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An Update on the BPCIA and the “Patent Dance”

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Biologics Price Competition & Innovation Act

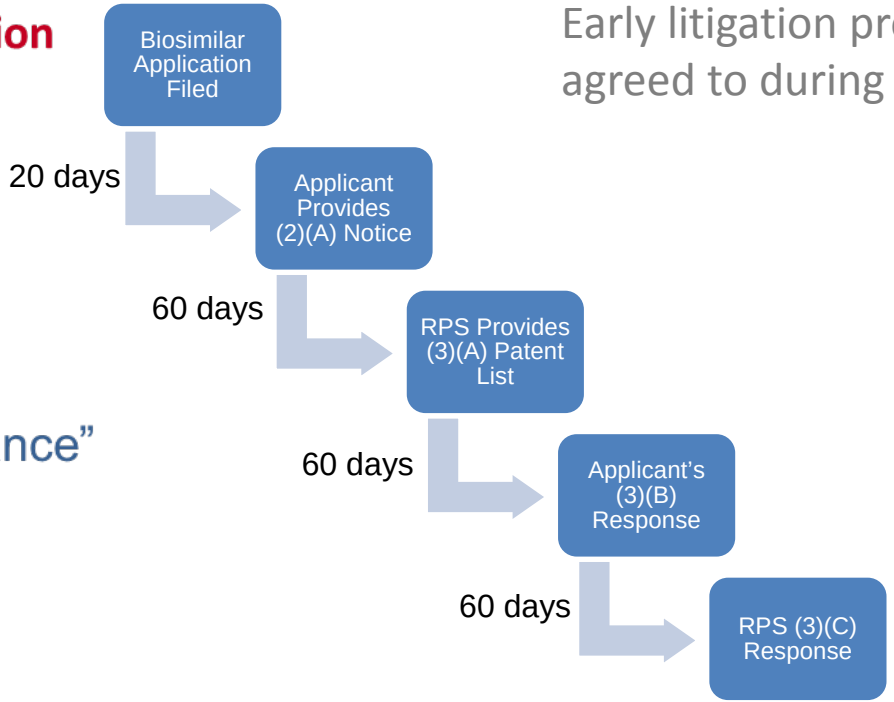
- Open questions involving the patent dance in the Federal Circuit in 2017
- The Supreme Court's opinion in *Sandoz v. Amgen*
- Other considerations from the Supreme Court's opinion
- *Sandoz v. Amgen* on remand
- Other recent BPCIA case law

Biologics Price Competition & Innovation Act

- Abbreviated pathway to FDA licensure for follow-on alternatives to biologics
- Timing
  - Applications may not be submitted until 4 years after Reference Product is licensed
  - Licenses “may not be made effective” until 12 years after Reference Product is licensed
- Two “phases” of patent litigation under the BPCIA scheme

Patent Dispute Process

Early Phase Litigation



"Patent Dance"

Early litigation proceeds on patents agreed to during negotiations

Negotiation
If parties disagree, Applicant selects number of patents at issue
A selection of 0 means that RPS may choose 1 patent

Patent Dispute Process

- Applicant provides Notice of Commercial Marketing.
  42 U.S.C. § 262 (*l*)(8)(A)
- Late phase litigation: Before the first commercial marketing, the reference product sponsor ("RPS") may seek a preliminary injunction prohibiting the commercial manufacture or sale of the biosimilar product until the court decides issues of patent validity, enforcement, and infringement

  Late litigation can proceed on any patent included on one of the initial "lists" provided by the RPS or Applicant that is not included on the early phase negotiated lists

Notice of Commercial Marketing

- The subsection (k) applicant ***shall provide*** notice to the reference product sponsor (RPS) not later than 180 days before the date of the first commercial marketing of the biological product ***licensed under subsection (k)***

- Failure to Provide Notice of Commercial Marketing
  - RPS may bring Declaratory Judgment action for patent infringement, validity or enforceability 42 U.S.C. § 262(*l*)(9)(B))

Amgen Inc. v. Sandoz Inc., No. 2015-1499 (Fed. Cir. July 23, 2015) (Neupogen®)

- Complying with 42 U.S.C. § 262(*l*)(2)(A) (providing aBLA and manufacturing process) is not mandatory because BPCIA provides a remedy
- The Applicant can provide effective notice of commercial marketing only ***after*** the FDA has licensed (approved) the biosimilar product
- Where the Applicant fails to provide its aBLA and manufacturing information, the 180-day notice of commercial marketing is mandatory; in this case, Sandoz may not market Zarxio before 180 days from March 6, 2015, *i.e.,* September 2, 2015
- If Applicant provides the aBLA and manufacturing information but fails to provide Notice of Commercial Marketing - RPS can seek a declaratory judgment (42 U.S.C. § 262(*l*)(9)(B))

Petition for Certiorari

- After petition for *en banc* rehearing denied, Sandoz petitions Supreme Court (Feb. 16, 2016)
- Questions presented:

  Whether notice of commercial marketing given before FDA licensure is effective?

