Mid-Year Review of BPCIA Litigation

August 9, 2017

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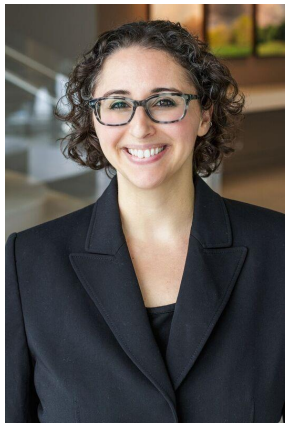

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Today's Topics

- Background on BPCIA and Biosimilars to Date
- *Amgen v. Sandoz*: Review of Supreme Court Decision
- BPCIA Issues at the Federal Circuit
- What's Trending in BPCIA District Court Litigation
- What's Trending in Biologics IPRs

Background

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Biologics Price Competition and Innovation Act

- Enacted in 2010 as part of the Affordable Care Act
- Provides an abbreviated regulatory pathway for biosimilars and interchangeables
- Lays out a patent dispute resolution framework
- Similarities and differences with the Hatch-Waxman framework

Stats to Date

- 5 FDA approved biosimilars
  - Zarxio (Neupogen biosimilar, Sandoz)
  - Amjevita (Humira biosimilar, Amgen)
  - Inflectra (Remicade biosimlar, Pfizer)
  - Erelzi (Enbrel biosimilar, Sandoz)
  - Renflexis (Remicade biosimilar, Samsung Bioepis)
- 3 commercially launched biosimilars
  - Zarxio
  - Inflectra
  - Renflexis
- No interchangeables approved to date
- 20 litigations thus far involving biologics/biosimilars and the BPCIA

SCOTUS: *Amgen v. Sandoz*

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Amgen v. Sandoz: SCOTUS

SCOTUS Issue #1: Enforcement of Patent Dance, § 262(l)(2)(A)

- Is the requirement that an applicant provide its application and manufacturing information to the manufacturer if the biologic is enforceable by injunction?
  - No.

SCOTUS Issue #2: Notice of Commercial Marketing, § 262(l)(8)(A)

- Must the applicant give notice to the manufacturer after, rather than before, obtaining a license from the FDA for its biosimilar?
  - No.

Amgen v. Sandoz: District Court

District Court Litigation

- Sandoz gives notice of commercial marketing of a biosimilar of Amgen's Neupogen® (filgrastim)
- Sandoz does not provide its BLA and manufacturing information to Amgen; declines to dance
- Amgen's Claims:
  - Unfair Competition under CA Bus. & Prof. Code § 17200
  - Conversion under CA common law
  - Patent Infringement under 35 U.S.C. § 271(e)(2)(C)(ii)
- District Court Outcome:
  - Sandoz not required to exchange BLA and manufacturing information;
  - Providing notice of commercial marketing before approval is permitted;
  - Unfair Competition Law ("UCL") and conversion claims dismissed because Sandoz did not violate BPCIA

Amgen v. Sandoz: Federal Circuit

A divided panel ruled:

1) The information exchange and "patent dance" procedures were optional and that a biosimilar applicant could choose not to engage in them
2) Sandoz did not violate BPCIA and BPCIA provides exclusive remedies for failure to dance, affirming dismissal of UCL and conversion claims
3) The 180-day notice requirement was mandatory, ***at least*** for applicants who had opted out of the patent dance, and that only a notice given ***after*** FDA approved the aBLA would be effective to start the 180-day clock.

Federal Circuit denied rehearing

- Petition for certiorari submitted by Sandoz appealing notice decision
- Amgen opposed cert. and added in conditional cross issue that dance should not be optional

Amgen v. Sandoz: SCOTUS Issue #1

SCOTUS Issue #1: Enforcement of Patent Dance, § 262(l)(2)(A)

- Is the requirement that an applicant provide its application and manufacturing information to the manufacturer of the biologic is enforceable by injunction?
  - No.

Amgen v. Sandoz: SCOTUS Issue #1

42 U.S.C. §262(*l*)(2)(A):

Within 20 days after FDA has accepted a biosimilar application for review, the applicant "shall provide to the reference product sponsor a copy of the application . . . and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application"

42 U.S.C. §262(*l*)(9)(C):

If the applicant "fails to provide the application and information required under paragraph (2)(A)," only the reference product sponsor "may 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."

