

# BPCIA UPDATE: ENTROPY IS THE PRICE OF AN ORDERED FRAMEWORK

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## I. INTRODUCTION

The pharmaceutical industry has often relied on patent law to protect its investments, recoup costs associated with research and development (e.g., clinical trials), and encourage innovation.<sup>1</sup> Simultaneously, because of patent law's strong protections, a premium is added to drug prices—which limits accessibility and affordability to these life-saving therapies. In order to address this concern, Congress created the Hatch-Waxman Amendments in 1984 for small molecule drugs.<sup>2</sup> The Act sought to balance incentives for the pharmaceutical industry as well as increase accessibility and affordability of life-saving drugs for patients.<sup>3</sup> Since the Hatch-Waxman Amendments were limited to the small molecule drug class,<sup>4</sup> Congress enacted another regulatory

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1. See Matthew J. Higgins & Stuart J. H. Graham, *Balancing Innovation and Access: Patent Challenges Tip the Scales*, 326 SCIENCE, 370, 370 (2009); see also Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1580, 1676 (2003) (discussing the various policies in patent law as it applies to the pharmaceutical industry).

2. See 21 U.S.C. § 355(j) (2012); see also Margaret A. Hamburg, *Celebrating 30 years of Easier Access to Cost-Saving Generic Drugs*, FOOD & DRUG ADMIN.: FDA VOICE, (Sept. 24, 2014), <https://www.fda.gov/newsevents/newsroom/fdavoices/default.htm>

[<https://perma.cc/R99Z-YG93>] (“President Ronald Reagan signed into law the Drug Price Competition and Patent Term Restoration Act of 1984, better known today as the Hatch-Waxman Amendments.”).

3. Krista H. Carver, Jeffrey Elikan & Erika Lietzan, *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 FOOD & DRUG L.J. 671, 676–77 (2010) (“The Hatch-Waxman amendments were a compromise between innovator industry interests and generic industry interests. They represented the marriage of two strands of public policy thinking in the late 1970s and early 1980s indeed, the joining together of two bills, one restoring to innovators a portion of the patent life that lapsed during research, development, and FDA premarket review, and the other creating a generic drug approval pathway.”).

4. See *id.* at 699–704 (2010) (“[t]he question quickly arose whether the agency [FDA] already had sufficient statutory authority to approve biosimilars or at least abbreviated applications under the [Hatch-Waxman Act],” because the Hatch-Waxman Act was limited to approving generic versions of small molecule drugs and not generic versions of biologics); see also Donald E. Segal et al., *Regulatory Pathway for “Biosimilar” Products Debated* 22 WASH. LEGAL FOUND. 1, 2–3 (2007) (“[The] FDA explicitly stated that the 505(b)(2) approval pathway

scheme for biologics, the Biologics Price Competition and Innovation Act (BPCIA) in 2009.<sup>5</sup> The major distinction between the two classes of drugs is that small molecule drugs are chemically synthesized whereas biologics are synthesized in a living system.<sup>6</sup> As a result of the differences in manufacturing processes, biologics are often significantly larger, costlier, and harder to characterize than small molecule drugs.<sup>7</sup>

Because of the Hatch-Waxman Amendments' success in spurring the generic market, Congress wanted the BPCIA to embody similar principles. Thus, like the Hatch-Waxman Amendments, the BPCIA creates a pre-market patent dispute resolution process in order to settle patent-related disputes before the biosimilar, "generic version" of a biologic, is commercially manufactured or sold. Courts and the pharmaceutical industry have struggled to interpret the BPCIA. Nonetheless, biosimilar manufacturers and reference product sponsors are engaging in the process and are actively trying to understand how the statute works.

Part II of this Note provides background information about biosimilars, Congress's motivation for the BPCIA and a brief explanation of the statutory scheme of the BPCIA. Part III of this Note discusses the current cases in this area of the law and synthesizes the cases to provide guidance about the statutory scheme. Part IV of this Note argues that the Supreme Court's recent holding in *Sandoz, Inc. v. Amgen, Inc.* may have resulted in unintended consequences and seems to be inconsistent with the greater purpose and text of the BPCIA. Part V concludes this Note.

## II. BACKGROUND

Section II.A provides preliminary information about the composition of a biosimilar to highlight the differences between the commonly known small molecule generics and biosimilars. Section II.B discusses Congress' primary motivations for enacting the BPCIA. Section II.C explains the statutory scheme of the BPCIA.

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[statutory pathway created before the BPCIA that possibly allowed for very limited approval of biosimilars] cannot be utilized for products originally licensed under section 351 of the PHSA [section of the PHSA that concerned biologics] . . . Many in [generic] industry believe that FDA does not have the authority to approve a proposed product under the 505(b)(2) pathway . . .").

5. 42 U.S.C. § 262 (2012); 35 U.S.C. § 271 (2012). The BPCIA was enacted as part of the Affordable Care Act (ACA). Under the current administration, it is possible that the ACA may be repealed or modified, which may have an impact the BPCIA.

6. Thomas Morrow, *Defining the Difference: What Makes Biologics Unique*, 4 BIOTECHNOLOGY HEALTHCARE 24, 25–26 (2004).

7. *Id.*

## A. WHAT IS A BIOSIMILAR?

A biosimilar is the generic version of a biologic drug.<sup>8</sup> Biologics are drugs that are typically created in living cells using recombinant DNA.<sup>9</sup> Essentially, researchers synthesize DNA responsible for producing the biologic and then insert the DNA into a bacterial or mammalian cell.<sup>10</sup> The cell is then grown in a proprietary cell line, which will induce expression of the biologic as well as other proteins. In order to get the final product, the biologic has to be isolated through various purification techniques.<sup>11</sup> This manufacturing information: the vector the DNA is inserted into, the cell line, the properties of cell expression, and the purification techniques, are often protected by trade secret and not patent law.<sup>12</sup> The manufacturing process is key in characterizing the biologic because any modifications to the manufacturing process can result in a different product despite the biosimilar being structurally similar to the original biologic.<sup>13</sup> This is because any variation to the manufacturing process may impact the safety and efficacy of the follow-on.<sup>14</sup>

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8. See 42 U.S.C. § 262(i)(2) (2012) (“The term ‘biosimilar’ or ‘biosimilarity’, in reference to a biological product that is the subject of an application under subsection (k), means—(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components . . . .”); Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3139(a)(2), 124 Stat. 119 (2010) (“The term ‘biosimilar biological product’ means a biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 351 of the Public Health Service Act.”).

9. See Benjamin P. Falit et al., *Biosimilar Competition in the United States: Statutory Incentives, Payers, and Pharmacy Benefit Managers*, 34 HEALTH AFFAIRS 294, 294–95 (2015); see also *The Law of Biologic Medicine: Hearing Before the Comm. on the Judiciary*, 108th Cong. 1–3 (2004).

10. Morrow, *supra* note 6, at 26.

11. Matthew J. Seamon, *Antitrust and the Biopharmaceutical Industry: Lessons from Hatch-Waxman and an Early Evaluation of the Biologics Price Competition and Innovation Act of 2009*, 34 NOVA L. REV. 629, 650–52 (2010).

12. Bruce S. Manheim, Jr., Patricia Granahan & Kenneth J. Dow, *Follow-On Biologics: Ensuring Continued Innovation in The Biotechnology Industry*, 25 HEALTH AFFAIRS 394 n.13 at 394–97 (2006).

13. W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023, 1035 (2016) (“This Article emphasizes these manufacturing details because final therapeutic proteins are influenced by each step in the manufacturing process. To take one well-studied example, the choice of organism from which to generate a cell line, and the culture conditions, can alter the pattern of carbohydrates attached to the surface of the protein, also known as the ‘glycosylation pattern.’ Changes in glycosylation can significantly impact the biologic in several ways, including the stability of the protein (both outside and inside the body), the length of time the protein remains with the bloodstream, the binding of the protein to its therapeutic targets, and the reaction of the body’s immune system to the protein.”).

14. *Id.* at 1035–36.

Biologics are used to treat cancer and can be used to manage and treat cystic fibrosis, diabetes, hemophilia, hepatitis, cancers, and autoimmune diseases (such as rheumatoid arthritis).<sup>15</sup> Biologic drugs differ from well-known small molecule drugs, like Advil, in size, manufacturing process, cost, and composition.<sup>16</sup> As a result of the differences, the FDA insisted on creating a separate statute from the Hatch-Waxman Amendments to govern the approval process for biosimilars.<sup>17</sup>

Since biosimilars are created without manufacturing data from the original biologic, there are inherent differences between the biosimilar and its corresponding biologic.<sup>18</sup> As a result, the FDA approval process for highly similar biosimilar requires that the biosimilar is a “similar” to the biologic and

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15. Morrow, *supra* note 6, at 24; *see also* Niti Goel & Kamali Chance, *Biosimilars in Rheumatology*, 56 RHEUMATOLOGY 187, 187 (2016); *see also* Seamon, *supra* note 11, at 640 (“Biologics represent the evolving future of prescription drug therapy. They have already revolutionized the treatment of cancer, diabetes, hemophilia, and rheumatoid arthritis, among other diseases. . .”).

16. *See Amgen Biosimilars*, AMGEN BIOSIMILARS, <https://www.amgenbiosimilars.com/expertise/discovery/> [https://perma.cc/P46Z-UXHR]; *see also* *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts & Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 8 (2009) (statement of Rep. Anna Eshoo) (“Biologics are expensive, and they are risky to develop. A recently released study sponsored by the National Venture Capital Association analyzed the relative cost for investors in biotechnology and found that the cost of capital for startup biotech companies is more than double the costs that other companies must pay. These costs stem from long developmental timelines of typically 10 years or more and extraordinary levels of risk. Fewer than 1 percent of biologics make it to the market. Imagine that. Fewer than 1 percent. And the large amounts of capital required . . .”).