  Whether treating Section 262(*l*)(8)(A) as a standalone requirement and creating an injunctive remedy that delays all biosimilars by 180 days after approval is improper?
- Federal Circuit erred by holding "than an applicant 'may only give effective notice of commercial marketing *after* the FDA has licensed its product."
- Federal Circuit erred by "creating a new remedy . . . an injunction against commercial marketing until 180 days after post-approval notice is given."

Petition for Certiorari

- Amgen opposes petition for certiorari
  - Argues that "notice of commercial marketing is effective only after FDA licensure of the Applicant's product under subsection (k)."
- Amgen files conditional cross-petition in March 2016 to introduce other "patent dance" questions into appeal
  - Is an Applicant required by 42 U.S.C. § 262(*l*)(2)(A) to provide the Sponsor with a copy of its biologics license application and related manufacturing information, which the statute says the Applicant "shall provide," and, where an Applicant fails to provide that required information, is the Sponsor's sole recourse to commence a declaratory-judgment action under 42 U.S.C. § 262(*l*)(9)(C) and/or a patent-infringement action under 35 U.S.C. § 271(e)(2)(C)(ii)?
- Supreme Court granted cert in January 2017
  - Represents first time Supreme Court weighs in on BPCIA passed in 2010
  - Oral argument held in April 2017

Sandoz Inc. v. Amgen Inc. et al., No. 15-1039 (S. Ct. June 12, 2017)

- **Unanimous** decision; opinion authored by Justice Thomas
- Reversed Federal Circuit on the simpler issue of when notice of commercial marketing must be provided
- Biosimilar applicant may provide notice of commercial marketing (intent to launch) **before** FDA licenses aBLA
  - Amgen's arguments "cannot overcome the statute's plain language."
  - "[T]he applicant may provide notice either before or after receiving FDA approval."
  - Consequently, the applicant can provide notice before the 12-year period has ended.
  - So Federal Circuit erred in issuing injunction preventing Sandoz from launching until 180 days after licensure, and relatedly, Amgen's state law unfair competition claim also fails because it was predicated on the argument that the BPCIA prohibits pre-licensure notice.

Sandoz Inc. v. Amgen Inc. et al., No. 15-1039 (S. Ct. June 12, 2017)

- Agreed with Federal Circuit on the more complex issue of whether a federal injunction is available to force the applicant's disclosure of aBLA
- Amgen (RPS) is **not** entitled to an injunction requiring Sandoz to provide its aBLA and manufacturing information.
  - The statute specifies a "remedy" for failure to provide these information to RPS → the RPS can seek an immediate declaratory judgment patent action under Sec. 262(*l*)(9)
  - The applicant cannot seek a declaratory judgment action before it launches – it must wait to be sued by the RPS
  - The federal remedy for Amgen is that it got control over the timing/content of patent litigation because Sandoz failed to provide the aBLA/manufacturing information
  - This is the "sole remedy" at least in federal law

Sandoz Inc. v. Amgen Inc. et al., No. 15-1039 (S. Ct. June 12, 2017)

- **Remanded** to Federal Circuit to determine state law remedies

> "There is no dispute about how the federal scheme actually works, and thus nothing for us to decide as a matter of federal law. The mandatory or conditional nature of the BPCIA's requirements [under §262(*l*)(2)(A)] matters only for purposes of California's unfair competition law, which penalizes 'unlawful' conduct. Whether Sandoz's conduct was 'unlawful' under the unfair competition law is a state-law question, and the court below erred in attempting to answer that question by referring to the BPCIA alone."

Sandoz Inc. v. Amgen Inc. et al., No. 15-1039 (S. Ct. June 12, 2017)

- Other remedies/consequences for noncompliance?
  - Court also suggests (FN 2) that a district court can consider the applicant's noncompliance in the "balance of equities" for a preliminary injunction… so an injunction under federal law could still issue that takes into account the applicant's noncompliance while patent case is pending
- Appears to be a win for biosimilars, but opinion left uncertainty around the mandatory nature of disclosure provision (and remedies for noncompliance) for all actors and how lower courts will decide on preliminary injunctions
- The question of whether disclosure of the aBLA and manufacturing information is required is remanded so the Federal Circuit can consider Amgen's state law unfair competition claims

Justice Breyer: Further FDA Role in Interpreting BPCIA?

