accordingly, § 271(e)(2)(C)(i) allows patents listed by the RPS during the BPCIA's patent resolution process to be the subject of an infringement action.<sup>130</sup> And § 271(e)(2)(C)(ii) allows patents that should have been listed in accordance with the BPCIA's patent resolution process to be the subject of an infringement action when the biosimilar applicant fails to follow the information disclosure provision.<sup>131</sup> Again, this separate provision contemplating noncompliance with the information disclosure provision is necessary because, with such an occurrence, the RPS would not have yet listed any patents. In context, this provision should not be read to uniquely provide a remedy in the case of noncompliance with information disclosure, but instead as filling the gap that such noncompliance would cause.

The court found that interpreting the information disclosure provision as mandatory would render both paragraph (l)(9)(C) and § 271(e)(2)(C)(ii) superfluous.<sup>132</sup> The court offered no reasoning for this conclusion, and it is unclear why the court believed so. Regardless of whether the information disclosure provision is mandatory, the statute must provide for an infringement action when such disclosures are not made. In fact, if such

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130. 35 U.S.C. § 271(e)(2)(C)(i) (2012).

131. *Id.* § 271(e)(2)(C)(ii).

132. *Amgen*, 794 F.3d at 1356.

disclosures were mandatory and neither paragraph (l)(9)(C) nor § 271(e)(2)(C)(ii) existed, then nondisclosure would lead to troubling results. The biosimilar applicant would have violated the BPCIA, but there may not be any actual patent-based remedy available to the RPS. With no identified patents, there would be no basis for the RPS to file an infringement action. Instead, these provisions clarify that when the patent lists have not yet been exchanged, failure to comply with the BPCIA's patent resolution provisions still supports the RPS bringing an infringement action.

Finally, the court's reliance on the "only remedies" language in § 271(e)(4) was misplaced. In whole, § 271(e)(4) provides injunctive and monetary relief for the artificial acts of infringement defined in § 271(e)(2), including the submission of a biosimilar application.<sup>133</sup> It describes these remedies as "the only remedies which may be granted by a court for an act of infringement."<sup>134</sup> The court interpreted this to mean that monetary and injunctive relief for patent infringement are the only remedies available for a failure to comply with information disclosure.<sup>135</sup> However, the language is open to an alternative reading. Instead, the provision may be interpreted to define the remedies available for a patent infringement action only. Such an interpretation would not preclude remedies based on other potential causes of action that the RPS may bring in response to the biosimilar applicant's failure to follow the information disclosure provision. Indeed, Amgen's unfair competition and conversion claims could be such examples of other causes of action for which § 271(e)(4) would not define the available remedies.

In conclusion, the structure of the BPCIA sets forth a two-phase litigation structure to resolve patent disputes. The provisions the court identified as providing exclusive remedies for noncompliance with the information disclosure provision can instead be read as support for the overall patent dispute resolution structure. Such an interpretation resolves the inconsistencies in the court's own reasoning that arose from its conclusions regarding textual and structural analyses.

### C. LEGISLATIVE PURPOSE AND LEGISLATIVE HISTORY

In construing a statute in accordance with Congress's intent, one must look at the purpose in addition to the structure and language of the

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133. *See* 35 U.S.C. § 271(e)(4).

134. *Id.*

135. *Amgen*, 794 F.3d at 1356.

statute.<sup>136</sup> Though the legislative history does not squarely address whether the patent dance should be mandatory, the BPCIA's purpose supports the mandatory nature of the biosimilar applicant's initial information disclosure. The legislative record here reveals that patent resolution provisions were important to the BPCIA's purpose: achieving a balance between the interests of innovators and the interests of consumers. Accordingly, interpreting the initial information disclosure as mandatory best reflects the balance Congress intended to strike in passing the BPCIA.

As Judge Newman noted in dissent, "[t]he BPCIA reflects an explicit balance of obligations and benefits."<sup>137</sup> This balance is a purpose expressed explicitly throughout the legislative record.<sup>138</sup> The proposed bills regulating biosimilars granted varying exclusivity terms to the RPS and allowed the biosimilar applicant to rely on the RPS's data to varying levels,<sup>139</sup> representing different attempts to strike this balance.