Amgen v. Sandoz: SCOTUS Issue #1

- § 262(*l*)(2)(A) information exchange is not enforceable by injunction under federal law.
- § 262(*l*)(9)(C) provides the exclusive federal remedy for an applicant's failure to turn over its BLA and manufacturing information.
- The presence of this remedy coupled with the absence of other remedies suggest Congress did not intend for other federal remedies to enforce the disclosure requirement.

Amgen v. Sandoz: SCOTUS Issue #1

- Rejects Federal Circuit rationale:
  - Failure to disclose application and manufacturing information is not an act of infringement under § 271(e)(2)(C)(ii).
  - Rather, biosimilar's aBLA submission to the FDA is the act of artificial infringement.
  - Therefore, § 271(e)(4), which provides the "only remedies" for an act artificial infringement, does not apply to failure to exchange information § 262(*l*)(2)(A).

Amgen v. Sandoz: SCOTUS Issue #1

- SCOTUS declines to resolve mandatory v. conditional nature of information exchange.
    - The federal scheme is clear depending on whether exchanges are made or not (immediate DJ under § 262(*l*)(9)(C)).
- Remand to Federal Circuit to decide if an injunction is available under state law to enforce § 262(*l*)(2)(A).
    - Look at state law to determine if violation of § 262*(l)(*2)(C) is "unlawful"
    - If the violation is "unlawful" under state law, must determine whether any state law remedies are pre-empted by BPCIA.

Amgen v. Sandoz: SCOTUS Issue #2

SCOTUS Issue #2: Notice of Commercial Marketing, § 262(l)(8)(A)

- Must the applicant give notice to the manufacturer after, rather than before, obtaining a license from the FDA for its biosimilar?
  - No.

Amgen v. Sandoz: SCOTUS Issue #2

- An applicant may provide notice of commercial marketing before obtaining a license.
  - § 262(l)(8)(A) contains a single timing requirement of 180 days before marketing.
  - "Commercial marketing" is the point in time by which the product must be licensed; product need not be licensed at the time notice is given.

Amgen v. Sandoz: Other Takeaways

- SCOTUS does not decide whether violation of § 262(*l*)(2)(A) or any other BPCIA provision can be considered in deciding preliminary injunction motion.

In holding that § 262(*l*)(9)(C) represents the exclusive remedy for an applicant's failure to provide its application and manufacturing information, we express no view on whether a district court could take into account an applicant's violation of § 262(*l*)(2)(A) (or any other BPCIA procedural requirement) in deciding whether to grant a preliminary injunction under 35 U.S.C. § 271(e)(4)(B) or § 283 against marketing the biosimilar. See *Winter v. Natural Resources Defense Council, Inc.,* 555 U.S. 7, 20, 129 S.Ct. 365, 172 L.Ed.2d 249 (2008) (court should consider "balance of equities" in deciding whether to grant a preliminary injunction).

Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664, 1675 (2017)

Amgen v. Sandoz: Next Steps

- **June 12, 2017**: SCOTUS Opinion
- **July 26, 2017:** Federal Circuit vacated its prior opinion and requested simultaneous supplemental briefing
- **August 23, 2017**: Current due date for supplemental briefing at the Federal Circuit
- Underlying district court case ongoing

Amgen v. Sandoz: Next Steps

Parties will brief whether….

(1) the BPCIA preempts additional remedies under state law for an applicant's failure to comply with 42 U.S.C. § 262(*l*)(2)(A);

(2) Sandoz has waived any preemption defense; and

(3) California law would treat noncompliance with 42 U.S.C. § 262(*l*)(2)(A) as "unlawful" under Cal. Bus. & Prof. Code § 17200.

