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# Declaratory Judgments Unavoidable For Biosimilar Applicants

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Since the enactment of the Biologics Price Competition and Innovation Act, debate has brewed over the type and amount of information a biosimilar applicant must disclose under its prescribed information exchange provisions.

The conventional belief was that, by partaking in the information exchange, a biosimilar applicant would be able to prolong, or avoid, a declaratory judgment action filed by the brand holder.

Recent data, however, suggests that a biosimilar applicant will inevitably face a declaratory judgment action irrespective of the amount and type of information it provides to the brand holder.

**Background**

The first 10 years under the BPCIA has seen over 30 litigated disputes between a biosimilar applicant and branded reference product sponsor, or RPS.

However, despite the yearslong legislative history and now considerable treatment by the courts, a basic set of questions remains regarding how much and what type of information the applicant should disclose to the RPS when engaging in the so-called patent dance.

In the 2017 case Sandoz Inc. v. Amgen Inc.,[1] the inaugural litigation under the BPCIA, the U.S. Supreme Court held that the patent dance is entirely discretionary — an abbreviated biologics license application, or ABLA, applicant can either participate in the prescribed information exchanges or forego the patent dance entirely by refusing to disclose its ABLA or any manufacturing information.

The consequence of refusing any of the BPCIA information exchanges is that the RPS can immediately file a declaratory judgment action "for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product."[2]

If an applicant elects to disclose its ABLA and thereby engage in the BPCIA information exchange, then the applicant "shall provide ... such other information that describes the process or processes used to manufacture the biological product that is the subject of such application."[3]

In considering this provision, the court in Sandoz stated that, even if an applicant participates in the patent dance by disclosing its ABLA, it may still be subject to declaratory judgment jurisdiction by failing to disclose other information to the RPS.

However, while recognizing that the purpose of this information exchange is to help the RPS identify which of its patents are infringed,[4] the court left open the quantity and type of information required to avoid declaratory judgment liability.

**All Roads Lead to a Declaratory Judgment Action**

The holding in Sandoz not only sanctions an applicant's refusal to engage in any aspect of the patent dance, it also leaves ample room for disputes if the dance is initiated. Indeed, under Sandoz, the RPS can readily short-circuit the patent dance by filing a declaratory judgment action questioning the sufficiency of an applicant's disclosure of other information.

Recent BPCIA litigation suggests that an action for declaratory relief may be the default outcome of the statutory patent resolution scheme: Out of 18 cases from 2018 to 2020, 16 resulted in a declaratory judgment action filed by the RPS. The other two cases involved a declaratory judgment action filed by the applicant. And in eight of these cases, the RPS filed a declaratory judgment against the applicant due to a failure to disclose other information.

In cases in which the RPS asserted nonadherence with the disclosure requirements as a basis of declaratory judgment jurisdiction, the amount of disclosure asserted in the pleading has run the gamut.

For example, some applicants have disclosed thousands of pages of other information, including all manufacturing batch records, cell culture conditions, purification processes, and the raw materials used during manufacture.[5] In contrast, other applicants did not disclose any other information beyond the ABLA itself.[6]

But the unvarying outcome whatever level of disclosure has been an apparently unavoidable declaratory judgment for patent infringement. Table 1 summarizes these observations in specific cases.

From the RPS' perspective, the adequacy of the applicant's information disclosure constrains its determination of the patents it "believes a claim of patent infringement could reasonably be asserted," and therefore add to its 3A list of asserted patents.[7]

In the absence of sufficient information, the RPS' options are to request supplemental disclosure from the applicant — other information — or file an immediate declaratory judgment for patent infringement against the applicant.[8] Cases litigated under the BPCIA indicate that the latter scenario is likely to eventually occur regardless of the amount the applicant discloses.

