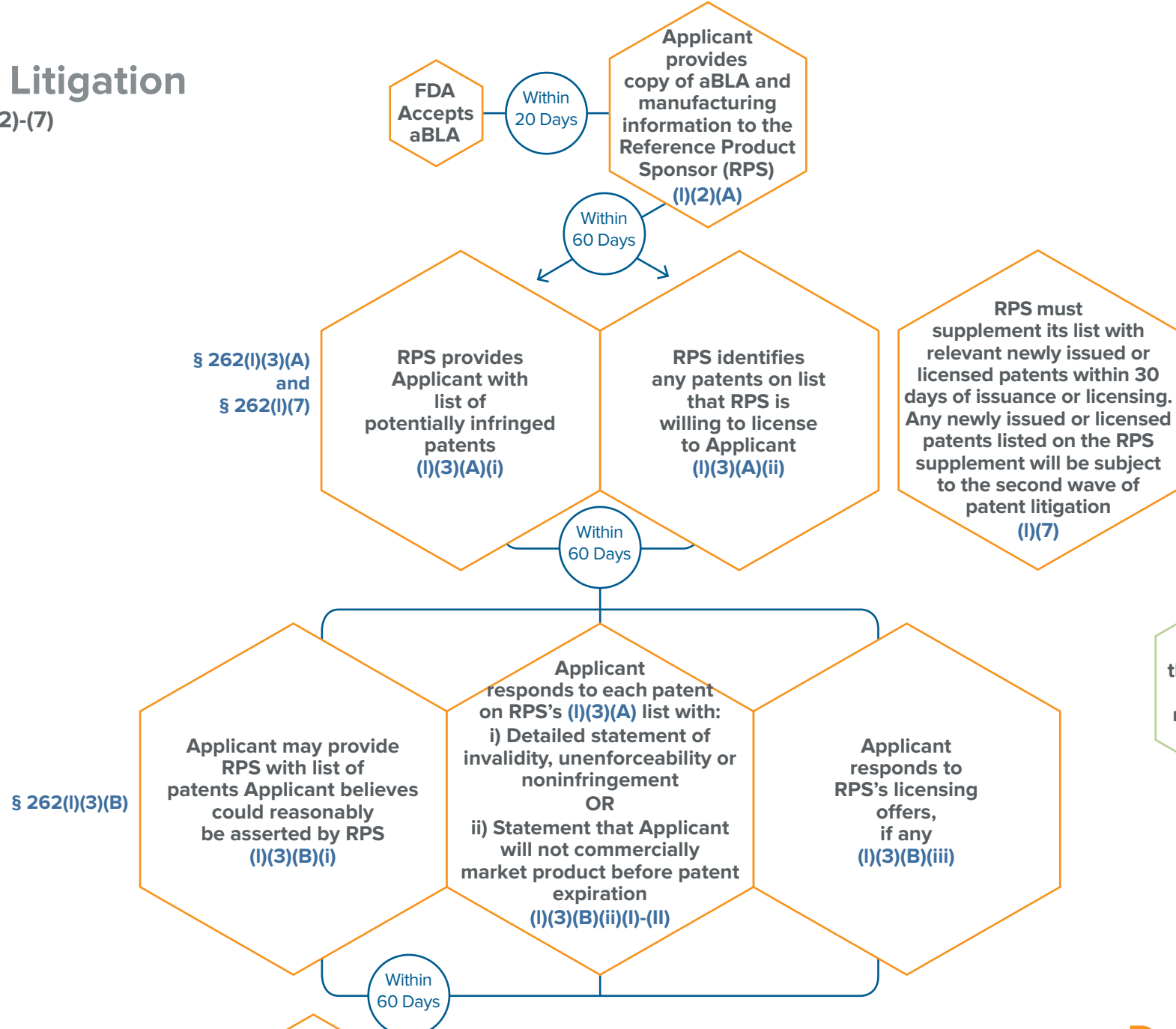


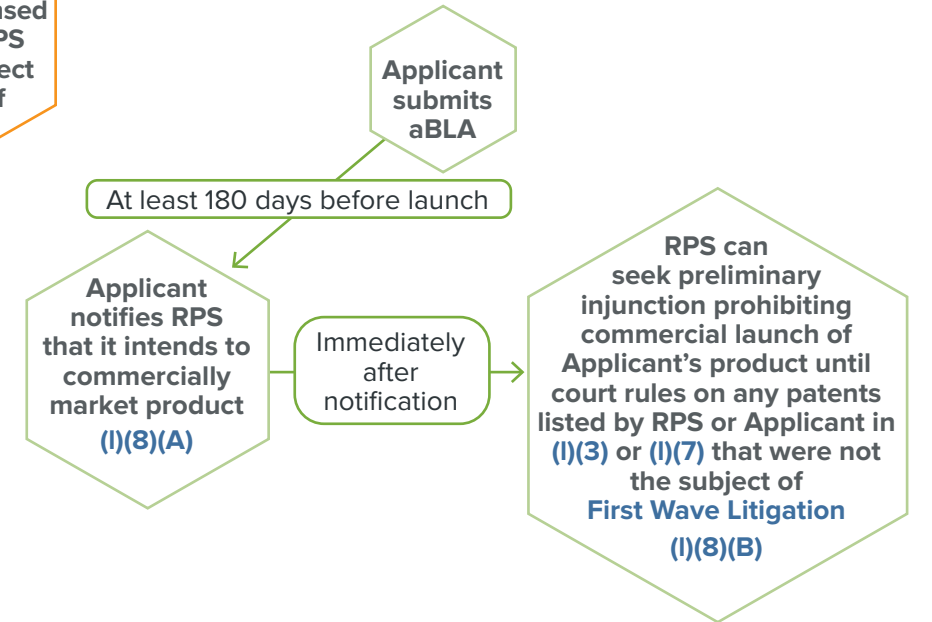
Guide to the BPCIA's **Biosimilars Patent Dance**

First Wave Litigation 42 U.S.C. § 262(l)(2)-(7)



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).