California Unfair Competition Law

"As used in this chapter, unfair competition shall mean and include any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising . . ." § 17200

"Any person who engages, has engaged, or proposes to engage in unfair competition may be enjoined in any court of competent jurisdiction." § 17203

"Actions for relief pursuant to this chapter shall be prosecuted exclusively in a court of competent jurisdiction . . . upon the complaint of a board, officer, person, corporation, or association, or by a person who has suffered injury in fact and has lost money or property as a result of the unfair competition." § 17204

Background: Unfair Competition Allegations

- Business Practice:
  - Filing BLA seeking approval to commercially market biosimilar product

- Potential "Unlawful" Conduct:
  - Sandoz violated 42 U.S.C. § 262(*l*)(2)(A) by failing to comply with its disclosure requirements
  - Sandoz violated 42 U.S.C. § 262(*l*)(8)(A) by failing to comply with notice requirements (based on Amgen's view notice could only be provided after FDA approval)

Background: Unfair Competition Allegations

- Amgen's Alleged Injury in Fact:
  - Sandoz didn't provide the information Amgen needed to identify patents and infringement claims, thereby delaying litigation and threatening to deprive Amgen of sufficient time to seek a preliminary injunction to avoid irreparable harm
  - Economic injury in the form of lost money spent dealing with Sandoz's unfair competition
  - Economic injury in the form of lost profits and increased costs if Sandoz enters the market
  - Economic injury in the loss of value of their patents by delaying their assertion
- Remedies requested:
  - An injunction prohibiting Sandoz from marketing, selling, offering to sell or importing its filgrastim product
  - Restitution for Amgen's losses as a result of unfair practices

Violations of Law Are "Unlawful" – But Where?

Under California's UCL, "virtually any state, federal or local law can serve as the predicate for an action." *E.g.*, *Podolsky v. First Healthcare Corp.* 50 Cal.App.4th 632, 647 (1996).

But, as Sandoz notes, "California's UCL is unique among state unfair and deceptive trade practices acts because it is the only such act that prohibits activity that is allegedly 'unlawful' under another state or regulation."

Did Sandoz Violate the BPCIA?

Federal Circuit:

"We therefore conclude that, even though under paragraph (*l*)(2)(A), when read in isolation, a subsection (k) applicant would be required to disclose its aBLA and the manufacturing information to the RPS by the statutory deadline, we ultimately conclude that when a subsection (k) applicant fails the disclosure requirement, 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e) expressly provide the only remedies as those being based on a claim of patent infringement. Because Sandoz took a path expressly contemplated by the BPCIA, it did not violate the BPCIA by not disclosing its aBLA and the manufacturing information by the statutory deadline."

Did Sandoz Violate the BPCIA?

SCOTUS:

"Under § 262(*l*), an applicant that seeks FDA approval of a biosimilar must provide its application materials and manufacturing information to the manufacturer of the corresponding biologic within 20 days of the date the FDA notifies the applicant that it has accepted the application for review."

"The first question presented by these cases is whether the requirement that an applicant provide its application and manufacturing information to the manufacturer of the biologic is enforceable by injunction."

"To encourage parties to comply with its procedural requirements, the BPCIA includes various consequences for failing to do so."

"In holding that § 262(*l*)(9)(C) represents the exclusive remedy for an applicant's failure to provide its application and manufacturing information, we express no view on whether a district court could take into account an applicant's violation of § 262(*l*)(2) (A) (or any other BPCIA procedural requirement) in deciding whether to grant a preliminary injunction under 35 U.S.C. § 271(e)(4)(B) or § 283 against marketing the biosimilar."

SCOTUS on Preemption

On remand, the Federal Circuit should determine whether California law would treat noncompliance with § 262(*l*)(2)(A) as "unlawful." If the answer is yes, then the court should proceed to determine whether the BPCIA pre-empts any additional remedy available under state law for an applicant's failure to comply with § 262(*l*)(2)(A) (and whether Sandoz has forfeited any pre-emption defense, see 794 F.3d, at 1360, n. 5). The court is also of course free to address the pre-emption question first by assuming that a remedy under state law exists.

Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664, 1676–77 (2017)

Preemption Analysis

Two cornerstones of federal preemption analysis.

1. “First, the question of preemption fundamentally is a question of congressional intent.”

2. “Second, in all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress. This is known as the presumption against preemption, and its role is to provide assurance that the federal-state balance will not be disturbed unintentionally by Congress or unnecessarily by the courts.”

People ex rel. Harris v. Pac Anchor Transp., Inc., 59 Cal. 4th 772, 778 (2014) (internal citations removed).

