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BPCIA LITIGATION CASES FILED AFTER  
*SANDOZ V. AMGEN*

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# KEEP ON DANCING: THE SUCCESS AND FAILURES OF PATENT DANCE AS SHOWN BY BPCIA LITIGATION CASES FILED AFTER *SANDOZ V. AMGEN*

Yun Dong\*

## ABSTRACT

Congress created the Biologics Price Competition and Innovation Act of 2009 (BPCIA) intending to establish a market of biosimilars. To enhance negotiation between the parties and to reduce the risks and uncertainties, Congress designed a complicated procedure commonly known as the “patent dance” for the exchange of information and determination of patents for litigation before the launch of a biosimilar. In 2017, the Supreme Court decided *Sandoz v. Amgen*, holding that the patent dance is not enforceable by injunction, and commentators worried that participation of biosimilar applicants might decrease afterward. This Article surveys the behaviors of the parties in the patent dance reflected by BPCIA litigations filed after the *Sandoz v. Amgen* decision until October 2021 and shows that the patent dance scheme facilitates negotiations and settlements between the parties. However, these litigations also indicated that the information exchange might be insufficient compared to what Congress might have envisioned and the two-phased litigation structure might be inefficient for certain kinds of parties.

This Article also discusses the proposals to improve the BPCIA and proposes a three-part solution to balance the information exchange and increase the flexibility of participation for better efficiency.

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## INTRODUCTION

Biological products are complex, big molecules created in and purified from living organisms and can be very effective therapies for many conditions.<sup>1</sup> Because of the complexities inherent in biological products, their development and price have been extremely expensive, and the burden on patients is consequently very heavy.<sup>2</sup> Congress created the Biologics Price Competition and Innovation Act of 2009 (“BPCIA”), intending to establish a market of biosimilars, which are follow-on biological products that are highly similar to the reference product.<sup>3</sup> To enhance negotiation between the parties creating biosimilars and to reduce the risks and uncertainties, Congress designed a complicated procedure for exchanging information and challenging patents in litigation, commonly known as the “patent dance.”<sup>4</sup> However, after the Supreme Court in *Sandoz v. Amgen* decided that the patent dance is not mandatory,<sup>5</sup> there has been worry that participation of biosimilar applicants may significantly decrease.

This Article will survey BPCIA litigations filed after the *Sandoz v. Amgen* decision through October 2021 and examine if and how the parties completed the patent dance. Part I will review the basic market situations and the framework of BPCIA. A comparison between analyzing biologics under the BPCIA and generic chemical pharmaceuticals will also be provided. Part II will survey and summarize how well the biosimilar applicants have completed the patent dance in the BPCIA litigations filed after *Sandoz v. Amgen*. Part III will analyze the behaviors reflected in the case survey and the possible reasons behind them. And Part IV will discuss proposals aimed at improving the patent dance scheme, including the recently passed Biological Product Patent Transparency section that amends the BPCIA. This Article argues that although the recently passed amendment will likely improve the efficiency of the scheme, a comprehensive solution that targets patent transparency, the number of asserted patents, and the flexibility of participation would better facilitate a prosperous biosimilar market.

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<sup>1</sup> Guodong Fu, *Can a Two-Pronged Attack from Congress and the FDA Make Up for the BPCIA’s limitations?*, B.C. INTELL. PROP. & TECH. F. 1 (Feb. 16, 2020), <http://bciprf.org/2020/02/two-pronged-attack> [https://perma.cc/8JTG-EG9B].

<sup>2</sup> Trenton Hatherill, *The Misstep within the Patent Dance That Sandoz Inc. v. Amgen Inc. Revealed and How It Can Be Corrected*, 47 AIPLA Q.J. 149, 155 (2019).

<sup>3</sup> 42 U.S.C. § 262(i)(2)(A).

<sup>4</sup> *Id.* at § 262(l).

<sup>5</sup> *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1674–75 (2017).

## I. BACKGROUND

### A. *The Significance of Biologics and Biosimilars*

Biological product, or biologic, is defined in § 351(i) of the Public Health Service Act (“PHSA”) to include “virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product” that are “applicable to the prevention, treatment, or cure of a disease or condition of human beings.”<sup>6</sup> Notably, this definition specifically identifies the subject matters by their biological properties, rather than by solely describing the intended use like the definition of drugs under the Food, Drug and Cosmetics Act (“FDCA”).<sup>7</sup> Because biologics are often comprised of big molecules such as proteins, nucleic acids, or analogs or combinations thereof, the chemical complexities of biologics are higher in orders of magnitude compared to small molecule drugs. The manufacturing processes rely on certain biological processes rather than chemical synthesis, which are subject to more variables and complexities and thus requires greater scientific expertise and experience.<sup>8</sup> Additionally, biologics often require special handling, processing, and administration to avoid contamination and to enhance the effectiveness.<sup>9</sup> These complexities allow biologics not only to provide novel pathways for the treatment of highly complex diseases such as multiple sclerosis, cancer, and hepatitis C, but also contribute to greater costs of development, manufacture, and use of biologics.<sup>10</sup>

With regard to research and development costs, the average cost for biologics is \$1.9 billion,<sup>11</sup> compared to \$1.4 billion for a new chemical compound for small molecule drug.<sup>12</sup> Although biologics only account for 2% of all prescriptions written in the United States, they are responsible for 37% of net drug spending and 93% of

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<sup>6</sup> 42 U.S.C. § 262(i)(1).

<sup>7</sup> 21 U.S.C. § 321(g)(1).

<sup>8</sup> Erwin A. Blackstone & Joseph P. Fuhr, *The Economics of Biosimilars*, 6 AM. HEALTH DRUG BENEFITS 469, 472 (2013).

<sup>9</sup> Hatherill, *supra* note 2, at 155.

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

<sup>11</sup> See Blackstone & Fuhr, *supra* note 8, at 473.

<sup>12</sup> U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-18-40, DRUG INDUSTRY: PROFITS, RESEARCH AND DEVELOPMENT SPENDING, AND MERGER AND ACQUISITION DEALS 5 (2017).

the overall growth in total spending since 2014.<sup>13</sup> The average daily costs for patients using biologics is \$45, while the daily cost for patients relying on small molecule drugs is only \$2.<sup>14</sup> The cost difference between small molecule drugs and biologics cannot be sufficiently explained by differences in research and development spending for entirely new products (about 35%), but may be related to the differences in costs of development and marketing of generic small molecule drugs and biosimilars.

The BPCIA defines biosimilars as biologics that are “highly similar to the reference product notwithstanding minor differences in clinically inactive components” and having “no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency.”<sup>15</sup> However, because of the complexities of biologics and the inherently uncontrollable factors in their manufacturing processes, biologics are sensitive to and altered by changes in their manufacturing processes.<sup>16</sup> Therefore, it is difficult and costly to achieve the required biosimilarity.<sup>17</sup> Compared to the \$1 million to \$4 million that is required to develop a generic small molecule drug, it takes between \$100 million and \$250 million to develop a biosimilar.<sup>18</sup> Because biologics emerge as an important form of therapy plagued by high costs and because the Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman Act”) has been successful in controlling the price of small molecule drugs, Congress sought to replicate the success of the Hatch-Waxman Act by creating the BPCIA to facilitate a new biosimilar market.

## B. *Hatch-Waxman Act and BPCIA*

### 1. Hatch-Waxman Act

The 1962 Amendment of the FDCA requires the Food and Drug Administration (“FDA”) to approve a new drug’s safety and effectiveness based on the data

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<sup>13</sup> Joel Lexchin, *Affordable Biologics for All*, JAMA NETWORK OPEN (Apr. 27, 2020), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2764808> [<https://perma.cc/45PU-JQEC>].

<sup>14</sup> Hatherill, *supra* note 2, at 155–56.

<sup>15</sup> 42 U.S.C. § 262 (i)(2).

<sup>16</sup> Blackstone & Fuhr, *supra* note 8.

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

<sup>18</sup> *Id.* at 470–71.

submitted in its New Drug Application (“NDA”) in order to enter the market.<sup>19</sup> Prior to the enactment of the Hatch-Waxman Act, generic applicants were required to conduct independent clinical trials whose costs comprised a major portion of the expenses for drug development.<sup>20</sup> In 1984, Congress passed the Hatch-Waxman Act, which allowed generic applicants to forego the expenses of research, development, and clinical trials by “piggy-backing” off the data from innovator drugs’ clinical trials through the filing of an Abbreviated New Drug Application (“ANDA”).<sup>21</sup> To obtain approval, the ANDA primarily needs to show that the generic product (1) uses the same active ingredient as the reference product and (2) is bioequivalent to the reference product.<sup>22</sup> The use of ANDAs allowed the generic market to form, and lowered consumer costs for small molecule drugs.<sup>23</sup>

The Hatch-Waxman Act also provided for procedures that allow innovators and generic applicants to litigate patent issues prior to generic market entry. For each NDA, the FDA lists sponsor-identified patents that claim the product or a method of using the product in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”).<sup>24</sup> When a generic applicant submits its ANDA, it must provide a certification with respect to the patents listed under the referenced product.<sup>25</sup> The certification may state (1) that such patent information has not been filed; (2) that such patent has expired; (3) the date on which such patent will expire; or (4) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug.<sup>26</sup> The last kind of certification is commonly known as a “paragraph IV certification” filing. When coupled with an ANDA, the paragraph IV certification constitutes statutory patent infringement that can potentially create a basis for litigation.<sup>27</sup>

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<sup>19</sup> 21 U.S.C. § 355(d).

