

## RUMBLE IN THE BPCIA: BIOLOGICS VS. BIOSIMILARS

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### INTRODUCTION

Modern medications can be separated into two distinct categories: synthetic chemical drugs (“synthetic drugs”) and drugs derived from biological sources (“biologics”). Synthetic drugs are small-molecule drugs made of chemicals and can typically be copied and reproduced cheaply.<sup>1</sup> Biologics are giant molecule drugs derived from living organisms and are relatively expensive to copy and

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<sup>1</sup> See Thomas Morrow, *Defining the Difference: What Makes Biologics Unique*, BIOTECHNOLOGY HEALTHCARE 24, 26 (2004), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3564302/>.

reproduce.<sup>2</sup> While vaccines and many therapeutic cancer drugs are well known biologics,<sup>3</sup> biologics used to be a relatively small portion of large pharmaceutical companies' revenue. Now, with advancements in the effectiveness of biotechnology, biologics generate more revenue for large pharmaceutical companies than ever before.<sup>4</sup>

After losing significant market share to generic producers in the synthetic drug industry due to an abbreviated new drug application established in the Hatch-Waxman Act,<sup>5</sup> large pharmaceutical companies are likely afraid that a similar scenario may arise with biologics. In particular, the arrival of relatively new legislation like the Biologics Price Competition and Innovation Act of 2009—enacted as a part of the Affordable Care Act and designed to streamline the complex FDA approval process for biologics<sup>6</sup>—has likely only confirmed that growing fear. As such, the purpose of this Comment is to inform the reader both of the current state of the biologic industry within the United States, and how new legislation is intended to maintain a desirable balance between innovation and affordability of biologic products.

In Part I, this Comment examines the relatively new legislative patent framework that governs biologics and the overall importance of biologics. In doing so, this Comment explores what biologics are and evaluates the high costs associated with researching and developing them. Part II analyzes the Biologics Price Competition and Innovation Act (BPCIA), and discusses the congressional intent behind the BPCIA through an evaluation of the Hatch-Waxman Act, the bills that preceded the BPCIA, and the legislative history of the BPCIA itself. Part III of this Comment explores areas of recent conflict

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<sup>2</sup> *See id.*

<sup>3</sup> PHARM. RESEARCH & MFRS. OF AM., MEDICINES IN DEVELOPMENT: BIOLOGICS 1 (2013), <http://www.phrma-docs.phrma.org/sites/default/files/pdf/biologics2013.pdf>.

<sup>4</sup> *Going Large*, ECONOMIST (Dec. 30, 2014), <http://www.economist.com/news/business/21637387-wave-new-medicines-known-biologics-will-be-good-drugmakers-may-not-be-so-good>.

<sup>5</sup> Letter from John E. Dicken, Dir., Health Care, U.S. Gov't Accountability Off. to Sen. Orrin G. Hatch, Ranking Member, U.S. Senate Comm. On Fin. 2 (Jan. 31, 2012), <http://www.gao.gov/assets/590/588064.pdf> [hereinafter Dicken Letter].

<sup>6</sup> *See generally* 42 U.S.C. § 262 (2006 & Supp. 2010).

between biologic companies, including state legislation that affects consumers, FDA naming conventions, and a recent legal battle between two large pharmaceutical companies. Finally, this Comment concludes that with the rising cost of healthcare, the BPCIA seeks to replicate the effects of the Hatch-Waxman Act by reducing the price of existing medicine, while encouraging spending on research and development.

## I. BIOLOGICS AND THEIR IMPORTANCE

Biologics are not a new concept. They have been used to cure, vaccinate, and alleviate the harm caused by a number of diseases for decades.<sup>7</sup> Oncology treatments are predicted to set the record for the highest worldwide sales with a growth rate of 11.2% from 2013 to 2020.<sup>8</sup> Other specific uses of biologics include the development and production of human growth hormone and insulin.<sup>9</sup> In fact, Humira—the world’s leading prescription drug, used for treating rheumatoid arthritis, with approximately \$11 billion in sales in 2013 alone—is a biologic.<sup>10</sup> In addition, in 2011, eight of the twenty top-selling drugs in the United States were biologics.<sup>11</sup> By 2017, the total global spending on medicines, both on synthetic drugs and biologics, is expected to reach about \$1.2 trillion.<sup>12</sup> In 2013, biologics contributed to approximately 22% of large pharmaceutical

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<sup>7</sup> Morrow, *supra* note 1, at 24.

<sup>8</sup> EVALUATE PHARMA, WORLD PREVIEW 2014, OUTLOOK TO 2020 5 (2014), <http://info.evaluategroup.com/rs/evaluatepharmaltd/images/EP240614.pdf>.

<sup>9</sup> Morrow, *supra* note 1, at 24.

<sup>10</sup> *Going Large*, *supra* note 4.

<sup>11</sup> IMS HEALTH, SHAPING THE BIOSIMILARS OPPORTUNITY: A GLOBAL PERSPECTIVE ON THE EVOLVING BIOSIMILARS LANDSCAPE 2 2011; ANDREW W. MULCAHY ET AL., THE COST SAVINGS POTENTIAL OF *BIOSIMILAR* DRUGS IN THE UNITED STATES 1 (2014), [http://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND\\_PE127.pdf](http://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf).

<sup>12</sup> IMS INST. FOR HEALTHCARE INFORMATICS, THE GLOBAL USE OF MEDICINES: OUTLOOK THROUGH 2017 4 (2013), [https://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Global\\_Use\\_of\\_Meds\\_Outlook\\_2017/IIHI\\_Global\\_Use\\_of\\_Meds\\_Report\\_2013.pdf](https://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Global_Use_of_Meds_Outlook_2017/IIHI_Global_Use_of_Meds_Report_2013.pdf).

companies' overall sales and are projected to grow another 10% in the next decade.<sup>13</sup>

### A. Producing Biologics is Expensive

Understanding the obstacles that the biologic industry faces requires knowing the key differences between synthetic drugs and biologics. Biologics are drugs with large, complex molecular structures that are derived from living systems, whereas synthetic drugs have relatively small molecular structures and are composed of chemicals.<sup>14</sup>

The creation of a biologic is a complex process that involves living organisms; thus, biologics are inherently more expensive to produce.<sup>15</sup> Because the process is so complex and involves unique living organisms, identical reproduction by a competing generic producer is impossible; however, generic versions do exist. These are known as biosimilars, and they are capable of operating identically to the corresponding reference biologic.<sup>16</sup> Biosimilars could reduce the amount that the United States' healthcare system spends on biologics by \$44 billion over the next ten years.<sup>17</sup> In 2012, biosimilars only accounted for 0.4% of the market share of global biologic product spending.<sup>18</sup>

Despite the rapid growth of biologics, by 2017, biosimilars will still only account for 2% to 5% of the total global amount spent on biologic products.<sup>19</sup> Unfortunately, the biosimilar industry is expected to grow modestly due to biologics' strongly protected patents and long periods of market exclusivity.<sup>20</sup>

Part of the reason why innovators of biologics might receive more protection from biosimilars than synthetic drug makers receive

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<sup>13</sup> *Going Large*, *supra* note 4.

