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DOES IT STILL TAKE TWO TO TANGO? A MODERN INTERPRETATION OF THE BPCIA'S PATENT DANCE

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INTRODUCTION

Since 1996, the annual spending on drugs per capita in the U.S. has been the highest among all the developed countries.[1] In 2017, the number reached $1220 per person in the U.S., making the U.S. pharmaceutical industry a $400 billion market.[2] One of the fastest growing segments of the pharmaceutical industry is biologic drugs, accounting for almost 40% of the U.S. prescription drug spending in 2015.[3] Unlike traditional small-molecule drugs, which are chemically synthesized, most biologic drugs are protein-based macromolecules produced by living cells.[4] In an effort to control the high price of biologics, Congress enacted the Biologics Price Competition and Innovation Act ("BPCIA") in 2009, which provides an abbreviated pathway for follow-on versions of the biologics to enter the market.[5] The BPCIA has initiated a new patent dispute resolution process that has subsequently been termed "the patent dance."[6] The patent dance demands the exchange of information and negotiation before litigation as well as divides the litigation into two phases.[7] Such a carefully calibrated scheme strives to achieve a balance between the interest of incentivizing innovators and the interest of providing more affordable medicine to consumers.[8]

There are normally two parties in biosimilar litigation: the Sponsor who holds patent(s) on a biologic drug and the Applicant who aims to market a follow-on version of the biologic. This Note focuses on the effects of the Supreme Court's recent decision that offers the Applicant the freedom to opt-out of the BPCIA's

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[1] Pharmaceutical spending (indicator), OECD, https://www.oecd-ilibrary.org/social-issues-migration-health/pharmaceutical-spending/indicator/english_998febf6-en (last visited Aug. 20, 2019).

[2] *Id.*

[3] Michelle Hoffmann, *Biosimilars: the cure for sky-high drug prices or a stake in the heart of innovation?*, STAT (Feb. 8, 2018), https://www.statnews.com/2018/02/08/biosimilars-biologics-drug-prices-innovation/.

[4] Thomas Morrow, *Defining the Difference: What Makes Biologics Unique*, BIOTECHNOLOGY HEALTHCARE 24, 25-26 (Sept. 2004).

[5] 42 U.S.C. § 262(k) (2017).

[6] Dennis Crouch, *BPCIA: Patent Dance Steps Becoming a Bit Clearer*, PATENTLY-O (Aug. 16, 2017), https://patentlyo.com/patent/2017/08/patent-becoming-clearer.html.

[7] 42 U.S.C. § 262(l).

[8] Jon Tanaka, "Shall" We Dance? Interpreting the BPCIA's Patent Provisions, 31 BERKELEY TECH. L.J. 659, 680 (2016).

patent dance. Since the Applicant can strategize whether to comply with the patent dance based on the nature of the biologic product, this Note advocates that the district courts should restore the carefully calibrated balance by applying a more lenient pleading standard and facilitating the discovery process. Part I of this Note provides background information on the Hatch-Waxman Act designed for small-molecule drugs, the differences between small-molecules and biologics, the reasons why the Hatch-Waxman Act would prove insufficient for biologics, and the BPCIA's patent dance. Part II analyzes the Supreme Court's interpretation of the patent dance in *Sandoz*. By refusing to order injunctive relief against the Applicant who failed to participate in the patent dance, the Court made the patent dance an optional choice. Part III outlines the strategies on whether and when the Applicant should skip or comply with the patent dance and analyzes the advantages and disadvantages of opting out of the patent dance. Part IV discusses how the foreclosure of the patent dance affects the Sponsor and suggests that the district courts are likely to apply a more lenient pleading standard when the patent dance is abandoned by the Applicant and analyzes the consequences of such a lenient standard. Part V concludes this Note.

I
BACKGROUND OF THE BPCIA AND THE PATENT DANCE

A. The Hatch-Waxman Act

As early as the 1980s, Congress tried to grapple with the growing problem of increasing pharmaceutical costs by passing the Drug Price Competition and Patent Restoration Act of 1984, often referred to as the Hatch-Waxman Act, to make small-molecule drugs more affordable.[9] Since 1938, every new drug must receive FDA approval before commercialization by filing a New Drug Application ("NDA") wherein an innovator company must submit full reports of investigations on the safety and efficacy of a new drug.[10] This requires that innovator companies conduct years of clinical trials and spend millions of dollars on these studies. In contrast, under the Hatch-Waxman Act, generic drug manufacturers only need to file an Abbreviated New Drug Application (ANDA), which permits them to bypass the requirement for safety and efficacy.[11] Instead, generic manufacturers can piggyback on the safety and efficacy data previously submitted by the innovator

[9] 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.).

[10] 21 U.S.C. § 355(b)(1) (2018).

[11] *Id.* § 355(j)(2)(A).

companies.[12] Generally, an ANDA only requires data to show that the generic drug is bioequivalent to the branded drug and has the same conditions of use, active ingredient, route of administration, dosage form, dosage strength, and labeling as the branded drug.[13]

The Hatch-Waxman Act has proven quite successful in making small-molecule drugs more affordable for patients.[14] Before the passage of the Hatch-Waxman Act, only 35% of the top-selling branded drugs whose patents had expired had generic counterparts.[15] By contrast, the generic drugs' share of U.S. prescriptions reached 85% in 2016.[16] The competitive pressure asserted by generic drugs causes the price of a branded drug to decline by an average of 80% within one year of the generic drug's introduction into the market.[17] Yet, even in 2016, people in the U.S. were spending far more on branded drugs compared to generic drugs, as branded drugs are much more expensive: total spending on generic drugs was only $50 billion compared to $334 billion on branded drugs.[18]

B. Biologics and the BPCIA

In addition to small-molecule drugs, biologic drugs have continued to grow rapidly and play an increasingly significant role in the modern therapeutic market. The BPCIA defines biologics as viruses, therapeutic serums, toxins, antitoxins, vaccines, blood, blood components or derivatives, allergenic products, and proteins that are designed to combat a variety of diseases and disorders.[19] Most modern biologics are protein-based macromolecules that are produced in genetically engineered living cells.[20] For instance, adalimumab, a blockbuster drug sold under the brand name Humira, is a monoclonal antibody targeting tumor necrosis factor-

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[12] *Id.*

[13] *Id.* at §§ 355(j)(2)(A)(i)-(v).

[14] Ryan Timmis, The Biologics Price Competition and Innovation Act: Potential Problems in the Biologic-Drug Regulatory Scheme, 13 NW. J. TECH. & INTELL. PROP. 215, 217 (2015).

[15] Garth Boehm et al., Development of the generic drug industry in the US after the Hatch-Waxman Act of 1984, 3 ACTA PHARMACEUTICA SINICA B 297, 298 (2013).

[16] Avik Roy, *The Competition Prescription: A Market-Based Plan for Affordable Drugs*, FREOPP (May 16, 2017), https://freopp.org/a-market-based-plan-for-affordable-prescription-drugs-931e31024e08.

[17] *Id.*

[18] *Id.*

[19] 42 U.S.C. § 262(i)(1) (2017).

[20] Andrew W. Mulcahy et al., *Biosimilar Cost Savings in the United States*, 7 RAND HEALTH Q. 3 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6075809/.

alpha (TNFα) to primarily treat rheumatoid arthritis and Crohn's disease.[21] In general, biologic drugs are much more expensive than small-molecule drugs.[22] For example, to treat arthritis, the biologic drug Enbrel costs $20,000 per year while the most expensive small-molecule drug only costs $300 per year.[23] In 2015, almost 40% of U.S. prescription drug spending was for biologic drugs.[24] In 2017, eight out of the fifteen globally best-selling drugs were biologics.[25] Since 2013, Humira alone has contributed more than $10 billion annually to biologics sales and this number has continued to rise, approaching $20 billion in 2018.[26]

Like the generic drugs of small-molecules, the lucrative market of biologics continually attracts follow-on versions to compete with the branded biologics, which is likely, in turn, to reduce the high price of biologics.[27] However, the Hatch-Waxman Act failed to provide a remedy for the high biologics prices by boosting competition for two reasons: the structural complexity of biologics and the intrinsic uniqueness of their manufacturing processes.[28] First of all, it is impossible for a competitor to manufacture an identical version of the active ingredient in the branded biologic drug as required by the Hatch-Waxman Act.[29] Protein-based biologics are made of amino acid sequences, which can be hundreds of times larger than small-molecule drugs.[30] For instance, adalimumab, the active ingredient in Humira, has a molecular weight of 144,190.3 g/mol while the small-molecule drug to treat Hepatitis C, under the brand name Sovaldi, has a molecular weight of 529.5

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[21] *Adalimumab*, WIKIPEDIA, https://en.wikipedia.org/wiki/Adalimumab (last visited Aug. 30, 2019).

[22] Ude Lu, Note, Biologics Price Competition and Innovation Act: Striking a Delicate Balance Between Innovation and Accessibility, 15 MINN. J.L. SCI. & TECH. 613, 633 (2014).

[23] *See id.*; *see also* Tori Marsh, *With No Humira Generic in Sight, Here's How You Can Save Now*, GOODRX (Sept. 22, 2018), https://www.goodrx.com/blog/humira-generic-availability-how-to-save/.

[24] Hoffmann, *supra* note [6].

