What's Your Move? The Development of Patent Dance Jurisprudence After *Sandoz* and Its Practical Impacts

AEJIN NOH*

ABSTRACT

The new patent dispute resolution process under the Biologics Price Competition and Innovation Act (BPCIA), so-called the "patent dance," has generated extensive debates in the field of biologics since its enactment. This Article explores the development of patent dance jurisprudence, discusses the incentives and disincentives created by the law, and assesses whether the law meets the legislative intent.

I. INTRODUCTION

Since the early days of its enactment, the Biologics Price Competition and Innovation Act (BPCIA) has generated extensive debates in the field of biologics as to how its statutory language is intended to be and should normatively be interpreted.[1] One of the most frequently debated topics in relation to the BPCIA was its new patent dispute resolution process, so-called the "patent dance."[2] The manufacturers of licensed biologics and the manufacturers of biosimilars each adopted a different interpretation of the statutory language that laid out the steps and limitations of the patent dance.[3] Consequently, the new regime that sought to facilitate patent disputes between the reference product sponsors and the biosimilar manufacturers gave rise to an additional layer of dispute as to whether the parties fully complied with the statutory obligations of the patent dance or acted unlawfully.[4] Over the past decade, courts have fleshed out the meaning and delineated the boundaries of the law by analyzing the structure and context of the statute.[5] One important aspect with which the courts have grappled is how the BPCIA's patent dispute mechanism functions. However, some question whether the law that stands now effectively achieves the goal of facilitating the patent litigation process between reference product sponsors and biosimilar manufacturers.

---

* J.D. Candidate, Georgetown University Law Center; B.S., Korea Advanced Institute of Science and Technology. I am indebted to Professor Hansjorg Sauer and Professor Melissa A. Brand for their invaluable guidance and feedback.

1 Jon Takata, *"Shall" We Dance? Interpreting the BPCIA's Patent Provisions*, 31 BERKELEY TECH. L.J. 659, 686 (2016).

2 *Id.* at 659.

3 *Id.*

4 *See, e.g.*, Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664 (2017).

5 *Id.*

This Article explores the recent developments in the patent dance jurisprudence and discusses its practical impacts on both reference product sponsors and biosimilar manufacturers. Part II provides a background of the BPCIA and its patent dance provision. Part III summarizes the key cases that shaped the current law of the patent dance. Part IV discusses the incentives and disincentives created by the law, observes how companies have responded to the law in practice, and assesses whether the law meets the goal that Congress originally intended.

II. BACKGROUND OF THE PATENT DANCE

A. Biologics, Biosimilars, and the BPCIA

A biological medicinal product—often referred to as a "biologic"—is defined as

> a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.[6]

Biologics differ from traditional, chemically derived drugs in many ways, including their size, complexity of manufacture, and cost.[7] Most biologics are protein-based macromolecules produced in living cells.[8] They are structurally complex and often require stringent quality control measures because the living cells that produce the protein molecules are highly susceptible to microbiological contaminations, and the protein molecules are extremely sensitive to changes in physical conditions such as temperature and lighting.[9] The inherent complexities involved in the development and manufacture of biologics contribute to high costs, which leads to high prices for consumers.[10] The average cost for patients using biologics is estimated to be $45 per day, whereas the average daily cost for patients using small-molecule drugs is estimated to be $2.[11] Soliris, a biologics medicine indicated for treatment of a rare disease called paroxysmal nocturnal hemoglobinuria, is currently the most expensive existing biologic medication and costs upwards of $250,000 annually.[12] Despite the high prices, however, biologics have been the fastest growing segment of the pharmaceutical market, accounting for an increasingly significant portion of it over the last decades.[13] For instance, Humira, a biologic medication used to treat

---

6 42 U.S.C. § 262(i)(1) (2017).

7 Thomas Morrow & Linda Hull Felcone, *Defining the Difference: What Makes Biologics Unique*, 1 BIOTECHNOLOGY HEALTHCARE 24, 24 (2004).

8 *Id.* at 26.

9 JUDITH A. JOHNSON, CONG. RSCH. SERV., R4462, BIOLOGICS AND BIOSIMILARS: BACKGROUND AND KEY ISSUES 11 (2017) (noting that filgrastim, a relatively small biologic, has 2,569 atoms in its structure, whereas aspirin, a small molecule product, has only twenty-one atoms).

10 *Id.*

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

12 JOHNSON, *supra* note 9, at 2.

13 Avik Roy, *Biologic Medicines: The Biggest Driver of Rising Dug Prices*, FORBES (Mar. 8, 2019), https://www.forbes.com/sites/theapothecary/2019/03/08/biologic-medicines-the-biggest-driver-of-rising-drug-prices/?sh=296dbdb018b0 [https://perma.cc/4727-RN83].

rheumatoid arthritis, has successfully defended its position as the top selling drug for several years with its full-year revenues surpassing $20 billion in 2020.[14]

In an effort to control the high prices of biologics, Congress enacted the Biologics Price Competition and Innovation Act (BPCIA) in 2010, modelling the success of the Hatch–Waxman Act.[15] The BPCIA is designed to achieve a balance between price competition and innovation in the biologics market.[16] To meet this goal, the BPCIA does two things.

First, the BPCIA provides an abbreviated regulatory pathway for biosimilars.[17] Biosimilars are biological products that are "highly similar to and [have] no clinically meaningful differences" from existing U.S. Food and Drug Administration (FDA)-approved biologics, called the reference products.[18] Under the abbreviated pathway, a biosimilar manufacturer ("applicant") may submit its application to FDA in reliance of the showing previously made by the sponsor of a reference biological product ("sponsor").[19] Instead of showing that the product is "safe, pure, and potent" as ordinarily required for a new biological product to obtain FDA approval, a biosimilar applicant has to only show that the product is "highly similar to the reference notwithstanding minor differences in clinically inactive components" and has "no clinically meaningful differences" from the reference product in terms of safety, purity, and potency.[20] Thus, the abbreviated regulatory pathway created under the BPCIA expedites the market entry of the biosimilars, which in turn accelerates price competition in the biologics market.

