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The Riddle of the Mysterious Patent Dance Wrapped in an Enigma: Is the Patent Dance of the BPCIA Optional or Mandatory?

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Cover Page Footnote

Staff Member, Fordham Intellectual Property, Media & Entertainment Law Journal, Volume XXVII; J.D. Candidate, Fordham University School of Law, 2018; B.A., Biology, Brooklyn College, 2015. I would like to thank Professor Janet Freilich for her constant and indispensable help and the IPLJ Editorial Board and staff for their efforts throughout the editorial process. I would also like to express my special appreciation to my wife, Adina, and daughter, Sophia, for their unwavering support and encouragement.

The Riddle of the Mysterious Patent Dance Wrapped in an Enigma: Is the Patent Dance of the BPCIA Optional or Mandatory?

Dov Hirsch*

Recently, the nature of one of the aspects of the Biosimilar, Price, Competition, and Innovation Act of 2009 (“BPCIA”) has been called into question: Is the “patent dance,” the structured patent dispute resolution process of the BPCIA, mandatory or optional? A mandatory patent dance requires a biosimilar applicant to comply with all its requirements, while an optional patent dance allows the biosimilar applicant to opt out of the entire dance if it so chooses. This question is important because it has the potential to affect that delicate balance of the BPCIA. This Note focuses on some of the consequential implications of deciding whether the patent dance of the BPCIA is optional or mandatory. This Note ultimately argues that the patent dance of the BPCIA should be mandatory.

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INTRODUCTION

Biologics are the future of the pharmaceutical industry.¹ While research, development, and spending for new innovative small-molecule drugs have remained stagnant,² there has been an explosion in spending and progress in the field of biologics.³ In 2016, the annual global spending on biologics alone was projected to be between \$200 billion and \$210 billion.⁴ Some healthcare industry analysts predict that, in the United States, biologics will represent half of the annual prescription drug spending by 2020.⁵ This explosion is well deserved, as the most prominent, promising, and profitable cures to major diseases are in the field of biologics.⁶ However, the very nature of biologics and its complex manufacturing and development process also make them some of the most expensive pharmaceuticals.⁷ To address this problem, Congress enacted the Biosimilar, Price, Competition, and Innovation Act of 2009 (“BPCIA”).⁸

The BPCIA has been described as a “riddle wrapped in a mystery in an enigma.”⁹ The BPCIA’s complexity stems partly from the fact that the nature of a biologic itself is extremely complex and not yet fully understood.¹⁰ The BPCIA’s location at the intersec-

¹ See, e.g., W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023, 1026 (2016).

² *Id.* (“Spending on small-molecule drugs is close to stagnant, especially in developed countries.”).

³ IMS INST. FOR HEALTHCARE INFORMATICS, *THE GLOBAL USE OF MEDICINES: OUTLOOK THROUGH 2016* at 3 (2012).

⁴ *Id.*

⁵ Price & Rai, *supra* note 1.

⁶ *Id.*; see Julia Kollwe, *World’s 10 Bestselling Prescription Drugs Made \$75bn Last Year*, GUARDIAN (Mar. 27, 2014), <http://www.theguardian.com/business/2014/mar/27/bestselling-prescription-drugs> [<http://perma.cc/ZYR6-3PQZ>].

⁷ See Henry Grabowski, *Follow-on Biologics: Data Exclusivity and the Balance Between Innovation and Competition*, 7 NATURE REVIEWS DRUG DISCOVERY 479, 482 (2008); Joyce Wing Yan Tam, Note, *Biologics Revolution: The Intersection of Biotechnology, Patent Law, and Pharmaceutical Regulation*, 98 GEO. L.J. 535, 535–36 (2010).

⁸ The principal section of the BPCIA is codified at 42 U.S.C. § 262 (2012). The BPCIA was passed as part of the Patent Protection and Affordable Care Act (“ACA”). Pub. L. No. 111-148, 124 Stat. 119 (2012) (codified as amended in scattered sections of 25, 26, 29, 42 U.S.C.).

⁹ *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1351 n.1 (Fed. Cir. 2015), *cert. granted*, 137 S. Ct. 808 (2017).

¹⁰ See Tam, *supra* note 7, at 536.

tion of patent law and pharmaceutical regulation exacerbates the BPCIA's complexity.¹¹ Furthermore, the BPCIA has the complicated responsibility of accomplishing two countervailing goals.¹² The BPCIA seeks to find the complex, yet delicate, balance between allowing biosimilar manufacturers to introduce competition to counter the unaffordable cost of biologics, while simultaneously preserving the incentive for innovators to bring pioneering and essential biologics to market.¹³ At the same time, the BPCIA must maintain the strict standard of pharmaceutical regulation that Americans have come to expect and rely upon despite the delicate and precise nature of biologics and biosimilars.¹⁴ The BPCIA attempts to balance all of these complex, yet crucial aspects.¹⁵

This complexity and sensitivity makes every aspect of the BPCIA essential, because the BPCIA was designed to maintain that delicate balance between the two countervailing goals of the BPCIA.¹⁶ Conversely, removing or changing any aspect of the

¹¹ See, e.g., Linfong Tzeng, *Follow-On Biologics, Data Exclusivity, and the FDA*, 25 *BERKELEY TECH. L.J.* 135, 156 (2010) (discussing how differences in data exclusivity in the patent and regulatory framework are troubling).

¹² See, e.g., Ude Lu, Note, *Biologics Price Competition and Innovation Act: Striking a Delicate Balance Between Innovation and Accessibility*, 15 *MINN. J.L. SCI. & TECH.* 613, 650 (2014) (“[T]he central mission of the BPCIA is to balance two competing interests: innovation and accessibility.”).

¹³ *Id.* at 613.

¹⁴ See Vinita Banthia, Note, *Biosimilar Regulation: Bringing the United States Up to Speed with Other Markets*, 16 *MINN. J.L. SCI. & TECH.* 879, 883, 885 (2015) (“An effective biosimilar approval pathway would necessarily need to strike a balance between ensuring safety and providing affordable access to biologic medicines.”).

¹⁵ See Banthia, *supra* note 14, at 885; Tam, *supra* note 7, at 540 (“The resulting statute balances the interests of the pioneer drug industry, the generic drug industry, and patients seeking access to the best available medicines.”). This balancing of interests is also present in other areas of the law. For an example of the balancing of interests in generic drugs, see Sarah E. Eurek, Note, *Hatch-Waxman Reform and Accelerated Market Entry of Generic Drugs: Is Faster Necessarily Better?*, 2 *DUKE L. & TECH. REV.* 2 (2003). For an example of the balancing of interests with medical devices, see Adam Lewin, Note, *Medical Device Innovation in America: Tensions Between Food and Drug Law and Patent Law*, 26 *HARV. J.L. & TECH.* 403, 404 (2012) (“The legal structures regulating the introduction of medical devices must therefore strike a careful balance between promoting new and better devices and ensuring that devices on the market are safe and effective.”).

¹⁶ See Richard A. Epstein, *The Constitutional Protection of Trade Secrets and Patents Under the Biologics Price Competition and Innovation Act of 2009*, 66 *FOOD & DRUG L.J.* 285, 286 (2011).

BPCIA may skew this important and delicate balance.¹⁷ Therefore, it is critical to keep this delicate balance in mind in making a determination regarding any aspect of the BPCIA.

Recently, the nature of one of the BPCIA's aspects has been called into question: Is the "patent dance," the structured patent dispute resolution process of the BPCIA, mandatory or optional? A mandatory patent dance requires a biosimilar applicant to comply with all its requirements, while an optional patent dance allows the biosimilar applicant to opt out of the entire dance if it so chooses. This question is important because it has the potential to affect that delicate balance of the BPCIA.

This Note focuses on some of the consequential implications of deciding that the patent dance of the BPCIA is optional versus mandatory. This Note ultimately argues that the patent dance of the BPCIA should be mandatory. Part I provides the background to the BPCIA by explaining what biologics and biosimilars are and what makes them unique. Part I continues by explaining what the patent dance is and what the Federal Circuit decided about this issue in *Amgen Inc. v. Sandoz Inc.*¹⁸ Part II discusses the implications that result as a consequence of an optional patent dance as opposed to a mandatory patent dance. Finally, Part III argues that the BPCIA constructs a delicate balance to its countervailing goals and, therefore, the patent dance should be mandatory to maintain that balance.

I. BACKGROUND ON THE BIOSIMILAR, PRICE, COMPETITION, AND INNOVATION ACT

This Part provides background on the BPCIA and details the origins of the question on whether the patent dance is optional or mandatory. Section I.A explains what biologics are and what makes them different than traditional small molecule drugs. Section I.B explains why process patents may be biologic's strongest source of protection. Section I.C outlines the process to bring a successful

¹⁷ Cf. Lu, *supra* note 12, at 646 (discussing how the current BPCIA's provisions on exclusivity tip the scale in favor of innovator companies, and proposing a different frame that better balances innovation and accessibility).

¹⁸ See 794 F.3d 1347, 1350 (Fed. Cir. 2015), *cert. granted*, 137 S. Ct. 808 (2017).

biologic to the public in compliance with the relevant federal regulations and how that leads to the astronomical costs of biologics, especially contrasted with small molecule drugs. Section I.D explains what biosimilars are and why traditional generics are not available to resolve the problem of high cost as it was for small molecule drugs. Section I.E outlines the BPCIA and the BPCIA's patent dance. Finally, Section I.F discusses the facts of *Amgen v. Sandoz* and follows its path to the Supreme Court.

A. *What Is a Biologic?*

A biologic is a type of pharmaceutical that is extremely complex¹⁹ and intricately dependent on its manufacturing process.²⁰ The BPCIA defines a biologic, or “biological product,” as a “virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings.”²¹ Essentially, biologics are protein-based macromolecules that have been created by living cells.²² Biologics are not directly manufactured by humans; instead they are created by harnessing unique characteristics of certain specialized living cells.²³ These cells are genetically engineered through recombinant DNA technology to create a cell line that expresses or secretes the desired protein-based molecules.²⁴ A familiar example of a biologic is Humulin, which is an insulin used to control high blood sugar in adults and children with diabetes.²⁵

¹⁹ See, e.g., Jenny M. Alsup, *You Can Dance If You Want To? Initial Interpretations of the BPCIA's Patent Dance with Sandoz and Amgen*, 8 HASTINGS SCI. & TECH. L.J. 137, 138 (2016).

²⁰ See Lu, *supra* note 12, at 617 (“A minor change in the manufacturing process, such as a minor change in temperature of cell culture, can change the overall characteristic of a final biologic product.”).

²¹ 42 U.S.C. § 262(i)(1) (2012).

²² See Lu, *supra* note 12, at 616–17.

²³ See Memorandum from the Pharm. Research & Mfrs. of Am. to the Food & Drug Admin 4 (Nov. 12, 2004), <https://www.fda.gov/ohrms/dockets/dockets/04n0355/04n0355-c000004-01-vol1.pdf> [<https://perma.cc/3ETX-BXRR>] [hereinafter Pharm. Memorandum].

²⁴ Lu, *supra* note 12, at 616 n.15.

²⁵ *About Humulin R U-500*, HUMULIN, <http://www.humulin.com/about-U-500.aspx> [<https://perma.cc/5YME-SJH8>] (last visited Feb. 21, 2017).

Traditional small molecule drugs, are smaller, relatively simpler, and man-made.²⁶ Small-molecule drugs are synthesized with discrete, linear steps progressing in a predictable way, using prescribed chemicals in a known formula.²⁷ In contrast, biologics are larger and more complex, and their manufacturing process is less predictable and more complicated.²⁸ A protein's function is dictated by its unique three-dimensional structure which is generated as the protein is being synthesized.²⁹ In addition, many proteins within the cell require the placement of different types of molecules, such as sugars or fatty acids, on specific regions to function properly.³⁰ Thus, biologics, which are created through hundreds of thousands of interconnected chemical reactions in complex metabolic pathways within a living cell, are very sensitive to environmental perturbations.³¹

The complex nature of biologics and the fact that they are produced within a living organism renders every component of the biologic important and indispensable.³² This is especially true regarding the components of the manufacturing process of biologics because it is an extremely sensitive process and may be altered by any slight change.³³ A slight alteration in a biologic's manufacturing process can have a drastic effect on the final product, which may cause adverse clinical consequences.³⁴ For example, a slight change in the cell expressing the desired protein can affect the way it ex-

²⁶ See Pharm. Memorandum, *supra* note 23, at 4.

²⁷ *Id.* at 3.

²⁸ *Id.*

²⁹ Elysa B. Goldberg, Note, *Fixing a Hole: Will Generic Biologics Find a Niche Within the Hatch-Waxman Act?*, 20 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 327, 333 (2009).

³⁰ *Id.*

³¹ Pharm. Memorandum, *supra* note 23, at 4.

³² See *id.* at 4-5.

³³ See Erwin A. Blackstone & Joseph P. Fuhr, Jr., *The Economics of Biosimilars*, 6 AM. HEALTH & DRUG BENEFITS 469, 472 (2013) ("Biologics and biosimilars are sensitive to and altered by changes in their manufacturing process.").