<sup>20</sup> Krista Hessler 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, 675 (2010).

<sup>21</sup> 21 U.S.C. § 355(j); Hatherill, *supra* note 2, at 157.

<sup>22</sup> 21 U.S.C. § 355(j)(2)(A)(ii), (iv).

<sup>23</sup> Hatherill, *supra* note 2, at 157.

<sup>24</sup> 21 U.S.C. § 355(b)(1)(A); Carver, Elikan & Lietzan, *supra* note 20, at 678.

<sup>25</sup> 21 U.S.C. § 355(j)(2)(A)(vii).

<sup>26</sup> *Id.*

<sup>27</sup> 35 U.S.C. § 271(e)(2).

For forty-five days after the NDA sponsor and the patent owner receive the paragraph IV certification, the ANDA applicant is barred from bringing declaratory judgment action, and the notified party has an opportunity to bring a patent infringement suit.<sup>28</sup> If an infringement suit is brought within the forty-five day period, the final approval of the ANDA is stayed for thirty months or until a court renders a decision of validity and non-infringement; there is no stay if the infringement suit is brought after the forty-five day period.<sup>29</sup> Additionally, the first generic applicant filing a paragraph IV certification for a reference product is entitled to 180-day market exclusivity, during which time no other ANDA that is based on the same reference product may be approved.<sup>30</sup> These provisions provide a framework where both the innovator and the generic manufacturers have incentives—additional period of exclusivity—to comply with the statutory obligations.

## 2. BPCIA

The ANDA provisions of the Hatch-Waxman Act do not apply to biologics, which require a Biologic License Application (“BLA”) to enter the market.<sup>31</sup> Rather, BPCIA provides an abbreviated regulatory path for a biologic to be approved for marketing by proving that: (1) it is biosimilar to a reference product; (2) it is applicable to the same conditions that the reference product has previously been approved for and utilizes the same mechanism of action for those conditions; (3) its route of administration, dosage form, and strength are the same as those of the reference product; and (4) the facility in which the biologic is handled meets the standards designed to assure its safety, purity and potency.<sup>32</sup> Such abbreviated Biologic License Application (“aBLA”) may include information demonstrating that the biologic is “interchangeable” with the reference product, meaning the biologic may be substituted for the reference product without the intervention of the prescribing health care provider because the risk of switching the biologic and the reference product “is not greater than the risk of using the reference product without such alternation or switching.”<sup>33</sup> The first biosimilar that is determined to be

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<sup>28</sup> 21 U.S.C. § 355(j)(5)(B)(iii).

<sup>29</sup> *Id.*

<sup>30</sup> *Id.* § 355(j)(5)(B)(iv).

<sup>31</sup> Carver, Elikan & Lietzan, *supra* note 20, at 677.

<sup>32</sup> 42 U.S.C. § 262(k)(2)(A)(i).

<sup>33</sup> 42 U.S.C. §§ 262(i)(3), (k)(4)(B).



interchangeable with the reference product enjoys a period of regulatory exclusivity for at least one year, preventing the FDA from determining the interchangeability of biologic on the same condition in any subsequent aBLA.<sup>34</sup> However, the FDA has not designated any biosimilar as interchangeable to its reference product.<sup>35</sup>

The BPCIA also provides a mechanism, the “patent dance,” by which the reference product sponsor (“RPS”) and a biosimilar applicant (“Applicant”) can resolve patent disputes before marketing the biosimilar. The patent dance involves two stages and multiple exchanges of information.

An Applicant’s filing of an aBLA triggers the first stage of the patent dance. Within twenty days of the FDA accepting the aBLA for review, the Applicant must provide to the RPS a copy of the aBLA and “such other information that describes the process or processes used to manufacture” the biosimilar.<sup>36</sup> Within sixty days of receiving the aBLA and other information, the RPS shall provide to the Applicant a list of patents (“3A list”) against which it believes a claim of patent infringement could reasonably be asserted and an identification of the patents on the 3A list that the RPS would be prepared to license to the Applicant.<sup>37</sup> Not later than sixty days after receiving the 3A list, the Applicant must respond with a detailed statement that describes the factual and legal basis of its opinion with respect to each listed patent, detailing its status (invalid, unenforceable, or non-infringing) or that the Applicant does not intend to begin commercial marketing of the biosimilar before the patent expires.<sup>38</sup> The Applicant shall also respond to the RPS’s offer to license.<sup>39</sup> The RPS shall respond within sixty days to the Applicant’s assertions of invalidity, unenforceability, or noninfringement.<sup>40</sup> Upon receipt of the RPS’s response, the parties have fifteen days to negotiate in good faith as to which patents should be the subject of an infringement suit.<sup>41</sup> If the parties agree on which patents to litigate, the

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<sup>34</sup> 42 U.S.C. § 262(k)(6).

<sup>35</sup> Philip Chen, Kayleigh McGlynn & Jenny Shmuel, *Biosimilars 2020 Year in Review*, JD SUPRA (Feb. 5, 2021), <https://www.jdsupra.com/legalnews/biosimilars-2020-year-in-review-4933102/> [<https://perma.cc/M6SH-VDQQ>].

<sup>36</sup> 42 U.S.C. § 262(l)(2)(A).

<sup>37</sup> 42 U.S.C. § 262(l)(3)(A).

<sup>38</sup> 42 U.S.C. § 262 (l)(3)(B).

<sup>39</sup> 42 U.S.C. § 262(l)(3)(B)(iii).

<sup>40</sup> 42 U.S.C. § 262(l)(3)(C).

<sup>41</sup> 42 U.S.C. § 262 (l)(4)(A).

RPS shall file suit within thirty days of the agreement.<sup>42</sup> Otherwise, the parties shall simultaneously exchange a list of patents that each believes should be litigated, but the RPS's list shall not outnumber the Applicant's list. The RPS has thirty days to file infringement claims on the lists.<sup>43</sup> The first stage of the patent dance ends with the Applicant notifying the FDA of the suit within thirty days of service, providing a copy of the complaint.<sup>44</sup> Counted from the Applicant's filing the aBLA to the RPS's filing the infringement lawsuit, the first stage should be completed within 245 days.

The second stage is triggered by the Applicant providing the RPS a notice of commercial marketing ("NCM") no later than 180 days before the date it seeks to market its biosimilar.<sup>45</sup> This stage of litigation involves patents that were included on the original 3A lists but not litigated in the first stage, and any patents that the RPS acquired after the exchange of lists occurred and added to the lists.<sup>46</sup> After the RPS receives the NCM and before the first commercial marketing of the biosimilar, the RPS may seek a preliminary injunction prohibiting the Applicant from manufacturing or selling the biosimilar, and both parties may bring declaratory judgment claim.<sup>47</sup> However, if the Applicant does not disclose the aBLA and the manufacturing information pursuant to 42 U.S.C. § 262(l)(2)(A), the RPS may immediately bring declaratory judgment action regarding a product or method-of-use patent; if the Applicant fails to complete the information exchange procedures after the § 262(l)(2)(A) disclosure, then only the RPS, but not the Applicant, may bring declaratory judgment action regarding the patents in the 3A list.<sup>48</sup>

To summarize, the patent dance framework differs from the ANDA litigation framework in four ways. First, there is nothing like the Orange Book, in which all relevant patents must be listed.<sup>49</sup> Although there is a Purple Book, or Lists of

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<sup>42</sup> 42 U.S.C. § 262(l)(6)(A).

<sup>43</sup> 42 U.S.C. §§ 262(l)(4)(B), (l)(5), (l)(6)(B).

<sup>44</sup> 42 U.S.C. § 262 (l)(6)(C).

<sup>45</sup> 42 U.S.C. § 262(l)(8).

<sup>46</sup> *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1672 (2017); 42 U.S.C. § 262(l)(7).

<sup>47</sup> 42 U.S.C. §§ 262(k)(9)(A), (l)(8).

<sup>48</sup> 42 U.S.C. § 262(l)(9).

<sup>49</sup> Adam Houldsworth, *What the Current Wave of Biosimilar Litigation Signals for the Future*, IAM MEDIA (Mar. 4, 2020), <https://www.iam-media.com/litigation/what-the-current-wave-of-biosimilar-litigation-signals-the-future> [<https://perma.cc/2VUW-6Z87>].

Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, that lists all licensed biological products, including biosimilars and their reference products, the patents that cover a biologic are not listed in the original form of the Purple Book.<sup>50</sup> Rather, it is up to the RPS to provide the 3A list according to the information provided by the Applicant.<sup>51</sup> Second, the patent dance procedure envisions resolution of patent disputes regarding manufacturing process patents, which are not included in the Orange Book.<sup>52</sup> Third, there is no 180-day period of exclusivity for the first imitator to market.<sup>53</sup> It seems that Congress might have purported to imitate the 180-day period of exclusivity by providing for the exclusivity for the first interchangeable biologic, but this provision is virtually nonexistent as no biosimilar has ever been determined interchangeable with its reference product. Lastly, patent plaintiffs are not granted an automatic thirty-month stay of approval.<sup>54</sup> It is worth pointing out that, an aBLA cannot be approved until twelve years after the approval of its reference product, but can be submitted merely four years after the approval of its reference product.<sup>55</sup> If the reference product was approved not too long before the effective date of the BPCIA, this provision provides an eight-year period for the parties to complete litigation, which is functionally equivalent to the thirty-month stay for small molecule drugs. However, because the reference products for all of the aBLA filed before October 2017 were approved no later than 2002, and the latest reference product which has an aBLA filed was approved in 2004, no cases have ever benefited from this time difference between permission to submit and approval.<sup>56</sup> The last two differences implicate that there might be less incentive for both the RPS and Applicant, especially those for a mature reference product, to comply with the patent dance procedure compared to the incentive provided by ANDA litigation framework.

The Supreme Court further clarified two issues with respect to the patent dance in *Sandoz v. Amgen*. First, the Court held that § 262(l)(2)(A)'s requirement that

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<sup>50</sup> See *About the Purple Book*, FDA, <https://purplebooksearch.fda.gov/about> [<https://perma.cc/MGE6-VJWW>].

<sup>51</sup> See 42 U.S.C. § 262(l)(3)(A).

<sup>52</sup> See *id.*; 21 U.S.C. § 355(b)(1)(A).

<sup>53</sup> Houldsworth, *supra* note 49.

<sup>54</sup> *Id.*

<sup>55</sup> 42 U.S.C. § 262(k)(7)(A)–(B).

<sup>56</sup> See *infra* Section II.

Applicant provides the RPS with its aBLA and manufacturing information is not enforceable by an injunction under federal law.<sup>57</sup> Specifically, the Court found that failure to disclose the information required by § 262(1)(2)(A) did not constitute an act of artificial infringement, and thus 35 U.S.C. § 271(e) does not apply.<sup>58</sup> Rather, the sole remedy for failure to disclose is found in § 262(1)(9)(C), which “vests in the [RPS] the control that the applicant would otherwise have exercised over the scope and timing of the patent litigation” by allowing the RPS but not Applicant to seek declaratory judgment.<sup>59</sup> On remand, the Federal Circuit held that this failure to disclose is not remedied by state law because BPCIA preempts state law claims.<sup>60</sup>

Second, the Court held that the NCM only had to occur before commercial marketing and that the FDA approval could be achieved later than filing the NCM, rather than the RPS argument that NCM could only be filed after FDA approved the aBLA.<sup>61</sup> This decision allows Applicant to provide the NCM early in the process so that once the FDA approves the biosimilar, Applicant can immediately begin commercial marketing.<sup>62</sup> Moreover, it gave Applicant control of when to start the second stage of litigation—where all patent infringement claims can be raised—allowing Applicant the choice of avoiding the entire patent dance in pursuit of “total war” with the RPS. It appears that *Sandoz* handed over an enormous amount of control over the course of the patent dance to Applicant.

## II. CASE SURVEY

Since the Supreme Court decided *Sandoz v. Amgen* on June 12, 2017, patent infringement lawsuits regarding nineteen different biosimilars have been filed.<sup>63</sup> With the exception of four biosimilars, the RPS has only filed one lawsuit, indicating potential settlement of the second-stage litigation prior to its initiation.<sup>64</sup> In the following case survey, cases directly related to the same biosimilar are not counted

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<sup>57</sup> *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1674 (2017).

<sup>58</sup> *Id.* at 1667.

<sup>59</sup> *Id.* at 1675.

<sup>60</sup> *Amgen Inc. v. Sandoz Inc.*, 877 F.3d 1315, 1327 (Fed. Cir. 2017).

<sup>61</sup> *Sandoz Inc.*, 137 S. Ct. at 1677.

<sup>62</sup> Hatherill, *supra* note 2, at 182.

<sup>63</sup> Goodwin Procter LLP, *BPCIA Litigations*, BIG MOLECULE WATCH, <https://www.bigmoleculerwatch.com/bpcia-patent-litigations/> [<https://perma.cc/H34D-CGCP>].

<sup>64</sup> *Id.*

repeatedly. No case that was filed during this time reached a final judgment on the merits, but all the cases were settled by the parties.<sup>65</sup> There were only three cases in which the biosimilar applicant entirely refused to participate in the patent dance—and in four cases, the biosimilar applicants terminated the first stage of the patent dance before the conclusion of negotiation under § 262(l)(6). Nevertheless, all the RPS recollect the information exchange with the biosimilar applicant during the patent dance in their complaints and alleged at least some deficiencies in the Applicant’s compliance to the procedures provided by BPCIA.

To describe the Applicant’s conduct, the patent dance procedure can be divided into four parts: (1) the initial disclosure, where Applicant provides the RPS a copy of the aBLA and “such other information that describes the process or processes used to manufacture” the biosimilar;<sup>66</sup> (2) the exchange, where the RPS and the Applicant exchange information regarding the patents that the Applicant may infringe by making or selling the biosimilar;<sup>67</sup> (3) the negotiation, where the parties negotiate to agree on a list of patents for litigation, or, if they disagree, come up with a list of patents to sue;<sup>68</sup> and (4) the Applicant provides the RPS with the NCM.<sup>69</sup> A table summarizing the nineteen cases is included at the end of this Section.

#### A. Initial Disclosure

Regarding the initial disclosure, Applicants that participated in the patent dance generally provided the RPS a complete copy of their aBLA. One Applicant that informed the RPS its refusal to participate still provided the RPS with access to its aBLA for 60 days.<sup>70</sup> However, a few Applicants did not entirely cooperate with the RPS from the commencement of patent dance. In three cases, Applicants provided their aBLA in a different format from the Electronic Common Technical Document (“eCTD”) format that is provided to FDA. For example, in *Amgen Inc. v. Mylan Inc.*,<sup>71</sup> the RPS Amgen complained that Mylan’s copy of its aBLA lacked functional hyperlinks that allowed Amgen to access the related document and data as an eCTD

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<sup>65</sup> *Id.*

<sup>66</sup> 42 U.S.C. § 262(l)(2)(A).

<sup>67</sup> 42 U.S.C. § 262(l)(3)(A)–(B).

<sup>68</sup> 42 U.S.C. § 262(l)(4)–(6).

<sup>69</sup> 42 U.S.C. § 262(l)(8).

<sup>70</sup> Complaint at 16, *Genentech, Inc. v. Sandoz Inc.*, No. 17-13507 (D.N.J. filed Dec. 21, 2017).

<sup>71</sup> Complaint at 14, *Amgen Inc. v. Mylan Inc.*, No.17-1235 (W.D. Pa. filed Sept. 22, 2017).

and prohibited Amgen from “saving, copying, annotating or printing” the related documents and data.<sup>72</sup> In *Genentech, Inc. v. Pfizer Inc.*<sup>73</sup> and *Genentech, Inc. v. Samsung Bioepis*,<sup>74</sup> the applicants refused to provide other subsections of the aBLA. In *Amgen Inc. v. Hospira, Inc.*,<sup>75</sup> the Applicant provided the RPS the aBLA in piecemeal, beginning with about 10,000 pages claimed as the full aBLA, and included over 70,000 additional pages in at least two later productions which ended after the statutory deadline.

More strikingly, in all cases but the two between Amgen and Hospira,<sup>76</sup> the RPS alleged that the Applicant failed to provide or only provided insufficient information regarding the manufacturing process of the biosimilar, although the Applicant may disagree about its obligation to provide such information. For example, in *Genentech, Inc. v. Amgen, Inc.*, “a small amount of manufacturing information” was included in aBLA, and the Applicant Amgen additionally produced two manufacturing documents in later productions, one after the RPS identified deficiencies in the Applicant’s production.<sup>77</sup> The RPS asserted that the information was insufficient to establish whether Applicant’s manufacture of the biosimilar would infringe each of the patents identified in the RPS’s 3A list, while the Applicant maintained that it had complied with its disclosure obligations.<sup>78</sup> In *Genentech Inc. v. Celltrion, Inc.*, the Applicant did not provide any manufacture information in its initial disclosure, but waited until providing its statements in response to the 3A list to provide such information so that the Applicant could rely on it.<sup>79</sup> In many other cases such as *Amgen, Inc. v. Mylan Inc.*,<sup>80</sup> the Applicant failed to provide any manufacturing information altogether, even after the RPS requested such documents. Assuming there is an obligation to provide the information

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<sup>72</sup> *Id.*

<sup>73</sup> Complaint at 4, *Genentech, Inc. v. Pfizer Inc.*, No. 19-638 (D. Del. filed Apr. 5, 2019).