[25] *See* Alex Philippidis, *The Top 15 Best-Selling Drugs of 2017*, GENETIC ENGINEERING & BIOTECHNOLOGY NEWS (Mar. 12, 2018), https://www.genengnews.com/a-lists/the-top-15-best-selling-drugs-of-2017/.

[26] Bob Herman, *Humira sales approach $20 billion*, AXIOS (Jan. 25, 2019), https://www.axios.com/abbvie-humira-2018-sales-20-billion-e4039176-baeb-44ff-b4fe-1b63005283b9.html.

[27] Mulcahy, *supra* note [20], at 3.

[28] *See* Dov Hirsch, *The Riddle of the Mysterious Patent Dance Wrapped in an Enigma: Is the Patent Dance of the BPCIA Optional or Mandatory?*, 27 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 645, 660-61 (2017).

[29] *Id.* at 654.

[30] Jason Kanter & Robin Feldman, *Understanding and Incentivizing Biosimilars*, 64 HASTINGS L.J. 57, 63-64 (2012).

g/mol.[31] Furthermore, the three-dimensional protein structure resulting from correct folding of the amino acid chain adds more complexity to the structure.[32] Due to their structural complexity, biologics cannot be synthesized from known substances by traditional chemical maneuvers like the small-molecule drugs.[33] Instead, they are produced by relying on living cells' inherent abilities to catalyze five to ten thousand biochemical reactions, compared to the five to ten chemical reactions necessary to synthesize small-molecule drugs.[34] Moreover, biologics "tend to be heat sensitive and susceptible to microbial contamination."[35] Therefore, it is almost impossible to obtain two identical biologics from different manufacturing batches.[36] Even if this were possible, current analytical techniques may not be able to detect all the structural differences between two biologics to satisfy a Hatch-Waxman equivalency requirement of biologics.[37] However, a biologic follow-on that is highly similar to the branded biologic drug might be sufficient to treat patients without any clinically meaningful differences in terms of safety, purity, and potency.[38] Thus, the correct terminology for these follow-on versions of biologics is "biosimilars," rather than "generics."[39]

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[31] Alexej Ladonnikov, Comment, *The Biosimilar Patent Dance – If You Don't Dance, You're No Friend of Mine*, 35 SANTA CLARA HIGH TECH. L.J. 135, 138-39 (2018).

[32] Kanter & Feldman, *supra* note [30], at 65.

[33] Hirsch, *supra* note [28], at 651.

[34] 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, 423 (2016).

[35] *What Are "Biologics" Questions and Answers*, FDA: CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER) (Feb. 2, 2018), https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answershttps://www.fda.gov/aboutfda/centersoffic.

[36] Hirsch, *supra* note [28], at 661.

[37] U.S. FOOD & DRUG ADMIN., SCIENTIFIC CONSIDERATIONS IN DEMONSTRATING BIOSIMILARITY OF A THERAPEUTIC PROTEIN DRUG TO A REFERENCE PRODUCT: GUIDANCE FOR INDUSTRY 5 (2015).

[38] U.S. FOOD & DRUG ADMIN., QUESTIONS AND ANSWERS ON BIOSIMILAR DEVELOPMENT AND THE BPCI ACT: GUIDANCE FOR INDUSTRY 5 (2018) ("Differences between the formulation of a proposed biosimilar product and the reference product may be acceptable. A 351(k) application must contain information demonstrating that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components.").

[39] *See* 42 U.S.C. § 262(i)(2) (2017) (stating that a biological product gains biosimilar status when "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"); *see also* Kanter & Feldman, *supra* note [30], at 59.

Another reason for the inapplicability of the Hatch-Waxman Act to biologics is that process patents cannot be litigated under the Hatch-Waxman Act.[40] Under the Hatch-Waxman Act, innovator companies are required to list all patents covering their new drugs in a publication known as the "Orange Book" after their drugs are approved by the FDA.[41] As a result, generic manufacturers are put on notice about which patents the innovator companies intend to assert, and the parties can litigate any patents from the Orange Book.[42] However, process patents, claiming how a drug is made or manufactured, cannot be listed in the Orange Book, and thus, cannot be litigated under the Hatch-Waxman Act.[43] This is because small-molecule drugs are made in a relatively straightforward manner so that the process patents would not be that important as several alternative processes could feasibly arrive at the equivalent final small-molecule drug.[44] In contrast to small-molecule drugs, process patents are vital for biologic innovators to maintain their exclusive protection under patent law.[45] Unlike small-molecule drugs, merely claiming the structure of a biologic would not give the inventor sufficient intellectual property protection because there are more potential design-arounds for biologics.[46] As discussed earlier, a biologic drug is usually hundreds of times larger than a small-molecule drug, and hence, there are more opportunities for competitors to design minor modifications of a branded biologic without changing the therapeutic effect.[47] Although broadening the claim scope might cover these design-arounds, the inventor would face challenges in proving that they had possession of the entire claimed invention and the disclosure enabled another to make or use the entire claimed invention at the time of filing the patent application.[48] By contrast, process claims can solve this problem because a small variation in the manufacturing process of a biologic may bring about dramatic changes to the purity, safety, and efficacy of the resulting product.[49] Such drastic

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[40] *See* Nathan Mannebach, Comment, *We Shall Dance, Unless You Choose Not To*, 65 KAN. L. REV. 687, 695 (2017).

[41] *See* 21 U.S.C. § 355(b)(1) (2018); *see also* Kate S. Gaudry, *Exclusivity Strategies and Opportunities in view of the Biologics Price Competition and Innovation Act*, 66 FOOD & DRUG L.J. 587, 602 (2011).

[42] *See* Mannebach, *supra* note [40], at 695-96.

[43] *See id.* at 696; *see also* 21 C.F.R. § 314.53(b)(1) (2019).

[44] *See* Mannebach, *supra* note [40], at 696.

[45] *Id.* at 697.

[46] Gaudry, *supra* note [41], at 614.

[47] *Id.*

[48] *Id.* at 590.

[49] *Id.* at 627.

changes occurred in Eprex, a biologic drug primarily sold in Europe.[50] It is a synthetic version of human erythropoietin protein, which stimulates the production of red blood cells to treat anemia.[51] The original process entailed Eprex being formulated, stored, and shipped in human serum albumin.[52] In 1998, the human serum albumin was replaced with polysorbate 80 and glycerin to avoid potential risk of contamination by the causative agent of Creutzfeldt-Jakob disease.[53] Unfortunately, such a shift in the process caused an unexpected immune response in many patients, meaning that the administration of the drug caused the patients' bodies to generate antibodies that began to attack the patients' own erythropoietin, leading to exacerbated anemia.[54] Therefore, it would be very challenging for a follow-on competitor to design-around a process patent to result in a biosimilar product while avoiding potentially deleterious effects of process changes.[55] Moreover, a process patent can also protect analytical testing methods that are done at key checkpoints during the manufacturing process to ensure that process intermediates are suitable to carry on to the next step.[56] Accordingly, new legislation would be needed not only to model the success of the Hatch-Waxman Act, but also to take into account the differences of composition and process between the small-molecule drugs and biologic drugs.

In 2009, Congress passed the BPCIA to provide an abbreviated approval pathway for a follow-on biological product that is sufficiently similar to a branded biologic to enter the market.[57] Before a new biologic drug can be introduced into the market, the innovator company must submit a Biologic License Application ("BLA") to the FDA to prove that the drug is safe, pure, and potent.[58] Under the BPCIA, a follow-on manufacturer, referred to as the "Biosimilar Applicant" ("Applicant"), can file an abbreviated Biologic License Application ("aBLA") to show its product is biosimilar to or interchangeable with the branded biologic, referred to as the "reference product."[59] Therefore, the Applicant can significantly

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[50] *See* Kanter & Feldman, *supra* note [30], at 66.

[51] *Eprex*, CANOE.COM, https://chealth.canoe.com/drug/getdrug/eprex (last visited Aug. 30, 2019).

[52] Kanter & Feldman, supra note [30], at 66.

[53] *Id.*

[54] *Id.* at 66-67.

[55] Gaudry, *supra* note [41], at 627.

[56] Hirsch, *supra* note [28], at 656.

[57] *See* 42 U.S.C. § 262(k) (2017).

[58] *See* 42 U.S.C. § 262(a)(2); *see also* 21 C.F.R. § 601.2(a) (2016).

[59] A biological product is interchangeable to a reference product when "the biological product may be substituted for the reference product without the intervention of the health care

save on the cost of getting their biologics approved by piggybacking on the data submitted to the FDA from the innovator company, known as the "Reference Product Sponsor" ("Sponsor").[60] For example, the cost of developing a biosimilar drug ranges from $100 million to $250 million, compared to $1.9 billion to develop a new biologic.[61]

C. The Patent Dance Provision

The BPCIA provides a carefully calibrated scheme to facilitate patent litigation between the Applicant and the Sponsor before the traditional infringing activities take place, such as making, using, offering to sell, selling, or importing.[62] This allows either for the Applicant to clear the roadblocks before marketing or for the Sponsor to stop the Applicant before actual damages occur.[63] Unlike the Hatch-Waxman Act, under which the branded company can sue any patent under the Orange Book all at once, the BPCIA steers the parties towards two phases of patent litigation.[64] The first phase follows the Applicant's submission of the aBLA to the FDA and the second phase is triggered by the Applicant's commercial marketing.[65]

To initiate the first phase of litigation, the Applicant and the Sponsor are required to engage in an elaborate back-and-forth process of information exchange, referred to as the "patent dance" by practitioners (See Figure 1).[66] First, after the FDA accepts the Applicant's application for review, within 20 days the Applicant should provide the Sponsor with a copy of the application and confidential information that describes the manufacturing process of the Applicant's biosimilar product. [67] Such information allows the Sponsor to determine whether the biosimilar would infringe the patents that the Sponsor owns pertaining to the

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provider who prescribed the reference product," 42 U.S.C. § 262(i)(3). The difference between a biosimilar and an interchangeable is when a patient is switched to a biosimilar product from the reference product, the patient's health care providers must take affirmative action whereas such action is not required to switch to an interchangeable product. *See id.*; 42 U.S.C. § 262(k)(2).