³⁴ Paul J. Declerck, *Biotherapeutics in the Era of Biosimilars: What Really Matters Is Patient Safety*, 30 DRUG SAFETY 1087, 1088 (2007) ("Small distinctions in the cell line, the manufacturing process or in any step from the cell line stage through to administration to the patient can make a major difference in adverse effects observed during treatment . . . Therefore, unlike chemical pharmaceuticals, substitution between biologics, including [follow-on biologics], can have clinical consequences and create health concerns for patients.").

presses that protein.³⁵ Thus, unlike small molecule drugs, biologics are unique in that the “process is the product, and the product is the process.”³⁶

B. Patents on Biologics: Biologic Manufacturing Process as the Strongest Source of Patent Protection

Due to the specific nature of biologics and its relationship with its manufacturing process, a patent on the manufacturing process is very important because the validity of a patent on the biologic itself is questionable under patent law. Patents are intended to “promote the Progress of Science and useful Arts”³⁷ by granting property rights in information in exchange for full disclosure of the invention.³⁸ A patent contains a specification and claims.³⁹ The specification is a narrative description of the invention,⁴⁰ while the claims define the “metes and bounds” of the patent’s scope.⁴¹ A patent’s

³⁵ *Id.*; Lu, *supra* note 12, at 625–26 (“Any minor change in the manufacture or drug-delivery process can change the overall characteristic of a final biologic product. For example, with exactly the same manufacturing process, a manufacturer of interferon beta-1a produced two batches of products with drastically different immunogenicity. One batch was safe and effective, yet another batch caused serious immune responses. The only difference between the two batches was the manufacture site. The manufacturing conditions that affect the properties of biologics generally include: the cell lines used to produce the biologics, culture/fermentation conditions, purification procedures, and container closure/packaging systems. Thus, a much higher quality control standard is required for biologics than for small molecule drugs.”).

³⁶ Tam, *supra* note 7, at 543.

³⁷ U.S. CONST. art. I, § 8, cl. 8.

³⁸ *See, e.g., Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 621 (Fed. Cir. 2000), *vacated*, 535 U.S. 722 (2002) (“To obtain this exclusive right, the inventor must disclose his invention to the public. Thus, the patent also is of value to the public because such disclosures will stimulate others to add to the sum of human knowledge through the creation of other inventions utilizing the lessons learned by the patentee.”); *see also Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 9 (1966) (“The patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge.”); *Mazer v. Stein*, 347 U.S. 201, 219 (1954) (“The economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors in ‘Science and useful Arts.’”).

³⁹ 35 U.S.C. § 112 (2012).

⁴⁰ *See id.*

⁴¹ *See, e.g., Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997) (describing the boundary of a patent as its “metes and bounds”); *Festo*, 234 F.3d at 622

claims give third parties notice of the existence of the invention and the location of the boundaries,⁴² but may also be used by competitors as a guide to designing around the patent.⁴³ Thus, the precise understanding of a patent's claims is essential to what the patent actually protects and in determining whether a patent has been infringed upon.

There is a separate requirement for a patent to describe the innovation the patent seeks to protect.⁴⁴ This requirement is “part of the *quid pro quo* of a patent; one describes an invention, and, if the law's other requirements are met, one obtains a patent.”⁴⁵ Among other things, the specification is required to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the same innovation.⁴⁶ If a person skilled in the art must engage in “undue experimentation” to make and use the patented invention, the patent may be found invalid for lack of enablement.⁴⁷ Additionally, “patents that claim unreproducible

(“In drafting an original claim of a patent application, the writer sets out the metes and bounds of the invention . . .”).

⁴² PSC Comput. Prods., Inc. v. Foxconn Int'l, Inc., 355 F.3d 1353, 1359 (Fed. Cir. 2004) (“[C]laims serve the important notice function of informing the public that anyone who makes, uses, or sells the claimed invention infringes the patent.”).

⁴³ See, e.g., Read Corp. v. Porter, Inc., 970 F.2d 816, 828 (Fed. Cir. 1992) (“We have often noted that one of the benefits of the patent system is the incentive it provides for ‘designing around’ patented inventions, thus creating new innovations.”).

⁴⁴ Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1345 (Fed. Cir. 2010).

⁴⁵ *Id.*

⁴⁶ *Id.* at 1344. Section 112 of the Patent Act states, in relevant part:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same

35 U.S.C. § 112(a) (2012).

⁴⁷ See, e.g., Genentech, Inc. v. Novo Nordisk, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993)). Several underlying factual inquiries are made to determine whether the experimentation is undue or not. These include:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

or inoperable results are . . . invalid for lack of enablement, for others skilled in the art cannot practice the invention.”⁴⁸ Moreover, failing to enable others of ordinary skill in the art to verify that what they have made is identical to the claimed product, may invalidate the patent.⁴⁹ Thus, both the claim and specification parts of a patent require a high-level of specificity regarding the innovation and are crucial to understanding what the patent protects and when it has been infringed upon.

The complex nature of biologics and how they are created reveals that patents on biologics rest on “shaky ground”⁵⁰ because the requirement to enable while simultaneously claim a biologic properly is paradoxical.⁵¹ First, the “enablement requirement presents a unique problem for inventions that involve living materials, such as biologics products,” because in many instances it is essentially impossible for a patent’s specification to provide an adequate account with the comprehensive taxonomic description necessary to enable others to make and use the biological invention.⁵² This specific problem may be resolved by depositing a physical sample of the invention in the United States Patent and Trademark Office’s (“USPTO”) publicly accessible depositories.⁵³ However, depositing samples in the USPTO depository does not completely resolve the enablement issue for biologics patents for the same reason why it is not plausible to create *generic* biologics, and why instead it is only plausible to create biosimilars.⁵⁴ As discussed below, it is virtually impossible for a competitor to create a biologic that is identical to the innovator’s version.⁵⁵ Theoretically, this should render most, if not all, patents on biologics invalid in the first place because the patent has not enabled a person skilled in the art to reproduce the claimed innovation at all, let alone without

⁴⁸ Dmitry Karshedt, *Limits on Hard-to-Reproduce Inventions: Process Elements and Biotechnology’s Compliance with the Enablement Requirement*, 3 HASTINGS SCI. & TECH. L.J. 109, 111–12 (2011).

⁴⁹ *Id.* at 112–13.

⁵⁰ Tam, *supra* note 7, at 544.

⁵¹ *See generally id.* at 545–47 (discussing the difficulty of meeting the enablement requirement for biologics).

⁵² *Id.* at 545.

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *See infra* Section I.D.

undue experimentation.⁵⁶ Thus, patents on biologics rest on “shaky ground.”⁵⁷

Biologics manufacturers anticipate that others may attempt to invalidate these seemingly questionable patents so that they can participate in the lucrative biologics industry.⁵⁸ Therefore, for security, biologics manufacturers regularly obtain separate patents for the biologic and the manufacturing process of that biologic.⁵⁹ Properly tailored process patents could be a possible solution to the enablement problem.⁶⁰ A biologic’s particular manufacturing process is indispensable in creating that specific biologic product without any variations.⁶¹ Any alteration or variation in that process will inevitably most likely produce a different biologic product.⁶² Therefore, obtaining a patent on a biologic’s specific manufacturing process effectively protects competitors from creating that biologic.⁶³ Thus, an important source of patent protection for biologics may be the patents on the manufacturing process of that biologic.⁶⁴

Furthermore, the “product is the process”⁶⁵ for biologics as even minor manufacturing changes may critically impact the final biologic product.⁶⁶ Some, if not all, of the essential steps or tools that are necessary to manufacture the biologic are protected by

⁵⁶ See generally Gregory N. Mandel, *The Generic Biologics Debate: Industry’s Unintended Admission that Biotech Patents Fail Enablement*, 11 VA. J. L. & TECH., no. 8, 2006, at 21–25 (discussing enablement law and how certain patents covering biologics will be invalid for lack of enablement, and suggesting that any changes in enablement law should be “narrowly limited”).

⁵⁷ See generally Tam, *supra* note 7, at 544–47.

⁵⁸ *Id.* at 546.

⁵⁹ *Id.*; see also Lu, *supra* note 12, at 624 (“Innovator companies often rely on method patents to protect the manufacturing process of the final products.”).

⁶⁰ Tam, *supra* note 7, at 546.

⁶¹ See, e.g., Janet Freilich, *Patent Infringement in the Context of Follow-on Biologics*, 16 STAN. TECH. L. REV. 9, 21 (2012) (“[S]mall differences in production process—or even production by the same process but in a different facility—can result in differences in the product, which can have adverse clinical consequences.”).

⁶² See *id.*

⁶³ See Tam, *supra* note 7, at 546.

⁶⁴ See *id.*

⁶⁵ *Id.* at 543.

⁶⁶ Donna M. Gitter, *Innovators and Imitators: An Analysis of Proposed Legislation Implementing an Abbreviated Approval Pathway for Follow-on Biologics in the United States*, 35 FLA. ST. U. L. REV. 555, 561 (2008).

their own patents and other intellectual property methods.⁶⁷ Thus, it would be virtually impossible to create this biologic without the ability to use the other steps or tools restricted by their own patent(s) because the process is integral for that specific biologic.⁶⁸ For example, the Pharmaceutical Research and Manufacturers of America (“PhRMA”), a trade group that represents the country’s leading pharmaceutical research and biotechnology companies, stated that due to the “complexity of the biological manufacturing process, extensive analytical testing is done at key process steps using validated assays that are often proprietary, with appropriate sample qualification to ensure that the process intermediates are suitable for progressing to the next step.”⁶⁹ Thus, the role of process patents on the manufacturing of biologics is crucial because it is key to manufacturing the biologic properly and may be the source of patent protection on the biologic itself.

C. The Development, Federal Regulation, and Unaffordable Cost of Biologics

There are strict regulations on the manufacturing and sale of biologics.⁷⁰ Biologics are regulated under the Public Health Service Act (“PHSA”), which sets forth a strict process for approval.⁷¹ A successful biologic begins with the biologic manufacturer’s innovation and can only enter the market after undergoing both research and development and clinical testing.⁷² The pre-clinical phase of development starts with experimentation and research, using in vitro (in glass) and in vivo (in cells) studies,⁷³ to discover a clinical

⁶⁷ See Freilich, *supra* note 61, at 20–21 (“[T]he details of the production process used by the pioneer company are protected by various intellectual property methods.”); Tam, *supra* note 7, at 546.

⁶⁸ See Freilich, *supra* note 61, at 20–21; Tam, *supra* note 7, at 546.

⁶⁹ See Pharm. Memorandum, *supra* note 23, at 4.

⁷⁰ See Public Health Service Act § 351, 42 U.S.C. § 262 (2012); Gitter, *supra* note 66, at 566; Goldberg, *supra* note 29, at 331–33 (discussing the various steps and tests that each innovator drug must undergo before being introduced to the public); Ernst R. Berndt et al., *Opportunities for Improving the Drug Development Process: Results from a Survey of Industry and the FDA* (Nat’l Bureau of Econ. Research, Working Paper No. 11425, 2005) (providing a brief overview of the approval pathway for pharmaceutical drugs).

⁷¹ Public Health Service Act § 351.

⁷² See Goldberg, *supra* note 29, at 331.

⁷³ See *id.* at 331–32; Berndt et al., *supra* note 70, at 7.

candidate compound.⁷⁴ If researchers successfully identify and purify a clinical candidate compound, they will subsequently conduct animal studies for further testing.⁷⁵ If the clinical candidate compound obtains positive results from the animal studies, the company developing the drug can file an Investigational New Drug (“IND”) application.⁷⁶ The Food and Drug Administration (“FDA”) then evaluates the IND and decides whether or not to allow the drug to be tested on humans.⁷⁷ If the FDA allows the drug to be tested on humans, then the clinical phases of testing, which consists of three mandatory, separate phases, begins.⁷⁸ Each of these phases is designed to avert drugs that are not suitable for general public use.⁷⁹ Phase I clinical trials test for “safety and tolerability” of the drug in a small group of human subjects.⁸⁰ Phase II trials are conducted in a much larger pool of volunteers who are diagnosed with the particular targeted condition to continue testing for safety and tolerability, and to assess the preliminary effectiveness of the drug.⁸¹ Phase III clinical trials are conducted on the largest pool of volunteers and are designed to evaluate the drug in a more diverse population over a longer period of time.⁸² The drugs that successfully complete these three phases can then be submitted as new Biologic License Applications (“BLAs”) to the FDA.⁸³ The BLAs contain analytical, preclinical, and clinical data showing that the product is safe, pure, and potent as well as elaborate discussions of the methods by which the product is manufactured.⁸⁴

⁷⁴ A clinical candidate compound is a chemical that provides a key breakthrough for consequent clinical trials. *See generally* Franz F. Hefti, *Requirements for a Lead Compound to Become a Clinical Candidate*, 9 BMC NEUROSCIENCE, Dec. 10, 2008.

⁷⁵ Berndt et al., *supra* note 70, at 7.

⁷⁶ Gitter, *supra* note 66, at 565; Berndt et al., *supra* note 70, at 7.

⁷⁷ Gitter, *supra* note 66, at 565; Berndt et al., *supra* note 70, at 8.

⁷⁸ Gitter, *supra* note 66, at 565; Berndt et al., *supra* note 70, at 8.

⁷⁹ Gitter, *supra* note 66, at 565–66.

⁸⁰ *Id.* at 565; Berndt et al., *supra* note 70, at 8.

⁸¹ Gitter, *supra* note 66, at 565–66; Berndt et al., *supra* note 70, at 8–9.

⁸² Gitter, *supra* note 66, at 565–66; Berndt et al., *supra* note 70, at 9.