<sup>14</sup> *Morrow*, *supra* note 1, at 25-29.

<sup>15</sup> MULCAHY ET AL., *supra* note 11, at 1.

<sup>16</sup> *See id.* at 2.

<sup>17</sup> *Id.* at 7.

<sup>18</sup> IMS INST. FOR HEALTHCARE INFORMATICS, *supra* note 12, at 9.

<sup>19</sup> *Id.*

<sup>20</sup> *Id.* at 1.

is the high cost of researching and producing biologics.<sup>21</sup> Generally, analyzing and determining a biologic's three-dimensional structure is difficult.<sup>22</sup> Clinical trials for biologics are costly and time-consuming, which ultimately shortens the length of time an innovator will have market exclusivity.<sup>23</sup> However, biosimilar producers face these problems as well. While the development of a traditional generic synthetic drug usually costs \$1-2 million, the cost of developing a biosimilar is estimated to be between \$10-80 million,<sup>24</sup> with some studies showing that the cost to develop a biosimilar is between \$100-250 million.<sup>25</sup> The extreme cost of developing a biosimilar can likely be attributed to the numerous barriers of market entry that biosimilar producers face.

The process to develop a biosimilar is fraught with numerous and inherent barriers "associated with manufacturing, marketing, storage, distribution, delivery devices, immunogenicity (i.e. adverse reactions due to live organisms), and special requirements for pharmacovigilance."<sup>26</sup> All of these factors undoubtedly add to the cost of producing a biosimilar that is cheaper than the reference biologic. Additionally, the complexity inherent in producing a biosimilar requires a high level of expertise, and even minor changes in the production process require FDA approval.<sup>27</sup> As such, achieving a sufficiently uniform product is a difficult and costly process that can discourage potential entrants.<sup>28</sup> Another barrier to entry is the lack of automatic substitution between biosimilars and reference biologics. Unlike original synthetic drugs and their generic

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<sup>21</sup> Parker Tresemer, *Interests in the Balance FDA Regulations Under the Biologics Price Competition and Innovation Act*, 16 UCLA J.L. & TECH. 1, 9 (2012).

<sup>22</sup> *Id.* at 8.

<sup>23</sup> *Id.* at 9.

<sup>24</sup> Suzanne M. Sensabaugh, *Biological Generics: A Business Case*, 4 J. GENERIC MED. 186, 189 (2007).

<sup>25</sup> Patricia Van Arnum, *Market Weaknesses and Strengths in Biosimilars*, 36 PHARMACEUTICAL TECH. 34, 38 (2012).

<sup>26</sup> Erwin A. Blackstone & Joseph P. Fuhr, *The Economics of Biosimilars*, 6 AM. HEALTH & DRUG BENEFITS 469, 471 (2013).

<sup>27</sup> *Id.* at 472.

<sup>28</sup> *Id.*

counterparts, it is impossible for a biosimilar to be molecularly identical to the reference biologic.<sup>29</sup> Thus, at the pharmacy level, a biosimilar cannot be automatically substituted in place of the reference biologic because to qualify for automatic substitution the FDA requires absolute molecular identity.<sup>30</sup> Generic synthetic drug producers were greatly helped when the Hatch-Waxman Act enabled pharmacists to automatically substitute generic drugs in place of original drugs without having to notify the patient or the health care provider.<sup>31</sup> Likewise, it is highly probable that biosimilar producers would also greatly benefit from automatic substitution. Knowing the inherent costs of researching and developing both biologics and biosimilars is helpful for a more complete understanding of the balance that Congress sought when it drafted and enacted the BPCIA.

## II. FEDERAL LEGISLATION

This section first discusses Congress' intent for the BPCIA by examining the Hatch-Waxman Act. Next, it explores the bills that preceded the BPCIA, like the Access to Life-Saving Medicines Act and Patient Protection and Innovative Biologic Medicines Act of 2007. Finally, it examines the legislative history of the BPCIA itself.

### A. Congressional Intent for the BPCIA

To see that Congress' intent for the BPCIA was to balance the public's need for access to cheaper biosimilars while still providing enough protection for biologic innovators requires examining a number of factors. This section first reviews the Hatch-Waxman Act and its effect on the synthetic drug market. Next, it reviews the drastically different biosimilar bills that preceded the BPCIA. Finally, by analyzing the legislative history of the BPCIA itself, this section attempts to clearly show the intent to balance the industry's competing factions.

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<sup>29</sup> *Id.* at 469, 472-73, 476.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.* at 472.

### 1. Hatch-Waxman Act

Similar to the current problems facing biosimilar producers, generic synthetic drug producers also struggled with long and expensive production costs over thirty years ago until the Hatch-Waxman Act was passed.<sup>32</sup> In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act, giving generic producers of synthetic drugs a chance to market their products.<sup>33</sup> Prior to the Hatch-Waxman Act, both original synthetic drug producers and generic synthetic drug producers had to endure the lengthy and expensive New Drug Application (NDA) process.<sup>34</sup> To shorten the sluggish FDA approval process all synthetic drugs had to endure, the Hatch-Waxman Act created the Abbreviated New Drug Application (ANDA) which expedited FDA approval by permitting generic synthetic drug producers with a bioequivalent product to avoid conducting their own preclinical trials.<sup>35</sup> Additionally, the Hatch-Waxman Act permitted generic synthetic drug producers to obtain FDA approval for their product before the reference product's patent expired.<sup>36</sup>

The Hatch-Waxman Act improved competition between generic producers and innovators while also driving prices down in most cases by 50% to 80%.<sup>37</sup> Generics currently represent 78% of all prescriptions, but prior to 1984, generics accounted for only 19% of all prescriptions.<sup>38</sup> This surge in cheaper generic products is estimated to have saved the global health care system over \$1 trillion.<sup>39</sup> Not only did the Hatch-Waxman Act successfully lower the

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<sup>32</sup> Garth Boehm et al., *Development of the Generic Drug Industry in the US After the Hatch-Waxman Act of 1984*, 3 ACTA PHARMACEUTICA SINICA B 297, 298 (2013).