17. Carver et al., *supra* note 3, at 699–704 (2010).

18. Because of the likelihood of the biosimilar being different from the corresponding biologic, it represented a threat to RPS since the FDA may approve of biosimilars that are unlikely to infringe the patents on the biologic. Moreover, the biosimilar manufacturer could release the biosimilar before the RPS’s patents expired and offer a 10 and 30 discount. *See 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 & Commerce*, 110th Cong. 183 (2007); *see also* *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts & Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 221–22 (2009); FED. TRADE COMM’N, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION (2009) <https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologics-report.pdf> [https://perma.cc/DT84-BFJ3] [hereinafter EMERGING HEALTH CARE ISSUES] (“These FOB entrants are unlikely to introduce their FOB products at price discounts any larger than between 10 and 30 percent of the pioneer products’ price”); *see also* Seamon, *supra* note 11 at 640 (“Within two months of losing patent protection, Prozac lost 70% of its multibillion dollar market share.”). To lessen the threat, Congress provided brand manufacturers a 12-year exclusivity period.

not the “same” (as it requires for generic small molecules).<sup>19</sup> This is due to the complexity of creating biologics. Often, a biologic may appear in different isoforms, which impacts its stability, efficacy, and safety.<sup>20</sup> While biologics undergo extensive clinical trials, biosimilars are able to piggyback off of the clinical trial data so long as the follow-on manufacturer is able to demonstrate “similarity.”<sup>21</sup>

B. CONGRESS’S PRIMARY MOTIVATION FOR ENACTING THE BPCIA:  
COST

In 2004, Congress began to consider legislation that would provide an approval process for biosimilars.<sup>22</sup> Much of the congressional testimony alluded to the fact that many patents on biologics were about to expire, so Congress could act to create a pathway to approve biosimilars in a way that balanced incentives for both the RPS and the biosimilar manufacturer.<sup>23</sup> As

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19. Manheim et al., *supra* note 12 at 397–98; Price & Rai, *supra* note 14, at 1036. Price and Rai note:

As discussed, biologics are highly variable, and such variability can have major impacts on a drug’s safety and efficacy. . . . In other words, even if manufacturing methods were different, the difference in manufacturing methods would matter less if the final products could be demonstrated to be identical. This approach works for small-molecule drugs. Indeed, the ease of proving product identity, independent of its manufacturing process, is what makes generic drugs under Hatch-Waxman possible. However, although the issue is somewhat disputed, in many cases analytical methods available to biosimilar firms are insufficient to verify identity. Although the analytical methods available are substantial, they cannot ensure that two proteins are identical. Therefore, in order for a follow-on manufacturer to be confident that it has duplicated an originator firm’s biologic, it must have knowledge of the originator firm’s manufacturing process and cell lines.

Price & Rai, *supra* note 14, at 1036.

20. Seamon, *supra* note 11 at 650–51.

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

22. See *The Law of Biologic Medicine: Hearing Before the Comm. on the Judiciary*, 108th Cong. (2004).

23. See, e.g., *The Law of Biologic Medicine: Hearing Before the Comm. on the Judiciary*, 108th Cong. (2004). Chairman Hatch stated:

Our society can ill afford to avoid a debate over the proper regulation of follow-on biologics. We simply cannot sustain over time programs such as Medicare unless we seriously explore what steps might prudently be taken to end an FDA regulatory system that effectively acts as a secondary patent for off-patent biological products . . . . [Statement on behalf of Generic Pharmaceutical Association, Washington D.C.] In 1984, we were at a crossroads. The brand industry was flourishing, and yet FDA had no regulatory pathway and no system which provided for generic versions of most of these brand products. So even after their patents expired, brand

was discussed during the 2007 Congressional hearings, biologics represented a \$18 billion industry in the US and \$56 billion industry globally in 2006.<sup>24</sup> By 2014, sales of biologics globally totaled \$200 billion.<sup>25</sup> Therefore, an approval process for biosimilars would prevent the pharmaceutical industry from continuing to reap outsized profits because a lack of competition from a generic market.<sup>26</sup>

The high cost of biologics not only impacted patients, but also impacted Medicare and other retirement-related insurance providers.<sup>27</sup> Chairman Orrin Hatch stated that without a regulatory pathway for low-cost biosimilars, government programs such as Medicare and Medicaid could not continue to provide coverage for biologics.<sup>28</sup> In a 2007 House hearing, Priya Mathur, on behalf of a public employees retirement agency CALPers, spoke in favor of creating a regulatory pathway because the current system presented an “unsustainable challenge to CALPers” in providing drug coverage.<sup>29</sup>

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companies continued to sell their products at monopoly prices because they had monopolies. Congress responded and enacted the very successful Hatch-Waxman Act. Today, we are at a similar crossroads, Mr. Chairman, only this time it is for what we call biopharmaceuticals, as opposed to the traditional pharmaceuticals. As you said in your opening statement, biotechnology products account for something like \$33 billion in pharmaceutical sales, and the sales are growing. Many of the large-selling biotech drugs have come off patent already or they will soon. More important, in contrast to the traditional drugs, these have exceedingly high costs, in the thousands of dollars per patient per year. So the potential savings and the stakes for the health care system are enormous.

*Id.* at 2, 19.

24. Donald E. Segal et al., *Regulatory Pathway for “Biosimilar” Products Debated*, 22 WASH. LEGAL FOUND. 1, 1–4 (2007).

25. Lindsay Kelly, *Biologics in the Practice of Law*, 39 HARV. J. L. & PUB. POL’Y 21, 21 (2016).

26. See *The Law of Biologic Medicine: Hearing Before the Comm. on the Judiciary*, 108th Cong. 19 (2004).

27. *Id.*; see also *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 & Commerce*, 110th Cong. 140–41 (2007).

28. *The Law of Biologic Medicine: Hearing Before the Comm. on the Judiciary*, 108th Cong. 2 (2004) (“Our society can ill afford to avoid a debate over the proper regulation of follow-on biologics. We simply cannot sustain over time programs such as Medicare unless we seriously explore what steps might prudently be taken to end an FDA regulatory system that effectively acts as a secondary patent for off-patent biological products.”).

29. *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 & Commerce*, 110th Cong. 140–41 (2007).

C. STATUTORY SCHEME OF THE BPCIA

BPCIA has two aspects it, the BPCIA enables three major events and it enumerates remedies for violations to its various statutory provisions<sup>30</sup>. First, the statute creates an artificial act of infringement when the biosimilar manufacturer submits its application to the FDA for initial approval.<sup>31</sup> Second, the statute encourages the RPS and the biosimilar manufacturer to engage in a “patent dance” to determine which patents will be licensed, litigated, and/or expired before the biosimilar is commercially manufactured.<sup>32</sup> Third, the statute forces the biosimilar manufacturer to provide the RPS with 180-day notice of when the biosimilar manufacturer intends to commercially market its product.<sup>33</sup> Each of these events are described in more detail below.

1. *Artificial Infringement*

The statute dictates that when the biosimilar manufacturer submits its application to the FDA for initial approval, the submission creates an artificial act of infringement.<sup>34</sup> That is, filing an application creates an act of infringement under the patent infringement statute.<sup>35</sup> As a result, the RPS has a right to sue for patent infringement.

2. *Patent Dance*

Once the biosimilar manufacturer receives notice from the Secretary of Health and Human Services that its application has been approved, the biosimilar manufacturer has 20 days to provide the RPS with its application and manufacturing information.<sup>36</sup> The RPS then provides the biosimilar manufacturer with a “patent list,” which lists the RPS’s patents that may be infringed and patents the RPS is prepared to license.<sup>37</sup> In response, the biosimilar manufacturer must provide a statement declaring whether it intends

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30. 35 U.S.C § 271(e)(6) (2012); 42 U.S.C § 262(l)(9)(B) (2012).

31. 35 U.S.C. §§ 271(e)(2)(C)(i), (ii) (2012) (“It shall be an act of infringement to submit . . . an application seeking approval of a biological product for a patent.”); 42 U.S.C § 262(k) (2012) (“Any person may submit an application for licensure of a biological product under this subsection.”); *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1674 (2017) (“Submitting an application constitutes an act of artificial infringement . . . .”) (citing §§ 271(e)(2)(C)(i), (ii)).

32. 42 U.S.C § 262 (l)(2)–(5) (2012).

33. § 262 (l)(8)(A).

34. 35 U.S.C. §§ 271(e)(2)(C)(i), (ii) (2012) (“It shall be an act of infringement to submit . . . an application seeking approval of a biological product for a patent.”); 42 U.S.C § 262(k) (2012) (“Any person may submit an application for licensure of a biological product under this subsection.”); *Sandoz*, 137 S. Ct. at 1674 (“Submitting an application constitutes an act of artificial infringement . . . .”) (citing §§ 271(e)(2)(C)(i), (ii)).

35. 35 U.S.C. § 271(e)(2)(c) (2012).

36. 42 U.S.C § 262(l)(2) (2012).

37. *Id.* at § 262(l)(3)(A) (2012).

to assert a defense against the listed patent (e.g., invalidity, unenforceable, or non-infringement),<sup>38</sup> agree to commercially market the biosimilar only after the patent expires, or license the listed patent.<sup>39</sup> The biosimilar manufacturer may also provide a list of patents that the RPS could also assert against it, but the biosimilar manufacturer is under no obligation to do so.<sup>40</sup>

After the RPS receives the detailed statement about the biosimilar manufacturer's defenses,<sup>41</sup> both parties must engage in good-faith negotiations to discuss which patents to litigate.<sup>42</sup> If the parties come to an agreement, the RPS "shall" bring an infringement suit on the agreed upon patents.<sup>43</sup> However, if, after 15 days of negotiations, both parties fail to agree on a final list, then the biosimilar manufacturer will decide the maximum number of patents the RPS can assert during litigation and both parties have to provide a list of patents, within that number, to litigate.<sup>44</sup> Once the parties compile the lists, the RPS "shall" bring an action for patent infringement on those patents.<sup>45</sup>

### 3. 180-Day Notice

The statute dictates that the biosimilar manufacturer must provide the RPS with notice 180 days before the biosimilar manufacturer begins to commercially market its product.<sup>46</sup> 180-day notice can be provided at any time, even before the FDA officially approves the biosimilar for commercial use.<sup>47</sup> Once 180-day notice has been given, the RPS gains two substantive rights. First, the RPS may seek a preliminary injunction enjoining the biosimilar manufacturer from commercially marketing its biosimilar until the court settles patent disputes stemming from the patent list, as amended,<sup>48</sup> that were not litigated.<sup>49</sup> Second, the RPS may enter into a second phase of litigation where

38. The patents in which the biosimilar manufacturer intends to assert a defense against, the biosimilar manufacturer must provide a statement with respect to each patent on a claim by claim basis "the factual and legal basis" for the biosimilar manufacturer's defenses. *Id.* at § 262(l)(3)(B) (2012).