⁸³ 42 U.S.C. § 262(A)(2) (2012); 21 C.F.R. § 601.2(a) (2016); Gitter, *supra* note 66, at 566.

⁸⁴ § 262(A)(2)(C).

Thus, the unique nature of biologics, their complex manufacturing processes,⁸⁵ and the strict approval procedures make them extraordinarily expensive to develop and bring to market.⁸⁶ As of December 2012, the average cost of developing a new biologic was estimated to be approximately \$1.9 billion.⁸⁷ In addition, only ten percent of approved drugs are commercially successful, and it typically takes thirteen and a half years to receive approval to market a drug.⁸⁸ Furthermore, between 2004 and 2010 only nine percent of the drugs that entered phase I clinical trials obtained approval, and only twenty-two percent of the biologics that reached phase II clinical trials received approval.⁸⁹ This expense is passed down to the consumer, thus making some of the most important biologics nearly unaffordable.⁹⁰ The annual expense for the consumer of a biologic regimen may cost hundreds of thousands of dollars.⁹¹

*D. Generic Small-Molecule Drugs and the Hatch-Waxman Act:
Biosimilars as a Solution to the Unaffordable Cost of Biologics*

The high costs of pharmaceuticals, including biologics, “put[s] a great burden on the financial stability of Americans.”⁹² The same

⁸⁵ See U.S. FOOD & DRUG ADMIN., SCIENTIFIC CONSIDERATIONS IN DEMONSTRATING BIOSIMILARITY TO A REFERENCE PRODUCT: GUIDANCE FOR INDUSTRY 5–6 (2015) (stating that “different cell line[s], raw materials, equipment, processes, process controls, and acceptance criteria” are all likely to affect the quality of produced biologics).

⁸⁶ See Grabowski, *supra* note 7, at 481–82 (providing an in-depth discussion of the unique characteristics of research and development activity and clinical testing that makes biologics more expensive); Lu, *supra* note 12, at 625 (“The cost to bring a biologic drug to the market is higher than that for a small-molecule drug. This higher cost is partly due to the high manufacture quality required in making a biologic.”).

⁸⁷ Blackstone & Fuhr, *supra* note 33, at 473.

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ See Anthony D. So & Samuel L. Katz, Opinion, *Biologics Boondoggle*, N.Y. TIMES (Mar. 8, 2010), <http://www.nytimes.com/2010/03/08/opinion/08so.html> [<https://perma.cc/3368-HHKD>].

⁹¹ See, e.g., Blackstone & Fuhr, *supra* note 33, at 473 (“Herceptin can cost as much as \$100,000 annually per patient and has sales of more than \$6 billion.”); So & Katz, *supra* note 90 (“And those who take Cerezyme to treat Gaucher disease, a rare inherited enzyme deficiency, spend a staggering \$200,000 a year.”).

⁹² Felix Shin, *Leaping from the “Patent Cliff” into the “Global Drug Gap”: Overcoming Exclusivity to Provide Affordable Biosimilars*, 37 LOY. L.A. INT’L & COMP. L. REV. 419, 443–44 (2016) (calculating proportion of gross domestic product attributable to health expenditures, and comparing this to other countries).

problem of unaffordable medicine faced small-molecule drugs, which Congress resolved by enacting the Drug Price Competition and Patent Restoration Act of 1984,⁹³ better known as the Hatch-Waxman Act.⁹⁴ By amending the Federal Food, Drug, and Cosmetic Act (“FDCA”), the Hatch-Waxman Act permitted pharmaceutical companies to produce generic small-molecule drugs quicker and cheaper by permitting them to piggyback off of the data of brand-name drugs and bypass FDA testing.⁹⁵ Under the Hatch-Waxman Act, a generic small-molecule drug does not have to undergo all of the aforementioned phases.⁹⁶ Instead, the generic manufacturer is only required to show that the generic drug:

- (1) contain[s] the same active ingredients as the [brand-name small-molecule drug]
- (2) [is] identical in strength, dosage form, and route of administration
- (3) [has] the same use indications
- (4) is bioequivalent⁹⁷ [to the brand-name small-molecule drug]
- (5) meet[s] the same batch requirements for identity, strength, purity, and quality
- (6) [is] manufactured under the same strict standards of FDA’s good manufacturing practice regulations required for innovator products.⁹⁸

⁹³ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 21 U.S.C. & 35 U.S.C.).

⁹⁴ E.g., Matthew J. Seamon, *Antitrust and the Biopharmaceutical Industry: Lessons from Hatch-Waxman and an Early Evaluation of the Biologics Price Competition and Innovation Act of 2009*, 34 NOVA L. REV. 629, 630 (2010).

⁹⁵ See 21 U.S.C. § 355(j) (2012); Ralph A. Lewis, *The Emerging Effects of the Drug Price Competition and Patent Term Restoration Act of 1984*, 8 J. CONTEMP. HEALTH L. & POL. 361, 362–63 (1984).

⁹⁶ See Lewis, *supra* note 95, at 362.

⁹⁷ § 355(j)(8)(B). Showing bioequivalence is essentially demonstrating that the generic drug acts the same way and has the same effect as the brand name drug. See H.R. REP. NO. 98-857, at 31 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2664 (“A drug shall be considered bioequivalent to a listed drug if the rate and extent of absorption of the generic drug do not show a significant difference from the rate and extent of absorption of the listed drug . . .”); CTR. FOR DRUG EVALUATION & RESEARCH, FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES SUBMITTED IN NDAS OR INDs—GENERAL CONSIDERATIONS 2 n.4 (2014) (describing “bioequivalence” as a statutory term under the FDCA).

This abbreviated scheme allowed by the Hatch-Waxman Act cuts costs and allows for cheaper generic alternatives to be introduced into the market.⁹⁹ In 2009, generic non-biological drug applications typically took three to five years to assemble at a corresponding cost of \$1 million to \$5 million.¹⁰⁰ The Hatch-Waxman Act also permits consumers to choose between brand-name and generic drugs earlier, driving down the cost of drugs by price competition.¹⁰¹ Overall, the Hatch-Waxman Act is generally considered to be a success and, as a result, small-molecule drugs are relatively more affordable.¹⁰² However, the *generics* solution is not directly available for biologics.¹⁰³

Indeed, it is effectively impossible to create a generic biologic.¹⁰⁴ The generic scheme works for small-molecule drugs because the brand-name companies have already proven that the molecule is effective.¹⁰⁵ Thus, as long as the generic companies are making a drug that has the identical active ingredient and is bioequivalent, then the generic can be presumed to be effective without the need for extensive clinical trials. However, the physical nature of biologics and biological manufacturing renders it virtually impossible to achieve identical composition between biologics produced by unrelated manufacturers.¹⁰⁶ While the manufacturing process for a

⁹⁸ *Generic Drugs: Questions and Answers*, FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm> [https://perma.cc/3CT4-QFXV] (last visited Feb. 22, 2017).

⁹⁹ Martha M. Rumore, *The Hatch-Waxman Act—25 Years Later: Keeping the Pharmaceutical Scales Balanced*, PHARMACY TIMES (Aug. 15, 2009), <http://www.pharmacytimes.com/publications/supplement/2009/genericsupplement0809/generic-hatchwaxman-0809> [https://perma.cc/ZG3L-VLMA].

¹⁰⁰ FED. TRADE COMM'N, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION iii (2009).

¹⁰¹ *Id.* at ii.

¹⁰² See Jason Kanter & Robin Feldman, *Understanding and Incentivizing Biosimilars*, 64 HASTINGS L.J. 57, 62 (2012) (“The Hatch-Waxman Act has been relatively successful in creating a system that is well defined for investors, incentivizing both new drug development and generic entry.”); Sara Margolis, Note, *Destined for Failure? An Analysis of the Biologics Price Competition and Innovation Act of 2009*, 2013 COLUM. BUS. L. REV. 209, 222–23 (“The Hatch-Waxman Act has had significant success in lowering the prices of pharmaceutical drugs.”); Rumore, *supra* note 99.

¹⁰³ See Kanter & Feldman, *supra* note 102, at 59.

¹⁰⁴ See Pharm. Memorandum, *supra* note 23, at 4.

¹⁰⁵ See *Generic Drugs: Questions and Answers*, *supra* note 98.

¹⁰⁶ Pharm. Memorandum, *supra* note 23, at 4.

small-molecule drug product typically involves only “several dozen discrete, linear steps progressing” in a controlled and predictable way, the “manufacturing processes for biologics are based on the synthetic capabilities of living cells that have inherent metabolic and synthetic variability.”¹⁰⁷ As PhRMA explained: “Using a living organism to produce a biological product involves hundreds to thousands of interconnected steps in complex metabolic pathways which are very sensitive to environmental perturbations.”¹⁰⁸ Each biologic manufacturing process results in a unique product where even small alterations may cause considerable differences in the clinical properties of the resulting biological product.¹⁰⁹ PhRMA asserted that “[c]hemically and pharmaceutically identical biologics will not result from unrelated manufacturers.”¹¹⁰ Instead, it is possible to create biologics that are “highly similar” to each other in that they have “no clinically meaningful differences in terms of safety and effectiveness.”¹¹¹ These macromolecules are highly similar, but not exact—hence, the name biosimilar.¹¹² A biosimilar is “highly similar” to a biologic, which is referred to as the “reference product.”¹¹³

Therefore, replicating the Hatch-Waxman system for biologics was initially believed to be impossible.¹¹⁴ However, in 2009, Con-

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*; see also Michal Nowicki, *Basic Facts About Biosimilars*, 30 KIDNEY BLOOD PRESSURE RES. 267, 268 (2007).

¹¹⁰ Pharm. Memorandum, *supra* note 23, at 4.

¹¹¹ *Information for Consumers (Biosimilars)*, FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm241718.htm> [<https://perma.cc/L872-ZPLT>] (last visited Feb. 23, 2017); see also Kanter & Feldman, *supra* note 102, at 59 (“[T]he term ‘generic’ does not currently apply to biological drugs copied from an original biologic. Rather, such copies are referred to as biosimilars, or follow-on biologics.”).

¹¹² Kanter & Feldman, *supra* note 102, at 59.

¹¹³ 42 U.S.C. § 262(i)(2)(A), (i)(4) (2012).

¹¹⁴ See Krista Hessler Carver et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 FOOD & DRUG L.J. 671, 711–16 (2010); see also Declerck, *supra* note 34, at 1089 (“As a consequence of the complexity of both the biotechnology product and the production process . . . and the limitation of sensitivity of analytical tools (i.e. the process determines the product), no solid scientific grounds exist to guarantee safe interchangeability between any biologics . . . obtained through different manufacturers.”).

gress enacted the BPCIA, a subtitle within the larger Patient Protection and Affordable Care Act, which provided a streamlined process for biosimilar approval.¹¹⁵

E. BPCIA

The BPCIA seeks to ensure that the biosimilars are held to a strict and safe standard by defining a biosimilar to mean: “(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and (B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.”¹¹⁶ The statute also requires that a biosimilar application—often referred to as “abbreviated biologic license application” (“aBLA”)¹¹⁷—fulfills strict data requirements.¹¹⁸ A biosimilar applicant must submit “analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components,” “animal studies,” and clinical studies that are “sufficient to demonstrate safety, purity, and potency in [one] or more appropriate conditions of use”¹¹⁹ The biosimilar applicant is also required to show that its biological product uses “the same mechanism[s] of action” as the reference product and that “the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product.”¹²⁰ Additionally, the biosimilar applicant must demonstrate in its aBLA that “the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for

¹¹⁵ The key provisions of the BPCIA are codified at 42 U.S.C. § 262 (2012).

¹¹⁶ § 262(i)(2).

¹¹⁷ *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1351 (Fed. Cir. 2015) (“[U]nder the abbreviated pathway created by the BPCIA, codified at 42 U.S.C. § 262(k), an applicant filing an abbreviated biologics license application (‘aBLA’ or ‘subsection (k) application’) instead submits information to demonstrate that its product is ‘biosimilar’ to or ‘interchangeable’ with a previously approved reference product.” (quoting 42 U.S.C. § 262(k)(2)–(5) (2012))), *cert. granted*, 137 S. Ct. 808 (2017); Lu, *supra* note 12, at 614.

¹¹⁸ See § 262(k)(2).

¹¹⁹ § 262(k)(2)(A)(i)(I).

¹²⁰ § 262(k)(2)(A)(i)(II), (IV).

the reference product.”¹²¹ Furthermore, the biosimilar applicant must demonstrate that the facility in which their biological product is produced “meets standards designed to assure that the biological product continues to be safe, pure, and potent.”¹²² If the biosimilar applicant meets all of these requirements, as well as packaging and labeling requirements, then the biological product may be deemed biosimilar to the reference product.¹²³ The BPCIA states that when a biological product “(i) is biosimilar to the reference product; and (ii) can be expected to produce the same clinical results as the reference product in any given patient . . .”¹²⁴ it may be deemed “interchangeable” with the reference product and be substituted for the brand name biologic by a pharmacist, even if the physician did not prescribe the biosimilar.¹²⁵

Like the Hatch-Waxman Act, the BPCIA encourages generic competition by allowing biosimilar manufacturers to piggyback off of the clinical data of the reference biologic.¹²⁶ In contrast to the approximately \$1.9 billion and thirteen and a half years it typically takes to fully develop a biologic, it takes only seven to eight years to develop a biosimilar at a relatively reasonable cost of \$100 to \$250 million.¹²⁷ Additionally, “biosimilars have a better chance to make it to market and are therefore less risky than branded biologics” because it is easier and cheaper to copy than to innovate.¹²⁸ This allows biosimilar manufactures to enter the market at a significantly cheaper price and thus introduce competition, making treatments significantly more affordable.¹²⁹

¹²¹ § 262(k)(2)(A)(i)(III).