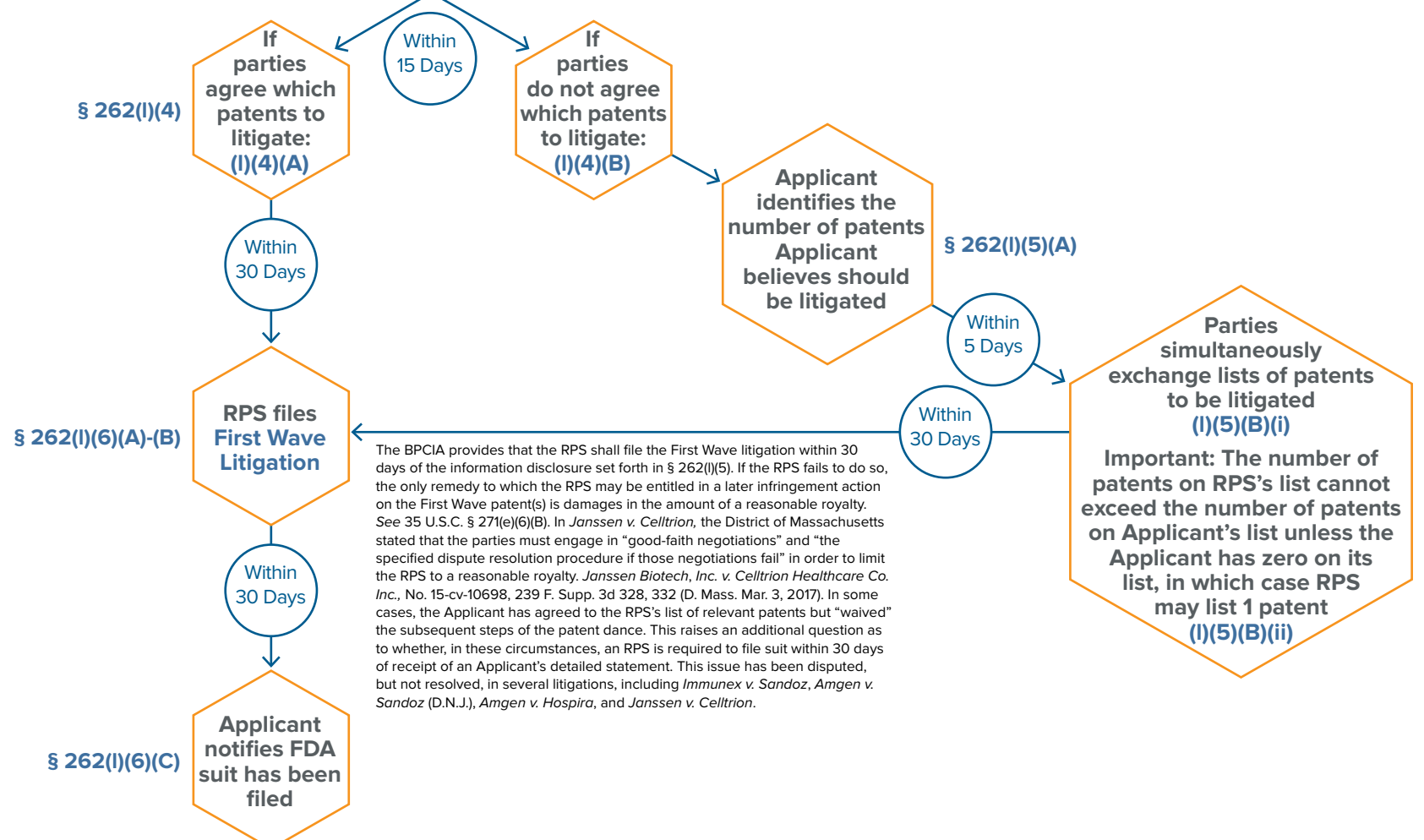
§ 262(l)(3)(C)
RPS provides Applicant with detailed statement of validity, enforceability, and infringement for each patent for which Applicant has provided (l)(3)(B) detailed statement