Next, the BPCIA establishes a process for resolving patent disputes between sponsors and applicants prior to the launch of biosimilar products.[21] The process for resolving patent disputes—often referred to as "the patent dance" by practitioners—is "a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement."[22] When the applicant submits its application under the abbreviated pathway, the statute requires both the applicant and the sponsor to exchange information and negotiate the number and scope of any potential patent infringement claims while the biosimilar application is under review.[23] By allowing the parties to access information necessary to determine whether there would be valid claims for patent infringement, the patent dance seeks to clear the roadblocks to patent litigation before the biosimilar product enters the market, ensuring that the sponsor's

---

14 Lisa Urquhart, *Top Companies and Drugs by Sales in 2020*, 20 NATURE REVS. DRUG DISCOVERY 253, 253 (2021).

15 Krista Hessler Carver, Jeffrey Elikan & Erika Lietzan, *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 FOOD & DRUG L.J. 671, 671 (2010).

16 Tanaka, *supra* note 1, at 680.

17 42 U.S.C. § 262(k).

18 *Biosimilars and Interchangeable Products*, U.S. FOOD & DRUG ADMIN. (2017), https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products#biosimilar [https://perma.cc/ATB4-GRNK].

19 42 U.S.C. § 262(k).

20 *Id.* §§ 262(i)(2)(A), (B); *see also* U.S. FOOD & DRUG ADMIN., SCIENTIFIC CONSIDERATIONS IN DEMONSTRATING BIOSIMILARITY TO A REFERENCE PRODUCT: GUIDANCE FOR INDUSTRY 8 (2015).

21 42 U.S.C. § 262(l).

22 Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664, 1670 (2017).

23 42 U.S.C. § 262(l).

patent rights can be protected before actual damages occur.[24] Thus, the patent dance complements the abbreviated regulatory pathway by helping to protect the sponsors' patent rights.

Ultimately, Congress sought to foster both price competition and innovation in the biologics market by adopting the abbreviated regulatory pathway for biosimilars on the one hand and the patent dance on the other, thereby providing more affordable and innovative biological medicinal products to the consumers.[25]

B. Patent Dance—Statutory Obligations and Limitations

The patent dance is triggered when the applicant's biosimilar application is accepted by FDA for regulatory review.[26] When FDA accepts a biosimilar application for review, the applicant should provide the sponsor a copy of its abbreviated biologics license application (aBLA) and manufacturing information within twenty days after FDA accepts the application.[27] The applicant also may provide additional information requested by the sponsor.[28]

The sponsor's ability to identify a relevant patent may depend largely on the scope of information provided by the applicant to the sponsor at this initial stage.[29] Many infringement claims in BPCIA litigation are related to manufacturing patents, and because the manufacturing process of a drug is usually protected as trade secrets, the sponsor cannot ascertain whether there is a valid claim of patent infringement unless the manufacturing information is disclosed by the applicant.[30] However, providing the manufacturing information is almost always resisted by the applicant because it may share important trade secrets with its potential competitors. Accordingly, there is an unavoidable tension created between the sponsor and the applicant regarding the scope of information that the applicant is obligated to disclose under the statute.

Within sixty days after receiving the application information, the sponsor should provide the applicant a list of patents that it believes to be infringed and any patent that it is willing to license to the applicant.[31] This list determines the scope of claims in litigation. Any patent not identified in this list cannot be claimed later in suit.[32] Therefore, to avoid any unintended forfeiture of important patent rights, the sponsor must include all relevant patents in its list.

Within sixty days of receiving the sponsor's list, the applicant should provide to the sponsor a detailed statement describing why each of the listed patents is invalid, unenforceable, or will not be infringed by the commercial marketing of its biosimilar

---

[24] Yang Li, *Does It Still Take Two to Tango? A Modern Interpretation of the BPCIA's Patent Dance*, 9 NYU J. INTELL. PROP. & ENT. L. 107, 115 (2019).

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

[26] 42 U.S.C. § 262(l)(2).

[27] *Id.* § 262(l)(2)(A).

[28] *Id.* § 262(l)(2)(B).

[29] *See* Arti K. Rai & W. Nicholson Price, *An Administrative Fix for Manufacturing Process Patent Thickets*, 39 NATURE BIOTECHNOLOGY 20, 21 (2021).

[30] *Id.* at 20.

[31] 42 U.S.C. § 262(l)(3)(A).

[32] 35 U.S.C. § 271(e)(6)(C).

product.[33] The applicant may also include a statement that it does not intend to begin commercial marketing of its product until such patents expire.[34] Then, within sixty days after receiving the applicant's statement, the sponsor should provide to the applicant a response and a detailed statement describing the factual and legal basis of why the sponsor believes the listed patents will be infringed by the commercial marketing of the applicant's product.[35]

After the applicant receives the sponsor's statement, the applicant and the sponsor should engage in a good faith negotiation to agree on which of the listed patents should be subject to an immediate patent infringement action.[36] If they agree on the final list of patents that should be immediately litigated, the sponsor should bring an infringement action with respect to each patent included in the final list within thirty days.[37] If the parties fail to reach an agreement within fifteen days after starting the negotiation, the applicant should notify the sponsor the number of patents that it believes should be subject to litigation.[38] Within five days after receiving the applicant's notification, the parties should simultaneously exchange the list of patents that each believes should be litigated, in which case the number of patents listed by the sponsor may not exceed the number of patents listed by the applicant.[39] If the applicant does not list any patent, the sponsor may list only one patent.[40] In other words, the statute allows the applicant to decide the number of patents that will be litigated subsequent to the patent dance. The applicant may strategically use such control to delay litigating certain claims while resolving other claims upfront to clear the roadblocks to expedite the launch of the biosimilar. The sponsor, on the other hand, has little or no control over what claims to bring and when to litigate them. After the exchange of the lists, the sponsor should bring an action for patent infringement within thirty days with respect to each patent included in the list.[41]

No later than 180 days prior to the launch of the biosimilar, the applicant should provide a notice of commercial marketing to the sponsor.[42] After receiving the notice and before commercially marketing the biosimilar for the first time, the sponsor may seek a preliminary injunction prohibiting the applicant from manufacturing or selling the biosimilar until any remaining issues in relation to the listed patents are resolved.[43] This second round of litigation, triggered by the applicant's notice of commercial marketing, is essentially the last opportunity where the sponsor can enjoin the applicant before actual damages can occur following the commercial marketing of the biosimilar.