39. § 262(l)(3)(B)(ii)–(iii).

40. § 262(l)(3)(B)(i).

41. *See* § 262(l)(3)(B)(ii).

42. § 262(l)(4).

43. § 262(l)(6)(A).

44. § 262(l)(4)(B); § 262(l)(5)(A).

45. § 262(l)(6)(B).

46. § 262(l)(8)(A).

47. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1677 (2017) ("Accordingly, the applicant may provide notice either before or after receiving FDA approval . . .").

48. The RPS may amend the original patent list to add newly issued or licensed patents that were issued or licensed after the patent list was created and the RPS "reasonably believes" that a claim for patent infringement can be asserted. 42 U.S.C. § 262(l)(7) (2012).

49. *Sandoz*, 137 S. Ct. at 1672 ("In addition, prior to the date of first commercial marketing, the sponsor may 'seek a preliminary injunction prohibiting the [biosimilar]

it can assert its patents that were listed on the amended list but had not yet been asserted.<sup>50</sup> If, however, the biosimilar manufacturer fails to provide 180-day notice, then the RPS is entitled to seek declaratory relief on the patents originating from the patent list.<sup>51</sup>

#### 4. Remedies

For statutory violations of the BPCIA, 42 U.S.C. § 262(l)(9) enumerates the remedies.<sup>52</sup> RPS manufacturers may also seek the traditional remedies for patent infringement under 35 U.S.C. § 271 and § 283.<sup>53</sup> Under the remedy provision of the BPCIA, if the biosimilar manufacturer provides its application to the RPS, then neither party can seek declaratory relief until 180-day notice has been given.<sup>54</sup> However, if the biosimilar manufacturer fails to provide its application, then the exclusive remedy<sup>55</sup> is that the RPS may immediately bring an action for declaratory judgment on “any patent that claims the biological product or a use of the biological product.”<sup>56</sup> The RPS may also seek relief

applicant from engaging in the commercial manufacture or sale of [the biosimilar] until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that was included on the § 262(l)(3) lists but not litigated in the first phase.” (citing § 262(l)(8)(B); *see also* § 262(l)(8)(B)).

50. § 262(l)(8)(A).

51. § 262(l)(9)(B).

52. *Sandoz*, 137 S. Ct. at 1675. The court stated:

The remedy provided by § 262(l)(9)(C) excludes all other federal remedies, including injunctive relief. Where, as here, “a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies.” The BPCIA’s “carefully crafted and detailed enforcement scheme provides strong evidence that Congress did *not* intend to authorize other remedies that it simply forgot to incorporate expressly.” The presence of § 262(l)(9)(C), coupled with the absence of any other textually specified remedies, indicates that Congress did not intend sponsors to have access to injunctive relief, at least as a matter of federal law, to enforce the disclosure requirement.

(citations omitted). *Id.*

53. The remedies under 35 U.S.C. § 271(e)(4) dictates remedies for infringement but it does not dictate remedies for when either party violates provisions of the BPCIA. *See Sandoz Inc.*, 137 S. Ct. at 1674.

54. *Sandoz*, 137 S. Ct. at 1672 (“In this second phase of litigation [once 180-day notice has been given], *either* party may sue for declaratory relief . . . .”) (citing 42 U.S.C. § 262(l)(9)(A)).

55. *Id.* at 1675 (“The remedy provided by § 262(l)(9)(C) excludes all other federal remedies, including injunctive relief.”).

56. *Id.* at 1672, which states:

Under § 262(l)(9)(C), if an applicant fails to provide its application and manufacturing information to the sponsor—thus effectively pretermittting the entire two-phase litigation process—then the sponsor, but not the applicant, may immediately bring an action “for a declaration of

when the biosimilar manufacturer fails to take others action required by the statute.<sup>57</sup> For instance, the RPS may seek immediate declaratory relief on any patents on the amended patent list when the biosimilar manufacturer fails to (1) provide the RPS with a detailed statement of the legal and factual basis, claim-by-claim, of the biosimilar manufacturer's defenses against the patents on the patent list or amended version, or (2) provide 180-day notice.<sup>58</sup>

Under the remedy provision of the Patent Act, § 271(e)(4), the RPS has a few additional options. The RPS may seek injunctive relief against the biosimilar manufacturer to prevent the biosimilar manufacturer from commercially marketing its biosimilar within the United States.<sup>59</sup> The RPS may also seek monetary relief if the biosimilar has been "commercial[ly] manufacture[d], use[d], offer[ed] to sell, or [sold] within the United States or import[ed] into the United States."<sup>60</sup> Under the BPCIA, if a patent on the patent list is found to be infringed, "the sole and exclusive remedy" is for the RPS to recoup is a reasonable royalty.<sup>61</sup>

### III. HOW HAVE THE SUPREME COURT AND FEDERAL CIRCUIT INTERPRETED THE BPCIA?

This Part provides recent case law to help piece together an understanding of how the BPCIA operates.

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infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product."

57. 42 U.S.C. § 262(l)(9)(B) (2012); *Sandoz*, 137 S. Ct. at 1672, where the Court noted: Similarly, when an applicant provides the application and manufacturing information but fails to complete a subsequent step, § 262(l)(9)(B) provides that the sponsor, but not the applicant, may bring a declaratory-judgment action with respect to any patent included on the sponsor's § 262(l)(3)(A) list of patents (as well as those it acquired later and added to the list).

58. § 262(l)(9)(B) (2016).

59. 35 U.S.C. § 271(e)(4)(B) (2012); *id.* § 283; *see also Sandoz*, 137 S. Ct. at 1675 n.2 ("[W]e express no view on whether a district court could take into account an applicant's violation of § 262(l)(2)(A) (or any other BPCIA procedural requirement) in deciding whether to grant a preliminary injunction under 35 U.S.C. § 271(e)(4)(B) or § 283 against marketing the biosimilar . . .").

60. 35 U.S.C. § 271(e)(4)(C) (2012).

61. § 271(e)(6)(B), which states:

In an action for infringement of a patent described in subparagraph (A) [BPCIA], the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

A. FEDERAL CIRCUIT IN *AMGEN V. APOTEX*

After the Federal Circuit decided *Amgen, Inc. v. Sandoz, Inc.*<sup>62</sup> (one of the first BPCIA cases), the Federal Circuit took up *Amgen v. Apotex* to determine whether 180-day notice was mandatory if both parties participated in the patent dance and if 180-day notice can be enforced by an injunction. Amgen (the RPS) and Apotex (the biosimilar manufacturer) engaged in the patent dance after Apotex's biosimilar application was approved.<sup>63</sup> After creating a patent list and negotiating which patents Amgen would assert against Apotex (but before receiving a license from the FDA), Apotex provided 180-day notice that it would begin commercially marketing its product.<sup>64</sup> Amgen then filed an infringement suit based on the agreed upon patent claims.<sup>65</sup> During the litigation, the Federal Circuit decided another BCPIA case, *Amgen v. Sandoz*, in which it held that 180-day notice could only be given after the biosimilar receives FDA approval (thus invalidating Apotex's pre-licensure notice).<sup>66</sup>

After the Federal Circuit's decision in *Amgen v. Sandoz* issued, Amgen filed a motion for a preliminary injunction against Apotex to delay any commercial marketing until Apotex provided proper 180-day notice post-FDA licensure.<sup>67</sup> The district court granted Amgen the preliminary injunction because notice provides a "window" for the RPS to assess all of its patents prior to the biosimilar being commercially marketed.<sup>68</sup> Apotex disagreed and argued that granting the injunction would extend the market exclusivity period from 12 years to 12.5 years, and the BPCIA states that notice violations are remedied by declaratory judgement.<sup>69</sup> The district court rejected Apotex's arguments and instead held that the BPCIA does not establish that the remedy provision within the statute is the exclusive remedy, and declaratory judgement would only rush the courts.<sup>70</sup> Apotex appealed the district court's grant of a preliminary injunction.<sup>71</sup>

The Federal Circuit affirmed and held that injunctive relief is proper to enjoin the biosimilar manufacturer from commercially marketing its product until after it provides post-licensure 180-day notice, and declaratory relief was not the exclusive remedy when the biosimilar manufacturer fails to provide

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62. 794 F.3d 1347 (Fed. Cir. 2015).

63. *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1059 (Fed. Cir. 2016).

64. *Id.*

65. *Id.*

66. *Id.* at 1059–60, 1066.

67. *Id.* at 1060.

68. *Id.*; see also *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1360 (Fed. Cir. 2015).

69. *Apotex Inc.*, 827 F.3d at 1060; see also 42 U.S.C. § 262(l)(9)(B) (2012).

70. *Apotex Inc.*, 827 F.3d 1060.

