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The Impact of *Amgen v. Sandoz*

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Agenda

- Introduction to the Biologics Price Competition and Innovation Act ("BPCIA")
- Overview: *Amgen v. Sandoz*
- Issues litigated in *Amgen v. Sandoz*:
  - 1. Remedies for an applicant's failure to provide its biosimilar application and manufacturing information to the reference product sponsor ("RPS") within 20 days of FDA acceptance of the application.
  - 2. When can an applicant provide its 180-day notice of commercial marketing?
- Impacts of *Amgen v. Sandoz*

The Biologics Price Competition and Innovation Act ("BPCIA")

- Passed as part of the Affordable Care Act, March 23, 2010
- Amended section 351 of the Public Health Service Act to create an **abbreviated licensure pathway** for biological products shown to be "biosimilar" to, or "interchangeable" with, a reference product that has already been licensed by FDA
  - "Biosimilar" biologic vs. "interchangeable" biologic vs. "generic" small molecule
  - "Section 262(k) pathway" (codified at 42 U.S.C. § 262(k))—permits a "biosimilar" product to be licensed on less than the full complement of preclinical and clinical test data normally required for a new biologic
- Patent dispute resolution pathway different from that used for small molecule drugs: the BPCIA "Patent Dance"
  - Question presented: what are the steps of the Dance, and which (if any) are mandatory?

The BPCIA Patent Dispute Resolution Scheme: The "Patent Dance"

- Differs from Hatch-Waxman Orange Book scheme: no "Orange Book" of relevant patents. Instead: private, confidential exchange of patent information.

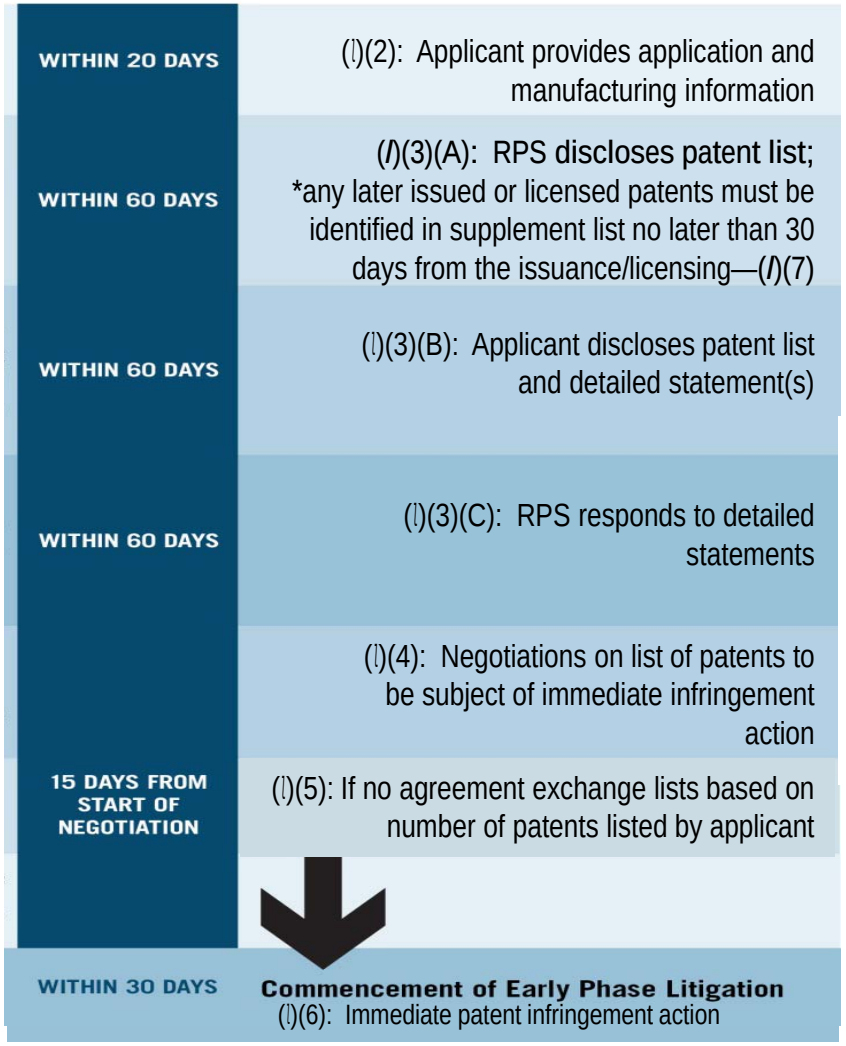
- § 262(*l*): schedule of information exchanges to identify patents that may be the subject of litigation, culminating in a negotiated final list of patents subject to a first wave of "immediate patent infringement action."