Alternatively, the RPS can let the initial patent dance play out and assert all patents in its 3A list in a declaratory judgment during second wave litigation after the applicant files a notice of commercial marketing. In some cases, this compelled the applicant to disclose more manufacturing process information in its 3B response to the RPS' 3A list of asserted patents.

| Date | Case | Alleged Deficiency in the "other information" |
|---|---|---|
| Nov. 21, 2020 | Genentech, Inc. v. Centus Biotherapeutics, 2-20-cv-00361* | RPS claimed applicant failed to provide manufacturing info. |
| Jun. 28, 2020 | Genentech v. Samsung Bioepis., No. 20-cv-00859* | RPS claimed applicant failed to provide manufacturing info related to host cell line, cell culture media, and dissolved oxygen levels during harvest. In response to RPS 3A list of asserted patents, applicant's 3B statement provided the ingredients of its cell culture media. |
| Apr. 24, 2020 | Amgen Inc. et al. v. Hospira, Inc. et al., 1-20-cv-00561 | RPS claimed applicant failed to provide manufacturing info. |
| Feb. 11, 2020 | Amgen Inc. et al. v. Hospira, Inc. et al., 1-20-cv-00201 | RPS claimed the applicant both provided an incomplete aBLA consisting of black and white tiff images without usable hyperlinks and failed to provide manufacturing info. |
| Jul. 23, 2019 | Amgen v. Tanvex, No. 19-cv-01374* | Disclosed two batch records. Then, disclosed additional "engineering information" in its 3B statement, but did not include all data on protein concentration measurements. |
| Apr. 29, 2019 | Immunex v. Samsung Bioepis, No. 19-cv-11755 | None |
| Apr. 5, 2019 | Genentech v. Pfizer, No. 19-cv-00638* | Disclosed over 560 thousand pages as part of its aBLA, which included all information related to its manufacturing processes. |
| Mar. 29, 2019 | Genentech v. Immunex, No. 19-cv-00602 | None – refused to disclose sBLA filed in Aug. 2018. |
| Sept. 4, 2018 | Genentech v. Samsung Bioepis, No. 18-cv-01363* | RPS claimed applicant failed to provide other information about manufacturing processes. |
| Aug. 10, 2018 | AbbVie v. Sandoz, No. 18-cv-12668 | RPS claimed applicant failed to provide other information about manufacturing processes. |
| Aug. 7, 2018 | Amgen v. Accord (formerly Apotex), No. 18-cv-61828, | Unavailable |
| Jul. 18, 2018 | Amgen v. Hospira, No. 18-cv-01064 | Disclosed aBLA sections pertinent to manufacturing process and process controls, process development & validation. |
| Jun. 21, 2018 | Genentech v. Amgen, No. 18-cv-00924* | Disclosed batch records describing source history, generation of cell substrate, cell culture and harvest, each and every purification process step, and the raw materials used during manufacture. |
| Mar. 8, 2018 | Amgen v. Kashiv (formerly Adello), No. 18-cv-03347 | None |
| Jan. 12, 2018 | Genentech v. Celltrion, No. 18-cv-00095* | RPS claimed applicant failed to provide other information about manufacturing processes. |
| Jan. 12, 2018 | Genentech v. Celltrion, No. 18-cv-00574* | RPS claimed applicant failed to provide other information about manufacturing processes. |
| Jan. 11, 2018 | Celltrion v. Genentech, No. 18-cv-00274 | Disclosed all batch records, upstream and downstream manufacturing reports, more than 280 thousand pages of details and batch records describing source history, generation of cell substrate, cell culture and harvest process, each and every purification process step, and raw materials for manufacture. |
| Jan. 11, 2018 | Celltrion v. Genentech, No. 18-cv-00276 | Same info as above, except 440 thousand pages disclosed. |

*Indicates cases where RPS filed a DJ citing applicant's failure to disclose "other information" related to manufacturing process of biosimilar.

For example, in the 2020 U.S. District Court for the District of Delaware decision Genentech Inc. v. Samsung Bioepis Co. Ltd., the applicant disclosed its ABLA, but did not initially disclose other manufacturing information such as the ingredients of its cell culture media.[9] Instead, in response to the RPS' 3A list of asserted patents, the applicant disclosed its cell culture media in its 3B[10] statement.[11]

Similarly in the 2019 U.S. District Court for the Southern District of California decision Amgen v. Tanvex BioPharma USA Inc., the applicant again disclosed its ABLA and only two batch records for its manufacturing process.[12] Then, in response to the RPS' 3A list of asserted patents, the applicant further disclosed additional engineering information in its 3B statement.[13]

Both cases resulted in a declaratory judgment. In fact, Genentech's declaratory judgment action was specifically based on the applicant's failure to provide other information under Section 262(l)(9)(C).