¹²² § 262(k)(2)(A)(i)(V).

¹²³ § 262(i)(2), (k).

¹²⁴ § 262(k)(4)(A).

¹²⁵ § 262(i)(3); *Information for Consumers (Biosimilars)*, *supra* note 111.

¹²⁶ Epstein, *supra* note 16, at 287; *see* Alsup, *supra* note 19, at 138–39 (“The [BPCIA] regulates the approval of biosimilars. Borrowing from the Hatch-Waxman Act, the BPCIA lays out an abbreviated pathway to FDA approval and market entry.”); Lu, *supra* note 12, at 614–15. *But see* Margolis, *supra* note 102, at 222–36 (arguing that the BPCIA will not succeed in lowering drug prices to the same degree that the Hatch-Waxman Act did for generic pharmaceuticals).

¹²⁷ *See* Blackstone & Fuhr, *supra* note 33, at 471, 473.

¹²⁸ *Id.* at 473.

¹²⁹ *See* Jacqueline T. Genovese, Note, *Biosimilar Naming: A Call for Uniformity in a Complex Field*, 41 BROOK. J. INT’L L. 293, 303 (2015) (“Essentially, the BPCIA creates a shorter pathway for biosimilar approval, which in turn allows for cheaper alternatives to

The BPCIA has many complex and interconnected aspects.¹³⁰ One of the central aspects¹³¹ is a process in which the original biologic manufacturer (the “reference product sponsor” or “RPS”) and biosimilar applicant exchange patents that they believe need to be litigated.¹³² This patent exchange is an elaborate back-and-forth process and has thus been dubbed the “patent dance” by practitioners.¹³³ The first step of this procedure requires the biosimilar applicant to provide the RPS access to the biosimilar application itself and “such other information that describes the process or processes used to manufacture the biological product” described in the application “[n]ot later than [twenty] days after the Secretary¹³⁴ notifies the [biosimilar] applicant that the application has been accepted for review.”¹³⁵ In addition, the applicant may in its own discretion supply additional information that the RPS requests.¹³⁶ In the next stage of the process, the RPS must give the biosimilar applicant a list of patents for which it “believes a claim of patent infringement could reasonably be asserted” against the biosimilar applicant within sixty days of receiving the application and information.¹³⁷ This list of patents includes process patents, unlike the Hatch-Waxman Act’s litigation provisions, which exclude process patents.¹³⁸ Once this is done, the dance turns to the

many life-saving biologic medicines.”). *But see* Erika Lietzan, *The Myths of Data Exclusivity*, 20 LEWIS & CLARK L. REV. 91, 107–10 (2016) (discussing how much cost savings biosimilars will actually provide).

¹³⁰ Carl J. Minniti III, *Sandoz v. Amgen: Why Current Interpretation of the Biologic Price Competition and Innovation Act of 2009 Is Flawed and Jeopardizes Future Competition*, 97 J. PAT. & TRADEMARK OFF. SOC’Y 172, 177 (2015) (“The BPCIA is undoubtedly a complex statute.”).

¹³¹ *Id.* at 178 (“The central feature of the BPCIA is the [p]atent [d]ance.”).

¹³² Lindsay Kelly, *Biologics in the Practice of Law*, 39 HARV. J.L. & PUB. POL’Y 21, 25 (2016).

¹³³ *Id.* (“The BPCIA ‘patent dance,’ as it is colloquially referred to by patent lawyers . . .”).

¹³⁴ 42 U.S.C. § 201(c) (2012) (“Unless the context otherwise requires, the term ‘Secretary’ means the Secretary of Health and Human Services.”).

¹³⁵ *Id.* § 262(l)(2)(A).

¹³⁶ § 262(l)(2)(B).

¹³⁷ § 262(l)(3)(A)(i).

¹³⁸ *See* Michael P. Dougherty, *The New Follow-on-Biologics Law: A Section by Section Analysis of the Patent Litigation Provisions in the Biologics Price Competition and Innovation Act of 2009*, 65 FOOD & DRUG L.J. 231, 234 (2010) (“The scope of the patents to be identified in this process is broader than under the Hatch-Waxman Act, embracing not

biosimilar applicant who may, but need not, supply a list of additional patents that it believes could be the basis for a reasonable claim against its biosimilar.¹³⁹ Either way, the biosimilar applicant must provide a “detailed statement” that explains why any patent listed (by either side) is “invalid, unenforceable, or will not be infringed.”¹⁴⁰ Alternatively, the biosimilar applicant may signal a truce with respect to any particular patent by providing a statement to the reference product sponsor that it “does not intend to begin commercial marketing of the biological product before the date that such patent expires.”¹⁴¹ The BPCIA also makes the submission of the biosimilar application an artificial act of infringement with respect to any patent identified by either party in this list exchange process.¹⁴² This creates federal court jurisdiction for the resolution of the patent litigation that will ultimately follow.¹⁴³

Once the biosimilar applicant has sent its statement regarding patent validity, enforcement, and infringement, the BPCIA provides a road map for litigation of the resulting patent issues.¹⁴⁴ In brief, the parties identify a set of patents to be litigated immediately, leaving the rest for litigation shortly before biosimilar market entry.¹⁴⁵ If the RPS prevails before the end of the twelve-year exclusivity period¹⁴⁶ on any patent in the first wave of litigation, the

only patents claiming the biological product and methods of using it, but also patents relevant to the product’s manufacturing process.”). *Compare* § 262(l)(3)(A)(i) (referring to “a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted”), *with* 21 U.S.C. 355(j)(2)(A)(vii) (2012) (requiring a generic applicant under Hatch-Waxman Act to file a certification with respect to “each patent which claims the listed drug . . . or which claims a use for such listed drug for which the applicant is seeking approval . . .”). As explained below, the process of manufacturing a biologic is crucial to the actual product and may be the sole source of intellectual property protection. *See infra* Section II.A.

¹³⁹ § 262(l)(3)(B)(i).

¹⁴⁰ § 262(l)(3)(B)(ii)(I).

¹⁴¹ § 262(l)(3)(B)(ii)(II).

¹⁴² 35 U.S.C. § 271(e)(2)(C) (2012).

¹⁴³ 28 U.S.C. § 1338 (2012); Alsop, *supra* note 19, at 141 (“This act of infringement is considered artificial and like its counterpart under the Hatch-Waxman Act, it enables an earlier adjudication of patent disputes and creates a justiciable case or controversy.”).

¹⁴⁴ *See* § 262 (l)(4)–(6).

¹⁴⁵ *See id.*; Dougherty, *supra* note 138, at 237–38.

¹⁴⁶ *See* 42 U.S.C. § 262(k)(7)(A) (2012) (“Approval of an application under this subsection may not be made effective by the Secretary until the date that is [twelve] years

BPCIA requires the court to enjoin infringement until the patent expires.¹⁴⁷ In an article discussing the BPCIA in relation to the constitutional protection of trade secrets and patents, Professor Richard Epstein predicted that “[w]here that statutory injunction provision does not apply,” the RPS will “presumably seek an injunction,” and damages, “if the biosimilar has been approved and marketed.”¹⁴⁸

F. Amgen v. Sandoz

In one of the first instances of the application of the BPCIA, the biosimilar applicant refused to initiate the patent dance. In 1991, the FDA approved Amgen, Inc.’s biologic filgrastim under the trade name Neupogen to reduce the risk of infection in patients undergoing chemotherapy.¹⁴⁹ Sandoz, Inc. developed its own filgrastim product, a close copy of Neupogen called EP2006, under the trade names Zarzio and Zarxio.¹⁵⁰ Sandoz began marketing Zarzio outside the United States in 2009, and launched Zarxio in the United States in September 2015.¹⁵¹

On July 7, 2014, Sandoz received notice that the FDA accepted its application for Zarzio, making it the first ever application for a biosimilar to be accepted by the FDA.¹⁵² As stated above, the first

after the date on which the reference product was first licensed under subsection (a).”); Dougherty, *supra* note 138, at 233 n.14.

¹⁴⁷ 35 U.S.C. § 271(e)(4)(D) (2012).

¹⁴⁸ Epstein, *supra* note 16, at 318.

¹⁴⁹ Andrew Pollack, *An F.D.A. Approval for Amgen*, N.Y. TIMES (Feb. 22, 1991), <http://www.nytimes.com/1991/02/22/business/an-fda-approval-for-amgen.html> [https://perma.cc/QB4Y-FZQN].

¹⁵⁰ Press Release, Novartis, Sandoz Launches Zarzio (Filgrastim-Sndz), the First Biosimilar in the United States, NOVARTIS (Sept. 3, 2015), <https://www.novartis.com/news/media-releases/sandoz-launches-zarxiotm-filgrastim-sndz-first-biosimilar-united-states> [https://perma.cc/C5SJ-VP4V]; *see also* Press Release, Sandoz, Zarzio Overtakes Neupogen and Granocyte to Become Most Prescribed Daily G-CSF in Europe (July 22, 2013), <http://www.evaluategroup.com/Universal/View.aspx?type=Story&id=444283> [https://perma.cc/N5JL-8CKT]; Sabrina Tavernise, *For First Time, F.D.A. Panel Approves Generic Copy of Costly Biologic Drug*, N.Y. TIMES (Jan. 7, 2015), <https://www.nytimes.com/2015/01/08/science/fda-panel-vote-biologics.html> [https://perma.cc/G42K-BPY6].

¹⁵¹ Press Release, Novartis, *supra* note 150; Tavernise, *supra* note 150.

¹⁵² *See* Amgen Inc. v. Sandoz Inc., No. 14-CV-04741-RS, 2015 WL 1264756, at *1, *3 (N.D. Cal. Mar. 19, 2015) *aff’d in part, vacated in part*, 794 F.3d 1347 (Fed. Cir. 2015), *cert. granted*, 137 S. Ct. 808 (2017); Tavernise *supra* note 150.

step of the patent dance is to supply the stipulated information no later than twenty days after the “Secretary notifies the [biosimilar] applicant that the application has been accepted for review.”¹⁵³ However, Sandoz chose not to comply with the BPCIA’s disclosure and negotiation procedures, taking the position that initiating the patent dance is optional.¹⁵⁴ Sandoz proposed an alternative arrangement—namely, that Amgen could “procure information via an infringement action.”¹⁵⁵ Amgen brought suit in the Northern District of California on October 24, 2014.¹⁵⁶ Nevertheless, on March 6, 2015, the FDA approved Sandoz’s filgrastim under the BPCIA, making it the first biosimilar approved and marketed in the United States.¹⁵⁷

On March 19, 2015, the district court sided with Sandoz on the patent dance issue, holding that the patent dance outlined by the BPCIA is optional and at the discretion of the biosimilar applicant.¹⁵⁸ Amgen appealed to the Federal Circuit, which issued a fractured decision on July 21, 2015.¹⁵⁹ Two judges on the panel, Judges Lourie and Chen, found that the patent dance procedures under paragraph (l)(2)(A) of the BPCIA were optional and at the discretion of the biosimilar applicant, affirming the district court’s decision on this aspect and siding with Sandoz.¹⁶⁰

Ultimately, Sandoz filed a petition for a writ of certiorari with the Supreme Court on a related issue,¹⁶¹ and Amgen filed a conditional cross-petition asking the Court to evaluate whether the pa-

¹⁵³ 42 U.S.C. § 262(l)(2)(A) (2012).

¹⁵⁴ *Amgen*, 2015 WL 1264756, at *3, *5.

¹⁵⁵ *Id.* at *3.

¹⁵⁶ *Id.* at *4.

¹⁵⁷ See Press Release, Novartis, *supra* note 150.

¹⁵⁸ *Amgen*, 2015 WL 1264756, at *6.

¹⁵⁹ *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1350 (Fed. Cir. 2015), *cert. granted*, 137 S. Ct. 808 (2017).

¹⁶⁰ *Id.* at 1357 (majority opinion); *id.* at 1367 (Chen, J., dissenting in part). *But see id.* at 1362 (Newman, J., concurring in part, dissenting in part) (noting that he does not share in the court’s opinion, which includes the portion of the decision finding the biosimilar manufacture is required to disclose pursuant to paragraph (l)(2)(A)).

¹⁶¹ Sandoz’s petition asked the Court to look at the issue of whether the clock on section 262(l)(8)(A)’s commercial marketing notice requirement, which requires the biosimilar applicant to give the RPS 180 days’ notice, starts before or after FDA approves the biosimilar. See *Petition for a Writ of Certiorari* at i–ii, *Sandoz Inc. v. Amgen Inc.*, No. 15-1039 (U.S. May 17, 2016).

tent dance was mandatory.¹⁶² On June 20, 2016, instead of deciding whether to grant certiorari on the patent dance dispute between Amgen and Sandoz, the Supreme Court invited the Solicitor General to file a brief in the case expressing the views of the United States.¹⁶³ In response, the acting Solicitor General recommended that the court review the Federal Circuit's decision because the questions presented are "sufficiently important to merit the Court's review" and "[b]iologic medicines are among the most important pharmaceuticals available today."¹⁶⁴ On January 13, 2017, the Supreme Court granted Sandoz's petition and Amgen's conditional cross-petition.¹⁶⁵ The Supreme Court will hear arguments in April 2017 and may issue a decision by the end of June.¹⁶⁶

It is imperative that the nature of the BPCIA's patent dance is decided correctly. The pharmaceutical industry must make critical choices on where to allocate their spending and direct their research and development of medicine that people desperately need. The decision on this issue will most likely influence how the pharmaceutical companies make that determination. Thus, the decision will affect many.