Forms of Preemption

1. Express Preemption: “Where Congress expressly specifies that its enactment preempts state law.”
2. Field Preemption: “Where the scheme of federal regulation is so pervasive that there is a reasonable inference Congress intended to dominate the field and state laws on the same subject are precluded.”
3. Conflict Preemption: “Where federal law actually conflicts with state law and it is impossible for a private party to comply with both requirements.”
4. Obstacle Preemption: “When state law stands as an obstacle to the full accomplishment and execution of congressional objectives.” *People ex rel. Harris v. Pac Anchor Transp., Inc.*, 59 Cal. 4th 772, 778, 329 P.3d 180, 184 (2014).

Federal Circuit Cases

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Federal Circuit: *Amgen v. Hospira*

- Drug at issue: Epogen® biosimilar
- BPCIA action filed September 2015 in D. Delaware
- Appeal Issue according to Amgen: "[t]he issue on appeal is not whether the discovery Amgen seeks is relevant; rather, the issue is whether Amgen is nevertheless entitled to the discovery as a matter of law under the BPCIA, even though it is irrelevant to the pending patent claims."
- Fully briefed; oral arguments held April 3, 2017

Federal Circuit: *Amgen v. Hospira*

Background of the case

- Patent Dance:
  - Hospira produced its aBLA during the patent dance
  - Amgen claimed Hospira refused to produce other manufacturing information as required under the BPCIA (262(*l*)(2)(A))
  - Amgen did not list any cell culture patents on its 3(A) list
- District Court
  - Amgen sought discovery into additional manufacturing to identify other infringed patents
  - Hospira refused the discovery
  - Amgen moved to compel
  - Judge Andrews of D. Delaware denied the motion to compel
- Amgen appealed (CAFC-16-2179)

Federal Circuit: *Amgen v. Hospira*

Background of the case, cont.

Federal Circuit:

- Motion to Dismiss the Appeal Based on Lack of Jurisdiction:
  - The Federal Circuit denied Hospira's motion to dismiss the appeal, but left open the question of jurisdiction
- Merits Briefing:
  - Amgen: denial of discovery "threatens to undermine the entire balance of the BPCIA"
  - Hospira: this is a simple discovery dispute governed by FRCP 26
- Oral Argument:
  - Panel: Dyk, Bryson, Chen

Federal Circuit: *Amgen v. Apotex*

- Drug at issue: Neulasta® and Neupogen® biosimilars
- BPCIA action filed October 2015 in the Southern District of Florida
- First completed BPCIA litigation on the merits of a patent dispute
- District court found that Apotex's biosimilar manufacturing processes did not infringe U.S. Patent 8,952,138
- Amgen's appeal (CAFC-17-1010):
  - Claim construction issues
  - Whether pre-litigation representations made by the biosimilar manufacturer are binding for the infringement analysis under the BPCIA
- Briefing completed in January 2017; oral arguments not yet scheduled
- IPR instituted on the patent-at-issue in February 2017

Federal Circuit: *Amgen v. Apotex*

Background of the case:

- '138 patent:

1. A method of refolding a protein expressed in a non-mammalian expression system and present in a volume at a concentration of 2.0 g/L or greater comprising:
(a) contacting the protein with a refold buffer comprising
a redox component comprising
a final thiol-pair ratio having a range of 0.001 to 100 and
a redox buffer strength of 2 mM or greater
and one or more of:
(i) a denaturant;
(ii) an aggregation suppressor; and
(iii) a protein stabilizer;
to form a refold mixture;
(b) incubating the refold mixture; and
(c) isolating the protein from the refold mixture.

Federal Circuit: *Amgen v. Apotex*

Background of the case, cont.:

- Apotex's Claim Construction Position:
  - "Refold mixture" = A mixture formed from contacting the protein and the refold buffer"
  - Argued that "a protein is present at a concentration of 2.0 g/L or greater *after dilution in a refold mixture."*

Claim Term	Court's Construction
"refold mixture"	A mixture formed from contacting (1) the volume in which the concentration of protein is 2.0g/L or greater with (2) the refold buffer. The refold mixture has a high protein concentration, where "high protein concentration" is at or above about 1g/L protein.

