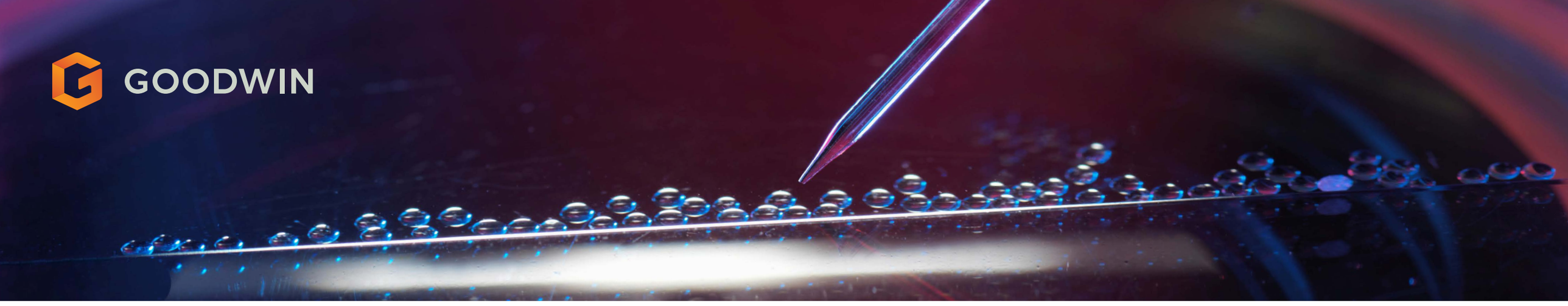


GOODWIN

Guide to the BPCIA's **Biosimilars Patent Dance**

First Wave Litigation

42 U.S.C. § 262(l)(2)-(7)

FDA Accepts aBLA — Within 20 Days — **Applicant provides copy of aBLA and manufacturing information to the Reference Product Sponsor (RPS) (l)(2)(A)**

Within 60 Days

§ 262(l)(3)(A) and § 262(l)(7)

- **RPS provides Applicant with list of potentially infringed patents (l)(3)(A)(i)**
- **RPS identifies any patents on list that RPS is willing to license to Applicant (l)(3)(A)(ii)**

RPS must supplement its list with relevant newly issued or licensed patents within 30 days of issuance or licensing. Any newly issued or licensed patents listed on the RPS supplement will be subject to the second wave of patent litigation (l)(7)

Within 60 Days

§ 262(l)(3)(B)

- **Applicant may provide RPS with list of patents Applicant believes could reasonably be asserted by RPS (l)(3)(B)(i)**
- **Applicant responds to each patent on RPS's (l)(3)(A) list with: i) Detailed statement of invalidity, unenforceability or noninfringement OR ii) Statement that Applicant will not commercially market product before patent expiration (l)(3)(B)(ii)(I)-(II)**
- **Applicant responds to RPS's licensing offers, if any (l)(3)(B)(iii)**

Within 60 Days

§ 262(l)(3)(C)

RPS provides Applicant with detailed statement of validity, enforceability, and infringement for each patent for which Applicant has provided (l)(3)(B) detailed statement

Whether an Applicant may "waive" its right to receive this detailed statement (for example, for purposes of accelerating the patent dance) has been disputed, but not resolved, in at least *Amgen v. Sandoz*, No. 16-cv-1276 (D.N.J. 2016).

Immediately after Applicant receives (l)(3)(C) statement

Parties negotiate patents to be litigated

Whether an Applicant may decline to participate in the negotiation process described in §§ 262(l)(4) and (5) has been disputed, but not resolved.