71. *Id.*

180-day notice.<sup>72</sup> This is because nothing in the statute makes declaratory relief an exclusive remedy for failure to comply with the patent dance and in “absence of a clear and valid legislative command” federal courts have equitable jurisdiction to provide relief.<sup>73</sup> Further, 180-day notice is mandatory, regardless of participation in the patent dance.<sup>74</sup> Therefore, 180-day notice is mandatory and can be enforceable via preliminary injunction.<sup>75</sup>

The Federal Circuit envisioned the BPCIA having two rounds of potential litigation, litigation that occurs after the patent list is created (§ 1)(6)) and litigation that occurs after the biosimilar manufacturer provides 180-day notice (§ 1)(8)).<sup>76</sup> In support of this interpretation, the Federal Circuit explained that § 1)(9)(A) reinforced the two-stage litigation scheme because it prevented both the RPS and the biosimilar manufacturer from seeking declaratory relief on any patent on the patent list and patents that were asserted in a § 1)(6) action until 180-day notice was provided.<sup>77</sup> Because the Federal Circuit envisioned that the second-phase of litigation occurred after the FDA approved the biosimilar for commercial use, the RPS has a chance to bring claims that may have been weak, but are now strong.<sup>78</sup> This is because until the biosimilar is licensed, much of its “[therapeutic] uses, and [manufacturing] processes” have not yet been fixed, resulting in uncertainty about many of the RPS’s patent claims.<sup>79</sup> In the end the Supreme Court denied certiorari,<sup>80</sup> which made the Federal Circuit’s opinion final.

#### B. SUPREME COURT IN *SANDOZ INC. V. AMGEN INC.*

After the Federal Circuit decided *Apotex*, the Supreme Court granted certiorari on the case that laid the groundwork for the Federal Circuit’s reasoning: *Sandoz v. Amgen*.<sup>81</sup> There, the Federal Circuit had decided that the 180-day notice is mandatory and must be provided after the FDA issues a license.<sup>82</sup> The Federal Circuit also held in *Sandoz* that the failure to turn over

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72. *Id.* at 1054–55.

73. *Id.* at 1063–64.

74. *Id.* at 1061 (“We ruled in *Amgen v. Sandoz* that this language is, indeed, ‘mandatory,’ and we did not say that it was mandatory only in no-(2)(A)-notice circumstances.”).

75. *Id.* at 1055.

76. *Id.* at 1056 (“Given the deadlines set in § 262(l), and the time commonly taken for FDA review, we may assume that the early litigation under paragraph (6) will be initiated before the FDA licenses the applicant’s biosimilar product.”).

77. *Id.* at 1057.

78. *See id.* at 1062.

79. *See id.*; *see also* *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1358 (Fed. Cir. 2015).

80. *Apotex Inc. v. Amgen Inc.*, 137 S. Ct. 591 (2016).

81. *Amgen Inc.*, 794 F.3d at 1347.

82. *Id.* at 1359 (“A question exists, however, concerning whether the ‘shall’ provision in paragraph (l)(8)(A) is mandatory. We conclude that it is.”).

its application and manufacturing information as required by the patent dance (§ 1(2)) cannot be enforced by an injunction.<sup>83</sup> The Supreme Court granted certiorari to reconsider both of these issues.

On June 12, 2017, the Supreme Court issued its first decision regarding the BPCIA. The Court settled two questions of interpretation, (1) whether the statutory requirement that the biosimilar manufacturer turn over its manufacturing information can be enforced by an injunction and (2) whether the biosimilar manufacturer must give 180-day notice after the FDA issues a license for the biosimilar.<sup>84</sup>

First, the Supreme Court ultimately agreed with the Federal Circuit and held that under federal law, the biologic manufacturer cannot seek an injunction when the biosimilar manufacturer fails to provide its application and manufacturing information.<sup>85</sup> However, the Supreme Court's reasoning greatly differed from that of the Federal Circuit. Under the BPCIA, the Court found that submitting an application to the FDA creates an act of artificial infringement under §§ 271(e)(2)(C)(i), (ii).<sup>86</sup> However, unlike the Federal Circuit's reasoning, failing to disclose the application and manufacturing information to the biologic manufacturer under § 262(l)(2)(A) does not create an act of artificial infringement. The Court explained that §§ 271(e)(2)(C)(i), (ii) merely "assists in identifying which patents" may be asserted during future litigation.<sup>87</sup> This is because § 271(e)(2) defines the scope of what "shall be an

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83. *Id.* at 1358. The court noted:

Requiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief. It provides a defined statutory window during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product. If a notice of commercial marketing could be given at any time before FDA licensure, the RPS would be left to guess the scope of the approved license and when commercial marketing would actually begin. Indeed, filing an aBLA only suggests that a subsection (k) applicant intends to commercially market its product someday in the future.

*Id.*

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

85. *Id.* at 1674. But, the question of whether Amgen can get injunctive relief under California law was remanded to the Federal Circuit. *Id.* at 1676–77.

86. *Id.* at 1674 ("Submitting an application constitutes an act of artificial infringement. *See* §§ 271(e)(2)(C)(i), (ii) ("It shall be an act of infringement to submit . . . an application seeking approval of a biological product . . .").

87. *Id.* at 1674–75. The court noted:

In this way, the two clauses of § 271(e)(2)(C) work in tandem. They both treat submission of the application as the act of artificial infringement for which § 271(e)(4) provides the remedies. And they both identify the patents subject to suit, although by different means depending on whether the biosimilar manufacturer disclosed its application and manufacturing

act of infringement” and § 271(e)(2)(C)(i) identifies the patents that can be asserted in future litigation.<sup>88</sup> Then, § 271(e)(2)(C)(ii) must also identify patents that can be asserted in future litigation in cases in which the biosimilar manufacturer fails to provide its application.<sup>89</sup> Therefore, § 271(e)(2)(C)(i) does not, by itself, create an “act of infringement” whose exclusive remedies are enumerated under § 271(e)(4).

The Federal Circuit reasoned that when a biosimilar manufacturer fails to provide its applications and manufacturing information under § 262(l)(2)(A), the act itself gave rise to a claim infringement.<sup>90</sup> The RPS would be thereby able to seek remedies under both § 271(e)(4) and § 262(l)(9), neither of which provide injunctive relief.<sup>91</sup> The problem is, as the Supreme Court noted, this interpretation created confusion and uncertainty over the appropriate

information under § 262(j)(2)(A). If the applicant made the disclosures, clause (i) applies; if it did not, clause (ii) applies. In neither instance is the applicant’s failure to provide its application and manufacturing information an element of the act of artificial infringement, and in neither instance does § 271(e)(4) provide a remedy for that failure.

*Id.*

88. *Id.* at 1674, states:

[H]is conclusion follows from the structure of § 271(e)(2)(C). Clause (i) of § 271(e)(2)(C) defines artificial infringement in the situation where the parties proceed through the list exchange process and the patents subject to suit are those contained in the § 262(j)(3) lists, as supplemented under § 262(j)(7). That clause provides that it is an act of artificial infringement to submit, “with respect to a patent that is identified in the list of patents described in [§ 262(l)(3)] (including as provided under [§ 262(l)(7)]), an application seeking approval of a biological product.”

(citations omitted).

89. *Id.* at 1674, states:

Clause (ii) of § 271(e)(2)(C), in contrast, defines artificial infringement in the situation where an applicant fails to disclose its application and manufacturing information altogether and the parties never prepare the § 262(j)(3) lists. That clause provides that the submission of the application represents an act of artificial infringement with respect to any patent that *could* have been included on the list.

(citations omitted).

90. *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1356 (Fed. Cir. 2015) (“Under 35 U.S.C. § 271(e)(2)(C)(ii), filing a subsection (k) application and failing to disclose the required information under paragraph (j)(2)(A) is an artificial ‘act of infringement’ of ‘a patent that could be identified’ pursuant to paragraph (j)(3)(A)(i) . . .”).

91. *Id.* at 1357 (“[W]e ultimately conclude that when a subsection (k) applicant fails the disclosure requirement, 42 U.S.C. § 262(j)(9)(C) and 35 U.S.C. § 271(e) expressly provide the only remedies as those being based on a claim of patent infringement.”); *cf.* *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1674 (2017) (“The flaw in the Federal Circuit’s reasoning is that Sandoz’s failure to disclose its application and manufacturing information was not an act of artificial infringement, and thus was not remediable under § 271(e)(4).”).

remedy.<sup>92</sup> Instead, the Supreme Court’s interpretation makes § 262(l)(9)(C), declaratory relief, the exclusive remedy when the biosimilar manufacturer fails to provide its application because “[t]he remedy provided by § 262(l)(9)(C) excludes all other federal remedies.”<sup>93</sup> Further, the Court recognized that this “punishment” for failure to provide manufacturing information is proper because it shifts control from the biosimilar manufacturer, who declined to follow the rules, to the RPS because “[i]t also deprives the applicant of the certainty it could have obtained by bringing a declaratory-judgment action prior to marketing its product.”<sup>94</sup>

Second, the Court reversed the Federal Circuit and held that 180-day notice may be given “either before or after receiving FDA approval.”<sup>95</sup> The Federal Circuit had held that 180-day notice must be given after the biosimilar manufacturer receives licensure from the FDA, because “the statutory

92. *See Sandoz*, 137 S. Ct. at 1675, which states:

Stating that “[t]he remedy provided by § 262(j)(9)(C) excludes all other federal remedies, including injunctive relief. Where, as here, ‘a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies.’ The BPCIA’s ‘carefully crafted and detailed enforcement scheme provides strong evidence that Congress did *not* intend to authorize other remedies that it simply forgot to incorporate expressly.’”

(citations omitted). Therefore, the courts would struggle whether to provide relief under § 271(e)(4) or the enumerated remedy, declaratory relief under § 262(l)(9)(C).

93. *Id.* at 1675, states:

The remedy provided by § 262(j)(9)(C) excludes all other federal remedies, including injunctive relief. Where, as here, ‘a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies.’ The BPCIA’s ‘carefully crafted and detailed enforcement scheme provides strong evidence that Congress did *not* intend to authorize other remedies that it simply forgot to incorporate expressly.’ The presence of § 262(j)(9)(C), coupled with the absence of any other textually specified remedies, indicates that Congress did not intend sponsors to have access to injunctive relief, at least as a matter of federal law, to enforce the disclosure requirement.

(citations omitted).