<sup>33</sup> Tresemer, *supra* note 21, at 5-6.

<sup>34</sup> See generally 21 U.S.C. § 355 (2012).

<sup>35</sup> See generally *id.* at § 355(j).

<sup>36</sup> See generally 21 U.S.C. § 355 (2012); see also Gregory N. Mandel, *The Generic Biologics Debate: Industry's Unintended Admission That Biotech Patents Fail Enablement*, 11 VA. J.L. & TECH. 1, 3 (2006).

<sup>37</sup> Tresemer, *supra* note 21, at 11 n.68.

<sup>38</sup> Dicken Letter, *supra* note 5.

<sup>39</sup> *Id.*

cost of synthetic drugs, but it also caused innovator companies to drastically increase spending on research and development of new drugs which increased between 1980 and 2004 from approximately \$6 billion to \$39 billion (in 2005 dollars).<sup>40</sup>

Arguably, BPCIA 42 U.S.C. § 262 is similarly structured to the Hatch-Waxman Act, but tailored to fit the unique aspects of biologics. However, the FDA recognizes that there are differences between synthetic drugs and biologics which will require different regulatory structures.<sup>41</sup> In addition, Congress and the FDA recognized that biosimilar producers will face lower costs and quicker approval, as compared with the biologic innovators. This is likely the reason for granting innovators data and market exclusivity.<sup>42</sup>

Armed with the historical evidence of the beneficial effects the Hatch-Waxman Act had on the American public and the synthetic drug industry by lowering prices and stimulating competition, it is very likely that the 111th Congress intended for the BPCIA to have a similar effect upon the biosimilar industry. Additionally, the BPCIA was passed under the umbrella of the Patient Protection and Affordable Care Act.<sup>43</sup> While not the strongest fact, it nevertheless supports the argument that in passing the BPCIA, Congress intended to lower the costs of biosimilar production.

## 2. *Bills that Preceded the BPCIA*

This section compares and contrasts two biosimilar legislation bills that preceded the BPCIA and were on opposite ends of the biosimilar regulatory spectrum.

The previously mentioned H.R. 6257 bill, authored by Representative Waxman and Senator Schumer, was also known as the Access to Life-Saving Medicine Act (ALSMA) and was introduced on September 29, 2006, during the 109th Congress but

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<sup>40</sup> CONG. BUDGET OFF., RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY PUB. NO. 2589 at 7 (2006), [www.cbo.gov/sites/default/files/cbofiles/ftpdocs/76xx/doc7615/10-02-drugr-d.pdf](http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/76xx/doc7615/10-02-drugr-d.pdf).

<sup>41</sup> MULCAHY ET AL., *supra* note 11, at 2.

<sup>42</sup> *Id.*

<sup>43</sup> See generally Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 (2010).



was never enacted.<sup>44</sup> ALSMA sought to drastically lower the costs of producing biosimilars and reduce FDA approval time by establishing two regulatory pathways for approval and licensure of biosimilar products.<sup>45</sup>

ALSMA would have permitted biosimilar applicants to bypass expensive clinical testing requirements by permitting the FDA to approve a product's "biosimilarity" much more liberally than the BPCIA currently does.<sup>46</sup> Under ALSMA, the determination of whether an applicant's product was biosimilar by the FDA could be based on non-clinical laboratory studies and clinical studies, but only if it was necessary to determine the product's safety, purity, and efficacy.<sup>47</sup> In addition, ALSMA would have greatly reduced the time and confusion associated with a product's application by defining biologic products that are inherently comparable while also reserving the FDA's discretion to find comparability between products as long as the applicant product and reference product operated in effectively identical ways.<sup>48</sup> Also, ALSMA explicitly forbids the FDA from requiring any additional post-marketing studies as a condition for approval.<sup>49</sup> Further, ALSMA stated that FDA approval of a biosimilar applicant carried with it approval for the exact same conditions and use of the reference product, and not just the conditions of use for which the application established biosimilarity.<sup>50</sup>

In regards to the interchangeability of an applicant's product, ALSMA required merely that the product had a *comparable* molecular structure to the reference product. Finally, ALSMA provided no exclusivity to the reference product, but did provide 180 days of

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<sup>44</sup> H.R. 6257, 109th Cong. § 3(a)(2) (2006) (proposed Public Health Service Act §§ 351(k)(1), (k)(2)).

<sup>45</sup> *See id.*

<sup>46</sup> *Id.*

<sup>47</sup> H.R. 6257, 109th Cong. § 2(2) (proposed Public Health Service Act §§ 351(i)(2)(A)-(B), (i)(4)).

<sup>48</sup> H.R. 6257 § 2(2) (proposed Public Health Service Act § 351(i)(5)).

<sup>49</sup> H.R. 6257 § 3(a)(2) (proposed Public Health Service Act § 351(k)(2)).

<sup>50</sup> *Id.*

exclusivity to the first interchangeable product.<sup>51</sup> ALSMA's lack of exclusivity protections to biologic innovators and their reference products would have enabled biosimilar applicants to seek licensure to FDA, conduct the necessary clinical trials, secure FDA approval, and begin marketing their product immediately upon the reference product's patent expiration. Despite some amendments to its substantive provisions, the revised ALSMA still did not provide any reference product exclusivity.

On the opposite end of the biosimilar regulatory approval spectrum, Representative Jay Inslee introduced the Patient Protection and Innovative Biologic Medicines Act of 2007 (PPIBM) on April 19, 2007.<sup>52</sup> In stark contrast to ALSMA, the PPIBM would have significantly decreased the number of biosimilar products that would be eligible to apply for FDA approval.