<sup>74</sup> Complaint at 7, *Genentech, Inc. v. Samsung Bioepis*, No. 18-1363 (D. Del. filed Sept. 4, 2018).

<sup>75</sup> Complaint at 9, *Amgen Inc. v. Hospira, Inc.*, No. 18-1064 (D. Del. filed July 18, 2018).

<sup>76</sup> *Id.*; Complaint at 8, *Amgen Inc. v. Hospira, Inc.*, No. 20-201 (D. Del. filed Feb. 11, 2020).

<sup>77</sup> Complaint at 6, *Genentech, Inc. v. Amgen, Inc.*, No. 18-924 (D. Del. filed July 2, 2018).

<sup>78</sup> *Id.* at 6–7.

<sup>79</sup> Complaint at 17, *Genentech Inc. v. Celltrion, Inc.*, No. 18-574 (D.N.J. Jan. 12, 2018).

<sup>80</sup> Complaint at 14, *Amgen, Inc. v. Mylan Inc.*, No. 17-1235 (W.D. Pa. filed Sept. 22, 2017).

regarding the manufacture processes and taking the RPS's allegation as true, compliance with this requirement is noticeably low.<sup>81</sup>

### B. Information Exchange

After the RPS provides the Applicant with the 3A list, the Applicant is required to respond with a statement that describes, claim-by-claim, the factual and legal basis that such patent is invalid, unenforceable, or not infringed.<sup>82</sup> Compared to the initial disclosure, compliance with this provision has varied greatly. In addition to the three cases where the Applicant refused to participate in the patent dance altogether, in *Genentech Inc. v. Pfizer Inc.*,<sup>83</sup> the Applicant sent the NCM to the RPS soon after receiving the 3A list and did not participate in further procedures. In six cases, the RPS did not allege any insufficiency regarding the Applicant's response to its 3A list. In two cases, the RPS alleged that the statements were conclusory, while in another four cases, the RPS asserted that there was insufficient manufacturing information or insufficient information to determine infringement or invalidity.

### C. Negotiation Participation and the Timing of NCM

The majority of Applicants participated in negotiation. Of the twelve cases where negotiation concluded, eleven completed negotiations before the statutory deadline.<sup>84</sup> In one case, the Applicant delayed the negotiation for a long time.<sup>85</sup> In all twelve cases, the parties ended the first stage of the patent dance with a list of patents to litigate.<sup>86</sup> However, in the cases filed by AbbVie Inc. regarding the reference product Humira, the RPS complained about the Applicant's "gamesmanship," claiming that the Applicant proposed to only litigate an extremely small number of patents under § 262(l)(5)(A) compared to the large number of patents that the RPS included in its 3A list or its statement under § 262(l)(3)(C). The most extreme example is in *AbbVie Inc. v. Sandoz Inc.*, where the RPS included eighty-four patents in its statement under § 262(l)(3)(C),<sup>87</sup> and the Applicant agreed

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<sup>81</sup> See *infra* Table 1, column "manufacture information disclosure."

<sup>82</sup> 42 U.S.C. § 262(l)(3)(B)(ii)(I).

<sup>83</sup> Complaint, *Genentech Inc. v. Pfizer, Inc.*, No. 17-cv-01672 (D. Del. Nov. 17, 2017).

<sup>84</sup> See *infra* Table 1, column "negotiation participation."

<sup>85</sup> Complaint at 9–10, *Genentech Inc. v. Centus Biotherapeutics LTD*, No. 20-361 (E.D. Tex. Nov. 12, 2020).

<sup>86</sup> See *infra* Table 1, column "number of patents in suit."

<sup>87</sup> Complaint at 18, *AbbVie Inc. v. Sandoz Inc.*, No. 18-12668 (D.N.J. Aug. 10, 2018).

under § 262(l)(5)(A) to litigate only one patent, which brought the maximum number that can be litigated at the first stage to merely two.<sup>88</sup>

Only in three cases, the Applicants refused to participate altogether and thus did not engage in negotiation.<sup>89</sup> In four cases, the Applicants terminated the first stage of the patent dance prematurely by sending the NCM to the RPS without completing the negotiation procedure.<sup>90</sup> For example, in *Genentech Inc. v. Celltrion Inc.*, the Applicant wrote to the RPS after receiving the RPS's statement under § 262(l)(3)(C) indicating that it wished to litigate all the patents on the RPS's 3A list.<sup>91</sup> However, the Applicant did not engage in good faith negotiations as provided under the statute but immediately brought a declaratory judgment lawsuit over all these patents while purporting to provide the RPS with a NCM.<sup>92</sup> Among the four cases, the earliest instance of an Applicant's noncompliance with the BCPIA process occurred when an applicant failed to send a statement under § 262(l)(3)(B), and its NCM was sent fourteen days after the RPS sent the 3A list.<sup>93</sup> Interestingly, Genentech Inc. is the RPS in all four cases where the Applicants partially participated in the patent dance, and six out of the seven cases where the Applicants did not complete the patent dance.<sup>94</sup>

However, although all Applicants that ended the patent dance early also sent the NCM early in the procedure, some Applicants in other cases completed the negotiation after they sent the NCM. Among the eleven cases where the negotiations were concluded, Applicants in five cases sent NCM before the end of the negotiation.<sup>95</sup> The earliest was in *Amgen Inc. v. Hospira, Inc.*, where the Applicant sent the NCM sixteen days after the RPS sent the 3A list.<sup>96</sup> In one other case the Applicant sent the NCM before sending the statement under § 262(l)(3)(B),<sup>97</sup> and in

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<sup>88</sup> *Id.* at 22–23.

<sup>89</sup> *See infra* Table 1, column “negotiation participation.”

<sup>90</sup> *See id.*, column “NCM.”

<sup>91</sup> Complaint at 8–9, *Genentech Inc. v. Celltrion Inc.*, No. 18-95 (D. Del. Jan. 12, 2018).

<sup>92</sup> *Id.* at 9.

<sup>93</sup> Complaint at 6, *Genentech, Inc. v. Pfizer, Inc.*, No. 17-cv-01672 (D. Del. Nov. 17, 2017).

<sup>94</sup> *See infra* Table 1.

<sup>95</sup> *See id.*, column “NCM.”

<sup>96</sup> Complaint at 9, *Amgen Inc. v. Hospira, Inc.*, No. 20-201 (D. Del. Feb 11, 2020).

<sup>97</sup> Complaint at 15, *Amgen Inc. v. Tanvex Biopharma USA, Inc.*, No. 19-cv-1374 (S.D. Cal. July 23, 2019).



two more cases, the Applicant sent the NCM before receiving the RPS's statement under § 262(1)(3)(C).<sup>98</sup>

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<sup>98</sup> Genentech, Inc. v. Pfizer Inc., No. 19-638 (D. Del. Apr. 5, 2019); Genentech Inc. v. Centus Biotherapeutics LTD., No. 20-361 (E.D. Tex. Nov. 12, 2020).

Table 1 Summary of BPCIA patent infringement litigations filed after *Sandoz v. Amgen*, sorted by date of complaint filing.<sup>99</sup>  
Cases with incomplete patent dance are shaded.

case	complaint filed	accused biosimilar	biosimilar status	reference product	reference product original approval	number of patents in 3A list	number of patents in suit	aBLA disclosure	manufacture information disclosure	Statement under sec. 262(i)(3)(B)	negotiation participation	NCM	case status or outcome
AbbVie Inc. v. Boehringer Ingelheim Int'l GMBH, 17-1065 D. Del.	8/2/2017	cytezo	approved	Humira (BLA125057)	12/31/2002	74	8	complete	lack	completed	concluded with agreement	not mentioned in complaint - likely after lawsuit initiated	settled
Amgen Inc. v. Mylan Inc. 17-1235 W.D. Pa.	9/22/2017	FULPHILA	approved and launched	Neulasta (BLA125031)	1/31/2002		2	different format	lack	completed	concluded without agreement	not mentioned in complaint - likely after lawsuit initiated	settled
Genentech Inc. v. Amgen Inc. 17-1407 D. Del.	10/6/2017	MVASI	approved and launched	Avastin (BLA125085)	2/26/2004	27	24	complete	lack	detail unknown	no participation	purported before the end of negotiation	settled
Genentech Inc. v. Pfizer Inc. 17-1672 D. Del.	11/17/2017	Trazemera	approved and launched	Herceptin (BLA103792)	9/25/1998		40	complete	insufficient	no 3B - terminated	no 3B or beyond	14 days after 3A	settled
Genentech Inc. v. Sandoz Inc. 17-13507 D.N.J.	12/21/2017	GP2013	not approved	Rituxan (BLA103705)	11/26/1997		24	60-day access	lack	no 3B - terminated	no participation	not mentioned in complaint - likely after	settled

<sup>99</sup> *BPCIA Litigations*, GOODWIN, <https://www.bigmoleculewatch.com/bpcia-patent-litigations/> [<https://perma.cc/W9SN-S2K3>].