¹⁶² Opposition to the Conditional Cross-Petition for a Writ of Certiorari at i, *Amgen Inc. v. Sandoz Inc.*, No. 15-1195 (U.S. May 17, 2016).

¹⁶³ Nathan Monroe-Yavneh & Aron Fischer, *Supreme Court Asks Solicitor General to Weigh in on Amgen v. Sandoz*, BIOLOGICS BLOG (June 20, 2016), <http://www.biologicsblog.com/blog/supreme-court-asks-solicitor-general-weigh-amgen-v-sandoz/> [<https://perma.cc/7RWP-63L8>].

¹⁶⁴ Brief for United States as Amicus Curiae at 22, *Amgen Inc. v. Sandoz Inc.*, Nos. 15-1039, 15-1195 (U.S. Dec. 7, 2016); see also John T. Aquino, *High Court Likely to Review Biosimilars Case After Solicitor General Brief*, BNA: LIFE SCI. L. & INDUSTRY REP. (Dec. 9, 2016), <https://www.bna.com/high-court-likely-n73014448341/> [<https://perma.cc/9KWG-KD9C>].

¹⁶⁵ John T. Aquino, *Supreme Court Grabs Chance to Clarify Biosimilar Law*, BNA: LIFE SCI. L. & INDUSTRY REP. (Jan. 17, 2017), <https://www.bna.com/supreme-court-grabs-n73014449884/> [<https://perma.cc/4EW6-TBHR>].

¹⁶⁶ *Id.*

II. IMPLICATIONS OF THE DECISION TO MAKE THE PATENT DANCE MANDATORY OR OPTIONAL

Statutory interpretation may be used to analyze whether the patent dance was meant to be mandatory or optional,¹⁶⁷ but that analysis is outside the scope of this Note. Instead, this Note discusses the purpose the patent dance purports to serve, and its role in the overall scheme of the BPCIA. This Part discusses several key implications¹⁶⁸ that result as a consequence of the patent dance being optional versus mandatory, and vice versa.¹⁶⁹ Section II.A notes some of the implications that a mandatory or optional patent dance would have on patent infringement disputes and the effect it would have on the overall scheme of the BPCIA. Section II.B discusses how the decision of whether the patent dance is mandatory or optional will determine whether the biosimilar applicants manufacturing information is shared upfront or not.

A. Consequences of the BPCIA Scheme and the Effect on Both Brand-Name Biologics Manufacturers and Biosimilar Manufacturers

If the patent dance is mandatory, then the sequence of events that follow an FDA approval of a biosimilar application is clear and predetermined: the biosimilar applicant must initiate and complete the strict patent dance process.¹⁷⁰ However, if the patent dance is optional, then the sequence of events that follows the FDA approval of a biosimilar application is more difficult to predict.¹⁷¹ Under the view that the patent dance is optional, the BPCIA allows two scenarios: “(1) the sharing of the biosimilar application and manufacturing information, in order to initiate the [p]atent [d]ance, or

¹⁶⁷ See *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1354–59 (Fed. Cir. 2015) (discussing and ultimately deciding this issue based on statutory interpretation), *cert. granted*, 137 S. Ct. 808 (2017).

¹⁶⁸ There are many important implications; however, this Note focuses on the implications that result from the effects that a mandatory or optional patent dance has on patent infringement disputes.

¹⁶⁹ The Federal Circuit’s decision focused on the statutory interpretation issues to determine whether the patent dance is optional or mandatory. It is true that there is a clear statutory interpretation question here, but this Note focuses on the policy choices based on the consequences of this important decision.

¹⁷⁰ See Carl J. Minniti III, *Biosimilar Litigation: The Tussle Over How to Resolve Biologic Patents*, 11 SCITECHLAWYER, no. 3, 2015, at 16, 17.

¹⁷¹ See *id.* at 19.

(2) the refusal to share this information, thereby requiring the RPS to file an immediate declaratory judgment [law]suit” or resort to traditional patent infringement litigation.¹⁷²

Thus, a clear difference is immediately apparent: A mandatory patent dance ensures that the patent dance will occur and will be the method to resolve patent infringement disputes between the RPS and the biosimilar applicant. On the other hand, an optional patent dance creates a system in which the biosimilar applicant has the advantage of choosing how to proceed and may opt out of the patent dance entirely. The difference in these two systems creates several critical implications.

1. Certainty for Both Brand Name Biologic and Biosimilar Manufacturers

The first apparent implication involves the level of certainty. A system where the patent dance is mandatory enables the patent infringement resolution process to be more certain and predictable for both brand name biologic and biosimilar manufacturers.¹⁷³ Both parties would know that, when a biosimilar applicant gets a biosimilar application approved, the next move is to follow the step-by-step process of the patent dance; thus, both parties would be able to prepare accordingly.¹⁷⁴ Although, in this system, neither party would seem to have any strategic advantage over the other, they both would have the benefit of knowing how the other party must conduct themselves.¹⁷⁵ There may of course be specific facts and circumstances that make opting out of the patent dance the better

¹⁷² *Id.*; see also Alsup, *supra* note 19, at 154 (“These subparagraphs allow the reference product sponsor to commence patent litigation immediately following the wrong move, removing availability to the applicant of a litigation safe harbor.”).

¹⁷³ See Epstein, *supra* note 16, at 317 (“This brings certainty to the biosimilar applicants (indeed, a risk-free opportunity to determine whether they may market their products), but it also allows the innovator to avoid multi-year patent litigation proceedings while an infringing biosimilar product is eroding its market share.”). *But see* Kanter & Feldman, *supra* note 102, at 77 (discussing how the disclosure requirements of the patent dance are unclear).

¹⁷⁴ See Epstein, *supra* note 16, at 317–19 (outlining the patent dance and concluding that the statutory sequence “makes good sense”).

¹⁷⁵ See *id.* at 319 (“The whole point of the system is to induce rapid and reliable exchange of relevant information in order to reduce the various risks on both sides of the transaction.”).

option for a biosimilar manufacturer, as was the case for Sandoz in the case currently facing the Supreme Court;¹⁷⁶ however, for biosimilar manufacturers in general, a mandatory patent dance would provide certainty from the onset.¹⁷⁷ This certainty could be a valuable asset for biosimilar manufacturers who must make significant decisions on how to allocate their resources and how to market their products.¹⁷⁸

An optional patent dance, on the other hand, would create a system where there is significantly less certainty.¹⁷⁹ In a system where the patent dance is optional, biosimilar manufacturers have two options and may choose to proceed with the option that best fits their current needs and circumstances.¹⁸⁰ Even though there are only two options, the RPS would not have any way of knowing which option the biosimilar applicant will choose as it would presumably be dependent on private facts of the biosimilar manufacturer's specific circumstances.¹⁸¹

2. Strategic Options for the Biosimilar Applicant

A second important implication concerns the strategic options available to the biosimilar applicant. If the patent dance was mandatory, the biosimilar applicant would be required to initiate the patent dance within the twenty-day period.¹⁸² However, an optional patent dance would provide the biosimilar applicant with more advantageous strategic options.¹⁸³ Under an optional regime, the biosimilar applicant may choose how they would like to proceed in a way that best fits their current needs and circumstances because the decision of whether to initiate the patent dance rests entirely in the hands of the biosimilar applicant.¹⁸⁴ In other words, the biosi-

¹⁷⁶ *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1353 (Fed. Cir. 2015), *cert. granted*, 137 S. Ct. 808 (2017).

¹⁷⁷ *See Epstein, supra* note 16, at 317.

¹⁷⁸ *See Amgen*, 794 F.3d at 1363; WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., RL33901, FOLLOW-ON BIOLOGICS: INTELLECTUAL PROPERTY AND INNOVATION ISSUES 13 (2009); Epstein, *supra* note 16, at 317.

¹⁷⁹ *See sources cited supra* note 178.

¹⁸⁰ *See Minniti, supra* note 170, at 19.

¹⁸¹ *See id.*

¹⁸² *See* 42 U.S.C. § 262(l)(2)(A) (2012).

¹⁸³ *See Minniti, supra* note 170, at 19.

¹⁸⁴ *See id.*

milar applicant would have the sole ability to decide how it wishes to proceed, and the RPS would simply have to wait until the end of the twenty-day period in which the BPCIA allows for the biosimilar applicant to provide the listed information and thus initiate the patent dance.¹⁸⁵ The RPS would need to wait until the end of that period to determine its next step.¹⁸⁶ If the biosimilar applicant provides the RPS with the necessary information, then the patent dance initiates and the RPS would need to follow it.¹⁸⁷ However, if the period lapses and the RPS has not received the prescribed information, then the RPS must file a patent infringement claim to protect the patents it believes the biosimilar applicant is infringing upon.¹⁸⁸

3. Comparing the Patent Dance to Traditional Patent Infringement Litigation

Another critical implication stems from the difference between the patent dance and traditional patent infringement litigation.¹⁸⁹ Under a mandatory patent dance system, patent infringement disputes between the RPS and the biosimilar applicant must be resolved through the patent dance.¹⁹⁰ However, under an optional patent dance system where the biosimilar applicant has opted out of the patent dance, the RPS must rely on traditional patent infringement litigation.¹⁹¹ One of the key distinctions between the patent dance and traditional patent infringement litigation is the efficiency of the patent dance over the potential expediency of an immediate patent infringement lawsuit.¹⁹²

¹⁸⁵ See *id.*; see also § 262(l)(2)(A).

¹⁸⁶ See § 262(l)(2)–(3) (showing that the RPS acts upon receipt of the biosimilar’s information); see also Minniti, *supra* note 170, at 19.

¹⁸⁷ See § 262(l)(3).

¹⁸⁸ See 35 U.S.C. § 271(e)(2)(C) (2012); see also Minniti, *supra* note 170, at 19.

¹⁸⁹ It is beyond the scope of this Note to explain every difference between the patent dance and traditional patent infringement litigation, so this Section instead focuses on the differences in the overall process with regard to manufacturing information.

¹⁹⁰ See Minniti, *supra* note 170, at 17.

¹⁹¹ See § 271(e)(2)(C).

¹⁹² See *Amgen Inc. v. Sandoz Inc.*, 14-CV-04741-RS, 2015 WL 1264756, at *6–7 (N.D. Cal. Mar. 19, 2015) (pointing out that section 262(l) “lays out a process that could take up to 230 days—just to commence patent litigation”), *aff’d in part, vacated in part*, 794 F.3d 1347 (Fed. Cir. 2015), *cert. granted*, 137 S. Ct. 808 (2017); Minniti, *supra* note 170, at 24–25 (“Ultimately, the tension between biosimilar makers and reference product sponsors is

Complying with the patent dance establishes an efficient process in which patent disputes can be resolved.¹⁹³ Once the patent dance is complete, the BPCIA requires the RPS and biosimilar application to engage in “good faith negotiations” regarding the disputed patents.¹⁹⁴ The BPCIA forces both sides to compromise and agree on a list of specific patents to be litigated immediately.¹⁹⁵ The remaining patents can only be litigated later.¹⁹⁶ This process is intended to guarantee that the patent infringement disputes will be resolved efficiently by ensuring that only the most pertinent patents are litigated immediately.¹⁹⁷ Furthermore, the prescribed negotiation requires that both parties provide explanations for their actions at several points during the patent dance’s negotiation, creating transparency as to what the points of contention will be when the patents are ultimately litigated.¹⁹⁸

Additionally, the patent dance prescribes specific deadlines for each of its parts ensuring that the exchanges and negotiations run efficiently and that the actual litigation of the agreed upon patents occurs within a given time.¹⁹⁹ The patent dances provides a more efficient process for the specific biologic and corresponding biosimilar because the patents that are necessary to determine how to proceed are identified early on.²⁰⁰ Although actual litigation may be delayed, relative to traditional patent litigation, both parties will

one of timing and disclosure. On the one hand, biosimilar makers want patent disputes resolved expediently to instill confidence in their investment, but do not want to share manufacturing information. On the other hand, reference product sponsors want patent disputes resolved methodically to delay the potential invalidation of their patents.”).

¹⁹³ See Dougherty, *supra* note 138, at 235–36 (providing a detailed analysis of the provisions comprising the patent dance).

¹⁹⁴ 42 U.S.C. § 262(l)(4)(A) (2012); Dougherty, *supra* note 138, at 237.

¹⁹⁵ See § 262(l)(4)(A); Dougherty, *supra* note 138, at 237–38 (“The patent resolution procedure begins with the applicant choosing a number of patents to be litigated. This step does not involve the identification of specific patents. Rather, it is only the applicant’s choice of *how many* patents should be litigated, e.g., one patent, two patents, etc. Within five days after the applicant chooses this number, the parties simultaneously exchange lists that identify the specific patents that each wants to litigate.”).