94. *Id.*, which states:

When an applicant [biosimilar manufacturer] fails to comply with § 262(j)(2)(A), § 262(j)(9)(C) authorizes the sponsor, but not the applicant, to bring an immediate declaratory-judgment action for artificial infringement as defined in § 271(e)(2)(C)(ii). Section 262(j)(9)(C) thus vests in the sponsor the control that the applicant would otherwise have exercised over the scope and timing of the patent litigation. It also deprives the applicant of the certainty that it could have obtained by bringing a declaratory-judgment action prior to marketing its product.

95. *Id.* at 1677 (“Accordingly, the applicant [biosimilar manufacturer] may provide notice either before or after receiving FDA approval.”).

language compels such an interpretation.”<sup>96</sup> The Supreme Court disagreed.<sup>97</sup> The Court stated that by providing 180-day notice after licensure, the Federal Circuit created two “timing requirements” that most likely was not what Congress intended.<sup>98</sup> While the Court seemed to acknowledge Amgen’s policy arguments in favor of making 180-day notice come after the FDA issues final approval, Justice Thomas stated, “those arguments could not overcome the statute’s plain language, which is our ‘primary guide’ to Congress’ preferred

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96. *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1357–58 (Fed. Cir. 2015), states: In subsection (j), only paragraph (j)(8)(A) refers to the product as “the biological product licensed under subsection (k).” In other provisions of subsection (j), the statute refers to the product as ‘the biological product that is the subject of’ the application, even when discussing its commercial marketing. If Congress intended paragraph (j)(8)(A) to permit effective notice before the product is licensed, it would have used the “subject of” language.

*Id.* (citations omitted).

97. Instead, the Supreme Court held that the meaning of a “licensed” biologic product in (l)(8)(A) is defined as the “date of the first commercial marketing” as opposed to the date the FDA issues a license for the biosimilar product. *See Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1677 (2017), which states:

The applicant [biosimilar manufacturer] must give “notice” at least 180 days “before the date of the first commercial marketing.” “[C]ommercial marketing,” in turn, must be “of the biological product licensed under subsection (k).” § 262(j)(8)(A). Because this latter phrase modifies “commercial marketing” rather than “notice,” “commercial marketing” is the point in time by which the biosimilar must be ‘licensed.’ The statute’s use of the word “licensed” merely reflects the fact that, on the ‘date of the first commercial marketing,’ the product must be “licensed.” Accordingly, the applicant may provide notice either before or after receiving FDA approval.

(citations omitted).

98. *Sandoz*, 137 S. Ct. at 1677, states:

Statutory context confirms this interpretation. Section 262(j)(8)(A) contains a single timing requirement: The applicant [biosimilar manufacturer] must provide notice at least 180 days prior to marketing its biosimilar. The Federal Circuit, however, interpreted the provision to impose two timing requirements: The applicant must provide notice after the FDA licenses the biosimilar *and* at least 180 days before the applicant markets the biosimilar. An adjacent provision expressly sets forth just that type of dual timing requirement. But Congress did not use that structure in § 262(j)(8)(A). “Had Congress intended to” impose two timing requirements in § 262(j)(8)(A), “it presumably would have done so expressly as it did in the immediately following” subparagraph . . . .

(citations omitted).

policy.”<sup>99</sup> Interestingly, Justice Breyer’s concurrence opines that Congress “implicitly delegated” power to the FDA to interpret.<sup>100</sup> Therefore, if the FDA “determines that a different interpretation would better serve the statute’s objectives, it may well have authority to depart from, or to modify, today’s interpretation . . . .”<sup>101</sup>

C. FEDERAL CIRCUIT IN *AMGEN V. HOSPIRA*

Subsequent to the Supreme Court’s decision in *Sandoz*, the Federal Circuit returned to questions about how to obtain manufacturing information from the biosimilar pursuant to § (l)(2) and which remedies may the RPS seek under the BPCIA in *Amgen v. Hospira*.<sup>102</sup>

In this case, Hospira (a biosimilar manufacturer) filed an application with the FDA seeking approval of its biosimilar in December 2014.<sup>103</sup> Hospira provided Amgen (the RPS) with its FDA application but it did not separately provide “information that describes the process or processes used to manufacture the biological product that is the subject of such application.”<sup>104</sup> Despite this, Amgen created a patent list of its patents that are allegedly infringed by Hospira’s biosimilar and exchanged it with Hospira.<sup>105</sup> Amgen

99. *Id.* at 1678 (“Even if we were persuaded that Amgen had the better of the policy arguments, those arguments could not overcome the statute’s plain language, which is our ‘primary guide’ to Congress’ preferred policy”).

100. *Id.*, states:

In my view, Congress implicitly delegated to the Food and Drug Administration authority to interpret those same terms. That being so, if that agency, after greater experience administering this statute, determines that a different interpretation would better serve the statute’s objectives, it may well have authority to depart from, or to modify, today’s interpretation, though we need not now decide any such matter.

(citations omitted)).

101. *Id.*, states:

In my view, Congress implicitly delegated to the Food and Drug Administration authority to interpret those same terms. That being so, if that agency, after greater experience administering this statute, determines that a different interpretation would better serve the statute’s objectives, it may well have authority to depart from, or to modify, today’s interpretation, though we need not now decide any such matter.

(citations omitted).

102. *Amgen Inc. v. Hospira, Inc.*, 866 F.3d 1355, 1360 (Fed. Cir. 2017) (“Under the BPCIA, there could be five potential avenues available to a sponsor seeking to secure process information pursuant to paragraph (l)(2)(A).”).

103. *Id.* at 1357.

104. *Id.*; 42 U.S.C. § 262(l)(2)(A) (2012).

105. *Hospira, Inc.*, 866 F.3d at 1358 (“Despite their disagreement over Hospira’s compliance with paragraph (l)(2)(A)—a disagreement that we do not resolve—the parties

noted that it could not provide a full list of its alleged infringed patents because it did not have information regarding Hospira's manufacturing process used to create its biosimilar, specifically information regarding the cell-culture medium.<sup>106</sup> Ultimately, Amgen filed suit asserting two of its patents, '349 and '298.<sup>107</sup>

In reliance on the Federal Circuit's holding in *Amgen v. Sandoz*, that an RPS may obtain manufacturing information through discovery, Amgen sought discovery on Hospira's cell-culture medium through requests for production.<sup>108</sup> However, Hospira refused and Amgen filed a motion to compel production of documents related to Hospira's cell-culture medium.<sup>109</sup> The District Court of Delaware denied Amgen's motion to compel because "cell-culture information sought by Amgen 'had essentially, no relevance to the patents that are asserted.'" <sup>110</sup> Amgen appealed this decision to the Federal Circuit and the Federal Circuit requested briefing on whether the court had jurisdiction "pursuant to the collateral order doctrine or under the All Writs Act."<sup>111</sup> The Federal Circuit dismissed Amgen's appeal to compel discovery and denied Amgen's writ for mandamus.<sup>112</sup> The Federal Circuit lacked jurisdiction under the collateral order doctrine and Amgen did not "satisfy the prerequisites for mandamus."<sup>113</sup> While the court refused to compel discovery on Hospira's cell-culture medium, the Federal Circuit provided some guidance on what Amgen and other similarly situated RPS's could do.

The Federal Circuit held that the RPS can obtain missing information from the biosimilar manufacturer's insufficient disclosure under § (l)(2) only by listing any and all patents relating to the insufficiency and asserting them in a subsequent patent infringement action.<sup>114</sup> By doing this, the RPS can obtain discovery pursuant to Federal Rule of Civil Procedure 26(b) on the missing information.<sup>115</sup>

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proceeded to the next phase of the BPCIA's information exchange by identifying patents subject to suit.").

106. *Id.* at 1358.

107. *Id.*

108. *Id.*

109. *Id.*

110. *Id.* (citing Transcript of Discovery Dispute Before the Honorable Richard G. Andrews at 37, *Amgen Inc. v. Hospira, Inc.*, 2016 U.S. Dist. LEXIS 102951 (D. Del. Aug. 5, 2016) (No. 1:15-cv-00839-RGA) [hereinafter Transcript of Oral Argument].

111. *Id.* at 1358.

112. *Id.* at 1356.

113. *Id.*

114. *Id.* at 1360–61.

115. *See id.* at 1361 (citing FED. R. CIV. P 26(b)(1)).

The Federal Circuit stated that Amgen could have asserted its cell-culture patents because of 35 U.S.C. § 271(e)(2)(C)(i), or (ii).<sup>116</sup> 35 U.S.C. § 271(e)(2)(C)(ii) allows the RPS to assert patent claims that “*could*” have been identified on the patent list had the biosimilar manufacturer provided sufficient disclosures under § (l)(2).<sup>117</sup> Alternatively, under 35 U.S.C. § 271(e)(2)(C)(i), Amgen is allowed to bring an action alleging infringement based on the patents on the patent list.<sup>118</sup> As the Supreme Court noted, both §§ 271(e)(2)(C)(i) and (ii) define the scope of patents that can be asserted prior to the biosimilar entering the commercial market.<sup>119</sup> Therefore, according to the Federal Circuit, the RPS has to assert its patents in order to get discovery on Hospira’s cell-culture medium or other aspects of the biosimilar manufacturer’s manufacturing process.<sup>120</sup> Amgen countered that if it were to bring an infringement action based on patent claims that it is unsure of, the RPS would be open to sanctions under Federal Rule of Civil Procedure 11 or antitrust liability.<sup>121</sup> However, the Federal Circuit stated that the BPCIA “merely requires” the RPS to list patents on its patent list that it “believes . . . *could* reasonably be asserted.”<sup>122</sup> Additionally, since the biosimilar manufacturer failed to provide information required under § (l)(2), the RPS would not be subjected to sanctions under Federal Rule of Civil Procedure 11.<sup>123</sup>

#### D. CASE SYNTHESIS: WHAT ARE THE REMEDIES?

The Federal Circuit’s and Supreme Court’s most recent cases provide further interpretation of the BPCIA, specifically the remedies available when some of its many requirements are not satisfied. First, if the biosimilar manufacturer fails to provide its application, the RPS can seek declaratory relief under § (l)(9)(C), which is the exclusive remedy, and not injunctive relief.<sup>124</sup> However, if the biosimilar produced its application, but provided deficient or no information regarding its manufacturing process, the RPS may not seek declaratory relief under the BPCIA statute. This is because § (l)(9)(C) only provides declaratory relief when the biosimilar manufacturer does not

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116. *Id.* at 1360–61.