case	complaint filed	accused biosimilar	biosimilar status	reference product	reference product original approval	number of patents in 3A list	number of patents in suit	aBLA disclosure	manufacture information disclosure	Statement under sec. 262(l)(3)(B)	negotiation participation	NCM	case status or outcome
												lawsuit initiated	
Genentech Inc. v. Celltrion, Inc. 18-574 D.N.J.	1/12/2018	Truxima	approved and launched	Rituxan (BLA103705)	11/26/1997	40	40	complete	lack; later provided some with 3B	completed (?)	no participation	before negotiation	settled
Genentech Inc. v. Celltrion, Inc. 18-95 D. Del.	1/12/2018	Herzuma	approved and launched	Herceptin (BLA103792)	9/25/1998	38 in 3B, 18 in 3C	20	complete	lack	insufficient manufacture info and other deficiencies	incomplete	during negotiation	settled
Amgen Inc. v. Kashiv 18-3347 D.N.J.	3/8/2018	TPI G-CSF	not approved	NEUPOGEN (BLA103353)	2/20/1991		17	no disclosure	lack	no 3B - terminated	no participation	immediately with letter re no patent dance	settled
Genentech Inc. v. Amgen Inc. 18-924 D. Del.	7/2/2018	Kanjinti	approved, launched	Herceptin (BLA103792)	9/25/1998	36+1 ((l)(7) addition)	37	complete	insufficient (disputed)	insufficient manufacture info	concluded with agreement	around the end of negotiation	settled
Amgen Inc. v. Hospira, Inc., 18-1064 D. Del.	7/18/2018	NIVESTYM	approved and launched	Neupogen (BLA103353)	2/20/1991	6 (one newly issued under (l)(7))	1	piecemeal; late complete	no mention in complaint	completed	concluded without agreement	not mentioned in complaint - likely after lawsuit initiated	Dismissed with prejudice
AbbVie Inc. v. Sandoz Inc. 18-12668 D.N.J.	8/10/2018	Hyrimoz	approved	Humira (BLA125057)	12/31/2002	84 in 3C	2	complete	lack	insufficient manufacture info	concluded with agreement	not mentioned in complaint - likely after lawsuit initiated	settled
Genentech Inc. v. Samsung Bioepis Co., 18-1363 D. Del.	9/4/2018	Ontruzant	approved and launched	Herceptin (BLA103792)	9/25/1998	>21	21	redacted portions	lack	insufficient manufacture info	concluded with agreement	not mentioned in complaint - likely after lawsuit initiated	settled
Genentech Inc. v. Pfizer Inc. 19-638 D. Del.	4/5/2019	Zirabev	approved and launched	Avastin (BLA125085)	2/26/2004	31	22	incomplete and	lack	not all patents	concluded with agreement	before 3C	settled

case	complaint filed	accused biosimilar	biosimilar status	reference product	reference product original approval	number of patents in 3A list	number of patents in suit	aBLA disclosure	manufacture information disclosure	Statement under sec. 262(1)(3)(B)	negotiation participation	NCM	case status or outcome
								different format					
Immunex v. Samsung Bioepis Co., 19-11755 D.N.J.	4/30/2019	ETICOVO	approved	Enbrel	11/2/1998		5	no disclosure	lack	No disclosure	no participation	after lawsuit initiated	Pending (administratively stayed)
Amgen Inc. v. Tanvex Biopharma USA Inc., 19-1374 S.D. Cal.	7/23/2019	TX-01	not approved	Neupogen (BLA103353)	2/20/1991		1	complete	lack	insufficient manufacture info	concluded with agreement	before 3B	settled
Amgen Inc. v. Hospira, Inc., 20-201 D. Del.	2/11/2020	Nyvepria	approved	Neulasta (BLA125031)	1/31/2002		1	different format	no mention in complaint (?)	completed	concluded with agreement	16 days after 3A	pending
Genentech Inc. v. Samsung Bioepis Co., 20-859 D. Del.	6/28/2020	SB8	not approved	Avastin (BLA125085)	2/26/2004		14	complete	lack	conclusory	concluded with agreement	not mentioned in complaint - likely after lawsuit initiated	pending
Genentech Inc. v. Centus Biotherapeutics LTD., 20-361 E.D. Tex.	11/12/2020	FKB238	not approved	Avastin (BLA125085)	2/26/2004		10	complete	lack	conclusory	concluded late with agreement	before 3C	settled
AbbVie Inc. v. Alvotech HF., 21-2258 N.D. Ill.	4/27/2021	AVT02	not approved	Humira (BLA125057)	12/31/2002	63 (62 in 3C)	4	complete	no mention but likely lack (complaint at 14, 15)	no additional evidence beyond aBLA; lack support for non-infringement of several patents	concluded with agreement	not mentioned in complaint – NCM provided on May 11, 2021	pending

### III. REASONS AND EFFECTS

#### A. Purpose of Patent Dance and Primary Issues

The BPCIA represents a compromise between the innovator industry and the biosimilar manufacturers that aim to achieve a balance between the interests of innovators and the interests of consumers.<sup>100</sup> Efficient resolution of patent disputes through the patent dance before the launch of a biosimilar is an important means to that end.<sup>101</sup> Starting in 2006, before the enactment of the BPCIA, Congress was actively engaged in legislation to regulate biosimilar approval.<sup>102</sup> Various bills that were introduced (but not passed) failed because of their imbalance or inefficiency; the reasons for their failure also reflected Congressional intent behind the BPCIA.

For example, H.R. 6257, introduced by Representative Henry Waxman in 2006, explicitly provided that the decision to initiate the patent dispute process “is left entirely to the discretion of the applicant.”<sup>103</sup> The patent provisions of this and Waxman’s other biosimilar bills were criticized by the innovator industry as having the potential to weaken biotechnology patents and incentives to develop new biological therapies.<sup>104</sup> For instance, Teresa Rea, President of the American Intellectual Property Law Association (“AIPLA”), criticized this approach because it did not provide the RPS with “any access to information to determine whether the follow-on product likely infringes any of the reference product holder’s patents.”<sup>105</sup> Without allowing for all patent disputes to be resolved prelaunch, these disputes would strain the federal judiciary system with their complex legal and scientific questions in preliminary injunction proceedings.<sup>106</sup>

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<sup>100</sup> Jon Tanaka, “*Shall*” We Dance? Interpreting the BPCIA’s Patent Provisions, 31 BERKELEY TECH. L.J. 659, 680 (2016).

<sup>101</sup> Dov Hirsch, *The Riddle of the Mysterious Patent Dance Wrapped in an Enigma: Is the Patent Dance of the BPCIA Optional or Mandatory?*, 27 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 645, 681–82 (2017).

<sup>102</sup> Tanaka, *supra* note 100, at 662.

<sup>103</sup> H.R. 6257, 109th Cong. § 3(a)(2) (2006).

<sup>104</sup> *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. On Courts and Competition Pol’y of the Comm. on the Judiciary H.R.*, 111th Cong. 197 (2009) [hereinafter *Biologics Hearings*].

<sup>105</sup> *Id.* at 208.

<sup>106</sup> *Id.* at 201.

In contrast, H.R. 5629, introduced by Representative Anna Eshoo in 2008, required the Applicant to provide the RPS the aBLA and manufacturing information,<sup>107</sup> and limited the Applicant's ability to bring a declaratory judgment action within the latter 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>108</sup> These provisions were criticized by generic companies and supporters primarily for the lengthy data exclusivity period and needless roadblocks to access.<sup>109</sup>

This legislative history implies that one of the innovator industries' primary concerns is access to information regarding the follow-on product. For biologics, the complexities of the big molecule present specific problems for enablement and written description of a product patent, but the particular manufacturing process is indispensable in creating that specific biologic product without any variations.<sup>110</sup> Thus, many innovator manufacturers not only protect their products with product patents, formulation patents, and method-of-use patents, but also with manufacturing process patents that can effectively exclude their competitors from making a biological product in the same manner.<sup>111</sup> However, without a scheme like the patent dance, competitors rarely have access to each other's manufacturing processes, because the information is almost always protected as a trade secret or other confidential information. Patented technology and FDA filings are kept confidential as well.<sup>112</sup> Therefore, the RPS might be unable to determine whether any of its manufacturing patents are infringed, and likely would not be able to sufficiently state a claim based on plausible factual allegations. On the other hand, the RPS might not want to risk its process patents for invalidity during litigation if it is likely that the patents are not infringed.<sup>113</sup> Therefore, accurate information regarding the Applicant's manufacturing process is crucial for protecting the RPS's innovation.

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<sup>107</sup> H.R. 5629, 110th Cong. § 101(a)(2) (2008) (proposing amendment to PHSA § 351(l)(4)(A)(i)); Biologics Hearings, *supra* note 104, at 204.

<sup>108</sup> *Id.* (proposing amendment to PHSA § 351(l)(6)).

<sup>109</sup> Tanaka, *supra* note 100, at 666.

<sup>110</sup> Hirsch, *supra* note 101, at 655.

<sup>111</sup> *Id.*

<sup>112</sup> *Id.* at 677.

<sup>113</sup> *Id.* at 677–78.