In regards to biosimilarity, the PPIBM would have, amongst other things, imposed strict product-class guidance requirements and stringent minimum data requirements before an applicant's product could even be reviewed by the FDA.<sup>53</sup> In addition, the PPIBM would have required biosimilar applicants to satisfy all data and clinical testing requirements for each condition of use sought rather than permit a wide application of use like the ALSMA had intended to.<sup>54</sup> Concerning interchangeability, the PPIBM flat out prohibited the FDA from designating any biosimilar products as interchangeable.<sup>55</sup> The PPIBM would have prohibited the FDA from accepting or approving biosimilar applications for twelve and fourteen years respectively.<sup>56</sup> In addition to extremely generous exclusivity, the PPIBM would have enabled biologic innovators to gain additional one-year exclusivity periods based on supplement approvals for reference products that provided clinical benefits to existing

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<sup>51</sup> H.R. 6257 § 3(a)(2) (proposed Public Health Service Act § 351(k)(9)(A)(ii)).

<sup>52</sup> Patient Protection and Innovative Biologic Medicines Act of 2007, H.R. 1956, 110th Cong. § 2(a)(2) (2007) (proposed Public Health Service Act § 351(k)(4)(B)(i)-(ii)).

<sup>53</sup> H.R. 1956, § 2(a)(2) (proposed Public Health Service Act § 351(k)(4)(C)(vii)).

<sup>54</sup> H.R. 1956, § 2(a)(2) (proposed Public Health Service Act § 351(k)(2)(C)(ii)).

<sup>55</sup> H.R. 1956, § 2(a)(2) (proposed Public Health Service Act § 351(k)(2)(D)).

<sup>56</sup> H.R. 1956, § 2(a)(2) (proposed Public Health Service Act § 351(k)(3)(A)(i)-(ii), (B)).

therapies.<sup>57</sup> This process, known as “evergreening,” is a strategy that was employed by brand name synthetic drug producers in the wake of the Hatch-Waxman Act to alter their brand name drug formulations just enough so that new and old generic formulations were no longer considered bioequivalent.<sup>58</sup> Thus, generic synthetic drug producers were forced to either re-enter the market under a new brand name or begin the ANDA process anew.<sup>59</sup>

The only aspect that PPIBM shared with ALSMA is that neither bill passed the House or the Senate. Both bills appeared to represent the competing interests of biosimilar producers, and biologic producers without showing any regard for compromise. However, due to the failures of ALSMA and PPIBM, the stage was set for the Biologics Price Competition and Innovation Act to enter and strike the balance the biologics and biosimilar industry desperately needed.

### 3. BPCIA's Legislative History

The current BPCIA underwent a number of amendments before being enacted. For the sake of brevity, this Comment attempts to highlight and evaluate only the crucial amendments of the Act throughout the legislative process.

The original Biologics Price and Competition Act was introduced on June 26, 2007, by Senator Edward Kennedy and the members of the Senate Committee on Health, Education, Labor, and Pensions (HELP) as S. 1695.<sup>60</sup> S. 1695 diverged from ALSMA in one significant way. S. 1695 intended to grant reference products four and twelve years of exclusivity against biosimilar application submissions and approval respectively, while also granting one-year exclusivity to the first interchangeable product.<sup>61</sup> S. 1695's exclusivity provision appears to be a compromise between ALSMA and PPIBM.

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<sup>57</sup> H.R. 1956, 110<sup>th</sup> Cong. §2(a)(2) (2007).

<sup>58</sup> See Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471, 1495 (2008).

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

<sup>60</sup> Krista H. Carver et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 FOOD & DRUG L. J. 671, 763 (2010).

<sup>61</sup> S. 1695, 110<sup>th</sup> Cong. § 2(a)(2) (2007) (proposed PHSA § 351(k)(7)(A), (B)); S. 1695, 110<sup>th</sup> Cong. § 2(a)(2) (2007) (proposed PHSA § 351(k)(6)(A)).

In regards to biosimilarity, S. 1695 was more similar to ALSMA because it permitted the FDA discretion to determine an applicant's approval on a case-by-case basis, while also allowing a product deemed biosimilar to have the same conditions of use as its reference product.<sup>62</sup> However, in a divergence from ALSMA, S. 1695 permitted FDA post-marketing requirements.<sup>63</sup> S. 1695's provision on interchangeability greatly supported biosimilar producers because it permitted automatic substitution of products that the FDA approved as interchangeable.<sup>64</sup>

The most notable amendment to S. 1695 was the Hatch/Enzi/Hagan Amendment. The Hatch/Enzi/Hagan Amendment, incorporated into S. 1695 and eventually into the current BPCIA, limited the exclusivity a biologic innovator could enjoy by preventing evergreening.<sup>65</sup> In a letter to the FDA, the principal authors of the BPCIA clarified their intent by stating, "We took very seriously the concerns about 'evergreening' and the legislation is clear that no product, under any circumstances, can be granted 'bonus' years of data exclusivity for mere improvements on a product."<sup>66</sup>

Because the currently enacted version of the BPCIA contains language largely identical to S. 1695,<sup>67</sup> it is not a reach to argue that the 111th Congress intended for the BPCIA to enable biosimilar applicants a greater chance to obtain FDA approval for biosimilarity, or interchangeability for their products, while also protecting the biologic innovators and their reference products with sufficient periods of exclusivity.

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<sup>62</sup> S. 1695, 110th Cong. § 2(a)(2) (2007).

<sup>63</sup> *Id.* (proposed Public Health Service Act § 351(k)(3)(B)).

<sup>64</sup> S. 1695, 110th Cong. § 2(b)(3) (2007).

<sup>65</sup> Carver et al., *supra* note 60, at 786.

<sup>66</sup> Letter from Anna G. Eshoo, Jay Inslee, Joe Barton Representative, Div. of Dockets Mgmt. (FDA) (Dec. 21, 2010) (on file with author).

<sup>67</sup> Compare 42 U.S.C. §262, with S. 1695, 110th Cong. § 1 (2007).