[60] 42 U.S.C. § 262(l)(1)(A).

[61] Erwin A. Blackstone & Joseph P. Fuhr, *The Economics of Biosimilars*, 6 AM. HEALTH & DRUG. BENEFITS 469, 471-73 (2013).

[62] *See* 42 U.S.C. § 262(l).

[63] *See* 35 U.S.C. § 271(e)(2)(C) (2018) (making the submission of the biosimilar application an artificial act of infringement).

[64] *See id.* at §§ 262(l)(6), (8).

[65] *See id*.

[66] Hirsch, *supra* note [28], at 664.

[67] 42 U.S.C. § 262(l)(2)(A).

reference product.[68] Thereafter, the Sponsor is given 60 days to provide the Applicant with a list of patents that they believed to be infringed by the biosimilar or by the process of manufacturing the biosimilar and a list of patents that the Sponsor is willing to license.[69] Then, within 60 days of receiving the list from the Sponsor, the Applicant is required to respond with a detailed statement explaining why they are not liable, assuming they believe this to be true, by asserting that the Sponsor's patents are invalid, unenforceable, or not infringed, or that the biosimilar product will not enter the market until the patents expire.[70] The Applicant is also required to respond to the Sponsor's licensing offer.[71] In addition, the Applicant may, but need not, supplement an additional list of patents which are relevant to the biosimilar product, but omitted by the Sponsor.[72] Next, the Sponsor is given an opportunity to provide its own contentions of validity, enforceability, or infringement on each of the identified patents within 60 days.[73]

Following this exchange, the Applicant and the Sponsor should "engage in good faith negotiations" to determine which patents, if any, will be litigated immediately.[74] The BPCIA also contemplates scenarios in which the parties fail to reach an agreement. In this case, the parties will simultaneously exchange lists of patents that they would like to litigate in the first phase.[75] The Applicant should inform the Sponsor of the number of patents it wants to litigate in the first phase, thereby setting a ceiling for how many patents the Sponsor can list.[76] If the Applicant does not list any patent to be litigated immediately, the Sponsor can list one patent.[77]

Only after the patent dance ends can the first phase of litigation begin.[78] Within 30 days of reaching an agreement or exchanging patent lists, the Sponsor must file a complaint to proceed with the first phase of litigation.[79] The BPCIA

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[68] *Id.* at § 262(l)(1)(D).
[69] *Id.* at § 262(l)(3)(A).
[70] *Id.* at § 262(l)(3)(B)(ii).
[71] *Id.*
[72] *Id.* at § 262(l)(3)(B)(i).
[73] *Id.* at § 262(l)(3)(C).
[74] *Id.* at § 262(l)(4)(A).
[75] *Id.* at § 262(l)(5)(B)(i).
[76] *Id.* at §§ 262(l)(5)(A), (B)(ii).
[77] *Id.* at § 262(l)(5)(B)(ii).
[78] *See id.* at § 262(l)(6).
[79] *Id.*

treats the submission of the biosimilar application to the FDA as an artificial infringement act.[80]

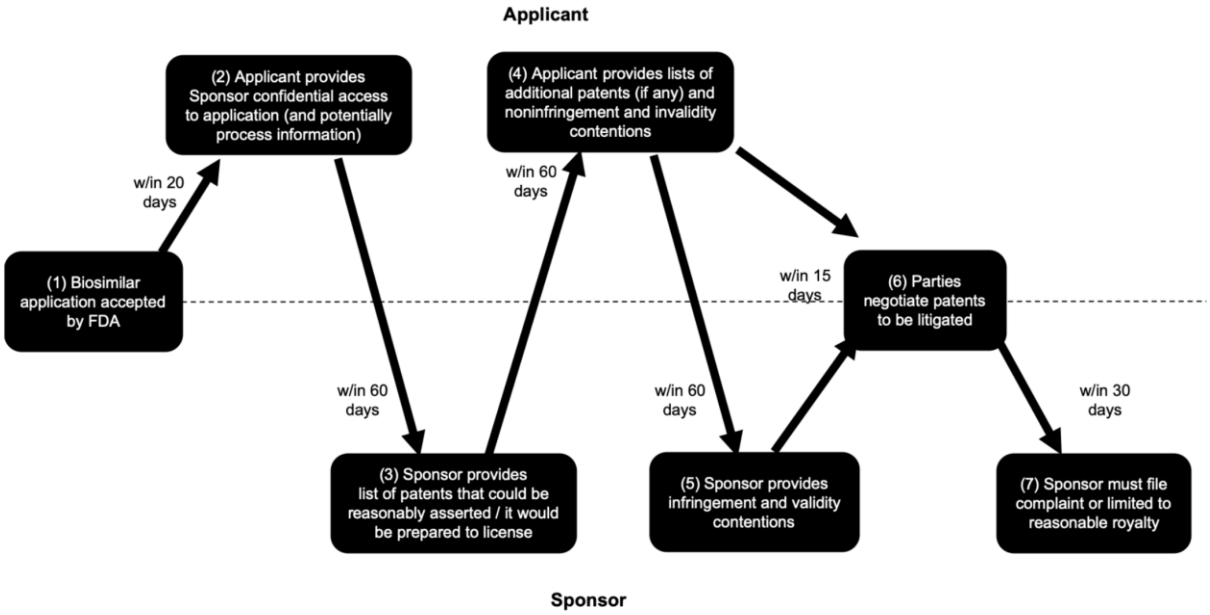

Figure 1. Overview of the patent dance.

The first phase of litigation allows the parties to tackle the most important patents while the biosimilar application is still under FDA review.[81] The patents that are enumerated on the original § 262(l)(3) lists, but not litigated in the first phase, can be litigated in the second phase.[82] The second phase of litigation is triggered by the Applicant's notice of commercial marketing to the Sponsor.[83] The Applicant must provide such notice no later than 180 days before the date of the first commercial marketing of the biosimilar product.[84] Moreover, this phase enables the Sponsor to seek a preliminary injunction to prevent the Applicant from launching the biosimilar "until the court decides the issue of patent validity, enforcement, and infringement."[85]

The BPCIA also provides incentives to comply with the patent dance by establishing the consequences for those failing to participate. If the Applicant fails the first step of the patent dance by refusing to disclose its aBLA application and/or manufacturing information to the Sponsor, the Sponsor can bring a

[80] *Id.* at § 262(e)(2)(C)(i).
[81] *See* Hirsch, *supra* note [28], at 674.
[82] *Id.*
[83] 42 U.S.C. § 262(l)(8)(A).
[84] *Id.*
[85] *Id.* at § 262(l)(8)(B).

declaratory judgement action on any patent that claims the biologic or a use of the biologic.[86] Meanwhile, if the Applicant provides the application and manufacturing information but fails to participate in a subsequent step, such as providing noninfringement or invalidity contentions, the Sponsor can bring a declaratory judgement action on any patent identified on the Sponsor's § 262(l)(3)(A) list.[87]

An illustrative example of a successful patent dance comes from the recent litigation between AbbVie Inc. ("AbbVie") and Boehringer Ingelheim International GmbH ("Boehringer Ingelheim"). AbbVie is the Sponsor for the best-selling biologic drug, adalimumab, under the brand name Humira.[88] On October 27, 2016, Boehringer Ingelheim applied to the FDA for its own biosimilar based off adalimumab.[89] Four days after the FDA accepted Boehringer Ingelheim's aBLA, on January 13, 2017, Boehringer Ingelheim provided AbbVie with confidential access to documents related to the application.[90] On March 13, 2017, AbbVie sent the § 262(l)(3) list of seventy-two patents as potentially infringed if Boehringer Ingelheim intended to bring Boehringer Ingelheim's aBLA product into the market.[91] Shortly after, Boehringer Ingelheim responded with a statement claiming either noninfringement or invalidity of the identified patents.[92] After AbbVie responded with rebuttal arguments, the parties exchanged lists of five patents on each side.[93] This list exchange led to eight chosen patents due to two patents in common between both of the lists.[94] On August 2, 2017, AbbVie filed a complaint on the eight patents in the District Court of Delaware.[95] Although the parties settled before finishing the first phase of litigation, if Boehringer Ingelheim provided the 180-day commercial market notice, the parties could have resolved the disputes over the remaining 64 patents in the second phase of litigation.[96]

Although Congress is silent on why the BPCIA includes such an intricate patent dance procedure, a feature absent from the Hatch-Waxman Act, the legislative history suggests that the purpose of the patent dance is to efficiently