---

[33] 42 U.S.C. § 262(l)(3)(B).

[34] *Id.*

[35] *Id.* § 262(l)(3)(C).

[36] *Id.* § 262(l)(4)(A).

[37] *Id.* § 262(l)(6)(A).

[38] *Id.* §§ 262(l)(4)(B), 262(l)(5)(A).

[39] *Id.* § 262(l)(5)(B)(ii)(I).

[40] *Id.* § 262(l)(5)(B)(ii)(II).

[41] *Id.* § 262(l)(6)(B).

[42] *Id.* § 262(l)(8)(A).

[43] *Id.* § 262(l)(8)(B).

If the applicant provides its aBLA and manufacturing information to the sponsor within twenty days after FDA accepts the aBLA, neither the sponsor nor the applicant can bring a declaratory judgment action for infringement until the applicant serves a notice of commercial marketing.[44] If, however, the applicant fails to provide its aBLA and manufacturing information within twenty days after FDA accepts the aBLA, the sponsor, not the applicant, may bring a declaratory judgment action for infringement of any patent that claims the biological product or the use of the biological product.[45] If the applicant provides its aBLA and manufacturing information to the sponsor within twenty days after FDA accepts the aBLA but fails to comply with the subsequent steps of the patent dance, the sponsor—not the applicant—may bring a declaratory judgment action for infringement of any patent included in the sponsor's list.[46]

C. Legislative Debates and Legal Questions

The patent dance provision in the BPCIA spurred extensive debates among various stakeholders in the field of biologics during the legislative period and through the early days of its enactment.[47] The records of legislative debates show concerns as to whether the statutory scheme achieves a proper balance between the interests of the applicants and those of the sponsors.

First, there was a concern that the patent dance would arbitrarily limit the number of patents that could be litigated before launching the biosimilar products.[48] Although the sponsor could still bring patent infringement actions after the applicant's product has been placed on the market, there existed a concern that "a court will not . . . issue an injunction preventing the continued marketing of the biosimilar" even if the patent is found valid and infringed.[49] Once the biosimilar is in the market, it would be impractical to recall all the products already being used by the patients, as well as inequitable to suddenly deprive them of an affordable treatment option. Thus, an award of monetary damages would be favored after biosimilar products have been launched. Because an injunctive relief will not likely be granted once the biosimilar is in the market, arbitrarily limiting the number of patents that could be litigated during the pre-launch period could essentially undermine the value of the patent rights that patentholders should rightfully enjoy.[50]

Moreover, some viewed the so-called "list it or lose it" provision problematic.[51] The provision seemed to "put an onerous burden" on the sponsor because it required the sponsor to list all patents that it believes would have valid claims of infringement against the applicant or otherwise would forfeit the right to bring an infringement action for any patent not included in the list.[52] It meant that the sponsor would have to

---

[44] *Id.* § 262(l)(9)(A).

[45] *Id.* § 262(l)(9)(C).

[46] *Id.* § 262(l)(9)(B).

[47] Carver et al., *supra* note 15, at 671.

[48] *Id.* at 800.

[49] *Id.*

[50] *Id.*

[51] *Id.* at 801.

[52] *Id.* at 800.

"review its entire patent portfolio, as well as patents it has in-licensed for any purpose" within the statutorily defined timeline.[53] Therefore, the "list it or lose it" provision seemed to incentivize the sponsors to list as many patents as they find reasonable at the outset to avoid any unintended forfeiture of its patent right. In such a case, the sponsor is likely to assert baseless claims, and determining whether the sponsor made valid assertions or baseless claims in bad faith requires looking at the subjective intent of the sponsor, which is often difficult to discern.[54]

Furthermore, some were concerned that the sponsor lacked an effective enforcement mechanism through which it could access the information necessary to determine whether there would be valid claims of patent infringement.[55] If the applicant refuses to provide the information, the sponsor's claims could lack sufficient factual basis and could easily be dismissed for failing to meet the pleading standard under the Federal Rules of Civil Procedure (FRCP) or sanctioned for being frivolous.[56] On the other hand, others expressed concerns that the sponsor could abuse the patent dance scheme to compel disclosure of information that may not be relevant to demonstrating infringement.[57] The lack of effective protective mechanisms against the sponsor's abuse could make the applicant even more reluctant to provide necessary information, heightening the tension between the applicant and the sponsor.

The patent dance provision opened the door to new legal questions as well. The sponsor and the applicant often interpreted the patent dance provision differently, raising a question as to how its statutory language ought to be interpreted.[58] The parties also adopted different positions on whether the BPCIA preempts the state law.[59] The various conflicts arising between the applicant and the sponsor ultimately shaped the jurisprudence concerning whether certain steps of the patent dance are mandatory and what recourse, if any, the sponsor or applicant may have if certain steps are not followed.

III. THE CURRENT LAW: *SANDOZ* AND ITS PROGENY

In 2017, the Supreme Court decided a landmark case in the patent dance jurisprudence, which interprets the statutory language regarding the applicant's obligation to provide its application materials and manufacturing information to the sponsor upon filing the aBLA.[60] *Sandoz v. Amgen* has significantly influenced the biologics industry ever since, and it has given rise to many progeny cases that have shaped the patent dance jurisprudence.[61] On the one hand, these cases provided a predictable guide for the companies as to what legal consequences they may face when they fail to comply with the statutory obligations of the patent dance. On the other

---

[53] *Id.*

[54] *Id.* at 801.

[55] *Id.*

[56] *Id.*

[57] *Id.* at 799.

[58] *See, e.g.*, Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664, 1674 (2017).

[59] *See* Amgen Inc. v. Sandoz Inc., 877 F.3d. 1315, 1330 (2017).

[60] *Sandoz Inc.*, 137 S.Ct. at 1675.

[61] Li, *supra* note 24, at 124.

hand, the case law has also created undesired incentive structure and generated unintended distortions in the companies' behaviors, giving rise to new complications.