### a. Biologics Price Competition and Innovation Act

Congress recognized the need for biosimilars – the industry term for generic biologics – and created a legislative pathway for producers of biosimilars to obtain timely FDA approval and enter the market quickly.<sup>68</sup> Although drafted in 2009, it was not until 2010 that the BPCIA was enacted by Congress as a subtitle of the Affordable Care Act.<sup>69</sup> Congress wanted to balance innovating companies' interests in protecting their costly investments with the consumers' and biosimilar companies' interests and in obtaining and selling less expensive competing products.<sup>70</sup> There are three main issues that the BPCIA and the bills preceding it address: biosimilarity, interchangeability, and exclusivity.<sup>71</sup> The preceding bills and their efforts to address these issues will be discussed later in this Comment.

The BPCIA granted the FDA the power to regulate biologics and biosimilars.<sup>72</sup> The BPCIA has set a high bar for an applicant's product to receive biosimilar approval. The BPCIA defines "biosimilarity" as a biological product that is highly similar to the reference product despite minor differences in clinically inactive components.<sup>73</sup> Furthermore, the biosimilar product must not be different in a clinically meaningful way in terms of the product's safety, purity, and potency.<sup>74</sup>

To be considered "interchangeable" is an even higher standard. An interchangeable biosimilar product may be substituted for the reference product by a pharmacist without the intervention of the health care provider who prescribed the reference product.<sup>75</sup> Finally,

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<sup>68</sup> Joanna M. Shepherd, *Biologic Drugs, Biosimilars, and Barriers to Entry*, 25 HEALTH MATRIX 139, 140 (2015).

<sup>69</sup> 42 U.S.C. §262 (2010); Tresemer, *supra* note 21, at 40.

<sup>70</sup> Tresemer, *supra* note 21, at 3.

<sup>71</sup> See 42 U.S.C. § 262; see generally H.R. 6257, 109th Cong. §2(2)(2006); see generally H.R. 1956, 112th Cong. § 2(a)(2) (proposed Public Health Service Act § 351(k)(4)(B)(i), (ii) (2007).

<sup>72</sup> Tresemer, *supra* note 21, at 40.

<sup>73</sup> 42 U.S.C.A. § 262 (i)(2)(A).

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

<sup>75</sup> *Information On Biosimilars*, FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/Dev>

for a continually administered biologic product, the BPCIA requires that the risk in terms of safety or efficacy when alternating between use of the biosimilar and the reference product must not be greater than the risk of using the reference product without alternating.<sup>76</sup>

In order to strike a balance, the BPCIA encourages innovation by allowing biologic innovators to obtain patent protection for twenty years from the date the patent application is filed.<sup>77</sup> In addition, the BPCIA grants biologic innovators four years of data exclusivity, and twelve years of market exclusivity beginning when the biologic product receives FDA marketing approval.<sup>78</sup> Upon expiration of the four years of data exclusivity, biosimilar producers are allowed to begin research and development work so that they are prepared to rapidly enter the market when the reference product's market exclusivity period expires.<sup>79</sup>

### III. THE WAR BETWEEN BIOLOGIC AND BIOSIMILAR PRODUCERS IS WAGED ON MANY FRONTS

Unsurprisingly, the enactment of the BPCIA of 2009 was only the beginning of the conflict in which the biologic industry is currently locked. This section assesses the various war fronts, including state legislation, biologic naming conventions, the BPCIA's abbreviated pathway provision, and a Ninth Circuit decision likely to be reviewed by the Supreme Court of the United States.

#### A. State Legislation that Undermines the BPCIA.

As previously mentioned, in the not so distant past, large pharmaceutical companies attempted to maintain their control over the market of original synthetic drugs, similar to its actions in the biologic industry today. Innovator biologic producers have

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elopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ (last updated May 10, 2016).

<sup>76</sup> 42 U.S.C.A. § 262 (West 2010) (K) (4)(B).

<sup>77</sup> Blackstone & Fuhr, *supra* note 26, at 470.

<sup>78</sup> See 42 U.S.C. § 262(k)(7).

<sup>79</sup> *Id.*

attempted to extend their profits by lobbying both the FDA and state legislatures to obstruct biosimilars from being prescribed.<sup>80</sup>

North Dakota, Florida, Utah, and Oregon have enacted laws that effectively obstruct the prescription of biosimilars.<sup>81</sup> These types of legislation typically rely on three mechanisms: (1) a notification and recordkeeping requirement for the prescribing physician of any biosimilar; (2) a patient's veto or patient notification requirement, or both; and (3) a set of burdensome recordkeeping requirements (or labeling provisions for pharmacists).<sup>82</sup> Over thirty-one states have considered and enacted legislation of varying degrees establishing state standards in relation to physician notification, patient notification, and recordkeeping.<sup>83</sup> North Dakota has the most extensive notification laws, requiring pharmacists who wish to substitute a biosimilar in place of a biologic must notify both the physician and patient within twenty-four hours by writing, electronic transmission, or orally, and it reserves both parties the right to refuse such substitution.<sup>84</sup> The final requirement is that the pharmacist must retain record of the substitution for five years.<sup>85</sup> While Utah and Oregon's enacted legislation is less extensive in comparison to North Dakota's, it still requires a pharmacist to notify the prescribing physician within three days after the substitution.<sup>86</sup> Florida law does

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<sup>80</sup> Shepherd, *supra* note 68.

<sup>81</sup> See N.D. CENT. CODE § 19-02.1-14.3(2013); FL. STAT. ANN. §465.0252, §465.019 (2016); UTAH CODE ANN. § 58-17b-605.5 (2015); OR. REV. STAT. § 689.522 (2016); Michelle Derbyshire, *U.S. State Legislation on Biosimilars Substitution*, 2 GENERICS & BIOSIMILARS INITIATIVE J. 155 (2013), <http://gabi-journal.net/us-state-legislation-on-biosimilars-substitution.html>.

<sup>82</sup> Shepherd, *supra* note 68.

<sup>83</sup> Richard Cauchi, *State Laws and Legislation Related To Biologic Medications And Substitution of Biosimilars*, NAT'L CONF. ST. LEGIS. (Aug. 1, 2017), <http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx>.

<sup>84</sup> N.D. CENT. CODE § 19-02.1-14.3(2013); Jessica S. Mazer, J.D., *Introduction to State Biosimilar Substitution Laws*, FTC FOLLOW-ON BIOLOGICS WORKSHOP 6 (Feb. 4, 2014), <http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx>.

<sup>85</sup> N.D. CENT. CODE § 19-02.1-14.3(2013); Mazer, *supra* note 84, at 6.