117. *Id.* (“The sponsor could also sue on a patent that ‘*could* be identified’ under paragraph (l)(3), 35 U.S.C. § 271(e)(2)(C)(ii) . . .”).

118. *Id.* (“The sponsor could sue on ‘patents described in [paragraph (l)(3) of the BPCIA],’ 35 U.S.C. § 271(e)(2)(C)(i), i.e., the ‘list of patents for which the . . . sponsor believes a claim of patent infringement could reasonably be asserted . . .’”).

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

120. *See Hospira, Inc.*, 866 F.3d at 1360–61.

121. *Id.* at 1361.

122. *Id.* at 1362.

123. *Id.* at 1362.

124. *Sandoz*, 137 S. Ct. at 1675.

provide the application.<sup>125</sup> Thus, if RPS wanted to obtain information about the biosimilar manufacturer's manufacturing process, the RPS may be able to obtain the information through discovery with requests for production and/or motions to compel in the context of an infringement suit over the relevant patents.<sup>126</sup> The Federal Circuit found that listing the RPS' patents that are potentially associated with the manufacturing process on the patent list will most likely allow the RPS to gain discovery on the manufacturing process.<sup>127</sup>

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Under the Court's ruling, the BPCIA turns into a choose-your-own-adventure, with biosimilar makers in control of how the tale unfolds. The biosimilar maker can provide its aBLA and manufacturing information, only some of its information, or nothing at all, with the innovator unable to enforce the BPCIA's provisions requiring these disclosures under federal law. Regardless of whether the patent dance is initiated or bypassed, the biosimilar maker is free to provide its notice of commercial marketing either before or after FDA licensure.

See Irena Royzman & Nathan Monroe-Yavneh, *The Supreme Court's Interpretation of the Biosimilars Statute and the Value of Certainty*, 35 NATURE BIOTECHNOLOGY 916, 917 (2017).

126. See *Hospira, Inc.*, 866 F.3d at 1360–61.

127. See *id.* However, in doing so the RPS runs the risk that the biosimilar manufacturer may try and seek an *inter partes* review on the manufacturing process and invalidate those method and process patents. See Courtenay C. Brinckerhoff & Kristel Schorr, *Have the Biosimilar Floodgates Been Opened in the United States?*, 14 NATURE REVS. DRUG DISCOVERY 303, 303 (2015), which states:

Along with litigation, we anticipate an increasing number of patent challenges in the US Patent and Trademark Office, with biosimilar competitors bringing *inter partes* (between the parties) review (IPR) proceedings to invalidate patents on the grounds that the patent does not differ enough from prior art. We expect biosimilar competitors to use IPRs to attain earlier market entry, by invalidating core patents and later-expiring 'improvement' or 'selection' patents. Any would-be competitors may have an incentive to challenge core patents, which usually have earlier expiration dates, as such patents probably cover any product that could be approved as a biosimilar. Competitors who are furthest along in biosimilar product development may be most likely to bring IPRs, whereas those at earlier stages may wait for the patent landscape to be cleared before making substantial additional investments in their own product development and freedom-to-operate efforts. However, even if one biosimilar competitor has filed an IPR petition, another biosimilar competitor may want to file its own IPR petition to preserve its rights to challenge the patent on similar grounds and participate in any settlement discussions.;

see also Saurabh Vishnubhakat, Arti K. Rai, & Jay P. Kesan, *Strategic Decision Making in Dual PTAB and District Court Proceedings*, 31 BERKELEY TECH. L.J. 45, 68, 94 (2016), which states:

Beyond these basic PTAB filing trends, we find that a number of patents have been targets of serial challenges spread across both multiple petitions and multiple challengers in IPR petitions. Patents in the Chemical, CCM [computers and communications], and Electrical areas are particularly prone to multiple petitions [during the time period of September 16, 2012

As a result, the RPS should be able to obtain discovery on the biosimilar manufacturer's manufacturing information.<sup>128</sup>

Second, caselaw now makes clear that the 180-day notice is mandatory, but may precede licensure.<sup>129</sup> Even if the biosimilar manufacturer did not provide its application and manufacturing information, the biosimilar manufacturer must still provide 180-day notice.<sup>130</sup> If 180-day notice is not given, the RPS may seek declaratory relief under § (l)(9)(B), but declaratory judgment is not the exclusive remedy, because courts still have equitable jurisdiction.<sup>131</sup> The Federal Circuit may have contemplated injunctive relief as a possible remedy

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and June 30, 2015]. As Figure 8 shows, a majority of patents in each of these fields were the subject of multiple IPR petitions: 60.6% of Chemical patents, 50.9% of CCM patents, and 58.4% of Electrical patents.

While IPR proceedings currently plays an instrumental role in the pharmaceutical context, the Supreme Court is considering “[w]hether inter partes review, an adversarial process used by the Patent and Trademark Office (PTO) to analyze the validity of existing patents, violates the Constitution by extinguishing private property rights through a non-Article III forum without a jury” in *Oil States Energy Serv., LLC v. Greene’s Energy Grp., LLC*. *Oil States Energy Services, LLC v. Greene’s Energy Group, LLC*, SCOTUSBLOG, <https://www.scotusblog.com/case-files/cases/oil-states-energy-services-llc-v-greenes-energy-group-llc/> [<https://perma.cc/5H3T-RJ9X>].

128. *Hospira, Inc.*, 866 F.3d at 1360–61.

129. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1677 (2017).

130. See *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1061 (Fed. Cir. 2016), which states:

Paragraph (8)(A) provides that “[t]he subsection (k) applicant [biosimilar manufacturer] 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).” The word ‘shall’ generally indicates that the directive is mandatory. We ruled in *Amgen v. Sandoz* that this language is, indeed, ‘mandatory’ and we did not say that it was mandatory only in no-(2)(A)-notice circumstances.

(citations omitted).

131. *Id.* at 1064, states:

We cannot infer such an exclusive-remedy conclusion from paragraph (9). The Supreme Court long ago ruled that the federal courts’ ‘equitable jurisdiction is not to be denied or limited in the absence of a clear and valid legislative command,’ whether ‘in so many words, or by a necessary and inescapable inference.’ Under that standard, or indeed under a straightforward understanding of paragraph (9) as it relates to (8)(A), we do not find that paragraph (9) establishes that a declaratory-judgment action is the sole remedy for violating (8)(A) . . . . (9)(A) bars certain declaratory-judgment actions, and (9)(B) & (C) state only that, in certain circumstances, the reference product sponsor ‘may bring’ such an action. There is no language that excludes other remedies for the conduct described.

(citations omitted). The Supreme Court has not confirmed this.

because it avoids the “rushed decision-making” that (l)(8)(A) is seems to circumvent.<sup>132</sup>

Once 180-day notice is given, the RPS may seek a preliminary injunction enjoining the biosimilar manufacturer from engaging in “commercial manufacturer or sale” until the court decides the issues of patent validity or infringement for patents on the amended patent list that were not litigated.<sup>133</sup> Additionally, as the Supreme Court noted, the RPS can seek injunctive relief under 35 U.S.C. § 271 or § 283 to prevent the biosimilar manufacturer from commercially manufacturing its product.<sup>134</sup>

#### IV. DISCUSSION: TIMING OF 180-DAY NOTICE

While the Supreme Court provided badly needed guidance on the remedies for statutory violations, the Court’s interpretation of the timing of 180-day notice may have been incorrectly decided. First, Sandoz’s holding allows 180-day notice to be given before the biosimilar “fixes,” which can lead to parties blindly litigating over controversies that may or may not “fully crystallize.”<sup>135</sup> Second, the purpose and the text of the BPCIA may not support *Sandoz*’s holding. Finally, by allowing the biosimilar manufacturer to provide notice “either before or after receiving FDA approval,”<sup>136</sup> the biosimilar manufacturer may use “notice” to encourage pay-for-delay schemes, i.e., reverse payments.

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132. *See id.* at 1065, which states:

The 180-day period gives the reference product sponsor time to assess its infringement position for the final FDA-approved product as to yet-to-be-litigated patents. And if there is such litigation, it gives the parties and the district court the time for adjudicating such matters without the reliability-reducing rush that would attend requests for relief against immediate market entry that could cause irreparable injury . . . . In particular, relegating a reference product sponsor to a patent-merits declaratory-judgment action would introduce the very problem of rushed decision-making as to the patent merits that it is (8)(A)’s purpose to avoid.

133. 42 U.S.C. § 262(l)(8)(B) (2012).

134. *Sandoz*, 137 S. Ct. at 1675 n.2 (2017), states:

In holding that § 262(j)(9)(C) represents the exclusive remedy for an applicant’s [biosimilar manufacturer] failure to provide its application and manufacturing information, we express no view on whether a district court could take into account an applicant’s violation of §262(j)(2)(A) (or any other BPCIA procedural requirement) in deciding whether to grant a preliminary injunction under 35 U.S.C. § 271(e)(4)(B) or § 283 against marketing the biosimilar.

135. *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1358 (Fed. Cir. 2015).

136. *Sandoz*, 137 S. Ct. at 1677.