A. Sandoz v. Amgen: The Landmark Case

The legal question presented by *Sandoz v. Amgen* was whether the requirement that the applicant should provide to the sponsor its aBLA and manufacturing information under § 262(l)(2)(A) is enforceable by an injunction.[62]

The case concerns a filgrastim product which had been marketed by Amgen under the brand name Neupogen since 1991.[63] In May 2014, Sandoz filed its aBLA with FDA, seeking approval to market a biosimilar of Neupogen.[64] On July 7, 2014, FDA accepted Sandoz's application for review.[65] On July 8, 2014, Sandoz informed Amgen that FDA accepted its application and that it intended to begin marketing its product immediately upon receiving FDA approval.[66] Sandoz did not provide Amgen a copy of its aBLA or any other information related to its manufacturing process.[67]

In October 2014, Amgen sued Sandoz for patent infringement and unlawful business practice, namely a failure to provide its application and manufacturing information under § 262(l)(2)(A) of the BPCIA.[68] Amgen sought injunctive relief, claiming that Sandoz's failure to provide a copy of its aBLA and manufacturing information violated the provision in § 262(l)(2)(A) that the applicant "shall provide" its aBLA and other manufacturing information to the sponsor within twenty days after FDA accepts the application.[69] The district court dismissed Amgen's claim with prejudice, reasoning that Sandoz's decision to not provide the application and manufacturing information was within its rights.[70] On appeal, the federal circuit affirmed the dismissal.[71]

The Supreme Court held that an injunction is not available under federal law to force the applicant to provide its application and manufacturing information to the sponsor as required under § 262(l)(2)(A) of the BPCIA.[72] In reaching this conclusion, the Court considered the structure and context of the statute.[73] It first noted that "when an applicant fails to comply with § 262(l)(2)(A), § 262(l)(9)(C) authorizes the sponsor, not the applicant, to bring an immediate declaratory judgment action for artificial infringement" with respect to any patent that could have been included in the list had the parties participated in the dance.[74] The Court also found that "[t]he presence of § 262(l)(9)(C), coupled with the absence of any other textually specified remedies,

---

62 *Sandoz Inc.*, 137 S.Ct. at 1669.

63 *Id.* at 1673.

64 *Id.*

65 *Id.*

66 *Id.*

67 *Id.*

68 *Id.*

69 *Id.*

70 *Id.*

71 *Id.*

72 *Id.* at 1674.

73 *Id.* at 1674–75.

74 *Id.* at 1675.

indicates that Congress did not intend sponsors to have access to injunctive relief, at least as a matter of federal law, to enforce the disclosure requirement."[75] Also, in light of the statutory context, the Court assumed that "Congress acted intentionally when it provided an injunctive remedy for breach of the confidentiality requirements [under § 262(l)(1)(H)] but not for breach of § 262(l)(2)(A)'s disclosure requirement."[76] Therefore, the sole remedy available to the sponsor when the applicant fails to turn over its application and manufacturing information as required under § 262(l)(2)(A) is "the control that the applicant would otherwise have exercised over the scope and timing of the patent litigation."[77] While many had thought that the applicant's information disclosure requirement under § 262(l)(2)(A) was mandatory, the Court's holding left that choice in the applicant's hand. After *Sandoz*, the applicant could lawfully choose to not provide its aBLA and manufacturing information to the sponsor based on various business considerations and litigation strategies.

The Court ordered remand for further proceedings to determine whether any additional remedy existed under the state law.[78] On remand, the federal circuit held that the BPCIA preempts any state law remedies on both field and conflict preemption grounds, leaving no other remedy available other than "the control that the applicant would otherwise have exercised over the scope and timing of the patent litigation" under the BPCIA; in other words, the sole remedy available to the sponsor when the applicant fails to comply with the patent dance obligations is the right to bring a declaratory judgment action against the applicant.[79]

B. Genentech v. Amgen: Further Elaboration on the Boundaries of Remedy

In *Genentech v. Amgen*, the District Court of Delaware construed the Supreme Court's holding in *Sandoz*.[80] The legal question presented by the case was whether the applicant is barred from making counterclaims in a patent infringement suit if it had failed to provide its aBLA and manufacturing information to the sponsor or otherwise precluded from making contentions beyond the scope of disclosures made during the patent dance.[81]

The case concerns a bevacizumab product which has been marketed by Genentech under the brand name Avastin.[82] On January 4, 2017, Amgen notified Genentech that its aBLA for a biosimilar of Avastin had been accepted by FDA.[83] Amgen refused to provide Genentech with anything other than its aBLA and ignored Genentech's request for Amgen to provide a list of other information.[84] On February 15, 2017,

---

[75] *Id.*

[76] *Id.*

[77] *Id.*

[78] *Id.* at 1676–77.

[79] Amgen Inc. v. Sandoz Inc., 877 F.3d. 1315, 1330 (2017).

[80] Genentech, Inc. v. Amgen Inc., No. 17-1407-CFC, 2020 WL 636439, at *2 (D. Del. Feb. 11, 2020).

[81] *Id.* at *3.

[82] First Amended and Supplemental Complaint at 1, Genentech, Inc. v. Amgen Inc., No. 17-1407-CFC, 2020 WL 636439 (D. Del. Feb. 11, 2020).

[83] *Id.* at 2.

[84] *Id.* at 3.

Genentech sued Amgen for infringing its patents and failing to comply with its statutory obligations under the BPCIA.[85] Amgen alleged in its counterclaims and affirmative defenses that the asserted patents were invalid or unenforceable.[86] Genentech filed a motion to dismiss Amgen's counterclaims and affirmative defenses for failing to comply with its disclosure obligations under the BPCIA or otherwise failing to disclose the contentions during the patent dance.[87]

The court held that the applicant is not barred from filing its counterclaims and affirmative defenses in a declaratory judgment action brought by the sponsor even when it had failed to provide its application and manufacturing information to the sponsor as required under § 262(l)(2)(A) of the BPCIA.[88] Following *Sandoz*, the court found that the exclusive remedy available to the sponsor when the applicant fails to comply with its obligations under § 262(l)(2)(A) is provided in § 262(l)(9)(C), which authorizes the sponsor, not the applicant, to "bring an action . . . for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product."[89] Reasoning that the filing of counterclaims or affirmative defenses does not constitute "bringing an action" under the phrase's plain meaning, the court held that the applicant's counterclaims and affirmative defenses are not barred by § 262(l)(9)(C) even when the applicant fails to comply with § 262(l)(2)(A).[90]