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[86] *Id.* at § 262(l)(9)(C).
[87] *Id.* at § 262(l)(9)(B).
[88] Complaint at 3, AbbVie Inc. v. Boehringer Ingelheim Int'l GmbH, No. 17-cv-01065 (D. Del. Aug. 2, 2017).
[89] *Id.* at 12.
[90] *Id.* at 13.
[91] *Id.* at 14.
[92] *Id.*
[93] *Id.* at 19.
[94] *Id.*
[95] *Id.* at 1, 21.
[96] *Id.* at 20.

resolve patent disputes before marketing the biosimilar product.[97] Aiming to balance the interest of incentivizing innovators and the interest of providing affordable medicine to consumers, the patent dance is also a compromise between the Sponsors and Applicants.[98] Both sides agreed that the patent dance, necessary for timely dispute resolution, would be beneficial.[99] The patent dance ensures that only the most pertinent patents will be litigated in the first phase.[100] On one hand, the Sponsor can fire its strongest arguments against the Applicant, and if it wins, the Sponsor can efficiently halt the Applicant through an injunction without the need to defend all of its patents at once, saving money and time.[101] Even if it loses, the Sponsor has another chance to fight on other patents in the second phase.[102] On the other hand, the patent dance bestows upon the Applicant more control over which patents, or at least how many patents, will be litigated immediately.[103] The Applicant can better prepare its arguments by concentrating resources on the narrow set of patents. In addition, the patent dance may take up to 230 days, during which time no suit may commence.[104] Hence, the Applicant could exploit the adversary's information from the patent dance "while protected by the statute's safe harbor from litigation."[105] Moreover, compared to traditional litigation, the Applicant has more flexibility to delay commercial marketing to protect its investment based on information gathered from the patent dance and the result of the first phase of litigation.[106]

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[97] *See* Hirsch, *supra* note [28], at 681-82. In a congressional hearing, Representative Anna Eshoo stated that the patent dance provision was intended "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." *Id.*

[98] *See* Tanaka, *supra* note [8].

[99] *Id.* at 680-81. In a House hearing, Dr. David Schenkein from Genentech, arguing on behalf of the Biotechnology Innovation Organization, noted the importance of resolving patent disputes prior to marketing approval. *Id.* In the same hearing, Bruce Downey, CEO of a generic manufacturer, argued on behalf of the Generic Pharmaceutical Association and echoed the importance of early patent resolution. *Id.* at 681.

[100] Hirsch, *supra* note [28], at 674.

[101] *Id.*

[102] *Id.*

[103] Tanaka, *supra* note [8], at 683.

[104] Hirsch, *supra* note [28], at 675.

[105] Amgen Inc. v. Sandoz Inc. (*Amgen I*), No. 14-cv-04741-RS, 2015 WL 1264756, at *6 (N.D. Cal. Mar. 19, 2015), *aff'd in part, vacated in part, remanded*, 794 F.3d 1347 (Fed. Cir. 2015), *rev'd in part, vacated in part*, 137 S. Ct. 1664 (2017), and *aff'd*, 877 F.3d 1315 (Fed. Cir. 2017).

[106] *Id.*

II
SANDOZ V. AMGEN

Sandoz Inc. v. Amgen Inc. 137 S. Ct. 1664 (2017) is a landmark case interpreting the BPCIA's patent dance. The Supreme Court's holding that failure to complete the patent dance would not lead to injunctive relief has offered the Applicant the freedom to opt out of the patent dance.[107] The foundations of the biotechnology industry have been shaken ever since.

A. Factual Background

Amgen Inc. ("Amgen") has been producing and selling the biologic drug filgrastim under the brand name Neupogen since 1991.[108] Filgrastim is produced by recombinant-DNA technology to treat low blood neutrophils in patients.[109] In May 2014, Sandoz Inc. ("Sandoz"), a generic manufacturer, filed an aBLA with the FDA seeking approval of its own biosimilar of filgrastim under the brand name Zarxio.[110] Shortly after receiving notice that the FDA had accepted its application, Sandoz notified Amgen that it had filed a biosimilar application that was anticipated to receive FDA approval in the first or second quarter of 2015.[111] Importantly, Sandoz informed Amgen of its intention to opt out of the patent dance, thereby refusing to provide its application and manufacturing information to Amgen.[112] In October 2014, Amgen filed a patent infringement suit against Sandoz in the Northern District of California.[113] One of Amgen's claims was unlawful competition for unlawful business practices under California state law because Sandoz allegedly violated the BPCIA by failing to comply with the patent dance established in 35 U.S.C. § 262(l).[114] Based on this state law claim, Amgen further sought injunctive relief to prevent Sandoz from launching its biosimilar product.[115]

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[107] *See generally* Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664.

[108] Amgen Inc. v. Sandoz Inc. (*Amgen II*), 794 F.3d 1347, 1352 (Fed. Cir. 2015).

[109] *Filgrastim*, WIKIPEDIA, https://en.wikipedia.org/wiki/Filgrastim - cite_note-AHFS2016-1 (last visited Aug. 30, 2019).

[110] *Amgen II*, 794 F.3d at 1352-53.

[111] *Id.*

[112] *Id.* at 1353.

[113] *Id.*

[114] *Id.*

[115] *Id.*

B. The Federal Circuit's Decision

The Federal Circuit affirmed the District Court's dismissal of Amgen's motion for injunctive relief because the Applicant is not required under the BPCIA to disclose its biosimilar application and manufacturing information.[116] Judge Lourie explained that the language stating "the subsection (k) applicant *shall* provide to the reference product sponsor a copy of the application" in 42 U.S.C. § 262(l)(2)(A) could not be read in isolation (emphasis added).[117] When interpreting this paragraph in connection with 42 U.S.C. § 262(l)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii), the term "shall" does not mean "must."[118] 42 U.S.C. § 262(l)(9)(C) sets forth a direct consequence of failing to comply with the patent dance, providing that, "[i]f a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A)," then the Sponsor, but not the Applicant, can bring a declaratory judgment action on "any patent that claims the biological product or a use of the biological product."[119] Furthermore, 35 U.S.C. § 271(e)(2)(C)(ii) makes the Applicant's failure to disclose the information required by the first step of the patent dance an artificial "act of infringement" of "a patent that could be identified" by the Sponsor in the patent dance.[120] Based on 35 U.S.C. § 271(e)(4), Judge Lourie concluded both 42 U.S.C. § 262(l)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) provide only one remedy for failing to disclose and that is a claim of patent infringement.[121] Moreover, if the term "shall" is construed as "must," 42 U.S.C. § 262(l)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) would be superfluous, and statutes should be interpreted to avoid rendering any provision superfluous.[122] Thus, drafters of the BPCIA contemplated a scenario where the

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[116] *Id*. at 1362.

[117] *Id*. at 1354-55.

[118] *Id*. at 1355.

[119] *Id.* at 1356 (quoting 42 U.S.C. § 262(l)(9)(C)).

[120] 35 U.S.C. § 271(e)(2)(C)(ii) provides that "[i]t shall be an act of infringement to submit" a biosimilar or interchangeable application "if the applicant for the application fails to provide the application and information required under" 42 U.S.C. § 262(l)(2)(A); *Amgen II*, 794 F.3d at 1356.

[121] 35 U.S.C. § 271(e)(4) provides that remedies prescribed in this paragraph "are the only remedies which may be granted by a court for an act of infringement described in paragraph (2)[.]"; *Amgen II*, 794 F.3d at 1356.

[122] *Id.*

Applicant failed to disclose the application and manufacturing information, and the sole remedy for the Sponsor is declaratory judgment.[123]

However, Judge Newman dissented and concluded that compliance with the patent dance is mandatory.[124] Judge Newman stated that 42 U.S.C. § 262(l)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) just provide one relief for non-compliance, but "do not ratify non-compliance." [125] Judge Newman noted that 42 U.S.C. § 262(l)(9)(C) only provides declaratory action by the Sponsor for a "patent that claims the biological product or a use of the biological product," but not a patent that claims manufacturing process.[126] As discussed in Part I, process patents are the most important patents for biologics, and thus, 42 U.S.C. § 262(l)(9)(C) cannot be understood to provide the sole remedy. [127] Further, Judge Newman noted that several provisions in the same paragraph use the term "may" to indicate the act is permissive, thereby leaving the term "shall" to refer to a mandatory act.[128] More importantly, Judge Newman believed that the BPCIA was enacted to achieve the balance of obligations and benefits. [129] When the Applicant benefits from piggybacking on the Sponsor's data submitted to the FDA, the Applicant should not circumvent its obligations of complying with procedures designed by the BPCIA. [130] Therefore, declining injunctive relief when the Applicant fails its obligation would strike the balance envisioned by the BPCIA.[131]

C. The Supreme Court's Decision

Amgen timely appealed from the Federal Circuit's affirmance of the denial of a preliminary injunction and the Supreme Court granted certiorari. [132] The Supreme Court affirmed the Federal Circuit's decision that injunctive relief was not available under federal law to enforce the patent dance, but based on slightly different reasons.[133] First, the Supreme Court found the interpretation of 35 U.S.C. § 271(e)(2)(C) by the Federal Circuit was incorrect.[134] The Court concluded that it

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[123] *Id.*
[124] *Id.* at 1363 (Newman, J., concurring in part, dissenting in part).
[125] *Id.* at 1366.
[126] *Id.* at 1364.
[127] *Id.*
[128] *Id.* at 1365 (citing Anderson v. Yungkau, 329 U.S. 482, 485 (1947)).
[129] *Id.* at 1366.
[130] *Id.*
[131] *Id.*
[132] Sandoz Inc. v. Amgen Inc., 137 S. Ct. at 1673.
[133] *Id.* at 1674.
[134] *Id.*

was the Applicant's submission of a biosimilar application to the FDA, rather than its failure to disclose, that constituted an act of infringement.[135] It follows that 35 U.S.C. § 271(e)(2)(C) does not provide an exclusive remedy for failure to disclose.[136] Rather, the Court relied on 42 U.S.C. § 262(l)(9)(C), which provides immediate declaratory judgment action as a remedy for the Sponsor when the Applicant refuses to engage in the patent dance.[137] The Court reasoned that this action is an appropriate remedy because it shifts the control over the scope and timing of litigation from the Applicant to the Sponsor.[138] More importantly, this action deprives the Applicant of the certainty of the legal consequences prior to marketing, thereby putting the Applicant at risk of losing its marketing investment without knowing if its commercial activities would be barred as a result of the litigation.[139] This reasoning indicates that BPCIA not only benefits the Applicant by abbreviating the regulatory pathway, but also reprimands the Applicant for failing to comply with its procedures, which responds to Judge Newman's dissenting opinion that declining injunctive relief would strike a balance between the BPCIA's benefits and obligations.