¹⁹⁶ See Kanter & Feldman, *supra* note 102, at 77 (“This process provides for initial litigation over essential patents and permits subsequent litigation or court action on the remaining patents only after resolution of that initial [law]suit.”).

¹⁹⁷ See *id.* at 77–78.

¹⁹⁸ See Dougherty, *supra* note 138, at 235–38.

¹⁹⁹ See § 262(l)(2)–(8) (providing a timeline for each step of the patent dance).

²⁰⁰ See Kanter & Feldman, *supra* note 102, at 77.

know approximately when the litigation will occur²⁰¹ and what it will encompass.²⁰² This allows both parties to prepare accordingly, ensuring an overall efficient process.²⁰³

This efficiency benefits both parties. The RPS benefits by litigating the patents it deems the most pertinent and strongest first, and any other patents later.²⁰⁴ If the RPS wins at either of the stages, it may be awarded an injunction.²⁰⁵ Thus, the patent dance grants the RPS an efficient method in which to deliver its strongest swipe at the biosimilar applicant, while guaranteeing that it can fight on the other patents (if applicable) should the RPS lose.²⁰⁶ In contrast, under traditional patent litigation, the RPS may need to fight all the patents at once.²⁰⁷

The biosimilar applicant also benefits because the patent dance “allows the applicant to preview which patents the [RPS] believes are valid and infringed, assess related factual and legal support, and exercise some control over which patents are litigated and when.”²⁰⁸ Additionally, the biosimilar applicant has the benefit of being “able to undergo the [patent dance’s] information exchange while protected by the statute’s safe harbor from litigation.”²⁰⁹ A

²⁰¹ Cf. § 262(l); Dougherty, *supra* note 138, at 235–39. Each step of the BPCIA’s patent dance provides a deadline; thus, litigation of the agreed upon patents must occur within the culmination of all of the deadlines. See Dougherty, *supra* note 138, at 235–39.

²⁰² See Dougherty, *supra* note 138, at 237–38.

²⁰³ See Epstein, *supra* note 16, at 319 (“The whole point of the system is to induce rapid and reliable exchange of relevant information in order to reduce the various risks on both sides of the transaction.”).

²⁰⁴ See Kanter & Feldman, *supra* note 102, at 77–78 (“The reference product sponsor must first provide a list of patents that it believes it can assert against the biosimilar applicant.”). *But see* Dougherty, *supra* note 138, at 237–38 (explaining that the biosimilar applicant chooses, and the RPS must comply with, the number of patents to litigate if the parties do not agree on which patents should be litigated).

²⁰⁵ See 35 U.S.C. § 271(e)(4) (2012); Dougherty, *supra* note 138, at 234.

²⁰⁶ See Epstein, *supra* note 16, at 318.

²⁰⁷ See Alsup, *supra* note 19, at 143–44 (“Paragraphs 4, 5, and 6 of subsection (l) establish a two-phase litigation process that represents a radical departure from traditional patent litigation.”).

²⁰⁸ *Amgen Inc. v. Sandoz Inc.*, 14-CV-04741-RS, 2015 WL 1264756, at *6 (N.D. Cal. Mar. 19, 2015), *aff’d in part, vacated in part*, 794 F.3d 1347 (Fed. Cir. 2015), *cert. granted*, 137 S. Ct. 808 (2017).

²⁰⁹ *Id.* *But see* Alsup, *supra* note 19, at 154 (“These subparagraphs allow the reference product sponsor to commence patent litigation immediately following the wrong move, removing availability to the applicant of a litigation safe harbor.”).

biosimilar applicant with a high or unknown risk of liability for infringement may find this “carrot of a safe harbor”²¹⁰ particularly advantageous because, otherwise, the applicant would remain vulnerable to risky patent infringement lawsuits.²¹¹ And, if necessary, the biosimilar applicant could “delay its product launch to protect the investment it made in developing its biosimilar.”²¹²

However, the efficiency of the patent dance comes at the cost of time and expediency. The process could take up to 230 days to commence patent litigation.²¹³ Comparatively, traditional patent infringement does not entail the same pre-litigation negotiations or communications and thus can provide a potentially more expedient process.²¹⁴ To some, this expediency may be more valuable than the efficiency delays provided by the patent dance.²¹⁵ For example, the efficiency of the patent dance may be outweighed by the disadvantage of unnecessary delay to a biosimilar “applicant who values expedience over risk mitigation.”²¹⁶ A biosimilar applicant may confidently believe in good faith that there are no relevant unexpired patents that its biosimilar infringe upon, and “that it is likely to prevail if challenged with an infringement [claim].”²¹⁷ The applicant may, in such an instance, wish to waive the efficiency and benefits that the patent dance provides, “and instead commence litigation immediately.”²¹⁸

Thus, the potential for expediency that an optional patent dance provides may be a tremendous benefit to the biosimilar applicant in certain circumstances. The only apparent benefit the RPS would gain under an optional patent dance regime is the lack of strict restrictions and constraints that the patent dance would have instigated, such as the safe harbor.²¹⁹

²¹⁰ *Amgen*, 2015 WL 1264756, at *6.

²¹¹ *Id.*

²¹² *Id.*

²¹³ *Id.* at *7.

²¹⁴ *See id.* at *6-7 (noting that Sandoz’s decision not to comply with the patent dance led Amgen to file a patent infringement lawsuit sooner than if it had complied with the patent dance).

²¹⁵ *See id.*

²¹⁶ *Id.* at *7.

²¹⁷ *Id.*

²¹⁸ *Id.*

²¹⁹ *Id.* at *6; Alsup, *supra* note 19, at 154.

B. Implications of Sharing the Biosimilar Applicant's Application and Manufacturing Information

Another crucial implication of the decision to make the patent dance mandatory or option is that, under the patent dance, the biosimilar applicant is required to share information that would not be shared in traditional patent infringement lawsuits.²²⁰ Under the first step of the patent dance, the biosimilar applicant must share a copy of the application with the RPS.²²¹ If the biosimilar applicant decided to opt out of the patent dance, it would not be obligated to disclose that information, and the RPS may be entirely unaware of the application because the FDA cannot disclose filings.²²² The first step of the patent dance also requires the biosimilar applicant to share information regarding the manufacturing processes of the biosimilar.²²³ This unique aspect of the patent dance,²²⁴ if adhered to, ensures that the RPS will know potential trade secret information regarding the process, or processes, used to manufacture the biosimilar in question.²²⁵ Comparatively, under traditional patent infringement litigation, there is no requirement for a party to share this information.²²⁶ Thus, the information-sharing steps of the patent dance give the RPS a significant advantage because it can use the information provided to determine whether the biosimilar applicant infringes on any RPS manufacturing patents issued for its original biologic.²²⁷

²²⁰ The biosimilar applicant must share a copy of the application that it submitted to the FDA. *See* 42 U.S.C. § 262(l)(2)(A) (2012). The biosimilar applicant must also share “such other information that describes the process or processes used to manufacture the biological product that is the subject of such application.” *Id.*

²²¹ *Id.*

²²² *See* Epstein, *supra* note 16, at 289–90; Minniti, *supra* note 170, at 19 (“Moreover, because FDA cannot disclose subsection (k) filings, the RPS could be placed in the difficult position of *not even knowing* an application has been filed for a drug that could undercut its sales, if the biosimilar applicant does not disclose that information.”).

²²³ § 262(l)(2)(A).

²²⁴ *See* Dougherty, *supra* note 138, at 234 (“The scope of the patents to be identified in this process is broader than under the Hatch-Waxman Act, embracing not only patents claiming the biological product and methods of using it, but also patents relevant to the product’s manufacturing process.”).

²²⁵ Epstein, *supra* note 16, at 317.

²²⁶ *See id.* at 319; Minniti, *supra* note 170, at 19.

²²⁷ *See* Minniti, *supra* note 170, at 19 (“Under the [patent dance], the biosimilar applicant must provide a copy of its application and manufacturing process information to

To adequately plead a claim of patent infringement, a patent holder must state plausible factual allegations based on information that is sufficient to state a claim that a product infringes its patent.²²⁸ Competitors rarely have access to each other's confidential manufacturing processes before litigation.²²⁹ If the biosimilar applicant does not share its manufacturing information with the RPS, then litigation of the process patents on the method of manufacturing its biologic is significantly more complicated because the RPS typically has no way of knowing the methods that the biosimilar applicant uses to manufacture the biosimilar.²³⁰ The RPS will typically "not be privy to the manufacturing processes used by the biosimilar applicant and[,] therefore, may be unable to determine whether any of its manufacturing patents are infringed."²³¹ Thus, it would be significantly more difficult for a RPS to sufficiently state a claim, based on plausible factual allegations, that the biosimilar applicant infringes on its process patents.²³² Additionally, the patent holder itself assumes the risk that it will be challenged on validity grounds each time it enters litigation because there is no guarantee that a patent will be found to be valid.²³³ Therefore, if there is no probable patent infringement, the patent holder would likely not want to litigate due to the risk that the patent may be invalidated.²³⁴ If the RPS does not have information about manufacturing, it

the RPS, enabling the RPS to assess whether its patents may be infringed by commercial marketing of the biosimilar.").

²²⁸ See *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1331 (Fed. Cir. 2012) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)) (discussing pleading standard to survive a motion to dismiss in the context of a patent litigation lawsuit).

²²⁹ See *Minniti*, *supra* note 170, at 19.

²³⁰ *Id.*

²³¹ *Id.*

²³² See *supra* note 228 and accompanying text.

²³³ See *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 967 F.2d 1571, 1573 n.3 (Fed. Cir. 1992) *rev'd on other grounds*, 508 U.S. 83 (1993) ("It is arguable that a counterclaim for invalidity of asserted claims is even mandatory . . .").

²³⁴ See Roger A. Ford, *Patent Invalidity Versus Noninfringement*, 99 CORNELL L. REV. 71, 90-91 (2013) ("And patent holders are, of course, happy to collect licensing revenue and are likely willing to discount their royalties to avoid the risk of an invalidity judgment.").

would not be able to make an accurate decision whether or not to enter litigation and risk the validity of its patent.²³⁵

Ultimately, the RPS may find confidential “relevant product information” regarding the biosimilar applicant’s manufacturing processes through discovery.²³⁶ However, compiling sufficient factual matter to make a plausible claim can be—and usually is—very time-consuming and expensive.²³⁷ Moreover, it is possible that, despite lengthy discovery, the patent holder may not actually find sufficient information regarding the alleged infringing manufacturing process to be able to show a plausible claim of infringement, even though the process is in fact infringing on the patent.²³⁸ This may be especially true with biologics because of their complex, and not yet fully understood, nature and manufacturing process.²³⁹ As discussed above, the complex manufacturing process of biologics occurs within a living cell, and therefore it may be nearly impossible to determine the specific manufacturing process that a competitor used to manufacture a biologic or biosimilar if the information is not shared.²⁴⁰ Thus, under an optional patent dance regime, bringing a viable claim for the infringement of one or more of process patents may be complex and costly for the RPS.

In contrast, under the patent dance’s procedures, all pertinent information must be shared.²⁴¹ Therefore, the RPS will know whether the biosimilar applicant’s manufacturing process potentially infringes its process patents, and it will be easier to show a

²³⁵ Some may argue that this point is not compelling on the basis that the RPS may not deserve much sympathy in this scenario because, if their patents are invalid, then there is no reason why they should be allowed to keep them.

²³⁶ See Epstein, *supra* note 16, at 322.

²³⁷ *Attorneys’ View of Discovery Problems*, 15 ALTS. TO HIGH COST LITIG. 132 (1997) (“A survey of attorneys released last month shows that discovery is expensive and full of problems—but attorneys seem to accept that as normal.”).

²³⁸ See Minniti, *supra* note 170, at 19 (“[Under an optional patent dance regime and where the biosimilar applicant refuses to share the required information], the RPS will not be privy to the manufacturing processes used by the biosimilar applicant and therefore, may be unable to determine whether any of its manufacturing patents are infringed.”)

²³⁹ See *supra* Section I.A.

²⁴⁰ See Pharm Memorandum, *supra* note 23, at 6 (discussing how each manufacturer has different standards and tests, which are developed based on each product).

²⁴¹ See 42 U.S.C. § 262(l)(2)(A) (2012).

plausible claim of infringement, if applicable.²⁴² This divergence demonstrates a key difference, and thus consequence, between rendering the patent dance optional versus mandatory. If the patent dance is mandatory, then the path is clear: The biosimilar applicant must share information regarding its manufacturing process within twenty days of acceptance for review,²⁴³ ensuring that the RPS will ultimately know whether its manufacturing patents are being infringed or not. This cuts a large amount of time away from the patent litigation.²⁴⁴ On the other hand, if the patent dance is optional, the path forward can be complicated and expensive.

III. THE PATENT DANCE SHOULD BE MANDATORY

This Part weighs the aforementioned implications and concludes that the patent dance of the BPCIA should be mandatory. Section III.A discusses the importance of the BPCIA's aim to balance its countervailing goals of incentivizing innovation of new biologics while trying to make these biologics affordable. Section III.B then discusses how the implications outlined in Part II of this Note require a mandatory patent dance to ensure that the BPCIA's balance is maintained. The Part concludes by arguing that the patent dance should be mandatory because the fundamental role of a biologic's manufacturing processes requires that the manufacturing information be shared from the onset, which can only be ensured if the patent dance is mandatory.