- Just when FDA thought it was out, the Court pulls it back in…
- Justice Breyer's concurrence raises interesting questions as to whether FDA may revisit the Court's interpretation of these provisions and reach a different interpretation following agency rulemaking
- The concurrence points out that FDA has the Congressional authority under the statute to interpret the same provisions and, after further experience administering the BPCIA, may opt to "depart from, or to modify" the Court's interpretation
- Will FDA have cause or desire to reconsider the Court's interpretation of these patent provisions? At present, it seems unlikely

On Remand . . . Federal Law is the Final Word

- Federal Circuit panel unanimously ruled that the BPCIA preempts any state law remedies compelling biosimilar sponsors to comply with the patent dance provisions. *Amgen v. Sandoz*, No. 2015-1499 (Fed. Cir. Dec. 14, 2017).
- The BPCIA did not expressly preempt state law, but is there field preemption or conflict preemption?
- Field preemption: State law preempted "where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively" where Congressional intent may be inferred from a "scheme of federal regulation ... so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it," or where an Act of Congress "touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject."

On Remand . . . Federal Law is the Final Word

- No presumption against preemption for biosimilar patent litigation because biosimilar patent litigation "is hardly a field which the States have traditionally occupied."
- Patents are "inherently federal in character" and FDA has exclusive authority to license biosimilars
- Moreover, "the [BPCIA] scheme here is 'comprehensive' and 'provide[s] a full set of standards governing' the exchange of information in biosimilar patent litigation, 'including the punishment for noncompliance.'"
- This supports the inference that Congress intended no room for the States

On Remand . . . Federal Law is the Final Word

- Conflict preemption: Conflict preemption occurs “where it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle” to Congress’ objectives
- Amgen’s state law claims “clash” with the BPCIA
  - Differences in remedies offered by the BPCIA and those sought under state law support conflict preemption
  - Moreover, making state law claims available under 50 states’ tort regimes and unfair competition standards would “dramatically increase the burdens” on biosimilar applicants *beyond what Congress contemplated*
- Accordingly, permitting the state law claims to proceed would “conflict with the careful framework Congress adopted.”
- “We must assume that Congress acted intentionally when it did not provide an injunctive remedy for breach of § 262(l)(2)(A)'s disclosure requirements.”

On Remand . . . Federal Law is the Final Word

- Petition for rehearing *en banc* possible
- Although decision does not address whether Sandoz's failure to comply with the patent dance provisions was unlawful, it essentially closes the door on remedies to enforce Sandoz's compliance with the patent dance provisions
- Going forward, biosimilar applicants may choose to opt out of disclosure and, thus, first phase patent litigations, leaving branded companies to file suit after receiving notice of commercial marketing (i.e., late phase) or in a declaratory judgment action
- Biosimilar sponsors retain more control over commercially sensitive information about their product instead of risking disclosure under state law remedies
- More certainty around the BPCIA provisions in view of the decisions in 2017

Additional Considerations

- Biosimilar sponsors will need to weigh benefits of embarking on the patent dance and the extent to which to make any disclosures of proprietary product/ process information
- *Abbvie Inc. v. Boehringer Ingelheim Int'l* (filed Aug. 2, 2017) (D. Del.)
  - Abbvie's Complaint alleges patent infringement of eight patents by Boehringer's aBLA for a Humira biosimilar
  - Abbvie identified 74 patents to Boehringer during the patent dance
  - The parties did not reach agreement during the patent dance on which patents should be the subject of a suit
  - Boehringer selected 5 patents that it could be sued on, (*l*)(5)(A), and Abbvie was therefore limited to asserting 5 patents, (*l*)(5)(B)(ii)(I). Two patents overlapped, allowing Abbvie to file a complaint in the first phase on only 8 of the 74 patents, (*l*)(6)(B).
  - A second phase of litigation may arise on the remainder of the patents once Boehringer gives notice of commercial marketing – **the timing of which is up to Boehringer**
  - The extent of the proprietary disclosure was also limited by Boehringer – it triggered the patent dance by providing its aBLA to Abbvie but **did not disclose "any other information that describes the process or processes used to manufacture the Boehringer aBLA product** . . . ."

Statements in BPCIA Pre-Litigation Letters

- *Amgen Inc. v. Apotex Inc.*, No. 2017-1010 (Fed. Cir. Nov. 13, 2017) (slip. op.) (affirming district court opinion that Apotex's filgrastim and pegfilgrastim products do not infringe Amgen's '138 patent)
- As part of the first phase of the patent dance, the biosimilar applicant and RPS exchange pre-litigation letters related to the infringement and validity of the patents on the patent list (§ 262(*l*)(3))
  - Apotex sent pre-litigation letters arguing that its biosimilars did not infringe the '138 patent because the concentration of its relevant protein intermediate was limited to 0.9-1.4 g/L.
  - Based on claim construction, literal infringement turned on whether Apotex's products had protein concentrations at or above 1 g/L. At trial, Apotex's fact witness testified that the concentrations cited in the pre-litigation letters were factually inaccurate and relied instead on the protein concentrations disclosed in the batch records. Based on this evidence, the district court found that Amgen failed to prove direct infringement.
- On appeal, the Federal Circuit addressed the probative value of statements in pre-litigation letters
  - Statements therein constitute "**party admissions**" and should not be ignored by the district court
  - District court did not err in assigning some probative value to the letters

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Questions?