Moreover, the court held that the applicant is not limited in making its counterclaims and affirmative defenses only to the extent of what had been disclosed during the patent dance.[91] Again, the court noted that the sole remedy available to the sponsor when the applicant fails to comply with its obligation to provide the sponsor a detailed statement responding to each patent included in the sponsor's list under § 262(l)(3)(B) is provided in § 262(l)(9)(B). Section 262(l)(9)(B) uses identical language as § 262(l)(9)(C), authorizing the sponsor, not the applicant, to "bring an action . . . for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product."[92] The use of the identical language, the court noted, is "to establish the same consequence of non-compliance—i.e., the loss of control over the scope and timing of the patent litigation."[93] In light of the BPCIA's "carefully crafted and detailed enforcement scheme," the court found that "the fact that Congress did not expressly limit an applicant's defenses in a declaratory judgment action brought pursuant to § 262(l)(9)(B) provides strong evidence that Congress did not intend to limit those defenses."[94] Therefore, the court concluded that the applicant is not limited in making

---

85 *Id.*

86 *Genentech, Inc.*, 2020 WL 636439, at *4.

87 *Id.* at *1.

88 *Id.* at *4.

89 *Id.*

90 *Id.*

91 *Id.* at *4–*5.

92 *Id.*

93 *Id.* at *4.

94 *Id.* at *5.

its counterclaims and affirmative defenses to the extent those defenses and counterclaims are based on the contentions disclosed during the patent dance.[95]

The court's holding implied that the applicant could strategically choose not to disclose certain information to the sponsor during the pre-litigation exchange and save it for the actual litigation. Like *Sandoz*, it again left the choice in the applicant's hand.

C. Amgen v. Hospira: Court's Baseless Claims and Rule 11 Sanction

Amgen v. Hospira discussed whether the sponsor may compel discovery of the information that had been withheld by the applicant during the patent dance and may not be relevant to the patents litigated in suit.[96]

The case concerns an epoetin alfa product that has been marketed by Amgen under the brand-name Epogen.[97] In December 2014, Hospira filed its aBLA to FDA seeking approval of the Epogen biosimilar.[98] After FDA accepted its application, Hospira provided Amgen a copy of its application but refused to provide information regarding the specific composition of the cell-culture medium used in the manufacture.[99] Although Amgen asserted that Hospira had failed to comply with the disclosure requirement under § 262(l)(2)(A) that the applicant provide its aBLA and manufacturing information, the parties continued to proceed with the subsequent steps in the patent dance.[100] Due to the lack of information regarding Hospira's cell culture medium, Amgen never identified its cell culture patent in the list of patents or the detailed statement provided to Hospira during the patent dance.[101] Moreover, Amgen did not assert a claim for infringement of its cell-culture patent in litigation.[102] Amgen then sought discovery on the composition of the cell-culture medium used by Hospira, but Hospira refused to produce the requested information.[103]

The federal circuit held that the district court correctly denied Amgen's motion to compel.[104] Reasoning that discoverable information must be "relevant to any party's claim or defense" under the FRCP, the court found "the denial of discovery in this case does not undermine the purpose of the BPCIA" as "nothing in *Sandoz* suggests that the BPCIA somehow supplants the preexisting rules of civil procedure."[105] The court also noted the information regarding Hospira's cell culture medium would have been discoverable if Amgen had listed its cell-culture patent during the patent dance in a belief that there would be a valid claim for infringement of the cell-culture patent.[106] Amgen argued that blindly listing a patent without the benefit of the applicant's

---

95 *Id.*

96 Amgen Inc. v. Hospira, Inc., 866 F.3d. 1355, 1356 (2017).

97 *Id.* at 1357.

98 *Id.*

99 *Id.*

100 *Id.* at 1358.

101 *Id.*

102 *Id.*

103 *Id.*

104 *Id.* at 1363.

105 *Id.* at 1361, 1363.

106 *Id.*

disclosures would be sanctioned under Rule 11 of the FRCP for baseless claims. The court rejected Amgen's argument.[107] It found that "the statute provides no sanction for holding or asserting a mistaken belief in good faith," and "if a sponsor forms a belief based on an inquiry limited by an applicant's withholding of information, the sponsor has still satisfied Rule 11."[108]

Amgen v. Hospira suggests that some courts will adopt a lower pleading standard in BPCIA litigation. However, whether a lenient pleading standard will be accepted by other courts and how lenient the standard should be remains uncertain.

D. Celltrion v. Genentech: Rejection of Short-Circuiting

The issue addressed by *Celltrion v. Genentech* was whether the applicant may bring a declaratory judgment action after serving a notice of commercial marketing to the sponsor but before completing all the steps in the patent dance.[109]

Here, Celltrion engaged in patent dances with Genentech regarding the two reference products developed by Genentech: Herceptin and Rituxan.[110] After Genentech provided Celltrion its detailed statement describing the factual and legal basis of why it believes the listed patents will be infringed by the commercial marketing of Celltrion's products in both dances as required under § 262(l)(3)(C), Celltrion indicated that it wished to litigate all patents listed by Genentech and served a notice of commercial marketing to Genentech without reaching an agreement through a good-faith negotiation or engaging in simultaneous exchange of lists as required under § 262(l)(5).[111] Celltrion then immediately filed declaratory judgment actions regarding those patents.[112] In its motion to dismiss, Genentech argued that Celltrion failed to state a claim for relief because it did not complete its obligation under § 262(l)(5).[113]

The court agreed with Genentech and held that the applicant may not bring a declaratory judgment action when it failed to complete all steps of the patent dance once the dance had been initiated.[114] The court rejected Celltrion's argument that it can "streamline its obligations under the statute and satisfy several steps at once" if one party believes the subsequent steps are "redundant" or "futile."[115] The court instead stated that "the statutory procedures do not allow an applicant to collapse its multiple distinct obligations into one or two perfunctory actions."[116] According to the holding, the applicant is barred from bringing an action under § 262(l)(9)(B) if it fails to complete any one of the statutory steps in the patent dance.[117] Furthermore, the court

---

[107] *Id.* at 1362.

[108] *Id.*

[109] Celltrion, Inc. v. Genentech, Inc., No. 18-cv-00274-JSW, 2018 WL 2448254, at *2 (N.D. Cal. May 9, 2018).

[110] *Id.* at *3.

[111] *Id.*

[112] *Id.*

[113] *Id.* at *4.