A. A Mandatory Patent Dance Is Essential to Maintaining the Balance of the BPCIA's Goals

The BPCIA lies at the intersection of two complex bodies of law: patent law and pharmaceutical regulation.²⁴⁵ Additionally, it walks the thin line between incentivizing innovation of new biologics while simultaneously trying to make these biologics afford-

²⁴² See Minniti, *supra* note 170, at 19 (noting that in a mandatory patent dance regime, the RPS will be able to “assess whether its patents may be infringed”).

²⁴³ § 262(l)(2)(A).

²⁴⁴ Amgen Inc. v. Sandoz Inc., 14-CV-04741-RS, 2015 WL 1264756, at *7 (N.D. Cal. Mar. 19, 2015), *aff'd in part, vacated in part*, 794 F.3d 1347 (Fed. Cir. 2015), *cert. granted*, 137 S. Ct. 808 (2017).

²⁴⁵ See Goldberg, *supra* note 29, at 352, 356; Tam, *supra* note 7, at 537–38, 564–65.

ble.²⁴⁶ These two goals are countervailing. If the process to allow biosimilars is too easy and favors the biosimilar manufacturers, the brand name biologics manufacturers may lose the incentive to allocate their resources to innovation of new essential biologics.²⁴⁷ On the other hand, if the protection is too strong, and it is too difficult to bring competing biosimilars to the market, the BPCIA may fail to bring down prices as intended.²⁴⁸

The legislative history shows that both biologic and biosimilar manufacturers were heavily involved in how the BPCIA was structured.²⁴⁹ It is clear that the final product was a negotiated compromise that took both sides into account.²⁵⁰ The compromise recognizes the complexity and difficulty of the countervailing goals that influenced the particular formation of the BPCIA as a whole.²⁵¹ To combat that complexity, both parties compromised and agreed on a system that provides clarity and transparency so that the only remaining issue is the subject matter itself.²⁵² Thus, all of the BPCIA's components were presumably intended to execute that theme—each aspect of the BPCIA was intended to achieve com-

²⁴⁶ See Epstein, *supra* note 16, at 286 (“This statute, like the Hatch-Waxman Act before it, is intended to balance twin goals that are necessarily in some tension.”); Lu, *supra* note 12, at 650 (“[T]he central mission of the BPCIA is to balance two competing interests: innovation and accessibility.”); Tam, *supra* note 7, at 540 (“The resulting statute balances the interests of the pioneer drug industry, the generic drug industry, and patients seeking access to the best available medicines.”).

²⁴⁷ John A. Vernon, Alan Bennett & Joseph H. Golec, *Exploration of Potential Economics of Follow-on Biologics and Implications for Data Exclusivity Periods for Biologics*, 16 B.U. J. SCI. & TECH. L. 55, 56 (2010) (“Inadequate incentives would likely diminish the economic attractiveness of undertaking new biotech [research and development] and investment in this sector.”).

²⁴⁸ See Margolis, *supra* note 102, at 212–13.

²⁴⁹ See Krista Hessler Carver et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 FOOD & DRUG L.J. 671, 816–18 (2010); Epstein, *supra* note 16, at 315 (“[T]he Biosimilars Act . . . was the subject of extensive four-year negotiations between the innovator and generic industry (both of which are sophisticated and well-informed).”).

²⁵⁰ Carver et al., *supra* note 249, at 817 (“[T]he final decisions on key issues were the subject of bipartisan agreement and represented a middle ground between innovator and generic interests.”).

²⁵¹ *Id.*

²⁵² *Id.* at 776 (“[The Federal Trade Commission] added that [a] system of premarketing patent litigation that is simple and transparent is less likely to result in competitive harm.” (internal quotation marks omitted)).

plete clarity and transparency to the furthest extent possible.²⁵³ It is this understanding that must inform the decision on every aspect of the BPCIA, including the patent dance.

The implications outlined in Part II show that the patent dance must be mandatory. The efficiency and transparency that the patent dance ensures was a crucial aspect of the compromise and is essential to maintaining the BPCIA's balance. Additionally, making the patent dance optional would significantly favor the biosimilar applicants, and these systematic implications would skew the balance and prevent the BPCIA from achieving its countervailing goals.²⁵⁴ Therefore, the patent dance should be mandatory.

B. The Patent Dance Should Be Mandatory Because It Is Better for the BPCIA's Purpose and Scheme

As part of Congress' efforts to balance the goals of competition and innovation, the BPCIA contains an extensive, integrated framework for the resolution of patent disputes between a biosimilar applicant and an RPS.²⁵⁵ However, what Congress intended by including the patent dance and what its exact role was intended to be is disputed: Did Congress intend the patent dance to be an efficient process or an expedient one?

1. Efficiency Is the Key to the Patent Dance and Is Crucial to the BPCIA's Balance

The legislative history suggests that Congress intended the BPCIA to provide an efficient process in which biosimilars could be approved while maintaining a delicate balance.²⁵⁶ In a congressional hearing, Representative Anna Eshoo of California noted that the purpose of the patent dance was "to ensure that litigation surrounding relevant patents will be resolved expeditiously and *prior to the launch* of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at

²⁵³ See *id.* at 776, 817.

²⁵⁴ See *supra* Section III.A.

²⁵⁵ See 42 U.S.C. § 262(l)(4)(A) (2012); see also Dougherty, *supra* note 138, at 237.

²⁵⁶ See Minniti, *supra* note 130, at 184–85 (citing *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts & Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 196 (2009) [hereinafter *Hearing*] (statement of Teresa Stanek Rea, President, American Intellectual Property Law Association)).

large.”²⁵⁷ Indeed, as Judge Newman of the Federal Circuit noted in his opinion in *Amgen*, one of the goals of the BPCIA was an “efficient resolution of patent issues.”²⁵⁸ Additionally, in a brief supporting Sandoz’s petition for certiorari, several biosimilar manufacturers explained: “To resolve such patent rights *efficiently*, subsection (l) of the statute, entitled ‘Patents,’ outlines a step-by-step process to *determine when litigation as to particular patents* may be filed.”²⁵⁹ However, Sandoz and the biosimilar industry seek to take it one step further by arguing that, essentially, the BPCIA gives them the option to choose the efficient “step-by-step process”²⁶⁰ or opt out if expediency is more advantageous for their particular circumstances.²⁶¹ Although the legislative history is silent on whether the BPCIA could allow the biosimilar applicant to choose how to proceed, it suggests that the patent dance was intended to ensure that an efficient process was utilized to resolve necessary patent infringement disputes.²⁶² Therefore, the patent dance must be mandatory in order to maintain the scheme so that the balance is not skewed.

The designated exchange of information is fundamental to the BPCIA’s purpose of efficient resolution of patent issues because the exchange was part of the compromise between the two sides, and it helps maintain the BPCIA’s balance of its countervailing

²⁵⁷ *Hearing, supra* note 256, at 9 (statement of Rep. Anna G. Eshoo) (emphasis added). At the time, Rep. Eshoo served on the House Energy and Commerce Committee and on the House Permanent Select Committee on Intelligence. *Id.* at 7. She also co-chaired the Congressional High-Tech Caucus and the House Medical Technology Caucus, and served as Vice Chair of the 21st Century Health Care Caucus. *Id.*

²⁵⁸ *Amgen, Inc. v. Sandoz, Inc.*, 794 F.3d 1347, 1364 (Fed. Cir. 2015) (Newman, J., concurring in part, dissenting in part), *cert. granted*, 137 S. Ct. 808 (2017).

²⁵⁹ Brief for Hospira, Inc., et al. as Amici Curiae in Support of the Petition for Certiorari at 4, *Sandoz Inc. v. Amgen Inc.*, No. No. 15-1039 (U.S. Jan 13, 2017) (No. 15-1039) (emphasis added).

²⁶⁰ *Id.*

²⁶¹ *See id.*; *Amgen*, 794 F.3d at 1353; *Amgen Inc. v. Sandoz Inc.*, No. 14-CV-04741-RS, 2015 WL 1264756, at *3 (N.D. Cal. Mar. 19, 2015), *aff’d in part, vacated in part*, 794 F.3d 1347 (Fed. Cir. 2015), *cert. granted*, 137 S. Ct. 808 (2017) (“Sandoz sent Amgen a second letter on July 25 again offering conditional access to its BLA. It also asserted therein that the BPCIA entitled it to opt out of subsection (l)’s procedures, and that Amgen could instead procure information via an infringement action.”).

²⁶² *See sources cited supra* notes 256–57.

goals.²⁶³ The BPCIA, including the patent dance scheme, was the subject of lengthy negotiations.²⁶⁴ Thus, the BPCIA, as enacted, represents a compromise in which each aspect was intended to maintain the balance.²⁶⁵ It is “clear that a meaningful exchange of information is critical to both sides if they are to be able to litigate patent infringement issues before biosimilar market entry.”²⁶⁶ Although there is debate as to whether patents increase innovation or not, it is generally accepted that for the pharmaceutical industry there would be no innovation if the pharmaceutical industry did not believe that their product had enough protection to be able to turn a profit.²⁶⁷

As noted above, the cost to properly bring a drug to the market is astronomically expensive.²⁶⁸ Additionally, pharmaceutical industries must recoup losses sustained when certain drugs do not pass the research and development stage, or any of the FDA-required clinical phases, even though they have already expended millions, if not billions of dollars.²⁶⁹ It is clear that brand-name pharmaceutical manufacturers require patent protection to incentivize innovation.²⁷⁰ Thus, for the BPCIA to succeed, it is imperative that nei-

²⁶³ See Carver et al., *supra* note 249, at 816 (“[T]he nature of (and even advisability of) the patent litigation process [was] thoroughly debated years before enactment of the legislation.”).

²⁶⁴ See *id.* (“[T]he BPCIA was enacted after many years of stakeholder discussions—within the industry, at the agency, through citizen petition dockets, in journals, in legislative hearings, in markups, and on the Hill more generally—of, as far as the authors can tell, every key scientific and policy issue that needed to be addressed. Every provision of the final legislation—from the clinical trial requirements to the data exclusivity term—had been publicly vetted for at least several years, and consensus on some points (such as the need for case by case determinations of the data requirements) had been evident for the better part of a decade.”); Epstein, *supra* note 16, at 315 (“[T]he Biosimilars Act . . . was the subject of extensive four-year negotiations between the innovator and generic industry (both of which are sophisticated and well-informed).”).

²⁶⁵ Carver et al., *supra* note 249, at 817 (“[T]he BPCIA represented a meaningful compromise between biosimilar industry and innovator industry interests.”).

²⁶⁶ Epstein, *supra* note 16, at 319.

²⁶⁷ See Vernon et al., *supra* note 247, at 56.

²⁶⁸ See *supra* notes 85–91 and accompanying text.

²⁶⁹ See Grabowski, *supra* note 7, at 486.

²⁷⁰ Gregory J. Glover, *The Influence of Market Exclusivity on Drug Availability and Medical Innovations*, AAPS J., Aug. 3, 2007, at E312, E315 (“The uncertainties associated with the development of pharmaceuticals are many and substantial. Maximizing the certainty that a research-based manufacturer can obtain, enforce, defend, and make full, legitimate use of IP rights is essential to maintaining the cycle of innovation for the benefit

ther side be allowed to unilaterally subvert the patent dance.²⁷¹ The patent dance was structured to ensure an efficient process in which patent litigation can be deliberated early on.²⁷² This efficiency is crucial for the BPCIA. As Richard Epstein explains in his article discussing the constitutional protection affected by the BPCIA, “[s]haring the information prescribed in the patent dance in confidence gives the RPS an opportunity to voice its view about any potential conflicts, at a point early enough in the process that the remainder of the dispute can be resolved in an orderly fashion under the well-articulated statutory procedures.”²⁷³

In this regard, and many others, complying with the patent dance is more efficient and effective than noncompliance. There may be times when it would be strategically advantageous for the biosimilar applicant to elect not to use the patent dance, but this complexity and lack of transparency is exactly what the BPCIA is trying to prevent.²⁷⁴ One of the countervailing goals of the BPCIA was to maintain the incentive to innovate.²⁷⁵ However, lengthy intellectual property litigation and the increased uncertainty that an optional patent dance causes would negatively impact innovation.²⁷⁶

Additionally, as compared to the BPCIA, the Hatch-Waxman Act has a distinctly different process by which patent infringement disputes are resolved.²⁷⁷ The abbreviated pathway under the

of the public health. In the absence of strong IP rights at each stage of the innovation cycle, the promise of pharmaceutical innovation could be lost.”).

²⁷¹ See Epstein, *supra* note 16, at 319.

²⁷² 42 U.S.C. § 242(l)(2) (2012); see Kanter & Feldman, *supra* note 102, at 77 (“This process provides for initial litigation over essential patents and permits subsequent litigation or court action on the remaining patents only after resolution of that initial [law]suit.”).

²⁷³ Epstein, *supra* note 16, at 319; see also Dougherty, *supra* note 138, at 235–38.

²⁷⁴ See Carver et al., *supra* note 249, at 776.

²⁷⁵ Epstein, *supra* note 16, at 286.

²⁷⁶ See Henry Grabowski et al., *The Market for Follow-On Biologics: How Will it Evolve?*, 25 HEALTH AFF. 1291, 1300 (2006) (“[I]ncreased uncertainty and [intellectual property] litigation in biotech also would have major negative-incentive effects on capital market decisions for developing private and public biotech firms with promising pipelines.”).