- No "automatic stay": RPS can seek a preliminary injunction based on patents that (i) were identified by the RPS during the patent dance, *and* (ii) were not included in the negotiated list of patents that both parties agreed would be the subject of an immediate infringement action.

The "Patent Dance": § 262(*l*) Provisions

First Wave: "Immediate Patent Infringement Action"

Applicant Notified that Biosimilar Application Accepted by FDA



(*l*)(7): RPS shall supplement (l)(3) list with later issued or exclusively licensed patents within 30 days of issuance or licensing; and applicant shall respond with detailed statement(s)

Second Wave:

"Preliminary Injunction"

(*l*)(8)(A): Applicant provides notice to the RPS not later than 180 days before the date of first commercial marketing.

(*l*)(8)(B): After receiving notice of commercial marketing, the RPS may seek a preliminary injunction on the basis of any patent that was listed under (l)(3) or (l)(7) and not included on the lists for (l)(4) or (l)(5).

Statutory consequences for failure to follow the dance

If the applicant does not…	***Then the RPS may…***
• Provide its application and manufacturing information within 20 days of notification of FDA acceptance per *(l)*(2)(A)…	➢ Bring a declaratory judgment action asserting "***any patent*** that claims the biological product or a use of the biological product."
• Provide a detailed statement in response each patent listed by the RPS, as provided in (*l*)(3)(B)(ii), (*l*)(7)(B)…	➢ Bring a declaratory judgment action asserting any patent listed by the RPS under (*l*)(3) or (*l*)(7).
• Notify the RPS of the number of patents the applicant will list under (*l*)(5), or does not simultaneously exchange the list of patents the applicant believes should be the subject of an immediate action for infringement per (*l*)(5)…	➢ Bring a declaratory judgment action asserting any patent listed by the RPS under (*l*)(3) or (*l*)(7).
• Provide the Secretary with notice and a copy of a Complaint for patent infringement filed by the RPS per (*l*)(6)(C)…	➢ Bring a declaratory judgment action asserting any patent listed by the RPS under (*l*)(3) or (*l*)(7).
• Provide notice to the RPS at least 180 days before the date of first commercial marketing per (*l*)(8)(A)…	➢ Bring a declaratory judgment action asserting any patent listed by the RPS under (*l*)(3) or (*l*)(7).

- ***If the RPS does not*** disclose a patent on its list in (*l*)(3) or (*l*)(7), ***then the RPS may not*** bring an action for that patent under 35 USC § 271(e).
- ***If the RPS does not*** bring suit within 30 days of agreement on a patent listed under *(l)*(4), or within 30 days of the exchange of lists under *(l)*(5)*,* ***then the RPS*** is limited to the remedy of a reasonable royalty.

Interpreting the BPCIA § 262(*l*) provisions

Pioneer case for testing and understanding the § 262(k) pathway

- First biosimilar application accepted for FDA review under § 262(k) (July 7, 2014)
- First biosimilar product approved by FDA (March 6, 2015)
- Determination of parties' rights and obligations under BPCIA § 262(*l*)

Key issues:

1. What is the effect of a biosimilar applicant's failure to provide its §262(k) application and manufacturing information to the reference product sponsor within 20 days of notification that FDA has accepted the application for review?
2. When does the 180-day notice of commercial marketing begin to run?

March 13th Hearing: Tentative Conclusions

- Hearing on Amgen's Motion for Preliminary Injunction, Amgen's Motion for Partial Judgment on the Pleadings, and Sandoz's Cross-Motion for Judgment on the Pleadings
- Tentative Conclusions:
  - Deny Amgen's motions, and grant Sandoz's motion in part.
  - 1. Effect of not providing information in accordance with 262(*l*) schedule: § 262(*l*)(9) is a self-effectuating remedy; Amgen cannot use the courts to force Sandoz to participate in the patent dance.
  - 2. 180-day notice of commercial marketing: § 262(*l*)(8)(A) is a notice provision only, and should not be interpreted to extend the 12-year exclusivity period for reference products to 12.5 years, as Amgen proposes.