<sup>86</sup> UTAH CODE ANN. § 58-17b-605.5 (2015); OR. REV. STAT. § 689.522 (2016).

not require physician notification, but patient notification is still required, as is record retention of at least two years.<sup>87</sup>

Generally, requiring pharmacists to notify physicians that a biosimilar will be used usually raises fear in physicians that they may be exposed to malpractice.<sup>88</sup> However, this directly contradicts the BPCIA language that FDA approved biosimilars are effectively the same as the biologic it mimics, as discussed earlier.<sup>89</sup> On the other side, patient notification requirements also elicit fear that they are receiving an inferior product.<sup>90</sup> When taken in conjunction with obstruction of non-proprietary naming conventions, a biosimilar may be wrongly considered inferior to the biologic.<sup>91</sup> When given the choice, patients will likely choose the name brand product simply because it was shown in an advertisement, which needlessly drives up the cost of the biologic because the manufacturer will spend money on advertising.<sup>92</sup> In addition, the recordkeeping provisions, requiring pharmacists to maintain lengthy and costly medical data records, also drive up the price and add to the inconvenience of prescribing biosimilars.<sup>93</sup> When the cost of one year of biologic medicine can range from \$50,000 to \$250,000, the government should strive to protect the well-being of its citizens by doing all that it can to lower unnecessary costs.<sup>94</sup> These notification and recordkeeping provisions result in artificially raised biosimilar prices.

In light of the already high production costs of biosimilars, something must be done to rein in state legislation that undermines the BPCIA and Congress' intent to provide the public with affordable

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<sup>87</sup> FL. STAT. ANN. § 465.0252 (2016), § 465.019 (2016).

<sup>88</sup> Bruce Leicher, *Anti-Competitive Deterrents to Investment and Innovation in Biosimilars and Interchangeable Biologics*, FED. TRADE COMM'N (Feb. 4, 2014), [http://www.ftc.gov/system/files/documents/public\\_events/Follow-On%20Biologics%20Workshop%20C3A%20Impact%20of%20Recent%20Legislative%20and%20Regulatory%20Naming%20Proposals%20on%20petition/leicher.pdf](http://www.ftc.gov/system/files/documents/public_events/Follow-On%20Biologics%20Workshop%20C3A%20Impact%20of%20Recent%20Legislative%20and%20Regulatory%20Naming%20Proposals%20on%20petition/leicher.pdf).

<sup>89</sup> Shepherd, *supra* note 68.

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

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

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

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

<sup>94</sup> Notices, 78 Fed. Reg. 221 (Nov. 15, 2013).



biosimilars. Unfortunately, this is likely more difficult in practice than in theory.

### B. Naming Conventions and Non-proprietary Naming

The BPCIA does not include specific statutory language in regards to naming approved biosimilars, instead the decision has been left to the FDA.<sup>95</sup>

There has been considerable debate over what the appropriate naming convention should be for biologics and their related biosimilars.<sup>96</sup> To ensure patient safety and aid in adverse effects tracking, some parties want biosimilars to be given completely unique non-proprietary names or, at the very least, to have a unique suffix or prefix attached to distinguish the biosimilar.<sup>97</sup> Others have advocated that biosimilars should have the same non-proprietary names as their reference biologic.<sup>98</sup>

Those in favor of giving biosimilars unique non-proprietary names argue that while non-unique naming is applicable to synthetic drugs, it is misleading when applied to biosimilars because biosimilars are not structurally identical to their reference biologic product.<sup>99</sup> Additionally, they argue that non-unique, non-proprietary names would hinder pharmacovigilance—the process of tracking patients and assessing any adverse effects associated with a product.<sup>100</sup> Thus, doctors and patients who wish to report adverse effects of a biosimilar would not be able to pinpoint which specific product was responsible.<sup>101</sup> In support of this argument, Dr. Helen Hartman presented results of a study that evaluated non-proprietary

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<sup>95</sup> Valentina Rucker & Roisin Comerford, *Notifications and Names: FTC Workshop Explores Effect of State Legislation and Naming Conventions on Follow-On Biologic Competition*, Anti-Trust Health Care Chron., Mar. 2014, <https://www.wsgr.com/publications/pdfsearch/antitrusthealthcarechronicle-rucker-comerford-0314.pdf>.

<sup>96</sup> *See id.*

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

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

<sup>99</sup> *See* Emily A. Alexander, *Reference Biologic Perspectives On Naming*, FTC FOLLOW-ON BIOLOGICS WORKSHOP 9 (Feb. 4, 2014).

<sup>100</sup> Rucker & Comerford, *supra* note 95.

<sup>101</sup> *Id.*

naming of synthetic drugs in which 14% of drugs with non-unique, non-proprietary names had unidentifiable manufacturers, whereas less than 1% of those with unique non-proprietary names could not be identified.<sup>102</sup> Thus, Dr. Hartman concluded that for proper attribution between manufacturer and drug, unique non-proprietary names are preferred.<sup>103</sup>

Supporters of non-unique, non-proprietary names countered their opponents' identity argument by asserting that "non-identity" is a normal principle in biotechnology and that variations exist even between batches of the same biologic.<sup>104</sup> To counter their opponents' pharmacovigilance argument, the supporters of non-unique, non-proprietary names argued that adding a unique prefix or suffix would confuse the role of the non-proprietary name, which is meant to describe the active ingredient of the product and not serve as the product name.<sup>105</sup> They also argued that problems with pharmacovigilance should be attributed to inherent flaws in the information collection process and have nothing to do with naming conventions.<sup>106</sup>

To date, the FDA has received several opposing citizen petitions concerning the non-proprietary naming of biosimilar products.<sup>107</sup> Johnson & Johnson's petition requests that the FDA require biosimilars to bear non-proprietary names that are similar, but not identical, to the related biologic reference product.<sup>108</sup> Contrastingly, the Generic Pharmaceutical Association and Novartis petition requests that the FDA require biosimilars to be identified by the same

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<sup>102</sup> Helen B. Hartman, Ph.D., *Looking Into the Future Biosimilar Landscape: A Case Study*, FTC FOLLOW-ON BIOLOGICS WORKSHOP 7 (Feb. 4, 2014).

<sup>103</sup> Rucker & Comerford, *supra* note 95.