§ 262(l)(4)

- **If parties agree which patents to litigate: (l)(4)(A)** — Within 30 Days — **RPS files First Wave Litigation** — **§ 262(l)(6)(A)-(B)** — Within 30 Days — **Applicant notifies FDA suit has been filed** — **§ 262(l)(6)(C)**
- Within 15 Days — **If parties do not agree which patents to litigate: (l)(4)(B)** — **Applicant identifies the number of patents Applicant believes should be litigated** — **§ 262(l)(5)(A)** — Within 5 Days — **Parties simultaneously exchange lists of patents to be litigated (l)(5)(B)(i)** — **Important: The number of patents on RPS's list cannot exceed the number of patents on Applicant's list unless the Applicant has zero on its list, in which case RPS may list 1 patent (l)(5)(B)(ii)** — **§ 262(l)(5)(B)** — Within 30 Days

The BPCIA provides that the RPS shall file the First Wave litigation within 30 days of the information disclosure set forth in § 262(l)(5). If the RPS fails to do so, the only remedy to which the RPS may be entitled in a later infringement action on the First Wave patent(s) is damages in the amount of a reasonable royalty. *See* 35 U.S.C. § 271(e)(6)(B). In *Janssen v. Celltrion,* the District of Massachusetts stated that the parties must engage in "good-faith negotiations" and "the specified dispute resolution procedure if those negotiations fail" in order to limit the RPS to a reasonable royalty. *Janssen Biotech, Inc. v. Celltrion Healthcare Co. Inc.,* No. 15-cv-10698, 239 F. Supp. 3d 328, 332 (D. Mass. Mar. 3, 2017). In some cases, the Applicant has agreed to the RPS's list of relevant patents but "waived" the subsequent steps of the patent dance. This raises an additional question as to whether, in these circumstances, an RPS is required to file suit within 30 days of receipt of an Applicant's detailed statement. This issue has been disputed, but not resolved, in several litigations, including *Immunex v. Sandoz*, *Amgen v. Sandoz* (D.N.J.), *Amgen v. Hospira*, and *Janssen v. Celltrion*.

Second Wave Litigation

42 U.S.C. § 262(l)(8)

The Court of Appeals for the Federal Circuit has held that regardless of whether an Applicant provides the RPS with a copy of its aBLA and manufacturing information pursuant to § 262(l)(2)(A), it must provide the notice of commercial marketing pursuant to § 262(l)(8)(A). *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1061 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 591 (2016). As to when the Applicant can provide notice of commercial marketing, the Supreme Court has ruled that the aBLA Applicant need not wait until FDA approval to provide such notice. Rather, the aBLA Applicant "may provide notice either before or after receiving FDA approval." *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1668 (2017).

Applicant submits aBLA

At least 180 days before launch

Applicant notifies RPS that it intends to commercially market product (l)(8)(A)

Immediately after notification

RPS can seek preliminary injunction prohibiting commercial launch of Applicant's product until court rules on any patents listed by RPS or Applicant in (l)(3) or (l)(7) that were not the subject of First Wave Litigation (l)(8)(B)

Declaratory Judgment Actions

42 U.S.C. § 262(l)(9)

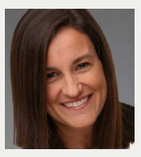
- **If Applicant provides (l)(2)(A) application and information** → **Neither RPS nor Applicant may file DJ action for First Wave Litigation patents** — **§ 262(l)(9)(A)**
- **If Applicant provides (l)(2)(A) application and information but fails to complete one of the remaining steps in (l)(3)-(8)** → **RPS may file DJ action for any (l)(3)(A) or (l)(7) patent** — **§ 262(l)(9)(B)**

In *Amgen v. Apotex*, the Court of Appeals for the Federal Circuit clarified that a declaratory judgment action is not the exclusive remedy for a violation of the (l)(8)(A) commercial marketing notice requirement, stating: "(9)(B) does not make declaratory judgments exclusive and thereby wipe out the remedies expressly provided for in 35 U.S.C. 271(e)(4)." *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1065 n.4 (Fed. Cir. 2016).

- **If Applicant does not provide (l)(2)(A) application and information** → **RPS may file DJ action for any patent that claims Applicant's product or its use** — **§ 262(l)(9)(C)**

Current as of September 24, 2021. The content herein is subject to change, as case law regarding the BPCIA continues to develop.

Contact Us



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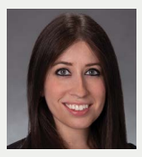

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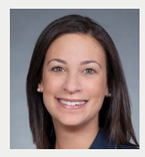

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