Nevertheless, for the disclosure of manufacturing process information, the Applicant may be concerned about its trade secrets or other confidential information even if BPCIA protects the confidentiality of such information and enforces the provisions with injunctive relief.<sup>114</sup> The stakes for losing the secrecy of that information are probably high. In regard to the legislative history, another one of the generic industry's concerns is time and efficiency.<sup>115</sup> With the high cost of developing a biosimilar, the difficulty of winning market share from the innovator biologics, and the lack of exclusivity against later-filed biosimilars with the same reference product, biosimilar applicants want fast clarity for the potential patent disputes.<sup>116</sup> This concern may also explain the lack of stay of approval under the BPCIA compared to the Hatch-Waxman Act.<sup>117</sup> The final provisions of the BPCIA as it passed reflects the compromise between the innovator industry and the generic industry, but as reflected in Section IV, these issues might not be completely solved.

### B. Analysis of Applicants' Behavior

#### 1. Completion of Negotiation

Complying with the patent dance procedure allows Applicants to choose the most critical patents to focus their resources on and to have certainty regarding these patents.<sup>118</sup> Under *Sandoz v. Amgen*, however, the sole "penalty" of noncompliance is merely losing this benefit.<sup>119</sup> Therefore, whether an Applicant would participate in and complete the patent dance mostly depends on whether it believes the benefits of obtaining the information from the RPS, controlling the litigation, and being able to bring declaratory judgment actions are worth the potential costs and risks.<sup>120</sup>

The facts in the cases in Section II above show that for a period of time after *Sandoz v. Amgen* was decided, the Applicants probably considered the benefits of

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<sup>114</sup> 42 U.S.C. § 262(l)(1)(H).

<sup>115</sup> See *supra* note 107.

<sup>116</sup> Houldsworth, *supra* note 49.

<sup>117</sup> See Carver, Elikan & Lietzan, *supra* note 20, at 736 (recalling that Mr. Downey, testifying on behalf of Barr Pharmaceuticals, a generic manufacturer, propose that the biosimilar legislation should not provide a stay of FDA approval of the biosimilar application based on initiation of patent litigation).

<sup>118</sup> Hatherill, *supra* note 2.

<sup>119</sup> *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1675 (2017).

<sup>120</sup> Goodwin Procter LLP, *Guide to Biosimilars Litigation and Regulation in the U.S. Appendix E* (Oct. 2021).

patent dance not worth the costs and risks. None of the six biosimilars involved in litigation from October 6, 2017, to March 8, 2018, had their Applicants complete the patent dance.<sup>121</sup> However, this trend ended soon afterwards, with only one biosimilar not having completed the patent dance.<sup>122</sup> One possible reason is that, at the end of this period, the biosimilar industry had observed some negative impacts resulting from failing to complete the patent dance.

First, at least partially participating in the patent dance would force the RPS to list all patents in the 3A list, or lose the right to assert them, and thus not participating increases the uncertainty for the biosimilars down the road.<sup>123</sup> Second, once the Applicant has made it clear that it would not complete the patent dance, the RPS may bring lawsuit on all the patents in its 3A list,<sup>124</sup> which may overwhelm the Applicant's resources and the federal district court, and lead to "the Applicant's biggest nightmare" of preliminary injunction against the Applicant.<sup>125</sup> For example in *Sandoz Inc. v. Amgen Inc.*, Sandoz was forced to delay the launch of its biosimilar and lost millions of dollars, spending time and money that could have been used to conduct the post-market research necessary to show interchangeability.<sup>126</sup> During litigation, Amgen capitalized on an exclusive market for an additional sixteen months and secured over one billion dollars from sales of the reference product.<sup>127</sup> Third, failing to complete the patent dance may cost the Applicant's right to file a declaratory judgment action.<sup>128</sup> Many district courts have held that an Applicant's declaratory relief is conditioned on full compliance with the patent dance up to the end of the negotiation, and thus will dismiss the Applicants' declaratory judgment actions for failure to state a claim for relief.<sup>129</sup> These reasons might be a cost that

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<sup>121</sup> See *supra* Table 1, shaded lines.

<sup>122</sup> *Id.*

<sup>123</sup> 35 U.S.C. § 271(e)(6); Yang Li, *Does it Still Take Two to Tango? A Modern Interpretation of the BPCIA's Patent Dance*, 9 N.Y.U. J. INTELL. PROP. & ENT. L. 107, 126 (2019).

<sup>124</sup> 42 U.S.C. § 262(l)(9)(B).

<sup>125</sup> Li, *supra* note 123, at 126–27.

<sup>126</sup> Fu, *supra* note 1, at 8.

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

<sup>128</sup> Li, *supra* note 123, at 128.

<sup>129</sup> See, e.g., *Celltrion, Inc. v. Genentech, Inc.*, No. 18-cv-00274-JSW, 2018 WL 2448254 \*1-\*2, \*8 (N.D. Cal. May 9, 2018).



many Applicants, at least when the reference product implicates a large portfolio, are not willing to take.

However, when the reference product's patent portfolio is very small, and the patents are known, it might be in the Applicant's best financial interest to skip the patent dance.<sup>130</sup> There would be no need to separate the litigation into two phases, and accelerating the litigation to clear the roadblocks barring market entry of the biosimilar for the Applicants seizing market share could be more beneficial than controlling the litigation, especially when the Applicant anticipates its biosimilar will obtain FDA approval in the short-term.<sup>131</sup> This idea is supported by the only case where the Applicant skipped the patent dance that was filed after the pattern of incomplete patent dances ended. That case was *Immunex Corp. v. Samsung Bioepis Co.*, where the RPS brought suit against five patents,<sup>132</sup> which is few compared to tens of patents often in a 3A list.

## 2. Choices of Patents

The Applicants' decision during negotiation may indicate that there might be some other scenario under which the Applicant would prefer to litigate all patents together. In *Genentech v. Amgen Inc.*,<sup>133</sup> the Applicant agreed to litigate all the patents in the 3A list in the first stage and sent the NCM around the end of the negotiation, which would enable declaratory judgment claims in the subsequent litigations.<sup>134</sup> It is possible that Amgen, as a player in both the innovator industry and biosimilar industry, has sufficient resource for a full-blown litigation on all patents to save time. In contrast, in *AbbVie Inc. v. Sandoz Inc.*, the negotiation concluded with the parties deciding to bring suit on two patents, while there were eighty-four patents included in the RPS's statement under § 262(1)(3)(C).<sup>135</sup> This means that the Applicant intended to push almost all the patents to the second stage of the litigations. There are three other cases with only one or two patents in suit (although the number

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<sup>130</sup> Li, *supra* note 123, at 125.

<sup>131</sup> *Id.*

<sup>132</sup> Goodwin Procter LLP, *supra* note 120.

<sup>133</sup> *Genentech, Inc. v. Amgen Inc.*, 460 F. Supp. 3d 510 (D. Del. 2019).

<sup>134</sup> *See* 42 U.S.C. § 262(1)(9)(A).

<sup>135</sup> Goodwin Procter LLP, *supra* note 120.

of patents in the 3A list is unclear from the complaint),<sup>136</sup> indicating a similar choice unless the patent portfolio of the reference product in each case was extremely small.<sup>137</sup> Notably, in two of these cases the Applicant also sent the NCM early in the process,<sup>138</sup> which indicates an intent to accelerate the launch of the biosimilar and disregard litigation risks from the patents in the second stage of litigation.<sup>139</sup> These cases imply that for many biosimilar applicants, there might not be much difference between the patents that may block their launching of the biosimilars and the rest of the patent portfolio, and the two stages of litigation under BPCIA might be unnecessary in their cases.

### 3. Disclosure of Manufacturing Process Information

Additionally, as failure to disclose under § 262(1)(2)(A) is not enforceable against by injunctive relief,<sup>140</sup> it is unclear what repercussions there are, if any, if the Applicant only fails to disclose some but not all of the information provided by § 262(1)(2)(A). Thus, whether an Applicant would completely disclose the information provided by § 262(1)(2)(A) entirely depends on how it would perceive the costs and benefits inherent in the disclosure itself.

Section II shows that in all the cases except the two between Amgen and Hospira, the RPS plead that the Applicant did not disclose sufficient information regarding manufacturing process.<sup>141</sup> As discussed above in subsection A, for biologic manufacturers, manufacturing processes are often covered by trade secrets and confidentiality, and frequently, a process may be used for different products. Therefore, when the information is no longer secret, the manufacturer will lose significant competitive advantage from that information. Although the BPCIA provides for confidential access to the disclosures and injunctive relief against violation of the confidentiality,<sup>142</sup> the stakes might simply be too high for the

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<sup>136</sup> See *supra* Table 1; Complaint at 15–16, *Amgen Inc. v. Mylan Inc.*, No. 17-1235 (W.D. Pa. Sept. 22, 2017); Complaint at 15–17, *Amgen Inc. v. Tanvex Biopharma USA Inc.*, No. 19-1374 (S.D. Cal. July 23, 2019); Complaint at 9–10, *Amgen Inc. v. Hospira, Inc.*, No. 20-201 (D. Del. Fed. 11, 2020).

<sup>137</sup> See *supra* note 136.