<sup>104</sup> Mark McCamish, *Effect of Naming on Competition and Innovation*, FTC FOLLOW-ON BIOLOGICS WORKSHOP 6 (Feb. 4, 2014), [https://www.ftc.gov/system/files/documents/public\\_events/Follow-On%20Biologics%20Workshop%3A%20Impact%20of%20Recent%20Legislative%20and%20Regulatory%20Naming%20Proposals%20on%20Competition/mccamish.pdf](https://www.ftc.gov/system/files/documents/public_events/Follow-On%20Biologics%20Workshop%3A%20Impact%20of%20Recent%20Legislative%20and%20Regulatory%20Naming%20Proposals%20on%20Competition/mccamish.pdf).

<sup>105</sup> Rucker & Comerford, *supra* note 95.

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

<sup>107</sup> ¶ 46,273 *FDA Hopes to Distinguish Biosimilars, Proposes Official Names For Six Products*, CCH DRUGS & COSMETICS L. REV., 2015 WL 5925673 (Aug. 28, 2015).

<sup>108</sup> See Dkt. No. FDA-2014-P-0077, <http://www.regulations.gov>.

non-proprietary name as their reference biologic product.<sup>109</sup> Novartis's petition also proposed that if a biosimilar sponsor elected not to use a unique proprietary name for its product, then the FDA should assign a unique non-proprietary name composed of the reference product non-proprietary name attached with a distinguishable suffix that links the biosimilar sponsor so that it can be easily differentiated from the reference product.<sup>110</sup>

In response to these petitions, the FDA issued a draft guidance document titled "Nonproprietary Naming of Biological Products."<sup>111</sup> The guidance document addresses the arguments and concerns of both sides of the conflict. The FDA is still trying to devise a viable solution because the guide only outlines the FDA's current thoughts and welcomes additional public comments on the issue.<sup>112</sup> Essentially, the FDA suggests that for originator biologic products it intends to use a core name that is adopted by the United States Adopted Names Council (USAN).<sup>113</sup> For biosimilars and interchangeable products the FDA suggests that a designated suffix composed of four lowercase letters will be attached to the core name by a hyphen.<sup>114</sup> Use of a shared core name would indicate a relationship between the reference biologic product and biosimilar.<sup>115</sup> To address issues with pharmacovigilance the FDA suggests that use of an attached suffix along with the shared core name should help health care providers identify the specific product that may have caused adverse effects in a patient.<sup>116</sup>

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<sup>109</sup> See Dkt. Nos. FDA-2013-P-1153 and FDA-2013-P-1398, respectively, <http://www.regulations.gov>.

<sup>110</sup> Kayla R. Bryant, *FDA Hopes to Distinguish Biosimilars, Proposes Official Names for Six Products*, WOLTERS KLUWER LEGAL & REGULATORY (Sept. 4, 2015), [http://www.dailyreportingnsuite.com/health-reform/news/fda\\_hopes\\_to\\_distinguish\\_biosimilars\\_proposes\\_official\\_names\\_for\\_six\\_products](http://www.dailyreportingnsuite.com/health-reform/news/fda_hopes_to_distinguish_biosimilars_proposes_official_names_for_six_products).

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

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

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

<sup>114</sup> *Id.*

<sup>115</sup> *Id.*

<sup>116</sup> *Id.*

Because consumers and drug prescribers prefer the brand name product over the generic version,<sup>117</sup> the name bestowed upon a biosimilar greatly matters towards the success of the product. FDA's guidance documents on naming conventions for biologics should honor Congress' intent of the BPCIA by permitting properly approved biosimilars the right to use the reference product's name.

**1. BPCIA 42 U.S.C. §262(k) & 42 U.S.C. §262 (l)(2)(a)**

A crucial element that gives "teeth" to the BPCIA's regulatory pathway is 42 U.S.C. § 262(k). The BPCIA granted the FDA authority to approve biosimilars to a reference product based on specific types of testing designed to establish specific aspects of biosimilarity.<sup>118</sup> First, it requires "analytical studies" demonstrating that the biosimilar is highly similar to the reference product.<sup>119</sup> Second, it requires animal studies to be performed.<sup>120</sup> Finally, the BPCIA requires clinical studies that sufficiently demonstrate the safety, purity, and potency of the biosimilar.<sup>121</sup> Section 262(k) lays the framework for an information disclosure and negotiations process by stating that a would-be biosimilar producer "shall" turn over its FDA application and research to the biologic producer.<sup>122</sup> If both parties participate and comply with the disclosure and negotiation processes, neither may bring a declaratory judgment action regarding validity, enforceability, and infringement of the patent until the applicant provides notice of its upcoming first commercial marketing.<sup>123</sup>

Section 262(k) expedites the information sharing procedures between the generic manufacturer and the innovator

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<sup>117</sup> Shepherd, *supra* note 68.

<sup>118</sup> Tresemer, *supra* note 21, at 41.

<sup>119</sup> *Id.*

<sup>120</sup> *Id.*

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

<sup>122</sup> Michael Scott Leonard, *Makers of Generic Biologics Don't Have to Warn Brand-Name Rivals, Federal Circuit Finds*, 23 WESTLAW J. HEALTH L. 9, \*1.

<sup>123</sup> Amgen Inc. v. Sandoz Inc., No. 14-cv-04741-RS, 2015 WL 1264756, at \*2 (N.D. Cal. Mar. 19, 2015).

manufacturer.<sup>124</sup> If a generic producer can prove its product was legally identical to an already FDA approved, safe and effective biologic, then it may file for an abbreviated biologics license application (aBLA), which allows it to utilize the innovator's research, ultimately expediting the approval process.<sup>125</sup> Not later than twenty days after the FDA has accepted the aBLA, the biosimilar applicant shall then provide the reference product sponsor a copy of the application it submitted to the FDA and other information that describes the process or processes used to manufacture the biosimilar product that is the subject of the application.<sup>126</sup> Thus, the reference product sponsor can review the biosimilar applicant's research so that the two companies can agree upon the scope of a potential patent infringement suit.<sup>127</sup> Essentially, the BPCIA enabled companies to engage in a series of disclosures and negotiations with the intent to narrow or even eliminate the prospect of patent litigation.<sup>128</sup> At the least, it was aimed towards making the patent infringement lawsuit more efficient and orderly.<sup>129</sup>

## 2. *Amgen v. Sandoz*

In early 2015, the United States District Court for the Northern District of California presided over a case between Amgen Inc. and Sandoz Inc., two big pharmaceutical companies.<sup>130</sup> The core of the dispute was the statutory interpretation of section 262.<sup>131</sup> The two companies had conflicting interpretations of the BPCIA, in particular the abbreviated pathway for generic producers to obtain FDA approval of their biosimilars.<sup>132</sup> Since 1991, Amgen has produced and

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<sup>124</sup> Leonard, *supra* note 122, at 2.