Federal Circuit: *Amgen v. Apotex*

Background of the case, cont.:

- Apotex's representations
  - In 262(*l*)(3)(B) statements, said refold mixture was 0.9-1.4 g/L of filgrastim
  - In rebuttal case, stated that its refold mixture had a washed inclusion-body concentration of 0.9-1.4 g/L, but 2/3 was water and therefore total protein was 0.3-0.5 g/L
- Amgen response:
  - aBLA did not limit protein concentration to non-infringing range
  - Washed inclusion-body concentration should equal protein concentration
  - 262(*l*)(3)(B) statements should be given weight
- District Court adopted Apotex's final theory in finding non-infringement

Federal Circuit: *Amgen v. Apotex*

Background of the case, cont.:

- Potential implications for future BPCIA litigants:
  - (1) is the infringement analysis in a BPCIA litigation governed by the disclosures in the aBLA?
  - (2) are statements made by biosimilar applicants under 42 U.S.C. § 262(*l*)(3)(B) of the BPCIA "optional pre-litigation letters" or binding party admissions?

Federal Circuit: *Janssen*

- *Janssen v. Celltrion* (17-1120) and *In re Janssen* (17-1257):
  - The two appeals "will be considered companion cases and assigned to the same merits panel for oral argument."
- Drug at issue: Remicade® biosimilar
- BPCIA action filed March 2015 in D. Massachusetts
- District court ruled that U.S. Patent 6,284,471 was invalid for double patenting
- PTAB also found '471 patent invalid for double patenting
- Briefing completed June 2017; oral arguments not yet scheduled

Federal Circuit: *Janssen*

Background of the case:

- District court granted Janssen's motion to amend protective order
  - Janssen could use information produced by Celltrion under the PO to file a new case against HyClone, a third party cell culture media supplier for Celltrion's biosimilar product
- District court granted Celltrion's motion for summary judgment that all claims of the '471 patent are invalid for obviousness-type double patenting (August 2016)
  - *Gilead* theory re later issued, earlier expiring patents
  - "Safe Harbor" theory re 35 U.S.C. § 121
- District court entered partial final judgment of invalidity of the '471 patent (September 2016)
- Janssen appealed invalidity rulings to the Federal Circuit

District Court Litigation

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Active District Court Litigations

Case	Reference Biologic	Current Status
Amgen v. Sandoz (N.D.Cal. 14-cv-4741;16-cv-02581)	Neupogen® (filgrastim); Neulasta® (pegfilgrastim)	• Remand from SCOTUS • Claim construction complete • Trial scheduled for March 2018
Janssen v. Celltrion (D.Mass. 15-cv-10698; 16-cv-11117; 17-cv-11008)	Remicade® (infliximab)	• Invalidity of '471 patent on appeal • Claim construction complete • Trial 2/2017 delayed • Motion to dismiss for lack of standing filed 7/11/2017
Amgen v. Apotex (S.D.Fla. 15-cv-61631; 15-cv-62081)	Neupogen® (filgrastim); Neulasta® (pegfilgrastim)	• On Appeal
Amgen v. Hospira (D. Del. 15-cv-839)	Epogen® (epoetin alfa)	• Dispositive motions pending • Trial scheduled for 9/18/2017
Immunex v. Sandoz (D.N.J.16-cv-1118)	Enbrel® (etanercept)	• Consent PI entered • Expert discovery closes 1/12/18. • Trial scheduled for April 2018