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).

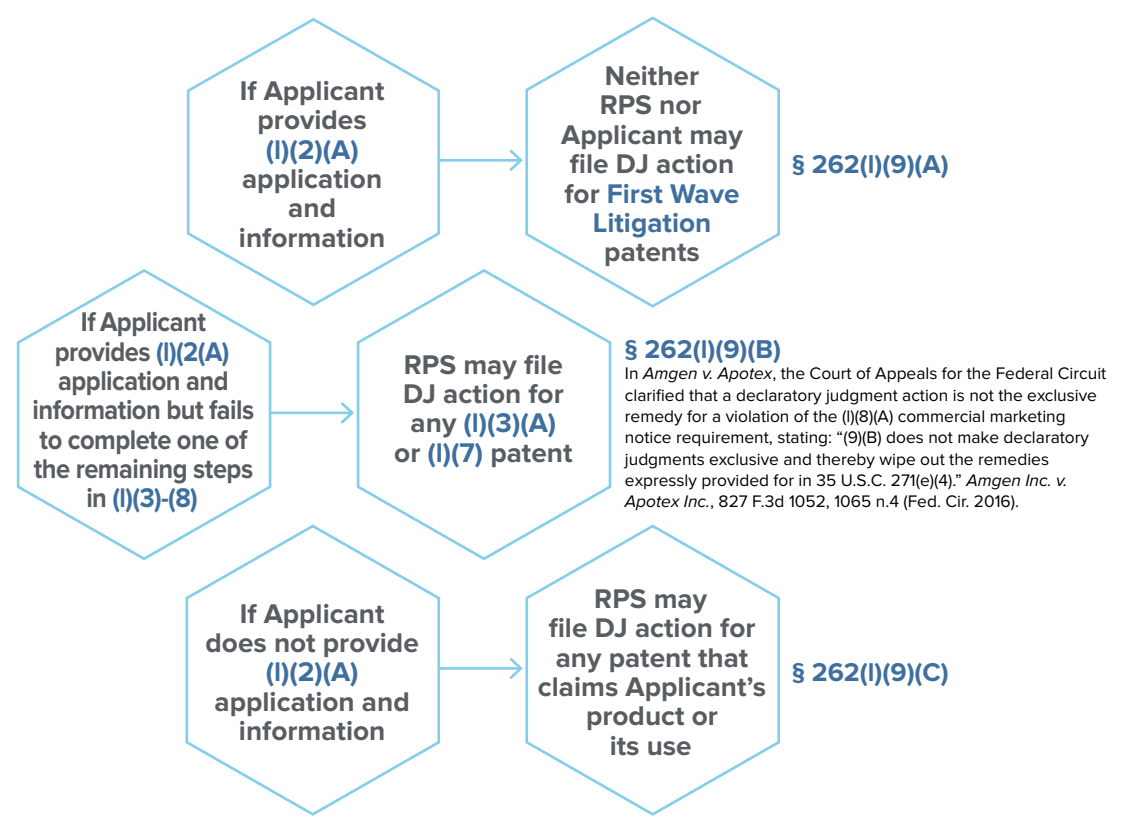
Immediately after Applicant receives (l)(3)(C) statement

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.



Declaratory Judgment Actions 42 U.S.C. § 262(l)(9)



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

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