In addition to exclusivity and data reliance provisions, the patent dispute resolution provisions in the bills factored into the balancing act. The congressional hearings regarding biosimilars make clear that intellectual property insurance in the form of these patent dispute resolution provisions was an important consideration for the incentives to innovate.

In a 2007 House hearing before the Committee on Energy and Commerce, Dr. David Schenkein, Vice President of Clinical Hematology and Oncology of Genentech, argued on behalf of BIO.<sup>140</sup> He emphasized the importance that patent disputes be resolved "prior to marketing approval" and also noted that "any follow-on biologics regulatory pathway

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136. *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 138 (1990) ("To discern Congress' intent we examine the explicit statutory language and the structure and purpose of the statute.").

137. *Amgen*, 794 F.3d at 1366 (Newman, J., dissenting).

138. *See, e.g.*, Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 § 7001(b) ("balancing innovation and consumer interests"); *Biologics Hearings*, *supra* note 33, at 2 (statement of Representative Johnson) ("fram[ing] the intellectual property protections in a pathway for biosimilars that incentivizes the extraordinary investment required to develop new biologics but does not discourage biosimilar introduction"); Press Release, HELP Committee, Lawmakers Praise Committee Passage of Biologics Legislation (June 27, 2007), <http://www.help.senate.gov/ranking/newsroom/press/lawmakers-praise-committee-passage-of-biologics-legislation> [<http://perma.cc/CL6H-9MSA>] ("a balanced approach that enables patients to have safe, effective and affordable biological drugs, while preserving the incentives that have brought these life-saving advances to the American public").

139. Tresemer, *supra* note 24, at 17-40.

140. *Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 110th Cong. 77 (2007).

should not create special patent litigation rules that favor follow-on biologics manufacturers.”<sup>141</sup> Arguing on behalf of the Generic Pharmaceutical Association (GPhA), Bruce Downey, CEO of Barr Pharmaceuticals, a generic manufacturer, echoed the importance of early patent resolution.<sup>142</sup> In addition to agreeing that patent disputes should be resolved prior to marketing, he emphasized the importance of quick and efficient resolution, including not being “forced to litigate every patent relating to the brand product.”<sup>143</sup> He also highlighted the risks associated with the RPS refusing to participate in the patent dispute resolution process. He advocated for provisions that would ensure the biosimilar maker would not be on the hook for exorbitant postmarketing damages should the RPS refuse to participate in the patent dispute resolution process.<sup>144</sup>

A 2009 House hearing before the Committee on the Judiciary addressed the merits of specific patent provisions in greater specificity.<sup>145</sup> Once more, speakers expressed central concerns of efficiency and speed. Representative Eshoo, whose H.R. 1548 bill was a subject of discussion, emphasized both the time requirements the bill imposed on related patent litigation and the information exchange process.<sup>146</sup> Bruce Leicher, Senior Vice President of Momenta Pharmaceuticals, a company engaged in manufacturing generics and novel therapeutics, criticized the patent provisions of H.R. 1548 for three reasons: (1) the three years it allowed for patent litigation was not long enough for the complex litigation process it laid out, (2) the allowance of third parties unnecessarily complicated the procedure, and (3) it mandated disclosure of information that was unrelated to determining infringement.<sup>147</sup> On the other side, representatives from BIO and AIPLA praised H.R. 1548's provision requiring a biosimilar applicant to disclose information regarding its biosimilar product.<sup>148</sup> The speakers continued to stress the importance of resolving patent disputes prior to marketing.<sup>149</sup>

These hearings make clear that the specifics of the patent dispute resolution provisions were important to the generic industry, the innovator

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141. *Id.* at 85.

142. *Id.* at 119.

143. *Id.*

144. *Id.*

145. *Biologics Hearings, supra* note 33, at 2.

146. *See id.* at 11–12 (statement of Representative Eshoo).

147. *Id.* at 21–22 (statement of Leicher).

148. *See id.* at 66, 197 (praising the enablement of the RPS to identify relevant patents based on information provided by the biosimilar applicant as part of a “significant feature” of the bill's provisions).