The question for the applicant, on the other hand, is how much other information it should disclose about its manufacturing process. Litigation under the BPCIA suggests that an unavoidable declaratory judgment for patent infringement is likely in most scenarios regardless of the quantity and quality of information it discloses. As the table indicates above, the applicants disclosed very little to a lot of manufacturing information to the RPS, and yet all cases resulted in a similar outcome.

Since a declaratory judgment is an unavoidable outcome of participating in the patent dance, it may be worthwhile for the applicant to skip the patent dance altogether. After all, the entire patent dance can take up to 245 days until the RPS even files a complaint — avoiding this delay may outweigh the strategic disadvantages of declaratory judgment liability.

However, failure to participate in the patent dance can result in an immediate declaratory judgment for infringement filed by the RPS against the applicant.[14] At this point, the applicant concedes control over the scope and timing of the patent litigation, which may be undesirable due to the litigation costs associated with several asserted patents by the RPS.[15]

Moreover, failure to participate in the patent dance affects future outcomes during the second wave of litigation after the applicant files its notice of commercial marketing.

For instance, the applicant might lose its ability to file a declaratory judgment after it files its notice of commercial marketing.[16] Not to mention, the lack of participation in the patent dance can factor into a court's decision to grant an injunction against the applicant after it files its notice of commercial marketing.[17]

**Conclusion**

There is no simple way for an applicant to avoid a declaratory judgment regardless of the level of its participation in the patent dance. Indeed, the RPS will most likely file a declaratory judgment for infringement — the only question is when. By foregoing the patent dance, the applicant may be able to expedite the unavoidable declaratory judgment and not have to potentially wait up to 245 days to be sued and resolve uncertainty before its market launch.

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[1] Sandoz Inc. v. Amgen Inc. 137 S. Ct. 1664 (2017).

[2] 42 U.S.C. § 262(l)(9)(C).

[3] 42 U.S.C. § 262(l)(2)(A).

[4] Sandoz, 137 S. Ct. 1664.

[5] See, e.g., Genentech v. Pfizer, No. 19-cv-00638, Dkt. Nos. 1, 14 (D. Del. Apr. 5, 2019).

[6] Genetech v. Celltrion, No. 18-cv-00574, Dkt. No. 1 (D.N.J. Jan. 12, 2018).

[7] Pursuant to 42 U.S.C. § 262(l)(3)(A), sixty days after the RPS receives the applicant's ABLA, the RPS must provide a list of patents that it will assert or license to the applicant. This is also referred to as a "3A list."

[8] 42 U.S.C. § 262(l)(9)(C).

[9] No. 20-cv-00859, Dkt. Nos. 1, 9 (D. Del. Jun. 28, 2020).

[10] Pursuant to 42 U.S.C. § 262(l)(3)(B), sixty days after the applicant receives the RPS' 3A list of asserted patents, the applicant must provide its "3B Statement" to the RPS that includes the following information: (1) a list of other patents to include in litigation (if any); (2) response to the RPS' license offer; and (3) factual and legal basis for invalidity, unenforceability, non-infringement, or a statement that it will not market its biosimilar before the RPS' patents expire.

[11] Id.

[12] No. 19-cv-01374, Dkt. No. 1 (S.D. Cal. Jul. 23, 2019).

[13] Id.

[14] See, e.g., Genentech v. Immunex, No. 19-cv-00602, Dkt. No. 1 (D. Del. Mar. 29, 2019).

[15] Sandoz, 137 S. Ct. at 1675 (providing that "[w]hen an applicant fails to comply with 42 U.S.C. § 262(])(2)(A), § 262(])(9)(C) authorizes the sponsor, but not the applicant, to bring an immediate declaratory judgment action for artificial infringement. Section 262(l )(9)(C) thus vests in the sponsor the control that the applicant would otherwise have exercised over the scope and timing of the patent litigation. It also deprives the applicant of the certainty that it could have obtained by bringing a declaratory-judgment action prior to marketing its product.").

[16] Celltrion v. Genetech, No. 18-cv-00274, Dkt. No. 1 (N.D. Cal. Jan. 11, 2018); and Celltrion v. Genetech, No. 18-cv-00276, Dkt. No. 1 (N.D. Cal. Jan. 11, 2018).

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