[114] *Id.* at *5.

[115] *Id.* at *6.

[116] *Id.*

[117] *Id.* at *5.

noted that serving a notice of commercial marketing does not allow the applicant to short-circuit the steps in the patent dance.[118] Even when the applicant complies with its obligation to provide a notice of commercial marketing to the sponsor, the applicant is obligated to complete all required procedures in the patent dance before it may file a declaratory judgment action.[119]

In a similar case involving a patent dispute between Amgen and Genentech, Amgen served a notice of commercial marketing and filed a declaratory judgment action before the parties had completed their obligations to engage in a good-faith negotiation under § 262(l)(5). The Central District of California held that the applicant is not entitled to bring suit after providing the sponsor a notice of commercial marketing but before completing the rest of the exchange steps.[120] The court stated that "allowing an applicant to side-step the BPCIA's exchange and negotiation requirements and bring suit on any patent simply by filing its notice of commercial marketing would effectively vitiate the BPCIA's provisions."[121] This meant that once the applicant and the sponsor began engaging in a dance, all subsequent steps had to be followed before the parties could initiate a second round of litigation. The right to bring a declaratory judgment action upon serving a notice of commercial marketing could be exercised only when all steps in the patent dance had been completed.

E. The Current Law

While each of the cases presented above adds value to the patent dance jurisprudence, together they provide several important insights. First, the sole remedy available to the sponsor when the applicant fails to provide its application and manufacturing information to the sponsor within twenty days after FDA accepts its application is the control over the timing and scope of a patent infringement action.[122] Section 262(l)(9)(C) provides that under such circumstances, the sponsor, not the applicant, bring an immediate declaratory judgment action for artificial infringement with respect to any patent that could have been included in the list had the parties participated in the dance.[123] No other remedy is available under federal law, which means that the applicant cannot be enjoined to provide its application and manufacturing information to the sponsor when it chooses not to do so. This makes the entire patent dance scheme optional on the applicant's end and permits the applicant to make strategic choices. As a result, the applicant is placed in the same position as any other defendant sued in a patent infringement suit outside the scope of the BPCIA.

Moreover, when the applicant chooses not to disclose all or some of its information, the applicant is not barred from filing counterclaims and affirmative defenses even if those contentions were not previously disclosed during the patent dance.[124] This

---

[118] *Id.* at *7–8.

[119] *Id.* at *8.

[120] Amgen Inc. v. Genentech, Inc., No. 17-cv-7349-GHW, 2018 WL 910198, at *12 (C.D. Cal. Jan. 11, 2018).

[121] *Id.* at *4.

[122] Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664, 1675 (2017).

[123] 42 U.S.C. § 262(l)(9)(C).

[124] Genentech, Inc. v. Amgen Inc., No. 17-1407-CFC, 2020 WL 636439, at *4–5 (D. Del. Feb. 11, 2020).

creates an imbalance of power between the applicant and the sponsor. The applicant can control the scope of information disclosed during the patent dance without forfeiting the right to make contentions outside that scope in subsequent litigation. In contrast, the sponsor has no choice but to disclose all relevant patents during the patent dance or otherwise forfeit the right to assert any patent not identified during the dance. This places the applicant in a more advantageous position than the sponsor in terms of litigation strategy.

If the applicant fails to provide information necessary for the sponsor to determine whether there is a reasonable claim for patent infringement, the sponsor can list the relevant patent without the support of such information.[125] If the applicant fails to respond to the listed patent, the sponsor then has a reasonable basis to believe that a claim for infringement could be asserted.[126] Asserting a claim for infringement in such a case would not be considered baseless or create the risk of Rule 11 sanction for the sponsor, which means that the pleading standard for the sponsor is effectively lowered in BPCIA litigation.[127] However, the lower pleading standard gives little to no benefit to the sponsor because listing as many patents as possible is not necessarily a winning strategy. For instance, over-inclusion increases the probability that at least some patents may become invalidated.[128] Moreover, the lenient pleading standard is not universally adopted by all courts, so the sponsor has to face the uncertainty as to which court may follow the more lenient standard and how lenient that standard would be.[129]

Finally, once the applicant initiates the patent dance by providing its application and manufacturing information to the sponsor, it must complete all subsequent steps in the patent dance in order to exercise its right to bring a declaratory judgment action upon serving a notice of commercial marketing on the sponsor.[130] If it fails to comply with all subsequent steps in the dance, § 262(l)(9)(B) authorizes the sponsor, not the applicant, to bring a declaratory judgment action.[131] The applicant cannot short-circuit the steps simply by serving a notice of commercial marketing and immediately filing a declaratory judgment action.[132] Further, no party is allowed to streamline its statutory obligations because it believes the subsequent steps are redundant or futile.[133] This effectively locks the applicant in the statutorily defined timeframe of the patent dance when the applicant chooses to engage in the dance. Accordingly, the applicant should wait for 230 days to finish all the steps required by the patent dance once it has been initiated.

---

[125] Amgen Inc. v. Hospira, Inc., 866 F.3d. 1355, 1362 (Fed. Cir. 2017).

[126] *Id.*

[127] *Id.*

[128] Hirsch, *supra* note 25, at 677.

[129] Li, *supra* note 24, at 135.

[130] Celltrion, Inc. v. Genentech, Inc., No. 18-cv-00274-JSW, 2018 WL 2448254, at *7–8 (N.D. Cal. May 9, 2018).