149. *See id.* at 11, 200.

industry, and Congress in creating a balanced biosimilar regulatory scheme. The chief concern of all parties involved was the resolution of patent disputes before the marketing of the biosimilar product. This greater purpose of timely dispute resolution, as well as specific responses to other concerns, is reflected in the BPCIA's patent provisions.

Overall, the BPCIA provides concrete time restrictions leading up to the first phase of litigation. Within 230 days, or fewer than eight months, of submitting the biosimilar application, the parties have to agree on a narrow set of patents to litigate and share their infringement and invalidity contentions on a claim-by-claim basis.<sup>150</sup> This timeframe is similar to the six to eight month timeframe in H.R. 1548 that Representative Eshoo described as "a simple, streamlined" process.<sup>151</sup>

Moreover, the BPCIA's patent provisions eliminated two criticisms of H.R. 1548: the three-year limit on declaratory judgment actions and the intervention of third parties into the process. Unlike H.R. 1548, which did not allow biosimilar applicants to bring a declaratory judgment action until three years prior to the end of the reference product's exclusivity period,<sup>152</sup> a biosimilar applicant may bring suit on the first litigation phase patents as soon as those patents are determined under the BPCIA.<sup>153</sup> As previously discussed, this must happen within eight months of the application submission, and the application can be submitted as early as four years into the twelve-year exclusivity period.<sup>154</sup> Thus, the parties will have up to seven and a half years to resolve patent disputes before commercial marketing. Also unlike H.R. 1548, which explicitly provides for third parties to join the litigation,<sup>155</sup> the BPCIA restricts the patent dispute resolution process to the biosimilar applicant and the RPS.<sup>156</sup> Both these differences from H.R. 1548 serve the greater purpose of ensuring that patent disputes are resolved early.

The BPCIA also addressed the generic industry's concerns about (1) RPSs declining to participate in the patent resolution process and (2)

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150. See explanation of this process, *supra* note 121.

151. See *Biologics Hearings*, *supra* note 33, at 11.

152. H.R. 1548, 111th Cong. § 101(a)(2) (1st Sess. 2009) (proposed PHSA § (l)(6)(A)).

153. 42 U.S.C. § 262(l)(6) (2012).

154. *Id.* § 262(k)(7)(B).

155. H.R. 1548, 111th Cong. § 101(a)(2) (1st Sess. 2009) (proposed PHSA § 351(l)(4)(B)).

156. See 42 U.S.C. § 262(l) (referencing only "subsection (k) applicant" and "reference product sponsor"). The BPCIA makes one exception: "the owner of a patent exclusively licensed to the reference product sponsor" may be provided the applicant's information. *Id.* § 262(l)(1)(B)(3).



needing to litigate every patent relating to the reference product prior to marketing. First, the BPCIA requires the RPS to list all of its potentially infringed patents or else lose the ability to enforce them on the biosimilar applicant.<sup>157</sup> Thus, the RPS faces great consequences if it declines to participate in the patent resolution process. Second, the two-phase litigation structure restricts the patents which must be litigated before the biosimilar product gets marketed. The biosimilar applicant gets to decide which patents, or at least how many patents if the parties cannot agree, get litigated in the first phase.<sup>158</sup> Any other patent then is subject to the second phase of litigation, which does not prevent the biosimilar applicant from marketing its product unless the RPS obtains a preliminary injunction.<sup>159</sup>

The provisions of the patent dispute resolution process, thus, serve to create a process that is calibrated to balance the protection of intellectual property rights and the efficient premarketing resolution of disputes. Interpreting the disclosures required by paragraph (1)(2)(A) as nonmandatory would undermine this careful calibration, as without paragraph (1)(2)(A) disclosures, nothing triggers the subsequent provisions.

In this way, every purpose served by the subsequent provisions is undercut by reading paragraph (1)(2)(A) as nonmandatory. The strict timing requirements set forth in each step of the patent dance would not be triggered, allowing the RPS to delay bringing suit. That delay risks patent disputes going unsettled, running counter to the central concern expressed in the legislative history of premarketing resolution.