Furthermore, the Court concluded that an expressive remedy in 42 U.S.C. § 262(l)(9)(C), declaratory judgment by the Sponsor, "excludes all other federal remedies, including injunctive relief."[140] The Court cited the canon of statutory interpretation that when "a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies."[141] Therefore, the statute's explicit mention of declaratory judgment action and silence on any other remedies indicates that Congress acted intentionally to deny injunctive relief under federal law.[142]

Finally, the Court held that Amgen's state claims of unfair competition should be remanded to consider whether noncompliance with the patent dance would be treated as "unlawful" under California law.[143] On remand, the Federal

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[135] *Id.*
[136] *Id.* at 1675.
[137] *Id.*
[138] *Id.*
[139] *Id.*
[140] *Id.*
[141] *Id.* (quoting Karahalios v. Fed. Emps., 489 U.S. 527, 533 (1989)).
[142] *Id.*
[143] *Id.* at 1676.

Circuit held that BPCIA preempts state law remedies, and thus, injunctive relief is also not available under state law.[144]

III
EFFECTS OF *SANDOZ* ON THE APPLICANT SIDE –WHETHER TO DANCE

The decision of *Sandoz* has effectively made the patent dance optional because the Sponsor's only remedy is to bring a declaratory judgment action when the Applicant opts out of the patent dance.[145] The Applicant is granted two options: either to disclose all relevant information to the Sponsor and divide the litigation into two phases or to leave the Sponsor in the dark and force the Sponsor to bring suits on all patents against the Applicant at once. Therefore, the Applicant can strategize and decide whether or not it is advantageous to engage in the patent dance under certain circumstances.

Indeed, companies do not always adhere to the same position on whether to fully comply with the patent dance. They often alter their attitudes towards the patent dance based on their financial stake, their role as either the Sponsor or the Applicant, and the specific biosimilars being litigated.[146] For instance, in *Amgen, Inc. v. Genentech, Inc.*, No. CV 17-7349, 2018 WL 910198 (C.D. Cal. Jan. 11, 2018), Amgen, who was the Sponsor and who previously insisted on enforcing the patent dance in *Sandoz*, was the Applicant in this biosimilar litigation. The dispute was initiated by Amgen's application of its biosimilar product, which was based on Genentech Inc. ("Genentech")'s cancer therapy biologic.[147] The parties participated in multiple steps of the patent dance as outlined by the BPCIA.[148] However, when both parties failed to reach an agreement about which patents should be litigated immediately, Amgen, the Applicant, did not provide a list of patents that it believed needed to be litigated in the first phase as required by 42 U.S.C. § 262(l)(5)(A).[149] As a result, Amgen failed to fully abide by the patent dance even though it demanded full compliance by its adversary in *Sandoz*.[150] Additionally, Sandoz, the Applicant who failed to engage in the patent dance in *Sandoz*,

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[144] Amgen Inc. v. Sandoz Inc. (*Amgen III*), 877 F.3d 1315, 1326 (2017).

[145] Sandoz Inc. v. Amgen Inc., 137 S. Ct. at 1674-75.

[146] Sanya Sukduang & Thomas J. Sullivan, *The Patent Dance*, FINNEGAN (July 2018), https://www.finnegan.com/en/insights/the-patent-dance-article.html.

[147] Amgen Inc. v. Genentech, Inc., No. CV 17-7349-GW(AGrx), 2018 WL 910198, at *1 (C.D. Cal. Jan. 11, 2018).

[148] *Id.* at *2.

[149] *Id.*

[150] *Id.*

maintained the role of Applicant in the litigation against AbbVie and fully complied with patent dance in this infringement suit.[151]

A. The Benefits of Skipping the Patent Dance

The biggest incentive for the Applicant to forego the patent dance is to expedite market entry.[152] As of July 2019, twenty-six suits related to biosimilars have been filed.[153] Of these suits, only five Applicants completely opted out of the patent dance (i.e., refused to provide access to aBLA and/or manufacturing information), but many of the Applicants engaged in a partial dance (i.e., provided access to aBLA and/or manufacturing information but failed to participate in subsequent steps).[154] Despite the differences of the allegedly infringing products and parties, all the Sponsors in these litigations have relatively small, known patent portfolios.[155] Therefore, there would be no need to separate the litigation into two phases. Rather than waiting for 230 days to finish all the steps required by the patent dance, it is in the Applicant's best financial interest to accelerate the litigation to clear the roadblocks barring its market entry, especially when the Applicant anticipates its biosimilar will gain FDA approval in the short-term.[156] Secondly, this strategy may shelter the Applicant from an infringement claim against some of its patents.[157] Since the Sponsor would have no idea how the Applicant's biosimilar is manufactured, the Sponsor may forego asserting a patent that would have been otherwise asserted had the Sponsor been privy to the information.[158] However, as will be discussed in Part IV, the Sponsor may choose

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[151] Complaint at 17-23, AbbVie Inc. v. Sandoz Inc., No. 18-cv-12668 (D.N.J. Aug. 10, 2018).

[152] Tanaka, *supra* note [8], at 684-85.

[153] *BPCIA Litigations*, BIG MOLECULE WATCH (last visited July 29, 2019), https://www.bigmoleculewatch.com/bpcia-patent-litigations.

[154] *See id.* The five biosimilar litigations in which the Applicants skipped the patent dance are: Sandoz v. Amgen over the biosimilar of filgrastim (Neupogen), Janssen v. Samsung Bioepis over the biosimilar of infliximab (Remicade), Genentech v. Sandoz over the biosimilar of rituximab (Rituxan), Amgen v. Adello over the biosimilar of filgrastim (Neupogen), and Immunex v. Samsung Bioepis over the biosimilar of etanercept (Enbrel).

[155] *See Amgen I*, 2015 WL 1264756, at *3 (N.D. Cal. Mar. 19, 2015) (asserting only one patent against Sandoz); Complaint at 7-8, Janssen Biotech, Inc. v. Samsung Bioepis Co., No. 17-cv-03524 (D.N.J. May 17, 2017) (asserting three patents against the Applicant); Complaint at 11-13, Immunex Corp. v. Samsung Bioepis Co., No. 19-cv-11755 (D.N.J. Apr. 30, 2019) (asserting five patents against the Applicant).

[156] *See* Complaint at 3-4, *Immunex*, No. 19-cv-11755 (pointing out that the biosimilar product was approved by the FDA within two years after the aBLA submission).

[157] *See* Hirsch, *supra* note [28], at 677-78.

[158] *See id.* at 678.

to list all patents and then amend the complaint at a later date once it obtains more information through discovery. Thirdly, foreclosure of the patent dance can help the Applicant protect sensitive trade secrets regarding the manufacturing process.[159] However, this benefit may be counterbalanced by the Sponsor's use of discovery to obtain these trade secrets. Lastly, foregoing the patent dance can save the Applicant from the obligation of disclosing early contentions of non-infringement and invalidity, which could be exploited by the Sponsor as admissions in later litigation.[160]

B. The Disadvantages of Opting Out of the Patent Dance

There are also many disadvantages for the Applicant if it opts out of the patent dance. As recognized by the *Sandoz* Court, the adverse consequences of failing to participate in the patent dance include the loss of control over the scope and timing of the litigation.[161] Moreover, participating in, or at least partially participating in, the patent dance would force the Sponsor to list all patents during the patent dance or lose the right to assert them.[162] 42 U.S.C. 262(l)(3)(A) obligates the Sponsor to provide a list of patents that could reasonably be asserted.[163] As a result, the Sponsor is precluded from litigating any patent not on the § 262(l)(3)(A) list since 35 U.S.C. § 271(e)(6) provides that "[t]he owner of a patent that should have been included in the list, . . . but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product."[164]

The Applicant's biggest nightmare resulting from skipping the patent dance may occur if the Sponsor holds a number of patents on a biologic product and the District Court grants a preliminary injunction against the Applicant.[165] For example, AbbVie owns more than 100 patents related to its blockbuster drug, Humira.[166] In the biosimilar litigations, AbbVie identified sixty-one patents against Amgen on the 42 U.S.C. § 262(l)(3)(A) list, eighty-four patents against Sandoz,

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[159] *Id.* at 676.