A. SANDOZ'S HOLDING MAY PRESSURE THE RPS TO ASSERT ALL OF ITS PATENTS AND "LITIGATE BLINDLY" TO PROTECT ITS RIGHTS

The Federal Circuit noted that until the biosimilar "fixes," or is approved by the FDA, patent disputes have yet to "fully crystallize."<sup>137</sup> Until the FDA "fixes" the biosimilar, "the RPS would be left to guess the scope of the approved" biosimilar.<sup>138</sup> Parties could therefore be litigating over the possibility of infringement, while neither party knows for sure if there is infringement. If the biosimilar manufacturer chooses to only provide its application and not its manufacturing information, the biosimilar manufacturer would further exacerbate the problem. This is because the RPS will be "litigating blind," since there is uncertainty around which process patents may be infringed.<sup>139</sup> In order for the RPS to protect its rights, it may have to assert all of its patents unnecessarily.<sup>140</sup>

On the other hand, if 180-day notice is given post-licensure, there will no longer be uncertainty over the biosimilar product. It is at this point that the RPS is better situated to determine if it should assert patents that were not asserted during the first-phase of litigation because it may have been weaker, or to seek licenses for its other patents.<sup>141</sup>

Since many of these biosimilar were first approved in Europe, arguably, the biosimilar already "fixed" and controversies were "fully crystallized."<sup>142</sup>

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137. *Sandoz*, 794 F.3d at 1358 ("Requiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy . . .").

138. *Id.*

139. Royzman & Monroe-Yavneh, *supra* note 128, at 918 ("Indeed, without the aBLA or manufacturing information, the innovator may be forced to litigate blind without knowing which patents to assert or when. *Amgen v. Hospira* illustrates why innovators may have little choice but to assert their patents blind in order to protect their rights.").

140. *Id.*

141. *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1062 (Fed. Cir. 2016), states:

As this court explained in *Amgen v. Sandoz*, the purpose is to ensure that, starting from when the applicant's product, uses, and processes are fixed by the license, the necessary decision-making regarding further patent litigation is not conducted under time pressure that will impair its fairness and accuracy. At the least, the reference product sponsor needs time to make a decision about seeking relief based on yet-to-be litigated patents, and a district court needs time for litigants to prepare their cases, in a complicated area, to provide a reliable basis for judgment.

(citation omitted).

142. See Mark McCamish & Gillian Woollett, *Worldwide Experience with Biosimilar Development*, 3 MABS 209, 211 ("Europe has led in the approval of biosimilars because EMA was the first regulatory authority to be given the mandate to review and approve biologic products that explicitly referred to a previously approved product and because patents on key products expired in Europe sooner than in the US."); see also Jacob F. Siegel & Irena Royzman, *2017 Biosimilar Approvals in Europe*, BIOLOGICS BLOG (Dec. 21, 2017),

Therefore, there is no uncertainty about the final approved biosimilar product. However, if the biosimilar manufacturer does not provide manufacturing data, the RPS cannot glean which of its process patents may be infringed from the final approved European biosimilar. Therefore, not all the controversies will be “fully crystallized.” Second, at some point, biosimilar manufacturers will submit applications simultaneously to both the EMA and the FDA. It is at this point, where controversies may not “fully crystallize” and much of the approved biosimilar is unknown.

B. SANDOZ’S DECISION IS INCONSISTENT WITH THE PURPOSE AND THE TEXT OF THE BPCIA

Justice Thomas’s textual interpretation that 180-day notice may occur before or after licensing,<sup>143</sup> seems to conflict with the greater purpose the statutory scheme lays out. If 180-day notice can be given as soon as biosimilar manufacturer submits its application, there would be no need for a patent dance, § (l)(4)–(5), and the distinction between the first-phase and second-phase of litigation that Congress seems to draw would be futile.

As the Solicitor General pointed out in its amicus brief and the Federal Circuit noted in *Apotex*, Congress created a statutory scheme in which the biosimilar manufacturer controls the first-phase of litigation and the RPS controls the second-phase of litigation.<sup>144</sup> Thus, 180-day notice is seen to mark the second-phase of litigation.<sup>145</sup> Once 180-day is given and the second-phase

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<https://www.biologicsblog.com/2017-biosimilar-approvals-in-europe> [<https://perma.cc/Z93D-4HXR>] (showing that as of December 2017, the European Medicines Agency (EMA) in Europe has approved of thirty-three biosimilars in Europe, dating back as early as 2007, whereas the FDA in the United States has approved of eleven biosimilars).

143. *Sandoz*, 137 S. Ct. at 1677.

144. *See Apotex Inc.*, 827 F.3d at 1062–63, which states:

Moreover, as we have described, § 262(l) affirmatively contemplates two stages of litigation (under paragraphs (6) and (8)), and it contemplates that the first stage of litigation may omit patents the reference product sponsor has good grounds to assert, whether patents already in the hands of the reference product sponsor or patents newly in its hands under paragraph (7). It gives the applicant substantial authority to force such a limitation on the scope of the first-stage litigation.

*See* Brief for United States as Amicus Curiae at 18, *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664 (2017) (No. 15-1195) (“Congress concluded that a sponsor should be given a fair chance to litigate the Round 2 patents prior to actual marketing, since the applicant controls the scope of the earlier Round 1 litigation.”).

145. *Apotex Inc.*, 827 F.3d at 1056 (“But the Biologics Act—having provided for a narrowing of the scope of the paragraph (6) litigation, including by allowing the applicant to exclude potentially meritorious patents from that litigation—provides, in paragraph (8), for a second stage of patent litigation.”).

is initiated, the RPS has “a fair chance to litigate” patents it could not assert in the first-phase.<sup>146</sup> Additionally, Congress intended to create the “patent dance” to streamline the patent litigation process. In fact, Representative Anna G. Eshoo testified that the house version of the bill envisioned the parties would engage in negotiations six to eight months before litigation to discuss litigation and resolve issues, i.e., the patent dance.<sup>147</sup> The bill envisioned that this discussion would occur after the application is submitted to the FDA and before the RPS’s data-exclusivity period expires in order.<sup>148</sup>

The first-phase of litigation is controlled by the biosimilar manufacturer because the biosimilar manufacturer can limit the number of patents that will be litigated in this phase. Under § (l)(4), the parties must negotiate to determine which patents to litigate in the first-phase. However, if the parties are unable to reach consensus, the biosimilar manufacturer sets the maximum number of patents that will be litigated, thereby limiting the scope of the first-phase of litigation.<sup>149</sup> For example, in *AbbVie v. Amgen*, Amgen (biosimilar manufacturer) limited the first phase of litigation to ten patents instead of the sixty-one patents AbbVie (RPS) wanted to assert.<sup>150</sup> Thus, AbbVie had to wait until it received 180-day notice to initiate the second-phase of litigation to assert its remaining fifty-one patents.<sup>151</sup>

However, if 180-day notice can be given before licensure, the first-phase and the second-phase collapse together. Once the parties engage in the patent dance, the RPS brings an infringement suit under § (l)(6). But, if 180-day notice is given simultaneously, patents not asserted during § (l)(6) can be asserted immediately under § (l)(8) and the narrow scope of § (l)(6) would be

146. Brief for United States as Amicus Curiae at 18, *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664 (2017) (No. 15-1195) (“Subsection (l)(8)(A)’s notice requirement therefore is properly viewed as affording the sponsor an adequate opportunity to commence litigation on the Round 2 patents that it previously was prevented from bringing while the applicant was following the process for controlling patent litigation.”).

147. *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts & Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 9, 218 (2009), Rep. Anna G. Eshoo states:

H.R. 1548 also establishes a simple, streamlined patent resolution process. This process would take place within a short window of time, roughly 6 to 8 months after the biosimilar application has been filed with the FDA. It will help ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large . . . .

148. *Id.*

149. 42 U.S.C. § 262(l)(5)(A) (2012).

150. *AbbVie, Inc. v. Amgen, Inc.*, No. 16-cv-666-SLR (D. Del. Aug. 4, 2016), Dkt. No. 1 at 6 ¶ 20.

151. *Id.*

eliminated.<sup>152</sup> This therefore begs the question, why did Congress create the patent dance, §§ (l)(4)–(5), if all patents can be asserted pre-licensure and immediately after 180-day notice is given. Further, if Congress created a pre-market dispute resolution process that created two rounds of litigation, having both rounds collapse into one seems to conflict with the purpose the statute lays out.

By contrast, as Apotex pointed out, 180-day notice occurring post-licensure would cause a 180-day delay and extend the reference product's exclusivity that Congress enacted by six months.<sup>153</sup> The Federal Circuit disposed of this argument because a biosimilar applicant can begin the process enumerated under the BPCIA “four years after licensure of the reference product, § 262(k)(7)(B)” and the FDA is permitted to issue a license on the biosimilar during the reference product's exclusivity period.<sup>154</sup> The Solicitor General also agreed and found that Congress permitted litigation on all relevant patents to occur seven years before licensing.<sup>155</sup> Therefore, 180-day notice given post-licensure may not delay the biosimilar from being commercially marketed. Further, this analysis supports that *Sandoz's* holding is in conflict with the purpose and greater scheme of the BPCIA.

C. SANDOZ'S HOLDING INCENTIVIZES PAY-FOR-DELAY SETTLEMENTS  
BECAUSE 180-DAY NOTICE CAN BE USED AS A BOUNTY

If 180-day notice can be given at any time, then the trigger for the second-phase of litigation can be bought off or leveraged between the parties.<sup>156</sup> The biosimilar manufacturer controls whether to provide notice immediately and settle patent disputes early-on, or it can wait and use the 180-day notice as leverage for a “pay for delay” settlement. The latter option may seem more lucrative for the RPS because it could avoid pending *inter partes* reviews, post-grant reviews and litigation that may invalidate its patents, and the RPS can negotiate to protect its investments and revenue. This is a very important

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152. *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1056 (Fed. Cir. 2016) (“But the Biologics Act—having provided for a narrowing of the scope of the paragraph (6) litigation, including by allowing the applicant to exclude potentially meritorious patents from that litigation—provides, in paragraph (8), for a second stage of patent litigation.”).

153. Brief for Petitioner at 10, *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052 (Fed. Cir. 2016) (No. 16-332) (“The Federal Circuit threw up a roadblock in the abbreviated-pathway by mandating that biosimilar provide a notice of commercial marketing . . . it functionally extended the 12-year exclusivity by an extra six months.”).

154. *Apotex Inc.*, 827 F.3d at 1062.

155. Brief for United States as Amicus Curiae at 16, *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664 (2017) (No. 15-1195) (“Accordingly, Congress itself chose to permit patent litigation on all relevant patents to commence more than seven years before such licensing.”).