Certainly, Congress showed it was capable of drafting unambiguously nonmandatory patent dispute resolution provisions. Representative Waxman's H.R. 1427,<sup>160</sup> which was debated in Congress alongside Representative Eshoo's H.R. 1548, contained a patent resolution process that was clearly nonmandatory. Though H.R. 1427 did not include a provision regarding disclosure from the biosimilar applicant, it did set forth a process for resolving patent disputes that began with the biosimilar applicant requesting a list of patents from the RPS.<sup>161</sup> The bill made clear that participation in this process was up to the discretion of the applicant: an applicant "may not be compelled, by court order or otherwise" to participate in the process and "[n]othing in this paragraph requires an

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157. 35 U.S.C. § 271(e)(6)(C) (2012).

158. 42 U.S.C. § 262(l)(4).

159. *Id.* § 262(l)(8)(B)–(C).

160. *See* H.R. 1427, 111th Cong. (1st Sess. 2009).

161. *Id.* § 3(a)(2) (proposed PHSA § 351(k)(18)(A)(i)).

applicant or a prospective applicant to invoke the procedures set forth in this paragraph.”<sup>162</sup>

The inability of an RPS to obtain information from the biosimilar applicant, in part due to the nonmandatory patent provisions, was criticized before Congress. The AIPLA suggested that an appropriate statute would have “a timely and confidential information exchange” to determine whether an infringement claim should be brought<sup>163</sup> and criticized H.R. 1427 because it left the RPS with no ability to make such a determination.<sup>164</sup> In contrast to H.R. 1427, the BPCIA includes an information exchange provision that indicates that a biosimilar applicant “shall” provide an RPS with information. However, if the BPCIA’s information exchange provision is read to be nonmandatory, the RPS would similarly be left without any way to determine whether to bring an infringement action.

Consequently, interpreting the BPCIA’s patent dance as mandatory allows it to both better serve the general legislative purpose of resolving patent disputes prior to marketing and address criticisms of other bills in the legislative history. Combined with the statutory language and structure, this further reinforces that Congress intended the BPCIA’s information disclosure provision to be mandatory.

#### IV. THE SHORT- AND LONG-TERM IMPLICATIONS OF *AMGEN*

The full effects of the *Amgen* decision may not be immediately felt. For Sandoz, the immediate effect is that it can market Zarxio, which it is doing at a fifteen percent discount from Amgen’s Neupogen.<sup>165</sup> For other biosimilar makers and RPSs, the potential implications of *Amgen* will likely vary based on the reference product’s remaining patent protection.

In the short term, for the many biologics that are past the twenty-year patent protection, the decision may be beneficial. Biosimilars may get to market more quickly and with lower cost to the biosimilar maker. Unencumbered by the procedures of a mandatory patent dance, biosimilar

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162. *Id.* § 3(a)(2) (proposed PHSA §351(k)(18)(F)). Other bills included provisions that, while not unambiguously nonmandatory, were more equivocal than the BPCIA. *See* S. 1505, 110th Cong. § 2(a)(2) (1st Sess. 2007) (proposed PHSA § 351(k)(8)(B)) (providing that a RPS “may” request information from the biosimilar applicant, but providing no guidance as to whether or by what means the biosimilar applicant must comply).

163. *Biologics Hearings*, *supra* note 33, at 199–200.

164. *Id.* at 208.

165. Jeff Overley, *Sandoz Launches First Biosimilar at 15% Discount*, LAW360 (Sept. 3, 2015), <http://www.law360.com/articles/698926/print?section=ip> [<http://perma.cc/BK4G-TM5H>].

makers will not need to interact with RPSs at all until they give notice of commercial marketing. As these reference products are not protected by patents, perfunctorily going through the steps of the patent dance would not actually lead to more efficient litigation. Thus, the *Amgen* decision allows biosimilar makers to forgo needless costs when there is little threat of patent infringement.

By contrast, in the long run, for reference products that may be protected by many patents, the decision may defeat all the intended benefits of the BPCIA's patent dispute resolution provisions. It will increase the uncertainty of patent protection for biologics, and patent litigation will lose the efficiency, expedience, and accuracy the BPCIA was designed to ensure.