<sup>138</sup> See *id.*

<sup>139</sup> See *id.*

<sup>140</sup> *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1667 (2017).

<sup>141</sup> See *supra* Table 1, column “manufacture information disclosure.”

<sup>142</sup> 42 U.S.C. § 262(l)(1).

Applicant to disclose the information to a competitor who has already been the incumbent in the market.

Additionally, without the disclosure provided by the patent dance, it is extremely unlikely that the RPS can have access to much information about the Applicant's manufacturing process. The BPCIA also provides that if the Applicant completes the patent dance, the RPS cannot enforce any patents that are not listed in the 3A list.<sup>143</sup> Therefore, it is possible that some Applicants are hoping that with the lack of information, the RPS would omit certain process patents from the 3A list and be further barred from litigating those patents. On the other hand, claiming that the Applicant disclosed insufficient information could be a pleading strategy of the RPS, who may attempt to preserve a potential claim for patents that might be implicated by manufacturing process information emerges during discovery. This possibility is indicated by the RPS complaint that states the Applicant failed to disclose manufacturing information but still finished the patent dance, as the RPS would probably proceed to bring a declaratory judgment lawsuit and utilize the discovery process if the information was indeed so scarce that it could not generate an effective 3A list, rather than patiently going through the rest of the exchange.<sup>144</sup> Nonetheless, other reasons may cause the RPS to continue the patent dance even though it suspects the Applicant concealed manufacturing information. This illustrates the difficulties in discerning whether the manufacturing information is sufficiently disclosed during the patent dance and further emphasizes that the enforcement to ensure disclosure is currently insufficient.

#### 4. The Impact of the Patent Dance

The major entry barriers against a biosimilar include the patent rights and the regulatory approval. The foundation of both is often information that is not available to the biosimilar applicant. Conversely, information regarding biosimilars that are unknown to the RPS may also lead to unwillingness to start negotiation and difficulties to start litigation. These difficulties comprise the high transactional costs for the parties to reach agreements for clearing the path for biosimilars. BPCIA lowers the entry barrier of regulatory approval by allowing an aBLA to obtain

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<sup>143</sup> 35 U.S.C. § 271(e)(6).

<sup>144</sup> Complaint at 7–9, *Genentech v. Samsung Bioepis*, No. 18-1363 (D. Del. Sept. 4, 2018) (noting the RPS asserted that the applicant failed to comply with § 262(l)(2) which “caused Bioepis to forfeit any rights under the BPCIA that were contingent upon its compliance with those obligations,” which seemed to allow Genentech to take over the control over the patent litigation. However, Genentech nonetheless completed the patent dance without bringing the declaratory judgment claim immediately and litigated only the patents that the parties agreed on during the patent dance.).

approval through showing the biosimilarity; it further recognizes the high heterogeneity of biologics by permitting the FDA to determine an element of aBLA listed in § 262(a)(2)(A)(i) to be unnecessary.<sup>145</sup> On the other hand, the BPCIA may intend to lower the entry barrier formed by the uncertainty with regard to the patent rights by prescribing the patent dance procedure for all biosimilars to go through.<sup>146</sup>

The outcomes of related patent litigations suggest that the patent dance has facilitated the negotiations and settlements between the RPSs and the Applicants.<sup>147</sup> For one thing, the patent dance requires information exchange that does not exist in traditional patent infringement suits. This increased information exchange weakens the entry barrier that an Applicant faces. Once both parties have exchanged a significant amount of information and the litigation begins, the patents in question and other technological details regarding the product become clear between the parties. This higher transparency leads to the parties having a better assessment and consensus of their situations, which ultimately facilitates the settlements that save litigation costs and significantly clear the risks for the parties. In many cases, however, it is also likely that the Applicants are forced into settlements of less favorable conditions because of the sheer number of patents that emerge during the patent dance and the associated potential litigation costs.<sup>148</sup>

Although the patent dance seems to be effective overall, its efficiency for specific cases may be questionable. Parties would benefit more from the information exchange when there is a large amount of inaccessible information. They would benefit from the two-phase litigation process when a large number of patents that the referenced product reads on remain in force for a majority of the twenty-year statutory period. When the unexpired patents are few and well known, the time and costs of the patent dance probably would outweigh the benefit that an Applicant

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<sup>145</sup> 42 U.S.C. § 262(k)(2)(A)(ii).

<sup>146</sup> See Carver, Elikan & Lietzan, *supra* note 20, at 776, 790, 799, 801 (noting Representative Eshoo, AIPLA, and Biotechnology Innovation Organization have expressed their support for a pre-market patent litigation process that allows early resolution of patent disputes. The Federal Trade Commission also commented that “a pre-marketing patent litigation process can create consumer benefits by enabling biosimilar applicants to enter the market sooner than they otherwise would by allowing early resolution of patent litigation,” but the agency later concluded in a report that such procedures were not necessary.).

<sup>147</sup> See *supra* Table 1, column “case status or outcome.”

<sup>148</sup> See *AbbVie v. Sandoz*, No. 18-12668 (D. N.J. Aug. 10, 2018) (Seventy-four patents were included in the 3A list, and the case was settled in sixty-seven days); *but see AbbVie v. Boehringer Ingelheim*, No. 17-1065 (D. Del. Aug. 2, 2017) (eighty-four patents were included in the 3A list and the parties spent 651 days since filing the complaint to reach a settlement).

would receive, and the Applicant may decline to participate.<sup>149</sup> Consequently, in the latter situations, a mandatory patent dance would impose costs on the Applicant including time, resources, and disclosure of its own information without much benefit. Therefore, it appears that the holding of *Sandoz v. Amgen*—that the patent dance is not mandatory—recognizes this potential and avoided additionally increasing costs for biosimilar Applicants, although choosing to not participate would preclude the Applicant from bringing declaratory judgment claims.<sup>150</sup> As time goes by and the exclusivities for the more mature biologics expire, it is possible that there will be more reference products that imply fewer patents which make the two-phased patent dance scheme less efficient for the market.

Furthermore, the intent of the patent dance to improve information flow may have been frustrated with respect to the manufacturing process information, demonstrated by the Applicant's unwillingness to disclose such information.<sup>151</sup> It is noticeable that the Applicant bears a greater burden from disclosure regarding manufacturing process during the patent dance; the RPS does not have to disclose beyond the extent that is necessary to enforce against the potential infringement that the Applicant's disclosure implicate. Typically the RPS discloses manufacturing process patents, which are public information.<sup>152</sup> Moreover, the RPS's 3A list might be inherently insufficient with regard to lowering the information barrier compared to the Orange Book listing in the Hatch-Waxman Act, because the Orange Book informs generic manufacturers even before their development, while the biosimilar Applicant receives the list of patents only after they have participated in the patent dance or have been sued. At this point the Applicant has incurred huge expenses for development and submitted the aBLA with a product that is at the doorstep of the market.<sup>153</sup> In conclusion, it appears that the patent dance scheme can be improved to further enhance the efficiency of the biosimilar market.

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<sup>149</sup> Houldsworth, *supra* note 49.

<sup>150</sup> See *Celltrion, Inc. v. Genentech, Inc.*, No-18-cv-00274-JSW, 2018 WL 2448254, at \*2 (N.D. Cal. May 9, 2018).

<sup>151</sup> See *supra* Table 1, subsection VI.B.3.

<sup>152</sup> 42 U.S.C. § 262(l)(3)(A); see Yaniv Heled, *Follow-on Biologics Are Set Up to Fail*, 2018 U. ILL. L. REV. ONLINE 113, 118–19 (2018).

<sup>153</sup> Fu, *supra* note 1, at 8–9.

#### IV. POTENTIAL SOLUTIONS FOR IMPROVING BPCIA

Many have commented that the BPCIA failed to meet its goal of accelerating biosimilar development or increasing biologic accessibility, as the approval of biosimilars in the United States keeps trailing that in Europe.<sup>154</sup> Various solutions have been proposed by both commentators and Congress members, with a focus on different aspects of BPCIA limitations.

Following *Sandoz v. Amgen*, some commentators opined that Congress should amend the BPCIA and make it clear that § 262(l)(2)(A) is enforceable by injunctive relief.<sup>155</sup> They argued that this would conform with the intent of the legislators as reflected by the legislative history,<sup>156</sup> better protect the interests of the RPSs, and encourage the parties “to use the entirety of the mechanism and consequently enjoy its benefit of streamlining litigation and statutorily supported negotiations.”<sup>157</sup> However, as analyzed above, injunctive relief may impose additional costs on the biosimilar Applicants, while under the current scheme, the Applicants mostly have complied with the patent dance procedure. Therefore, this paper argues that injunctive relief enforcement of disclosure under § 262(l)(2)(A) is unnecessary and unhelpful for improving biosimilar development.