1. What happens when an applicant does not provide the initial disclosures under § 262(*l*)?

§ 262(*l*)(2)(A): **Subsection (k) application information**:

- *Not later than 20 days* after the Secretary notifies the subsection (k) applicant that *the application has been accepted* for review, *the subsection (k) applicant—(A) shall provide* to the reference product sponsor *a copy of the application* submitted to the Secretary under subsection (k), *and* such other information that describes the *process or processes used to manufacture* the biological product that is the subject of such application.

§ 262(*l*)(9): **Limitation on declaratory judgment action**:

- Provides different consequences depending on whether the applicant provides its subsection (k) application and manufacturing information.
- Are these the only consequences?

§ 262(*l*)(9)(A), (B): Subsection (k) application provided

If the applicant provides its application and manufacturing information:

- The RPS shall disclose a list of every patent that it might reasonably assert against the applicant's proposed product, or else lose the right to assert those patents in later litigation. 35 USC § 271(e)(6)
- If the applicant follows along with *every step* of the patent dance: neither the RPS nor the applicant can bring a declaratory judgment action before the applicant provides at least 180-days' notice of commercial marketing.
- If the applicant *stops following the patent dance steps*: the RPS may bring a declaratory judgment action on any patent it identified in its initial disclosure, plus any later issued or licensed patents that it timely identified in a supplement list.

  Steps by the applicant that will trigger the RPS's right to bring a d.j. action:

  - Not providing a detailed statement in response each patent listed by the RPS. (*l*)(3)(B)(ii); (*l*)(7)(B)
  - Not notifying the RPS of the number of patents the applicant will list under (*l*)(5), or not simultaneously exchanging the list of patents the applicant believes should be the subject of an immediate action for infringement. (*l*)(5)
  - Not providing the Secretary with notice and a copy of a Complaint for patent infringement. (*l*)(6)(C)
  - Not providing notice to the RPS at least 180 days before the date of first commercial marketing. (*l*)(8)(A)

§ 262(*l*)(9)(C): Subsection (k) application not provided

(C) Subsection (k) application not provided

- If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), *the reference product sponsor, but not the subsection (k) applicant*, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of *any patent that claims the biological product or a use of the biological product*.

Conforming Amendments: 35 U.S.C. § 271(e)

35 U.S.C. § 271(e)(2)(C): creates the technical act of infringement for jurisdiction: It shall be an act of infringement to submit—

- (i) with respect to a patent that is identified in the list of patents described in section 351(*l*)(3) of the Public Health Service Act (including as provided under section 351(*l*)(7) of such Act), an application seeking approval of a biological product, or
- (ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(4): Remedies for an act of infringement under (2)

- Injunctive relief
- Damages/other monetary relief
- Permanent injunction (only if final court decision before FDA approval of biosimilar)

What is the consequence of an applicant's failure to provide its application and manufacturing information within 20 days of acceptance at FDA?

- **Amgen**: the reference product sponsor ("RPS") can seek a court order requiring the applicant to provide the information and comply with the information disclosure provisions of § 262(*l*).
  - Absent a private right of action under the BPCIA to enforce the provisions of § 262(*l*), state laws can provide a legal mechanism by which to enforce the BPCIA information exchange procedures.
- **Sandoz**: the applicant faces only those consequences spelled out in 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e).
  - Per 42 U.S.C. § 262(*l*)(9)(C), the RPS can 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; and
  - Per 35 U.S.C. §§ 271(e)(2),(4), the RPS can bring an action for patent infringement of any patent it might have listed under the patent dance (§§ 262(*l*)(3),(7)), seeking injunctive relief and monetary damages.

Amgen: The § 262(*l*) disclosure provisions are mandatory, and can be enforced through external remedies.

Amgen:

- Mandatory language: the § 262(*l*) disclosure provisions use the word "shall," refer to "information *required* under paragraph (2)(A)," and refer to non-compliance with the disclosure provisions as a "failure."
- Statutory Scheme: § 262(*l*)(9)(C) cannot be the only remedy because it does not permit the RPS to bring infringement suits for patents on methods of manufacturing, which are critical to biologics regulation.
  - § 271(e)(2) and (e)(4) don't remedy this because they are unclear on whether the RPS can bring suit for methods of manufacturing patents.
- Congressional intent / Policy: Unless the disclosure of manufacturing information is mandatory under § 262(*l*)(2), there is no way for a reference product sponsor to know which patents it can reasonably assert.