²⁷⁷ See Carver et al., *supra* note 249, at 815 (“In several respects, the patent provisions of the BPCIA represented a radical departure from those contained in the Hatch-Waxman amendments.”); Noel Courage & Ainslie Parsons, *The Comparability Conundrum: Biosimilars in the United States, Europe and Canada*, 66 FOOD & DRUG L.J. 203, 215 (2011)

BPCIA differs greatly from that of generic small-molecule drugs prescribed by the Hatch-Waxman Act.²⁷⁸ The Hatch-Waxman Act requires the FDA to publish “a list”—known as the Orange Book²⁷⁹—and update it on a monthly basis.²⁸⁰ A manufacturer must then identify the numbers and expiration dates of the patents that cover its branded drug publicly in the Orange Book.²⁸¹ In contrast, the BPCIA does not require the FDA to publish a list of licensed biological products, including applicable patent and non-patent exclusivities,²⁸² but instead provides the patent dance as the means in which patent disputes are resolved.²⁸³ The fact that the BPCIA contains such a different process demonstrates that it is a crucial aspect of the statute. Specifically, the statutory substitution shows—and the legislative history agrees—that the efficiency of the patent dance was part of this compromise between the two industries.²⁸⁴ Though the BPCIA is based on the Hatch-Waxman Act, it has “several obvious differences.”²⁸⁵ The fact that the patent dance intentionally departs from the Hatch-Waxman Act’s patent dispute process indicates that Congress believed that this new process was better for the BPCIA and biologics.

(“There are also very distinct differences in the patent litigation pathways under the BPCI Act and the Hatch-Waxman Act.”).

²⁷⁸ Compare 21 U.S.C. § 355(j) (2012), with 42 U.S.C. § 262(l) (2012).

²⁷⁹ See Jacob S. Wharton, “Orange Book” *Listing of Patents Under the Hatch-Waxman Act*, 47 ST. LOUIS U. L.J. 1027, 1032 (2003) (“When the FDA approves a [new drug application], the patent information submitted therewith is published in a publication entitled ‘Approved Drug Products With Therapeutic Equivalence,’ known in agency parlance as the ‘Orange Book.’” (citing *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1079 (D.C. Cir. 2001); Terry G. Mahn, *Patenting Drug Products: Anticipating Hatch-Waxman Issues During the Claims Drafting Process*, 54 FOOD DRUG COSM. L.J. 245, 249–50 (1999))).

²⁸⁰ § 355(j)(7).

²⁸¹ § 355(b)(1)(G); see Wharton, *supra* note 279, at 1032.

²⁸² The “Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, or “Purple Book,” which is modeled after the Hatch-Waxman’s Orange Book, is not required by the BPCIA. Kurt R. Karst, *The “Purple Book” Makes Its Debut!*, FDA L. BLOG (Sept. 9, 2014), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2014/09/the-purple-book-makes-its-debut.html [<https://perma.cc/38DS-VSHH>]. The FDA decided to initiate the Purple Book as a reference guide, but it is still unclear how it will be used. *Id.*

²⁸³ See § 262(1).

²⁸⁴ See *supra* note 264.

²⁸⁵ *Amgen, Inc. v. Sandoz, Inc.*, 794 F.3d 1347, 1351 (Fed. Cir. 2015), *cert. granted*, 137 S. Ct. 808 (2017); Lu, *supra* note 12, at 626.

The BPCIA's patent provisions contain other radical departures from those contained in the Hatch-Waxman Act. Under the BPCIA, process patents, which may not be listed in the Orange Book, are addressed and may be asserted during litigation.²⁸⁶ Bringing a lawsuit under the BPCIA does not stay approval of the biosimilar application, as occurs under the Hatch-Waxman Act, when a lawsuit is brought against the generic drug applicant in a timely fashion.²⁸⁷ Similarly, there is no statutory bar on FDA approval even where the applicant indicates that it will wait until patent expiration, or—in very limited circumstances—where the RPS wins the patent lawsuit.²⁸⁸ There also is no parallel in the BPCIA to the 180-day exclusivity provided by the Hatch-Waxman amendments as an incentive to challenge or design around patents.²⁸⁹ Perhaps the most important departure from the patent litigation regime established by the Hatch-Waxman amendments is the conduct of the litigation itself. Litigation under the Hatch-Waxman amendments is traditional patent litigation—patentees can assert any non-process patents as to which a reasonable claim of infringement could be made.²⁹⁰ In contrast, the BPCIA operates to prevent patentees from asserting the relevant patents during the initial phase of litigation because the biosimilar applicant dictates how many patents can be asserted in the first instance.²⁹¹

The clearly purposeful decision to depart from the Hatch-Waxman Act's method of resolving patent disputes shows that Congress believed that the efficiency of the patent dance is more suitable for dealing with patent disputes of biologics. This presents

²⁸⁶ See § 262 (l)(2)(A) (providing that the applicant must provide information that “describes the process or processes used to manufacture the biological product that is the subject of such application”).

²⁸⁷ See 21 U.S.C. § 355(j)(5)(B)(iii) (2012) (providing for a thirty-month stay if the new drug application holder sues the generic small-molecule drug applicant for patent infringement under the Hatch-Waxman Act's provisions within forty-five days of the generic's notice letter).

²⁸⁸ See § 355(j)(5)(B) (specifying the timing of approval for an abbreviated new drug application).

²⁸⁹ Compare § 355(j)(5)(B)(iv), with § 262(l)(8)(A) (“The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).”).

²⁹⁰ See *supra* note 138 and accompanying text.

²⁹¹ See *supra* text accompanying note 204.

another reason why the patent dance should be mandatory. A mandatory patent dance ensures that that efficiency of the patent dance is carried out in accordance with the compromise to maintain the delicate balance.

2. A Mandatory Patent Dance Provides Certainty and Transparency Which Is Necessary for the BPCIA's Balance

Additionally, a mandatory patent dance provides certainty and transparency that is crucial for both the biologic and biosimilar industry.²⁹² The BPCIA deals with extremely complex issues.²⁹³ One of the goals of the BPCIA is to incentivize innovation of new biologics, not just biosimilars.²⁹⁴ Further convoluting the path to innovate and mitigating the ultimate reward may jeopardize that incentive.²⁹⁵ An optional patent dance places all the power in the hands of the biosimilars and allows them to choose a path that best suits them strategically.²⁹⁶ Furthermore, the biologics manufacturers will not know for certain if they will be able to protect their biologics because they may not be able to enforce the manufacturing patent(s).²⁹⁷ As discussed above, the manufacturing process patent(s) may be a biosimilar applicant's strongest source of protection over the brand name biologic.²⁹⁸ For this issue itself, the patent dance should be required so that the RPS can efficiently determine, at the very least, if there is infringement. However, the need for certainty and clarity is imperative and can only be achieved when the steps are known (i.e., when the patent dance is mandatory).²⁹⁹ Mandating the patent dance brings certainty to all parties because it permits the RPS, who owns (or licenses) patents that may be infringed by the biosimilar product, to litigate possible infringement prior to the biosimilar's market entry.³⁰⁰ This brings certainty to the biosimilar applicants (indeed, a risk-free opportunity to deter-

²⁹² See *supra* text accompanying notes 204–12.

²⁹³ See *supra* note 130 and accompanying text.

²⁹⁴ See *supra* notes 13–15.

²⁹⁵ Lu, *supra* note 12, at 626 (“Patent uncertainty seriously affects the profitability of innovator drug companies.”).

²⁹⁶ See *supra* Section II.A.2.

²⁹⁷ See *supra* Section II.B.

²⁹⁸ See *supra* Section I.B.

²⁹⁹ See *supra* Section III.A.

³⁰⁰ See *id.*

mine whether they may market their products), and it also allows the innovator to avoid multi-year patent litigation proceedings while an infringing biosimilar product is eroding its market share.³⁰¹

3. Manufacturing Patents of Biologics

The intersection that the BPCIA creates between pharmaceutical regulation and patent law is complex and sensitive.³⁰² Biosimilar manufacturers “will be forced to create a product that is similar enough to satisfy the FDA, but different enough to avoid infringing on the reference drug’s patent.”³⁰³ However, “the product is the process,”³⁰⁴ and even small differences in a biologic’s manufacturing process may cause significant differences in the clinical properties of the final product.³⁰⁵ Therefore, the FDA must ensure that the biosimilar’s manufacturing process closely resembles the RPS’s manufacturing process.³⁰⁶ As explained above, the strongest patents for biologics may be on the biologic’s manufacturing process.³⁰⁷ Thus, biosimilar manufacturers must find an even narrower ground where they follow the process enough to comply with the FDA’s regulations, yet do not infringe the biologic manufacturer’s patents.³⁰⁸ The variations that are allowed by the FDA must also be significant enough to avoid an infringement under the doctrine of equivalents.³⁰⁹

The key role manufacturing process patents play in biologics makes it crucial that the biosimilar’s private manufacturing information is shared at the onset. Thus, the patent dance should be

³⁰¹ See Epstein, *supra* note 16, at 317.

³⁰² See *supra* note 11.

³⁰³ See Freilich, *supra* note 61 (offering a thorough discussion on how exactly these alterations may occur).

³⁰⁴ Tam, *supra* note 7, at 543.

³⁰⁵ See Pharm. Memorandum, *supra* note 23, at 4.

³⁰⁶ See Janet Freilich, *The Paradox of Legal Equivalents and Scientific Equivalence: Reconciling Patent Law’s Doctrine of Equivalents with the FDA’s Bioequivalence Requirement*, 66 SMU L. REV. 59, 108 (2013).

³⁰⁷ See *supra* Section I.B.

³⁰⁸ See generally Freilich, *supra* note 61, at 29–48 (explaining exactly how biosimilars may be able to find the specific area in which their product is similar enough to comply with the requirements of the BPCIA, yet not infringe on the patents of the original biologic).

³⁰⁹ *Id.* at 30; see also Freilich, *supra* note 306, at 80.

mandatory to ensure that the requirement to share the secret manufacturing information of the biosimilar applicant is carried out. This ensures that the original biologics patents, if infringed upon, will be properly protected in a timely fashion, and indicates another way in which the patent dance is more efficient and transparent. The requirement to share the secret manufacturing information of the biosimilar applicant can be a disadvantage for the applicant, because sometimes they do not want it to be quick for strategy purposes; however, that is exactly what the BPCIA was trying to prevent. One of the countervailing goals of the BPCIA was to maintain the incentive to innovate.³¹⁰ Inefficient patent infringement litigation and the increased uncertainty that it causes negatively impact innovation.³¹¹

As discussed, the purpose of the patent dance regime of the BPCIA was “to ensure that litigation surrounding relevant patents will be resolved expeditiously and *prior to the launch* of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large.”³¹² By sharing the manufacturing information upfront both parties know immediately which patents, if any, need to be litigated, thus bringing certainty to all parties.³¹³ Additionally, the BPCIA was a negotiated compromise.³¹⁴ The addition of the manufacturing information was a key component of this compromise. The compromise was essential to maintain the balance of the BPCIA. A slight variation from that compromise may skew the balance. Thus, the patent dance should be mandatory as intended to protect the BPCIA’s balance.

Contrasting the BPCIA’s patent dance with the patent infringement litigation scheme of the Hatch-Waxman Act emphasizes the need for the patent dance to be mandatory. Among other differences between the BPCIA’s patent dance and the Hatch-

³¹⁰ See Epstein, *supra* note 16, at 286 (“Its first goal is to preserve the incentive to bring innovative biological medicines to market.”).

³¹¹ See Grabowski et al., *supra* note 276, at 1300 (“[I]ncreased uncertainty and [intellectual property] litigation in biotech also would have major negative-incentive effects on capital market decisions for developing private and public biotech firms with promising pipelines.”).

³¹² *Hearing*, *supra* note 256, at 9 (statement of Rep. Anna G. Eshoo).

³¹³ *Id.*

³¹⁴ See Carver et al., *supra* note 249, at 817.

Waxman Act's patent infringement litigation scheme, the BPCIA's procedures noticeably include manufacturing patents while the Hatch-Waxman Act's does not.³¹⁵ This alteration strongly suggests that this was intentional.³¹⁶ The biosimilar applicant should not be allowed to subvert this useful aspect by opting out of the patent dance. Thus, the patent dance should be held to be mandatory to ensure that the manufacturing information is shared as it was intended to be.

CONCLUSION

Determining exactly how to incentivize innovation in the pharmaceutical industry while keeping prices relatively affordable has historically been daunting and complicated. In drafting the BPCIA, Congress attempted to accomplish that challenging feat through transparency and communication.³¹⁷ Congress solicited and received input from all pertinent industries, reviewed the input elicited, and used it to form a negotiated compromise that balances the countervailing goals.³¹⁸ That balance is represented in the BPCIA, and every aspect that formed that compromise is crucial to maintaining the balance. The patent dance, one of those key aspects, provides an efficient process that allows for the patents relevant to the biologic and biosimilar in question to be resolved as quickly as possible. This process must not be allowed to be subverted at the biosimilar manufacturer's whim. The negotiated compromise was a mandatory patent dance and that is what must be ensured.

³¹⁵ See *supra* note 138.

³¹⁶ Carver et al., *supra* note 249, at 815.

³¹⁷ See generally Carver et al., *supra* note 249.

³¹⁸ See *id.* at 816.