An approach that is much more favorable to biosimilars has been proposed before Congress as The Biologic Patent Transparency Act (2019 Bill).<sup>158</sup> By requiring the RPS’s disclosure of potentially infringeable patents, this bipartisan bill addressed a common criticism of the BPCIA that “the patent dance has a potential to tip the scales in favor of an already advantaged RPS by graciously offering them a biosimilar applicant’s product and manufacturing information, which can be leveraged to engage in preliminary market-exclusion tactics.”<sup>159</sup> Specifically, the bill requires holders of an approved biologic to submit a list of patents the holders believe a claim of patent infringement could reasonably be asserted within thirty days of approval, which must be further updated within thirty days if a new patent regarding

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<sup>154</sup> See, e.g., Simone A. Rose & Tracea Rice, *The Biosimilar Action Plan: An Effective Mechanism for Balancing Biologic Innovation and Competition in the United States?*, 51 U. PAC. L. REV. 539, 557 (2020).

<sup>155</sup> See, e.g., Hatherill, *supra* note 2, at 182–89.

<sup>156</sup> *Id.* at 182–86.

<sup>157</sup> *Id.* at 186–88.

<sup>158</sup> The Biologic Patent Transparency Act, S. 659, 116th Cong. (1st Sess.) (2019).

<sup>159</sup> Rose & Rice, *supra* note 154, at 573.

the product is issued.<sup>160</sup> These requirements track some key provisions of the Hatch-Waxman Act, but are broader as they include manufacturing process patents, probably because of their central role in defining the identity of a specific biologic product.<sup>161</sup>

The Biologic Patent Transparency Act steps up the BCPIA's undertone of improving transparency, which would save the Applicants' own "patent search and analysis efforts to discern the nature of the often large and complex patent estates protecting biologics."<sup>162</sup> This information will likely enhance settlement between parties before the litigation, and allow the Applicant to construct more realistic predictions in anticipation of litigation so that it may reduce litigation costs and expedite settlement negotiations.<sup>163</sup> However, this bill does not offer a complete solution to the manufacturing process disclosure problem, as much of the imbalance within the patent dance scheme results from a majority of the information being protected as trade secret.<sup>164</sup> Additionally, as this bill is focused on patent transparency, it also does not address the power over the Applicant that is brought by the number of patents associated with a specific product. Moreover, this bill is contradictory to the current information exchange provisions during the patent dance.<sup>165</sup> Assuming that the bill only displaces the § 262(l)(3)(A) requirements, the incentive for an Applicant to participate in patent dance may be further reduced, and comparatively stronger enforcement approach would be necessary to ensure participation of the Applicants.

The Biologic Patent Transparency Act was not passed. Instead, Congress altered the BPCIA framework by § 325 of Division BB of the Consolidated Appropriations Act (2020 Amendment) enacted on December 27, 2020, like BPCIA

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<sup>160</sup> The Biologic Patent Transparency Act, *supra* note 158, § 2(a); Lisa Mandrusiak, *Biologic Patent Transparency Act—New Bill Aimed at Biologics*, OBLON (Mar. 12, 2019), <https://www.oblon.com/biologic-patent-transparency-act-new-bill-aimed-at-biologics>.

<sup>161</sup> Mandrusiak, *supra* note 160.

<sup>162</sup> Adam Houldsworth, *Surprise change to FDA Purple Book creates risks and opportunities for biosimilar producers*, IAM (Jan. 7, 2021), <https://www.iam-media.com/law-policy/surprise-change-fda-purple-book-creates-risks-and-opportunities-biosimilar-producers> [hereinafter Houldsworth, *Surprise change to FDA Purple Book*].

<sup>163</sup> Fu, *supra* note 1, at 12.

<sup>164</sup> See Rose & Rice, *supra* note 154, at 574–75.

<sup>165</sup> See *id.* at 573.

was passed as a part of the massive Affordable Care Act.<sup>166</sup> Titled as “Biological Product Patent Transparency,” this section requires the FDA to publish in its Purple Book—which is the Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations—a list of biologic exclusivities and patents that the RPS have included in the 3A lists they send to Applicants during patent dance.<sup>167</sup>

Compared to the 2019 Bill, which provides the benefit of the RPS’s patent listing to all potential Applicants before their development, the 2020 Amendment does not benefit the first Applicant that imitates a specific reference product.<sup>168</sup> If the first or more Applicants did not participate in the patent dance and thus the patent dance did not generate a 3A list, such listing would not exist.<sup>169</sup> Moreover, each 3A list is specific to a biosimilar. Thus, for each new Applicant, there is always the possibility that certain patents applicable to its biosimilar have not been listed, which remains an uncertainty until the Applicant spends resources for patent research or analysis or until the patent dance begins.<sup>170</sup> Additionally, sensitive information about the biosimilar, including its secret processes, may also be revealed by the listing, as many biosimilar manufacturers favor confidential exchange of the 3A lists.<sup>171</sup> Considering the competition and litigation between biosimilar manufacturers, concerns about the 3A list revealing biosimilar information and the listing helping a biosimilar manufacturer that comes later may further discourage a biosimilar manufacturer to be the first applicant for a specific reference product. Nevertheless, the 2020 Amendment shares most of the benefit with the 2019 Bill and will probably result in a more prosperous biosimilar market.

Additionally, Senator John Cornyn proposed to balance the BPCIA from another aspect, which is the power carried by the number of patents associated with a specific reference product, in the Affordable Prescriptions for Patients Act

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<sup>166</sup> Houldsworth, *Surprise change to FDA Purple Book*, *supra* note 162; Heled, *supra* note 152, at 116–17.

<sup>167</sup> Consolidated Appropriations Act of 2021, Pub. L. No. 116–260, 134 Stat. 1182, 2936–38; Houldsworth, *Surprise change to FDA Purple Book*, *supra* note 162.

<sup>168</sup> Houldsworth, *Surprise change to FDA Purple Book*, *supra* note 162.

<sup>169</sup> *Id.*

<sup>170</sup> *Id.*

<sup>171</sup> *Id.*



(“Cornyn Bill”).<sup>172</sup> Specifically, this bill proposes to limit the number of asserted patents that were filed more than four years after the reference product was approved or cover manufacturing processes that the RPS does not use in an infringement action to twenty.<sup>173</sup> The limitation only applies when the Applicant has completed the patent dance, and the RPS can only increase the number of patents asserted when the court decides that good cause is shown.<sup>174</sup> It also does not apply to a patent that claims a biological product or a method of using that product.<sup>175</sup>

The Cornyn Bill targets with surgical precision the RPS’s use of newly applied manufacturing process patents to extend its exclusivities of mature biologics and heightens the entry barriers to the markets that the RPS has already monopolized. If passed, the bill could discourage the RPS from applying for manufacturing process patents just to reinforce its stronghold on mature products and encourage them to develop new products. At the same time, the Cornyn Bill provides the limitations on asserted patents as an incentive for the applicant to complete the patent dance. As discussed above in Section II, however, parties have disputed whether the Applicant has completed § 262(l)(2)(A) disclosure. Therefore, this Article argues it might be clearer to specify that the court should dismiss the claims on patents beyond the limit only when the Applicant shows that it has completed the patent dance and has disclosed all the required information including the manufacturing process information. This bill is a reintroduction of a similar 2019 version but has yet to be passed.

This Article argues that the 2019 Bill combined with the patent number provisions in the Cornyn Bill and the Applicant’s completion of the patent dance determined by a court, would improve the balance of the BPCIA and enhance the prosperity of biosimilar market. Rigorous enforcement of the Cornyn Bill’s requirement that the Applicant must complete the patent dance may also improve the manufacturing process information disclosure situation. The Author has not found any proposal addressing the possibility that the patent dance scheme may not be efficient for biosimilars with a reference product with few unexpired patents. This Article argues that, within the scheme of the 2019 Bill, when the listed patents for a specific product is below a certain number and other limited circumstances decided by the Congress, the Applicant should be allowed to petition to the FDA to not participate in the patent dance once it has satisfied the disclosure requirement under

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<sup>172</sup> Affordable Prescriptions for Patients Act of 2021, S.1435, 117th Cong. (2021).

<sup>173</sup> *Id.* § 3(a)(2).

<sup>174</sup> *Id.*

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

§ 262(l)(2)(A). Once the petition is granted, both parties are relieved from the duties of the patent dance except for the NCM and can immediately bring lawsuits regarding all the patents listed in the Purple Book. These proposals in combination should improve the transparency, balance and flexibility of the BPCIA, and facilitate a more prosperous biosimilar market.

## V. CONCLUSION

The BPCIA litigations brought after *Sandoz v. Amgen* showed that the patent dance scheme facilitates negotiation and settlements between the RPS and the Applicants, although there are limitations such as insufficient disclosure of an Applicant's manufacturing process information and the possibility that two-phased litigations are inefficient under certain circumstances. The patent dance has also been criticized for the imbalance of disclosure requirements between the RPS and the Applicants. Different proposals of improving the patent dance scheme have been proposed. Congress has amended the BPCIA to require inclusion of 3A lists in the Purple Book, which would reduce the entry barrier for biosimilar Applicants, but the impact might be limited. A three-part solution that includes: mandatory listing of reference product patents, limiting assertion of later filed manufacture process patent, and increasing flexibility on patent dance participation may improve the efficiency of the patent dance scheme and develop a more prosperous biosimilar market.