[160] Brian D. Coggio, *Biosimilars: "The Patent Dance" "I Won't Dance/Don't Ask Me"*, 27TH ANNUAL FORDHAM IP CONFERENCE (Apr. 25-26, 2019), http://fordhamipinstitute.com/wp-content/uploads/2019/02/Goggio-Brian_-Biosimilars_27th-Annual-Fordham-IP-Conference.pdf.

[161] Sandoz Inc. v. Amgen Inc., 137 S. Ct. at 1675.

[162] Coggio, *supra* note [160].

[163] 42 U.S.C. § 262(l)(3)(A).

[164] 35 U.S.C. § 271(e)(6).

[165] *See* Coggio, *supra* note [160].

[166] Complaint at 1, AbbVie Inc. v. Amgen Inc., No. 16-cv-00666 (D. Del. Aug. 4, 2016).

and seventy-two patents against Boehringer Ingelheim.[167] Each of the three Applicants participated in the patent dance and exchanged a list of a smaller number of patents to be litigated in the first phase in an attempt to avoid a preliminary injunction.[168] Had the patent dance not occurred in these three litigations, AbbVie would have filed an infringement suit on at least sixty patents. The district court is likely to be overwhelmed by the large number of patents and the complexity of the technology, and thus, the likelihood of granting a preliminary injunction would be high. Moreover, in a footnote of *Sandoz*, the Supreme Court noted that its holding "express[ed] no view on whether a district court could take into account an applicant's violation of § 262(l)(2)(A) (or any other BPCIA procedural requirement) in deciding whether to grant a preliminary injunction."[169] The Court further cited precedent to suggest considering a "balance of equities" in deciding whether to issue a preliminary injunction.[170] It seems that the Court left it to the district court's discretion to consider the Applicant's failure to engage in the patent dance as a factor in deciding whether to grant injunctive relief when the Sponsor seeks declaratory judgment under 42 U.S.C. § 262(l)(9)(C).[171] Such a preliminary injunction can be disastrous for the Applicant.[172] For example, many Applicants settled with AbbVie on the Humira litigation, which allows these Applicants to enter the U.S. market in 2023.[173] Meanwhile, if a new Applicant files an application, opts out of the patent dance, gets sued by AbbVie, and faces a preliminary injunction, AbbVie would have incentives to stall the litigation.[174] Considering the number of patents involved, it is possible that the dispute may not be resolved until after 2023, the time when other companies are entitled to sell their biosimilar versions of Humira, thereby foreclosing the market of the new

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[167] *Id.* at 11; Complaint at 18, AbbVie Inc. v. Sandoz Inc., No. 18-cv-12668 (D.N.J. Aug. 10, 2018); Complaint at 14, AbbVie Inc. v. Boehringer Ingelheim Int'l GmbH, No. 17-cv-01065 (D. Del. Aug. 2, 2017).

[168] *See* Complaint at 10-16, AbbVie Inc. v. Amgen Inc., No. 16-cv-00666; *see also* Complaint at 16-23, AbbVie Inc. v. Sandoz Inc., No. 18-cv-12668; *see also* Complaint at 12-20, AbbVie Inc. v. Boehringer Ingelheim Intl GmbH, No. 17-cv-01065.

[169] Sandoz Inc v. Amgen Inc., 137 S. Ct. at 1677, n.2.

[170] *Id.* (citing Winter v. NRDC, Inc., 555 U.S. 7, 20 (2008)).

[171] Ladonnikov, *supra* note [31], at 146-47.

[172] Bruce Wexler, Partner, Paul Hastings, LLP, Address at N.Y.U. Sch. Of Law: Life Sci. and Patent Law (Mar. 27, 2019) (on file with author).

[173] *See AbbVie and Boehringer Ingelheim Settle Over Biosimilar Adalimumab*, CTR. FOR BIOSIMILARS (May 14, 2019), https://www.centerforbiosimilars.com/news/abbvie-and-boehringer-ingelheim-settle-over-biosimilar-adalimumab.

[174] Wexler, *supra* note [172].

Applicant.[175] On the contrary, if the Applicant would have fully complied with the patent dance, the likelihood of suffering from a preliminary injunction would have been diminished.[176] Under 42 U.S.C. § 262(l)(8)(B), a preliminary injunction is only available after the Applicant provides the Sponsor with a notice of commercial marketing.[177] Normally, a preliminary injunction is off the table in the first phase of litigation, during which time the district court can attempt to comprehend the technology and sort out the disputes on representative patents. Thus, when the Sponsor floods the court with a large number of patents in the second phase, the district court would be in a better position to tackle the difficult issues and may not so easily grant a preliminary injunction against the Applicant.[178]

Another disadvantage of skipping or failing to fully complete the patent dance is the Applicant's loss of the right to file a declaratory judgment action.[179] Although the Supreme Court in *Sandoz* did not explicitly deny the Applicant's action, many district courts later held that the Applicant's declaratory relief is conditioned on full compliance with the patent dance.[180] In *Celltrion, Inc. v. Genentech, Inc.*, the Applicant did not fulfill the 5(A) step required by 42 U.S.C. § 262(l)(5) when it refused to exchange with the Sponsor the number of patents to be immediately litigated.[181] Instead, the Applicant served a notice of commercial marketing and then filed a declaratory judgment lawsuit against the Sponsor.[182] The Northern District of California subsequently dismissed the Applicant's action for failure to state a claim for relief.[183] The court held that the Applicant's right to file a declaratory action after sending a notice of commercial marketing is conditioned on compliance with every step of the patent dance.[184] In addition, the Central District of California also dismissed the Applicant's declaratory judgment lawsuit in *Genentech* when the Applicant attempted to bypass the step of exchanging the

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[175] *Id.*

[176] *Id.*

[177] 42 U.S.C. § 262(l)(8)(B).

[178] Wexler, *supra* note [172].

[179] *See* Stacie L. Ropka et al., *A Hard Choice for Abbreviated Biologics License Applicants*, LAW360 (Feb. 4, 2019, 2:36 PM), https://www.law360.com/articles/1125158/a-hard-choice-for-abbreviated-biologics-license-applicants.

[180] *See* Celltrion, Inc. v. Genentech, Inc. (*Celltrion*), No. 18-cv-00274-JSW, 2018 WL 2448254, at *2 (N.D. Cal. May 9, 2018), *appeal dismissed*, No. 2018-2160, 2018 WL 7046651 (Fed. Cir. Nov. 30, 2018); *see also* Amgen Inc. v. Genentech, Inc., 2018 WL 910198, at *3.

[181] *Celltrion*, 2018 WL 2448254, at *3.

[182] *Id.*

[183] *Id.* at *5.

[184] *Id.* at *8.

number of patents to be asserted in the first phase of litigation.[185] The court concluded that allowing such an action would "override congressional intent and do away with the 'carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement' set out in the BPCIA."[186]

Furthermore, total foreclosure of the patent dance would cost the Applicant the opportunity to obtain the Sponsor's early contentions on infringement and validity issues,[187] which may help the Applicant flesh out legal and factual arguments, reduce the chance for an unexpected ambush, and make investment decisions.

C. Legislative Attempts to Encourage Compliance with the Patent Dance

On June 27, 2019, the Senate Judiciary Committee passed the Affordable Prescription for Patients Act of 2019 (S. 1416), which limits the number of patents that can be litigated under the BPCIA.[188] This bill proposes to reward the Applicant's compliance with the patent dance by limiting the Sponsor to assert no more than twenty patents in a patent infringement claim.[189] Sponsors of the bill aim to help the Sponsor and the Applicant resolve the patent disputes faster, with the goal of decreasing drug prices for consumers.[190] Moreover, the court has the discretion to increase the number of patents to be asserted if the Applicant "fails to provide information . . . that would enable the . . . [S]ponsor to form a reasonable belief with respect to whether a claim of infringement under this section could reasonably be asserted."[191] Therefore, if this bill becomes the law, the Applicant would have more incentives to fully engage in the patent dance since full compliance is the prerequisite condition to expedite the resolution of patent disputes and to clear the roadblocks for market entry.

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[185] Amgen Inc. v. Genentech, Inc., 2018 WL 910198, at *4.

[186] *Id.* (citing Sandoz Inc. v. Amgen Inc., 137 S. Ct. at 1670).

[187] Coggio, *supra* note [160].

[188] Affordable Prescription for Patient Act, S. 1416, 116th Cong. § 3 (2019) (as passed by S. Comm. on the Judiciary, June 27, 2019).

[189] *Id.* at § 3(a)(2).

[190] *See* Bruce Wexler et al., *Biosimilar Patent Litigation Bill Would Change BPCIA Strategy*, LAW360 (July 11, 2019, 12:54 PM), https://www.law360.com/articles/1176215/biosimilar-patent-litigation-bill-would-change-bpcia-strategy.

[191] S. 1416 at § 3(a)(2).