[131] *Id.*

[132] *Id.*

[133] *Id.*

IV. PRACTICAL CONSIDERATIONS

A. Incentives and Disincentives Created by the Law

Sandoz and its progeny cases have left choices in both the applicant's and the sponsor's hands. First, the applicant has the choice to opt out of the patent dance entirely. The obvious incentive for the applicant to opt out of the patent dance is that it can expedite the market entry.[134] If the applicant chooses not to engage in the patent dance, it can save the 230 days it otherwise would have had to wait to complete all the required steps.[135] For instance, if the applicant expects to obtain FDA approval within a short period of time, it may be in the applicant's best interest to skip the patent dance to accelerate the litigation and expedite market entry. Moreover, opting out of the patent dance can help the applicant protect proprietary and confidential information. Although the information may later be sought through discovery, deferring the production may be advantageous to the applicant, especially when it involves trade secrets.[136] Moreover, if the applicant chooses not to disclose the information at the outset, the sponsor may forego some of the claims it could have asserted had the information been available.[137]

The biggest disadvantage for the applicant if it opts out of the patent dance is that it would lose control over the timing and scope of the litigation. If the applicant complies with the steps required by the patent dance, it can limit the number of patents that will be litigated immediately and may push off certain claims to the next round of litigation. Alternatively, the applicant may strategize to frontload as many claims as possible in the first round of litigation and leave only few or none for the second round. In any case, the applicant will lose the advantage of gaining control over the litigation strategy if it opts out of the patent dance. The applicant will also forego the opportunity to gain early access to the sponsor's claims, which may help the applicant to prepare for its defenses and counterarguments as well as make appropriate business judgments.[138]

Even when the applicant decides to participate in the patent dance, it may choose to not disclose certain contentions during the dance and raise them only in litigation. Withholding certain claims of non-infringement or invalidity during the patent dance may be beneficial to the applicant because it could save the applicant from the sponsor's exploitation of the disclosure as an admission.[139]

On the other hand, the sponsor may strategize to over-include patents in the list under a lenient pleading standard. Over-inclusion can be advantageous to the sponsor because the sponsor may reduce the possibility of forfeiting its patent rights by failing to include relevant patents in the list. Moreover, over-inclusion can serve as a signal to the applicant when the sponsor has a large patent portfolio. A long list of patents may hint at the sponsor's aggressiveness and be used to intimidate the applicant.

---

[134] Li, *supra* note 24, at 125.

[135] *Id.*

[136] *Id.* at 126.

[137] *Id.* at 125.

[138] *Id.* at 129.

[139] *Id.*

The obvious disadvantage of over-inclusion is that the sponsor will have to face the risk of Rule 11 sanctions.[140] Although some courts may adopt a lenient pleading standard in BPCIA litigation, the sponsor is faced with uncertainties because not all courts have adopted a lenient pleading standard. Even in the courts that follow a lenient pleading standard, there is no clear guide as to how lenient the standard would be or how far the court is willing to tolerate claims that lack sufficient basis.[141] Moreover, when the sponsor includes too many patents in the list, there is a higher chance that at least some of the patents may be invalidated.[142]

B. Observations from the BPCIA Litigation

The choices made available to the applicant and the sponsor throughout the development of patent dance jurisprudence created a variety of strategic behaviors in practice, which also created new complications in the litigation process. As of May 2021, thirty-one complaints have been filed under the BPCIA.[143] The various strategic choices made by the applicant and the sponsor can be gleaned from these complaints.

Among the thirty-one complaints, only a few indicate that the applicant completely opted out of the patent dance. For instance, Amgen's compliant filed against Adello Biologics in March 2018 notes that Adello refused to provide its aBLA and manufacturing information to Amgen and purported to provide notice of its intent to commercially market its Neupogen biosimilar upon receiving FDA approval.[144] Additionally, in Immunex's complaint against Bioepis regarding the Enbrel biosimilar, Immunex alleges that Bioepis did not provide a copy of its aBLA and also has not provided a notice of commercial marketing.[145] Immunex also seeks an injunction preventing Bioepis from commercially marketing its product for at least 180 days from the date Bioepis provides such notice to Immunex, alleging that it is reasonable to infer that Bioepis might not provide notice to Immunex in light of its failure to provide its aBLA and manufacturing information to Immunex.[146]

Although Adello and Bioepis both opted out of the patent dance, the motivations behind their choices seem to differ. Adello immediately provided Amgen a notice of commercial marketing, triggering what would have been the "second round" of litigation had the parties participated in the patent dance.[147] It is reasonable to infer that it was in Adello's best interest to skip the patent dance, which would have taken 230 days to complete, to expedite the litigation. Adello also might have found little benefit to engage in the patent dance, considering that Amgen had already filed infringement suits against two other biosimilar manufacturers—Sandoz and Apotex—

---

[140] *Id.* at 135.

[141] *Id.*

[142] Hirsch, *supra* note 25, at 677.

[143] *BPCIA Litigations*, BIG MOLECULE WATCH, https://www.bigmoleculewatch.com/bpcia-patent-litigations/ (last visited May 18, 2021) [https://perma.cc/JN84-ML2Z].

[144] Complaint at 6, Amgen Inc. v. Adello Biologics, LLC, No. 18-cv-03347 (D.N.J. Mar. 8, 2018).

[145] Complaint at 10–11, Immunex Corp. v. Samsung Bioepis Co., No. 19-cv-11755 (D.N.J. Apr. 29, 2019).

[146] *Id.*

[147] *See* Complaint, *supra* note 144.

where both Sandoz and Apotex prevailed on non-infringement grounds.[148] The number of relevant patents that could potentially be litigated and the likelihood of prevailing the litigation could be anticipated from these preceding suits even without engaging in the patent dance.

On the other hand, Samsung Bioepis did not provide Immunex a notice of commercial marketing upon opting out of the patent dance.[149] As Immunex suggests, Bioepis might have intended to skip both the patent dance and notice of commercial marketing to expedite the market entry, in which case it would not have to wait 230 days plus another 180 days before commercial marketing.[150] However, it is also possible that Bioepis was simply delaying the notice, exercising its control over when to trigger the declaratory judgment action.

Unlike Adello and Samsung Bioepis, several applicants initiated and engaged in the patent dance but attempted to withhold certain information. In Amgen's complaint against Mylan regarding the Neulasta biosimilar, Amgen alleged that Mylan provided Amgen with access to its aBLA "in a format different than and less complete than the format provided to FDA."[151] For instance, its aBLA was uploaded to a virtual data room that was "slow and cumbersome" and had periodic technological failure, and the file prohibited saving, copying, annotating, printing, and lacked fully working hyperlinks.[152] In Amgen's complaint against Hospira regarding the Neulasta biosimilar, Amgen argued that Hospira provided Amgen with black-and-white tiff images of its aBLA without usable hyperlinks.[153] In Genenentech's complaint against Samsung Bioepis regarding the Herceptin biosimilar, Genentech alleged that Bioepis provided redacted versions of only four subsections of its aBLA.[154] When the sponsors made requests for access to other information describing the processes of manufacture used for the applicants' products, many applicants refused to provide such information beyond what was available in the applications or in the market.[155]

In response to the applicants' outright refusal to participate in the patent dance, the sponsors often immediately brought actions against the applicants. When the applicants refused to provide necessary information or showed uncooperative and evasive behaviors during the patent dance, the sponsors made explicit remarks in their correspondences, which could later be used as records when disputes arose. For instance, the sponsors sent letters to the applicants stating that it had failed to provide its manufacturing information, failed to explain what the prior art reference disclosed

---

[148] *Filgrastim and Pegfilgrastim Litigation Updates*, BIG MOLECULE WATCH (Mar. 28, 2018), https://www.bigmoleculewatch.com/2018/03/28/filgrastim-and-pegfilgrastim-litigation-updates/ [https://perma.cc/BE5P-2CGN].