Sandoz: The § 262(*l*) provisions are optional, and the alternatives are spelled out in the BPCIA and conforming amendments.

Sandoz:

- "Shall" is not so restrictive—for each step under § 262(*l*), the statute itself provides the consequences of choosing an alternative route.
  - Amgen's reading would lead to absurd results.
- 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e) clearly contemplate that applicants may choose not to provide the initial disclosure under §262(*l*)(2), and these provisions provide the only remedies available for the RPS when the applicant chooses this alternative route.
  - In other words, the BPCIA permits applicants to *choose* the level of certainty they want regarding patent infringement issues before they launch their products.
- The RPS does not need the applicant to provide its manufacturing information in order for the RPS to bring an infringement suit.

Court: The BPCIA includes a self-effectuating remedy for an applicant's failure to provide its § 262(k) information.

Court:

- "Shall" means: "you shall do this or else" specified consequences will follow.
- Insofar as Amgen argues that the consequences provided are inadequate, that does not change what the statute says, and it is not the Court's function to re-write the statute to provide otherwise.
- § 262(*l*)(9)(C) seems to be the more likely intended remedy; it can not be that the intended remedy was to force the RPS to go search for state law claims to obtain compliance with the BPCIA exchange provisions.

2. When does the 180-day notice of commercial marketing begin to run?

§ 262(*l*) 8) Notice of commercial marketing and preliminary injunction.

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

When do the 180 days begin to run?

- **Sandoz**:
  - Immediately upon service of notice.
  - The term "applicant" in § 262*(l)*(8)(A) shows that notice can be served by someone with an application still pending before FDA.
  - If the "notice" provision is interpreted so that the 180 days begin to run only after FDA approval, then the notice provision would be converted to a de facto *exclusivity* provision, providing an additional 6 months of exclusivity.
- **Amgen**:
  - Not until after FDA approval.
  - The term "licensed" in § 262*(l)*(8)(A) shows that notice can be served only as to a product that has been approved by FDA.
    - Prior litigation: *Sandoz v. Amgen*
  - "Applicant" is a defined term under in § 262*(l)*, which encompasses a successful applicant who has obtained FDA approval.

When do the 180 days begin to run?

- **Court**:
  - Inclined to rule in favor of Sandoz on this issue
  - Section (*l*)(8)(A) is entitled "*Notice* of commercial marketing"→ does not appear to be an exclusivity provision.
  - But Amgen's argument would convert the 12-year exclusivity period to 12.5 years in every case.
  - Doesn't believe that is how to read the provision.
  - Congress knows how to provide extra exclusivity when it means to.
  - Here, Congress simply intended to give Notice to allow the RPS to file for a preliminary injunction on any identified patents not already asserted in litigation.

Likely Impacts of *Amgen v. Sandoz*

- Nothing happened at the hearing that appeared likely to have moved Judge Seeborg from his tentative conclusion.
- Parties cannot be forced to participate in the patent dance, but must face the consequences that follow each exit ramp from the BPCIA provisions.
  - § 262(*l*)(9)
  - 35 U.S.C. § 271(e)
- Notice of commercial marketing may be given upon FDA acceptance of the 262(k) application.

What might we expect next?

- Decision soon, and in Sandoz's favor
  - The parties have agreed that Sandoz will hold off on launching its approved product until the earlier of April 10, 2015, or a decision in Sandoz's favor on Amgen's Motion for Preliminary Injunction.
- Immediate appeal to the Federal Circuit
  - Amgen may ask the Federal Circuit for a stay of Sandoz's launch pending appeal.
  - Amgen will likely seek an expedited appeal.
- Attempts at a legislative remedy

Private Right of Action?

- *Janssen v. Celltrion*, No. 15-cv-10698 (D. Mass., filed Mar. 6, 2015).
- Similar issues:
  - Can a court compel a § 262(k) applicant to comply with the information exchange provisions of BPCIA § 262(*l*)?
    - Different approach by Janssen: private right of action to seek a court order forcing the applicant to follow the patent dance.
  - When can a § 262(k) applicant provide its 180-day notice of commercial marketing?
- Acknowledged but not considered by the Court in *Amgen v. Sandoz*.

Questions?

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