156. See Darren S. Tucker & Gregory F. Wells, *Emerging Competition Issues Involving Follow-On Biologics*, 29 ANTITRUST 100, 103 (2014).

consideration for the RPS because a single biosimilar may implicate 30 to 40 patents at a time.<sup>157</sup> This may also be a better option for the biosimilar manufacturer because it can avoid lengthy litigation that could delay the launch of its biosimilar,<sup>158</sup> avoid expenses related to litigation, and prevent releasing confidential information regarding its manufacturing process through discovery.<sup>159</sup> However, these considerations must be weighed against the fact that the average price discount for a biosimilar is estimated to be ten to thirty percent and may not serve as strong factor to encourage negotiations in comparison to the price discount was for generic small molecule drugs.<sup>160</sup>

In *AbbVie v. Amgen*, Amgen created a biosimilar for AbbVie's biologic, Humira. AbbVie's product, Humira, "recorded more than \$16 billion in global sales [in 2016]."<sup>161</sup> According to AbbVie's complaint, the two parties engaged in creating a patent list and the patent dance.<sup>162</sup> However, Amgen (the biosimilar manufacturer) provided AbbVie with its application but not its manufacturing information.<sup>163</sup> AbbVie then created a patent list identifying 61 patents and five pending patents.<sup>164</sup> While the parties were supposed to engage in negotiations over which patents to assert during the first-phase, AbbVie

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157. *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 & Commerce*, 110th Cong. 116 (2007).

158. Alice Yuen-Ting Wong, Martha M. Rumore & Albert Wai-Kit Chan, *Biosimilars in the United States: Emerging Issues in Litigation*, *BIODRUGS*, 31, 189, 201 (2017) ("In addition to BPCIA interpretation, patent infringement issues are also being litigated. Since biologics have a 'patent thicket', the infringement litigation in the second round of litigation could delay market entry for the biosimilar for years.")

159. *See Amgen Inc. v. Hospira, Inc.*, 866 F.3d 1355 (Fed. Cir. 2017) (holding that it is likely that the biosimilar manufacturer's manufacturing process information is discoverable. Therefore, a settlement may be in the biosimilar manufacturer's best interest because then it does not have to reveal its process and can protect its process under trade secret). This is particular important because it prevents the RPS from learning about the biosimilar's manufacturing process to introduce a bio-better product that could directly compete with the biosimilar.

160. Ameet Sarpatwari et al., *Progress and Hurdles for Follow-on Biologics*, *NEW ENGLAND J. MED.* 2380, 2380–81 (2015) ("The introduction of generic versions of small-molecule drugs can reduce prices by 90% from the brand-name version . . . . In the European Union, where 22 follow-on biologics are available, the median price savings for biosimilar epoetin alfa is just 35%"); *EMERGING HEALTH CARE ISSUES*, *supra* note 18 ("These FOB entrants are unlikely to introduce their FOB products at price discounts any larger than between 10 and 30 percent of the pioneer products' price.")

161. Jeff Overley, *AbbVie, Amgen End Patent Fight Over Humira Biosimilar*, *LAW360* (Sept. 28, 2017), <https://www.law360.com/articles/968996/abbvie-amgen-end-patent-fight-over-humira-biosimilar> [<https://perma.cc/SQ8W-9VGR>].

162. *AbbVie, Inc. v. Amgen, Inc.*, No. 16-cv-666-SLR (D. Del. Aug. 4, 2016), Dkt. No. 1 at 11 ¶¶ 38, 39.

163. *Id.* at 11 ¶ 38.

164. *Id.* at 11 ¶ 39.

claims Amgen did not engage in negotiations under § (l)(4).<sup>165</sup> As a result, § (l)(5) was triggered and Amgen determined that AbbVie could only assert ten of its sixty-one patents against Amgen in the first phase of litigation.<sup>166</sup> AbbVie noted in its complaint that it explicitly asked Amgen to assert all 61 patents in the first-phase to avoid two phases of litigation and for judicial economy, but Amgen did not engage.<sup>167</sup> Instead, as AbbVie noted, AbbVie would need to wait until Amgen provides 180-day notice in order to assert the rest of its patents.<sup>168</sup> In the end, the two parties settled their patent disputes and agreed to “delay” Amgen’s release of its biosimilar to until 2023 in U.S. pharmacies and until 2018 in European pharmacies.<sup>169</sup> In exchange, Amgen would license AbbVie’s patents and pay a royalty on other patents.<sup>170</sup> While both parties denied that this was a “pay for delay” settlement, it raises an interesting issue of “pay for delay” settlements.<sup>171</sup> Congress envisioned a pre-market litigation process to resolve patent disputes before the biosimilar is commercially manufactured, prior congressional proposals were introduced that aligned with “the FTC and DOJ’s requests and [would have] made reverse payment settlements presumptively illegal.”<sup>172</sup> Interestingly, after AbbVie’s settlement

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165. *Id.* at 15 ¶¶ 46, 47.

166. Under (l)(5), Amgen (biosimilar manufacturer) can cap the number of patents that can be asserted in the first round of litigation. Amgen capped the number at six patents, which meant that the two parties had to create a list of six patents that could be litigated. Therefore, the total number of patents that could have been asserted was twelve. In this case, since both parties identified the same patent, the total number of patents that could be litigated in the first-phase was ten. See Dani Kass, *Amgen’s Humira Biosimilar Infringes 61 Patents, AbbVie Says*, LAW360 (Aug. 5, 2016), <https://www.law360.com/articles/825393/amgen-s-humira-biosimilar-infringes-61-patents-abbvie-says> [<https://perma.cc/D652-Y5BE>].

167. *AbbVie, Inc. v. Amgen, Inc.*, No. 16-cv-666-SLR (D. Del. Aug. 4, 2016), Dkt. No. 1 at 15 ¶ 46.

168. *Id.* at 6 ¶ 20.

169. Jeff Overley, *AbbVie, Amgen End Patent Fight Over Humira Biosimilar*, LAW360 (Sept. 28, 2017), <https://www.law360.com/articles/968996/abbvie-amgen-end-patent-fight-over-humira-biosimilar> [<https://perma.cc/SQ8W-9VGR>].

170. *Id.*

171. *Id.*, states:

The settlement does not include provisions that could make it resemble a “pay-for-delay” deal in which copycat drugs are delayed in exchange for financial compensation, AbbVie spokeswoman Mary Kathryn Steel told Law360. “This is absolutely not a ‘pay for delay,’” Steel said by email. “While the terms of the agreement are confidential, I can tell you that AbbVie is not paying Amgen anything. This is a straightforward patent license.”

172. See Brenna E. Jenny, *Pay For Delay, There For The Taking?*, LAW360 (Mar. 14, 2012), <https://www.law360.com/articles/314750/pay-for-delay-there-for-the-taking-> [<https://perma.cc/C8NS-4MFV>], which states:

Previous congressional proposals, including one introduced last year by Sen. Herb Kohl, D-Wis., would have granted the FTC and DOJ’s requests and made reverse payment settlements presumptively illegal. Rush’s bill

with Amgen, the President closed a loophole in the statute to now require biosimilar settlements to be reviewed by the FTC and DOJ.

## V. CONCLUSION

While the Supreme Court settled questions about remedies for statutory violations, the Court's interpretation of the timing of 180-day notice may have some unintended consequences. First, 180-day pre-licensure can lead to parties blindly litigating over controversies that may or may not "fully crystallize."<sup>173</sup> Second, by giving the biosimilar manufacturer flexibility on when it can provide 180-day notice, the biosimilar manufacturer may use "notice" to encourage pay-for-delay settlements. Arguably, the Supreme Court's holding that 180-day notice may be provided "either before or after receiving FDA approval,"<sup>174</sup> seems to be in conflict with the purpose and the text of the BPCIA. For instance, if 180-day notice can be given as soon as biosimilar manufacturer submits its application, there would be no need for the congressionally created patent dance and Congress's possible distinction between the first-phase and second-phase of litigation would be futile.

Further, the Supreme Court's ruling seems to leave open some questions, and the district courts will have to reconcile the spirit and the policies of the BPCIA with the modern realities of patent litigation. For instance, how should the RPS propound discovery to determine which of its process patents are infringed when the biosimilar manufacturer fails to turn over its manufacturing information.<sup>175</sup> Since 180-day notice marks a significant transition from the first-phase of litigation to the second-phase of litigation and provides the RPS with injunctive relief remedy and both parties with declaratory relief remedy, and 180-day notice hinges on the FDA's licensure process, should the FDA have a role in interpretation of the BPCIA?<sup>176</sup> Since much of the BPCIA is not settled, the district courts will need to struggle with the bounds of gap-filling and its role in developing this area of law.

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goes a step further: any settlement involving a generic drug filer receiving something of value and agreeing not to research, develop or sell a drug that is the subject of an infringement claim would be an 'unfair method of competition,' in violation of Section 5 of the FTC Act.

173. *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1358 (Fed. Cir. 2015).

174. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1677 (2017).

175. As Judge Richard G. Andrews noted: "[R]egardless of what Congress might have thought, and I'm sure they never contemplated the intersection of this with the Discovery Rules, or the actual -- I mean maybe they did, actually. But in terms of how you get these things if people didn't do what the statute envisioned." Transcript of Oral Argument at 13.

176. As Justice Breyer stated in his concurrence: "if [the FDA], after greater experience administering this statute, determines that a different interpretation would better serve the statute's objectives, it may well have authority to depart from, or to modify, today's interpretation." *Sandoz*, 137 S. Ct. at 1678.

Finally, borrowing from the third law of thermodynamics, entropy or disorder, is at zero when a system achieves perfect order. Currently, disorder is at a maximum because much of the BPCIA remains an open question and it requires more interpretation. But, as the courts wrestle with these questions and issues that arise under the BPCIA, the framework will move closer to a perfectly ordered system where entropy will achieve zero. Therefore, entropy is the price of an ordered framework.