[149] Complaint at 10–11, Immunex Corp. v. Samsung Bioepis Co., No. 19-cv-11755 (D.N.J. Apr. 29, 2019).

[150] *Id.*

[151] Complaint at 14, Amgen Inc. v. Mylan Inc., No. 17-cv-01235-DSC (D.W.D. Pa. Sept. 22, 2017).

[152] *Id.*

[153] Complaint at 8, Amgen Inc. v. Hospira, Inc., No. 20-cv-00201 (D. Del. Feb. 11, 2020).

[154] Complaint at 6, Genentech, Inc. v. Samsung Bioepis Co., No. 18-cv-01363 (D. Del. Sept. 4, 2018).

[155] *See, e.g.*, Complaint at 22, Janssen Biotech, Inc. v. Celltrion Healthcare Co., No. 15-cv-10698 (D. Mass. Mar. 6, 2015).

and how it rendered any claim obvious, or that the applicant's production was otherwise deficient.[156]

Some sponsors inundated the applicants with a long list of patents and related claims. For example, AbbVie notified Boehringer Ingelheim that it would infringe as many as 1,600 claims from among seventy-one AbbVie patents.[157] Similarly, AbbVie stated that Amgen would infringe more than 1,100 claims of the sixty AbbVie patents in its exchange with Amgen.[158]

C. Proposal for Legislative Fix

The patent dance is designed to facilitate the resolution of patent disputes between the applicant and the sponsor by creating a mechanism through which the parties can access necessary information to determine whether there could be valid claims of patent infringement. There are built-in incentives and disincentives in the statute that encourage the parties to comply with the patent dance. Over the past decade, however, the cases that interpreted the statute added another layer of incentives and disincentives for complying with the patent dance. Nevertheless, the new incentive structure derived from the case law seems to move away from the legislative goal of the patent dance, which is to promote transparency and efficiency in patent litigation between the applicant and the sponsor.

First, the patent dance jurisprudence has developed in a way that creates litigious gamesmanship. The Supreme Court's holding in *Sandoz* effectively made the patent dance optional. By giving the applicant the freedom to choose whether to participate in the dance or not, the applicant could utilize the patent dance scheme to strategize the litigation. The patent dance thus became a tool for gamesmanship rather than a mandatory obligation that must be followed even when it goes against the applicant's best interest. Moreover, the disputes arising from non-compliance of the patent dance procedure could lag the resolution of the actual patent disputes, creating inefficiency. Whether the parties have complied with their obligations of the patent dance is a fact-intensive inquiry. Raising these claims in litigation would place additional burdens on courts when the focus of litigation should be on patent infringement claims. The patent dance could become a source of secondary disputes between the applicant and the sponsor when it is meant to facilitate the resolution of disputes.

There have been legislative efforts to fix the problems in the patent dance scheme. In June 2019, the Senate passed the Affordable Prescriptions for Patients Act of 2019 (S. 1416), which creates incentives for the applicant to fully comply with the patent dance.[159] The bill proposes to limit the number of patents that can be litigated under the BPCIA to twenty when the applicant fully complies with the patent dance.[160] If the applicant fails to comply, the bill proposes that the court would have the discretion to increase the number of patents that can be litigated.[161] This statutory fix may restore

---

[156] *See, e.g.*, Complaint at 12, AbbVie Inc. v. Amgen Inc., No. 16-cv-00666 (D. Del. Aug. 4, 2016).

[157] Complaint at 15, AbbVie Inc. v. Boehringer Ingelheim GMBH, No. 17-cv-01065 (D. Del. Aug. 2, 2017).

[158] Complaint at 12, AbbVie Inc. v. Amgen Inc., No. 16-cv-00666 (D. Del. Aug. 4, 2016).

[159] Affordable Prescription for Patients Act of 2019, S. 1416, 116th Cong. (2019).

[160] *Id.* § 3.

[161] *Id.*

the effectiveness of the patent dance and reduce the gamesmanship and inefficiency that result from non-compliance.

In addition to providing stronger incentives for the applicants to comply with the patent dance, legislation that provides stronger disincentives for non-compliance may also address the problems. For instance, a remedial provision that creates a presumption of infringement of any patent that the sponsor asserts to be infringed when the applicant fails to comply with the patent dance obligations may encourage the applicants to engage in a dance. The presumption will shift the burden of proof to the applicant in litigation, and such disadvantage can lead the applicant to participate in the patent dance when faced with the option to do so. Such remedial provision will also be in line with the legislative purpose of the patent dance because it will help protect the sponsors' patent rights while minimizing any interference with the biosimilars' market entry.

V. CONCLUSION

Congress enacted the BPCIA in an effort to control the high price of biologics. On the one hand, the statute encourages price competition in the biologics market by expediting the market entry of biosimilars through the creation of abbreviated regulatory pathway. On the other hand, it seeks to incentivize the development of innovative drugs by protecting the patent rights of innovator companies through the creation of the patent dance mechanism. The patent dance is intended to facilitate the resolution of patent disputes between the applicant and the sponsor. It subjects the applicant and the sponsor to a number of statutory obligations that are purported to help both parties. Nevertheless, the patent dance jurisprudence seems to have evolved in a way that contradicts such congressional intent. Instead of promoting transparency and efficiency in the resolution of the patent disputes between the applicant and the sponsor, the patent dance, in practice, encouraged gamesmanship and created undesirable distortions. To restore the original meaning of the patent dance provision as intended by the legislators, it is now the legislature's turn to make its move and adopt a proper statutory fix.