IV
EFFECTS OF *SANDOZ* ON THE SPONSOR SIDE - PLEADING STANDARD

As discussed in Part III, *Sandoz* has granted the Applicant the freedom to opt out of the patent dance when it is more beneficial to do so. However, this may put the Sponsor at a disadvantage because if the Sponsor cannot access the Applicant's manufacturing information, the Sponsor may not be able to state plausible factual allegations for a claim of patent infringement.[192] This is especially true with process patents because there is no way for the Sponsor to know how the Applicant intends to manufacture its biosimilar product and whether the Applicant's manufacturing process infringes the Sponsor's process patents.[193] Even if the Sponsor were able to pass the initial hurdle of a pleading requirement, there is a concern of whether the missing information, caused by the Applicant's failure to comply with the patent dance, is obtainable through discovery.[194]

A. Pleading Standard for a Patent Infringement Claim

Federal Rule of Civil Procedure 8(a) governs the pleading standard, which requires only "a short and plain statement of the claim showing that the pleader is entitled to relief" in order to "give the defendant fair notice."[195] The defendant may challenge the sufficiency of a complaint by filing a motion to dismiss under Rule 12(b)(6).[196] Under *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 570 (2007), in order to survive such a motion, the plaintiff must plead "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'"[197] To reach the facial plausibility bar, the complaint must contain "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged."[198]

"Direct infringement under § 271(a) occurs where all steps of a claimed method are performed by or attributable to a single entity."[199] To survive the motion to dismiss, the plaintiff of an infringement claim must "place the alleged

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[192] Hirsch, *supra* note [28], at 677.
[193] *Id.*
[194] *Id.* at 678.
[195] Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007).
[196] Fed. R. Civ. P. 12(b)(6).
[197] Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570).
[198] *Id.*
[199] Akamai Techs., Inc. v. Limelight Networks, Inc. 797 F.3d 1020, 1022 (Fed. Cir. 2015) (citing BMC Res., Inc. v. Paymentech, L.P., 498 F.3d 1373, 1379–81 (Fed. Cir. 2007)); *see* 35 U.S.C. § 271(a).

infringer 'on notice of what activity . . . is being accused of infringement.'"[200] With the abrogation of Form 18 in the newly amended Federal Rules of Civil Procedure in 2015, a direct infringement complaint is now governed by the facial plausibility standard.[201] Although the change is recent, some Federal Circuit cases have begun to shed some light on what is required in a complaint.[202] First of all, the plaintiff should identify the specific allegedly infringing product or activity.[203] For instance, in *Disc Disease Solutions Inc. v. VGH Solutions, Inc*., 888 F.3d 1256, 1260 (2018), the Federal Circuit found the complaint sufficient as it identified "the three accused products—by name and by attaching photos of the product packaging as exhibits[.]" By contrast, the Federal Circuit affirmed the district court's dismissal of a patent infringement claim in *Artrip v. Ball Corp.,* 735 Fed. Appx. 708 (2018). The court distinguished *Artrip* from *Disc Disease* because the plaintiff, Artrip, only pleaded that his patents were infringed "by use of one or more of the machines" at the defendant's plant.[204] Although Mr. Artrip's counsel toured the defendant's factory and photographed the defendant's equipment, the complaint contained broad functional language rather than identifying any particular machine.[205]

Secondly, whether the complaint requires an explanation of how the defendant's product or activity infringes the plaintiff's patent may depend on the complexity of the technology.[206] For example, in *Disc Diseases*, although the complaint identified specific allegedly infringing products, it did not explain how these products infringed the plaintiff's patents.[207] Rather, the plaintiff asserted that these products meet "each and every element of at least one claim of" the patents-in-issue, "either literally or equivalently."[208] Despite the broad language in the complaint, the Federal Circuit held that the complaint satisfied the facial plausibility standard because the patents-in-issue are related to a spinal brace, which was deemed to be "simple" technology by the court, and the number of

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[200] Lifetime Indus., Inc. v. Trim–Lok, Inc., 869 F.3d 1372, 1379 (Fed. Cir. 2017) (quoting K-Tech Telecomms., Inc. v. Time Warner Cable, 714 F.3d 1277, 1284 (Fed. Cir. 2013)).

[201] *See* Jonathan J. Fagan & Jason E. Stach, *Life After Form 18: A One-Year Retrospective on Pleading Direct Infringement*, FINNEGAN (Jan./Feb. 2017), https://www.finnegan.com/en/insights/life-after-form-18-a-one-year-retrospective-on-pleading-direct.html.

[202] *See* Steven J. Corr & Louis L. Touton, *Pleading Patent Infringement in the United States: Evolving Standards,* JONES DAY (Nov. 2018), https://www.jonesday.com/en/insights/2018/11/pleading-patent-infringement-in-the-united-states.

[203] *See id.*; *see also* Artrip v. Ball Corp., 735 F. App'x. 708, 715 (Fed. Cir. 2018).

[204] Artrip v. Ball Corp., 735 F. App'x at 714.

[205] *Id.* at 715.

[206] *See* Corr & Touton, *supra* note [202].

[207] Disc Disease Sols. Inc. v. VGH Sols., Inc., 888 F.3d 1256, 1258 (Fed. Cir. 2018).

[208] *Id.*

independent claims involved was small.[209] However, this opinion may not apply when the technology is relatively complex or the number of independent claims is large.[210] Indeed, many district courts require details explaining how the asserted claims are infringed upon by the accused products.[211] For example, in *Atlas IP LLC v. Pacific Gas & Electric Co.*, No. 15-cv-05469-EDL, 2016 WL 1719545, at *4. (N.D. Cal. Mar. 9, 2016), the Northern District of California held that a complaint was insufficient because the asserted claims recited an apparatus' "power off" by "using cycle establishing information" and the complaint only stated that the accused product had the ability to power off, but failed to mention the limitation "by using cycle establishing information."

B. How Does the Sponsor Plead When the Applicant Refuses to Engage in the Patent Dance?

When the Applicant refuses to disclose or insufficiently discloses its manufacturing information, the Sponsor can still identify the specific infringing product, the biosimilar, which is readily ascertained from the aBLA. However, as discussed in Part I, the biosimilar could be a designed-around version of the branded biologic, thereby circumventing the patent(s) claiming the biologic product. Thus, the Sponsor may have to rely on the Applicant's infringing activities, such as certain steps in the manufacturing process, which are, however, secret from the Sponsor. Failing to pinpoint the specific infringing activity, the Sponsor would not satisfy the pleading requirement under *Artrip*.[212] Even if the Sponsor is able to identify specific infringing activities, it would still be difficult to explain why the Sponsor's patent(s) is (are) infringed without knowing the specific details of the Applicant's manufacturing process. Unfortunately, such an explanation might be necessary to pass the *Iqbal*/*Twombly* standard given the fact that the biotechnology field is relatively complex and unpredictable, and the biologic invention is usually covered by a large number of patent claims.

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[209] *Id.* at 1260.

[210] *See* Uniloc USA, Inc. v. Avaya Inc., No. 6:15-cv-1168-JRG, 2016 WL 7042236, at *3 (E.D. Tex. May 13, 2016) ("[C]ases involving more nebulous, less tangible inventions such as computer software methods may require a higher degree of specificity to provide proper notice to the defendant.").

[211] *See e.g.*, Modern Telecom Sys., LLC v. TCL Corp., No. 17-583-LPS-CJB, 2017 WL 6524526, at *3 (D. Del. Dec. 21, 2017) ("Plaintiff must have some basis to believe that compliance with certain portions of" the accused product "require the practice of each of the limitations of claim 18 of the patent-in-suit[.]").

[212] *See* Artrip v. Ball Corp., 735 Fed. Appx. at 715.

However, it seems unfair to punish the Sponsor for failing to provide sufficient factual matter to state a claim since the Sponsor was left with no alternative. Rather, it is the Applicant, who strategically chose to skip the patent dance that caused the Sponsor's insufficiency of factual content. Perhaps courts should apply a more lenient pleading standard when the plaintiff cannot access the infringing information.[213] For example, in *DermaFocus LLC v. Ulthera*, Inc., 201 F. Supp. 3d 465, 470 (D. Del. 2016), the court denied the motion to dismiss an infringement claim. Although the plaintiff identified the specific infringing product and explained how the product used the patented technology, the defendant complained that the plaintiff failed to specify which particular combinations of components of the defendant's product infringed the patent or how the claimed method steps were performed.[214] Quoting the Federal Circuit, the court emphasized that "[a] defendant cannot shield itself from a complaint . . . by operating in such secrecy that the filing of a complaint itself is impossible."[215] Because the court was unable to determine whether the factual allegations demanded by the defendant were reasonably accessible to the plaintiff, the court held "that plaintiff has given the defendant reasonable notice of a plausible claim for direct infringement."[216] However, one cannot infer from past examples of such leniency that there is no limit. In *Panduit Corp. v. Corning Inc.*, No. 5:18-CV-229-FL, 2019 WL 189817, at *5 (E.D.N.C. Jan. 14, 2019), the court dismissed a direct infringement claim because the plaintiff did not identify the specific infringing product, service, or activity, thereby failing to put the defendant on notice of what was accused.

In the context of biosimilar litigation, it is possible that the district court could lower the pleading standard even more if key information is withheld from the Sponsor. For instance, in the Federal Circuit's decision of *Amgen Inc. v. Sandoz Inc.* (*Amgen II*), 794 F.3d 1347, 1356 (2015), Judge Lourie noted that once the Sponsor sued the Applicant for infringement, the Sponsor could access the information that was foreclosed by the Applicant's failure to engage in the patent dance through discovery. Judge Lourie provided a solution to obtain information that would have otherwise been available from the patent dance without addressing the pleading standard, suggesting that specific information only available from the patent dance would not be a hurdle for the Sponsor to meet the pleading standard.