<sup>125</sup> *Id.*

<sup>126</sup> 42 U.S.C. §262 (l)(2)(A) (2016).

<sup>127</sup> Leonard, *supra* note 122, at 2.

<sup>128</sup> *Amgen Inc.*, 2015 WL 1264756 at \*6.

<sup>129</sup> Leonard, *supra* note 122.

<sup>130</sup> *Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741-RS, 2015 WL 1264756, at \*1 (N.D. Cal. Mar. 19, 2015).

<sup>131</sup> *See id.*

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

marketed the biologic product filgrastim as Neopogen.<sup>133</sup> In 2014, Sandoz applied to the FDA to receive biosimilar status of their filgrastim product, Zarxio.<sup>134</sup> Amgen averred that Sandoz failed to disclose its manufacturing process in the aBLA, and thus infringed upon Amgen's filgrastim patent.<sup>135</sup> Ultimately, the Court held that the BPCIA's disclosure and negotiations process was optional and not mandatory like Amgen had argued.<sup>136</sup> Amgen immediately appealed the ruling.<sup>137</sup>

On appeal, the Ninth Circuit affirmed in part and reversed in part the lower court's holding, stating that the language of §§ 262(k) and 262(l)(2)(a) indicates that the application process is optional and not mandatory.<sup>138</sup> Specifically, the Court held that in relation to the BPCIA, Sandoz, the generic producer, did not violate the BPCIA by failing to disclose its application and manufacturing information to the reference product sponsor (RPS), Amgen, by the statutory deadline.<sup>139</sup> However, the Court held that Sandoz did not satisfy its obligation under the BPCIA to provide notice of commercial marketing to the RPS, Amgen, by the statutory deadline of at least 180 days before the first day of commercial marketing.<sup>140</sup> It determined that Sandoz violated 42 U.S.C. § 262(l)(8) that required the biosimilar applicant to provide notice of commercial marketing of their licensed product to the reference product sponsor.<sup>141</sup> The Court held that this notice was mandatory and could only be properly provided after the applicant's product had been FDA approved.<sup>142</sup> Because Sandoz had provided Amgen with notice of commercial

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

<sup>134</sup> *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1352-53 (Fed. Cir. 2015).

<sup>135</sup> *Amgen Inc.*, 2015 WL 1264756 at \*1, \*5.

<sup>136</sup> *Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741-RS, 2015 WL 1264756, at \*11 (N.D. Cal. Mar. 19, 2015).

<sup>137</sup> *Amgen Inc.*, 794 F.3d at 1350-51.

<sup>138</sup> *Id.* at 1351, 1361.

<sup>139</sup> *Id.* at 1357.

<sup>140</sup> *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1358, 1360 (Fed. Cir. 2015).

<sup>141</sup> *Id.* at 1360-61.

<sup>142</sup> *Id.* at 1358.

marketing before its product was FDA approved, meaning it was still unlicensed, the notice was insufficient.<sup>143</sup> Thus, Sandoz would have to wait at least 180 days after FDA approval and provide notice of commercial marketing to Amgen before it could begin selling its product.<sup>144</sup>

Ultimately, neither party emerged completely unscathed. On one hand, Sandoz won a tentative victory that will help other biosimilar producers because they will now have the option to either participate in the negotiations and disclosure process with the corresponding biologic innovators or risk a messy lawsuit that could result in harmful declaratory judgments.<sup>145</sup> On the other hand, Amgen succeeded in delaying Sandoz from marketing Zarxio for another 180 days.<sup>146</sup>

By interpreting 42 U.S.C. § 262(l)(2)(a) as optional, the Court reserved the biosimilar producer's right to keep its potentially patent infringing, but precious manufacturing process information confidential. The biosimilar producer could either choose to engage in the information disclosure process and avoid declaratory judgment actions from the RPS, or choose not to engage in the information disclosure process and risk declaratory judgment and a potentially devastating trial. Despite the potential risks with the latter option, many companies will likely follow in Sandoz's footsteps in order to protect their product's process information.

The Court's decision in *Amgen Inc. v. Sandoz Inc.* maintains the precarious balance established by Congress in the BPCIA. The BPCIA attempts to provide adequate protection for the biologic innovators costly investments in the form of exclusivity periods, but also encourages biosimilar producers to enter the market by lowering costs by providing the aBLA in 42 U.S.C. § 262(k). Here, the Court in comparable fashion, has granted Amgen respite from Sandoz's biosimilar product, while also encouraging Sandoz and other biosimilar producers to enter the market by providing more flexibility to pursue the development of their biosimilar products.

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<sup>143</sup> *Id.* at 1359.

<sup>144</sup> *Id.* at 1359–1360.

<sup>145</sup> *See id.* at 1368.

<sup>146</sup> *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1360 (Fed. Cir. 2015).

## CONCLUSION

This Comment explores the current legislative and judicial issues surrounding the biologic and biosimilar industry. Nourishing the fledgling biosimilar market will require more than just the BPCIA. It requires support from the FDA, judiciary, and state legislative bodies. Without a cooperative effort, the BPCIA may flounder and prove to be incapable of serving the American public in a positive manner. Despite its flaws the BPCIA provides an initial federal statutory framework that imitates the Hatch-Waxman Act, but is tailored to fit the unique needs of the biologic and biosimilar industry through extended exclusivity periods for biologic producers and faster approval processes for biosimilar producers. The federal courts' holdings in *Amgen I* and *Amgen II* attempted to maintain the delicate balance that the BPCIA intended between the biologic producers and biosimilar producers.

As healthcare costs continue to rise, hopefully the BPCIA can achieve results for the biosimilar industry comparable to what the Hatch-Waxman Act accomplished for the American public and the generic drug industry by lowering the price of existing medicine and spurring research and development of new ones.