Due to the differences between biosimilars and their reference products, it is already unclear to what extent a follow-on product may be biosimilar without infringing.<sup>166</sup> And, as a biologic drug is highly dependent upon its manufacturing process,<sup>167</sup> manufacturing patents, specifically, may play an important role in biosimilars patent litigation. However, as Judge Newman noted, manufacturing patents are not included as part of the remedy in paragraph (1)(9)(C).<sup>168</sup> Thus, should a biosimilar applicant decline to participate in the patent dance, the BPCIA does not provide for declaratory judgment actions based on manufacturing patents. Without the manufacturing information from the biosimilar maker, the RPS may not be able to even meet pleading standards to survive a motion to dismiss on a patent infringement claim for a manufacturing patent.<sup>169</sup>

More generally, patent dispute resolution will lose the efficiency and timeliness afforded by the BPCIA's patent dance. When the biosimilar applicant declines to disclose its information, the RPS is less informed about which of its patents are likely to succeed in an infringement action. Additionally, the careful narrowing function of the BPCIA, in which the parties must agree on which patents to litigate, is no longer mandatory. As such, this gives the RPS the incentive to assert every potentially relevant patent at the start of litigation and use litigation to determine which claims are truly meritorious.

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166. Janet Freilich, *Patent Infringement in the Context of Follow-On Biologics*, 16 STAN. TECH. L. REV. 9, 11–12 (2012); see also Yaniv Heled, *Why Primary Patents Covering Biologics Should Be Unenforceable Against Generic Applicants Under the Biologics Price Competition and Innovation Act*, 21 ANNALS HEALTH L. 211, 212 (2012).

167. Tzeng, *supra* note 4, at 138.

168. *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1364 (2015) (Newman, J., dissenting).

169. See *id.* at 1364–65 (Newman, J., dissenting).

Thus, instead of using the BPCIA's statutorily determined timeframes and provisions, parties will instead have to use discovery to sort out which patents are relevant. Unlike under the BPCIA, in litigation there is no set amount of time within which information exchange and the narrowing of patents must occur. While district court judges may limit the number of claims asserted,<sup>170</sup> they are not required to do so, and there is no standardized time by which it must happen. Thus, it may take much longer for the patent list to be narrowed and for initial infringement and invalidity contentions to be exchanged than the 230-day maximum set forth by the BPCIA. As more patents will potentially stay in a case through more advanced stages of litigation, such as claim construction or expert discovery, litigation will cost the parties and the court more resources than addressing these issues through administrative procedures. Ultimately, the efficiencies built into the BPCIA would be lost without a mandatory patent dance.

## V. CONCLUSION

Patent litigation surrounding biosimilars is just beginning, and, accordingly, parties are just beginning to test the limits of what the BPCIA's patent dance requires. While some biosimilar applicants have opted to follow Sandoz's lead and skipped the initial information disclosure, at least one biosimilar applicant has proceeded through the early stages of the patent dance.<sup>171</sup> These decisions to opt in or out of BPCIA's patent process have yet to play out fully in the courts, and so their implications are currently unclear.

With many more biosimilars patent disputes in the future, it is critical that a clear, streamlined, and efficient patent dispute resolution scheme be applied by courts interpreting the BPCIA. Though the Federal Circuit may see the BPCIA as an "enigma," Congress had a clear aim in creating the two-phase litigation structure of the BPCIA. Such a structure and its benefits rely upon the mandatory nature of the information disclosure provision. Thus, to faithfully effectuate Congress's will, the *Amgen* decision should be reexamined, and the patent dance should be interpreted as mandatory.

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170. *In re Katz Interactive Call Processing Patent Litig.*, 639 F.3d 1303, 1311–13 (Fed. Cir. 2011).

171. Margaret E. Ives, *Apotex Sets Stage for Next Fed. Cir. BPCIA Dispute*, LAW360 (Oct. 21, 2015), <http://www.law360.com/articles/716478/apotex-sets-stage-for-next-fed-circ-bpcia-dispute> [<https://perma.cc/AB7Q-QW4P>].