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[213] *See* Fagan & Stach, *supra* note [201].

[214] DermaFocus LLC v. Ulthera, Inc., 201 F. Supp. 3d 465, 470 (D. Del. 2016).

[215] *Id.* at 469 (quoting K-Tech Telecomms., Inc. v. Time Warner Cable, Inc., 714 F.3d at 1286).

[216] *Id.* at 470.

Two years later, the Federal Circuit clarified its position on the pleading requirement.[217] In *Amgen Inc. v. Hospira, Inc.*, 866 F.3d 1355 (Fed. Cir. 2017), Amgen was the Sponsor of a biologic product under the brand name Epogen. The Applicant, Hospira, Inc. ("Hospira"), filed a biosimilar application with the FDA seeking approval of a biosimilar product of Epogen. In an attempt to comply with the patent dance, Hospira sent a copy of its application to Amgen and asserted that the application contained all the manufacturing information.[218] Amgen contended that Hospira failed to comply with the patent dance because the composition of the cell-culture medium used in the manufacture was missing, while Hospira maintained that such composition was provided in its application.[219] Despite their disagreement, the parties proceeded to the subsequent steps of the patent dance.[220] Amgen listed three patents that it believed to be infringed by Hospira's biosimilar product.[221] None of the three patents claimed the specific cell-culture medium used in the manufacturing process, because without knowing Hospira's cell-culture medium, Amgen claimed it could not assess the reasonableness of asserting infringement claims on the cell-culture medium.[222] Ultimately, Amgen brought an infringement suit on two of the three patents and sought to obtain information on the composition of Hospira's cell-culture medium during discovery.[223] After Hospira's refusal, Amgen filed a motion to compel discovery, but the district court denied it.[224]

The Federal Circuit affirmed the district court's denial of the motion to compel discovery pursuant to Federal Rule of Civil Procedure 26(b)(1), which governs discovery, and noted that, "discoverable information must be relevant to any party's claim or defense."[225] Since Amgen didn't sue any patent related to the cell-culture medium, information of Hospira's cell-culture medium is not relevant to any infringement claim asserted by Amgen or any defense that was raised by Hospira.[226]

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[217] *See* Amgen Inc. v. Hospira, Inc., 866 F.3d 1355 (Fed. Cir. 2017).
[218] *Id.* at 1357.
[219] *Id.*
[220] *Id.* at 1358.
[221] *Id.*
[222] *Id.*
[223] *Id.*
[224] *Id.*
[225] *Id.* at 1361.
[226] *Id.*

Furthermore, the Federal Circuit offered some guidance on what Amgen or any similarly situated Sponsor should have done: Amgen should have listed all the patents it believed to be infringed in the patent dance even without any specific information, including the ones covering cell-culture medium, and then asserted these patents in the subsequent infringement action.[227] Amgen argued that blindly listing and suing the patents on cell-culture medium would make Amgen vulnerable to sanctions under Federal Rule of Civil Procedure 11 or antitrust liability for baseless claims.[228] The Federal Circuit responded that the BPCIA merely required the Sponsor to list patents that it believed could reasonably be asserted and such a reasonableness requirement did not prohibit the Sponsor from listing a patent when the Applicant failed to provide information that could be related to the patent.[229] Furthermore, the Federal Circuit held that the Rule 11 sanction would not be applicable here because the Sponsor's inquiry was limited by the Applicant's withholding of information.[230] In summary, the Sponsor should simply add all patents that could be potentially infringed in a complaint and then use discovery to amend the complaint.[231]

Although the Federal Circuit did not directly rule on the pleading standard, the court's suggestion to include a patent in a complaint even without facts to support an infringement claim implies the court's tolerance of less sufficient factual allegations. Therefore, the pleading difficulty without the patent dance might be cured by the court's adoption of a lower standard than *Iqbal*/*Twombly*. The Sponsor can carefully document its request for manufacturing information, detailing both why it is necessary and the Applicant's refusal to disclose to ward against any sufficiency attack.[232] However, the uncertainty inherent to this more lenient standard may still put the Sponsor at a disadvantage because it is hard to predict which district court may follow the more lenient standard and how lenient the standard would be.

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[227] *Id*.
[228] *Id.*
[229] *Id*. at 1362.
[230] *Id*.
[231] Ladonnikov, *supra* note [31], at 152.
[232] Linda A. Wadler & Barbara R. Rudolph, *Practical Implications of the Federal Circuit's Decision in Amgen v. Hospira on Biosimilars Patent Litigation*, 29 INTELL. PROP. & TECH. L.J. 16, 17 (2017).

C. Consequences of the Lenient Pleading Standard

Under *Hospira*, an Applicant who fails to fully abide by the patent dance is likely to be punished by allowing the Sponsor to proceed with an infringement claim under a lenient pleading standard. However, the Sponsor has to assert all patents that might be potentially infringed since there is no way to determine the ultimate scope of the Applicant's infringement without access to the Applicant's detailed manufacturing information.[233] Thus, the Sponsor is forced to litigate blindly in order to protect its rights.[234] This is certainly inconsistent with the essence of the BPCIA, which aims to expedite the resolution of patent disputes prior to the entry of the biosimilar into the market.[235] The BPCIA purposely divides litigation into two phases with the hope that parties will gain some clarity after the first phase, which would curtail seemingly endless patent infringement litigation.[236] Unfortunately, requiring the Sponsor to assert all patents would run against the BPCIA's spirit because unnecessary patents will be litigated, thereby wasting judicial resources as well as both parties' money and time.

Listing everything will not serve as a cure-all since the over-inclusion exposes a risk that at least some patents may be invalidated.[237] Without the Applicant's detailed manufacturing information, the Sponsor faces a dilemma of whether to list a patent. On one hand, if the Sponsor does not list a patent which ultimately turns out to be infringed by the Applicant's activity, the Sponsor forever loses its right to exclude the Applicant from practicing the invention covered by the patent. On the other hand, if the Sponsor does list a patent which later turns out to be irrelevant during discovery, the Sponsor will have to assume the risk of losing the battle of the subsequent invalidity attack on the patent.[238]

Furthermore, the requirement of listing everything also imposes a financial burden on the Sponsor because the information that could have otherwise been available can now only be obtained through costly discovery.[239] Although such information, or part of it, may be subject to the initial disclosure or pretrial disclosure obligations under Federal Rule of Civil Procedure 26(a), which, in

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[233] Rithika Kulathila, *BPCIA Update: Entropy Is the Price of an Ordered Framework*, 33 BERKELEY TECH. L.J. 1277, 1299 (2018).

[234] *Id.*

[235] Ladonnikov, *supra* note [31], at 153.

[236] *Id.*

[237] *See* Hirsch, *supra* note [28], at 677.

[238] *Id.*

[239] *Id.*

theory, reduces the Sponsor's cost of discovery, the Applicant can use attorney-client privilege or relevance to block discovery. Since the BPCIA does not address a scenario in which the Sponsor has to heavily rely on discovery to state a claim and the law on this topic has not been settled, it is the district courts' job to fill these gaps.[240] The district courts should not reward the Applicant's gamesmanship if it purposely stalls discovery of the information that could have otherwise been obtained from the patent dance. Rather, the courts should allow the Sponsor's motion to compel if the Sponsor can articulate what information is missing from the failure to fully comply with the patent dance and explain why the information is relevant to the infringement claim. Only this would put the parties back on track for efficiently resolving the patent disputes, which embodies the goals of the BPCIA: creating more transparency and reducing litigious gamesmanship.

CONCLUSION

The BPCIA creates a finely calibrated balance between the biologic innovators who are motivated to solve new therapeutic problems through huge investment of money and time and biosimilar manufacturers who are likely to bring more affordable therapeutics to patients by piggybacking on the innovators' data.[241] The Supreme Court's holding in *Sandoz* bestows on the Applicant the freedom to choose whether to participate in the BPCIA's patent dance.[242] On one hand, when the Sponsor holds a small patent portfolio and the FDA approval for a new biosimilar is anticipated to be quick, it is more beneficial for the Applicant to opt out of the patent dance. On the other hand, when the Sponsor holds a large number of patents, the Applicant would be wise to fully engage in the patent dance to gain some control over the litigation, reduce the risk of a preliminary injunction, reserve the right to file declaratory judgement action, and exploit the Sponsor's contentions on legal issues.

However, such freedom and strategies are luxuries solely for the Applicant. The lack of choice for the Sponsor may slightly tip the intricate balance towards the Applicant. Thus, the burden to carefully tune and restore the balance rests on the district court. To reconcile the spirit of the BPCIA and the difficulties in obtaining sufficient facts to support an infringement claim in the absence of the patent dance, the district court should apply a more lenient pleading standard to protect the Sponsor's right. Furthermore, when the Sponsor has to heavily rely on discovery to dig for information withheld by the foreclosure of the patent dance,

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[240] Kulathila, *supra* note [233], at 1305.
[241] *See* Tanaka, *supra* note [8], at 680.
[242] *See* Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664.

the district court should facilitate the discovery process to place the parties back on track for efficiently resolving disputes. Doing this would realize the BPCIA's two goals: stimulating and rewarding innovations as well as providing the public with affordable therapeutic agents.