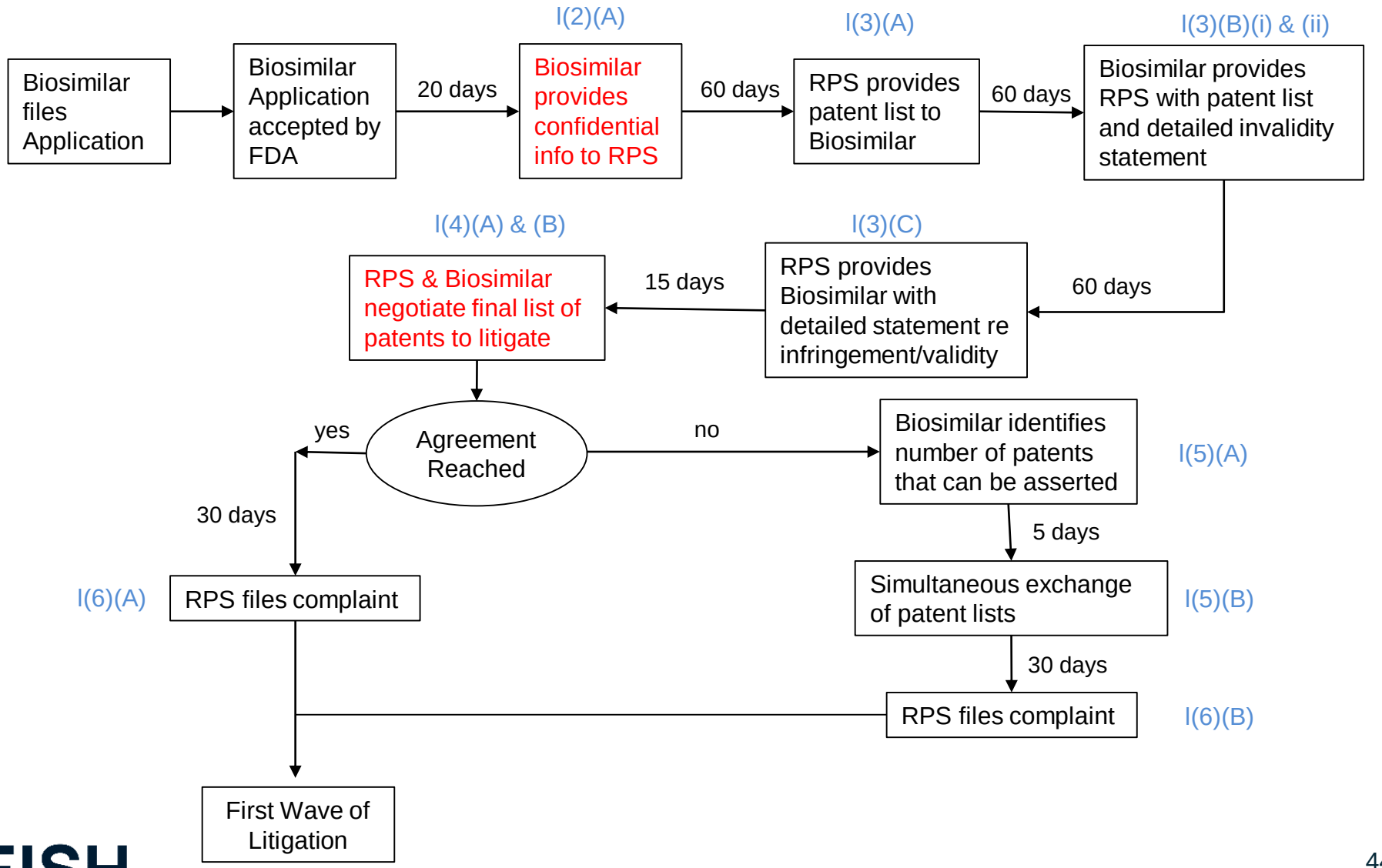
Active District Court Litigations *cont.*

Case	Reference Biologic	Current Status
Janssen v. Hyclone (D.Utah 16-cv-00071)	Remicade® (infliximab)	• Stayed pending completion of trial in *Janssen v. Celltrion* or other disposition at district court level
AbbVie v. Amgen (D.Del. 16-cv-00666)	Humira® (adalimumab)	• Involves 10 patents out of over 60 identified during patent dance • Fact discovery closes Jan. 2018 • Trial scheduled for Nov. 2019
Amgen v. Coherus (D.Del. 17-cv-546)	Neulasta® (pegfilgrastim)	• Motion to dismiss pending • Motion to stay pending
Janssen v. Samsung Bioepis (D.N.J. 17-cv-03524)	Remicade® (infliximab)	• Answer filed July 21, 2017
AbbVie v. Boehringer Ingelheim (D. Del. 17-cv-01065)	Humira® (adalimumab)	• Complaint filed August 2, 2017 • Involves 8 of the 74 patents identified during the patent dance

Key Issues in BPCIA District Court Litigation

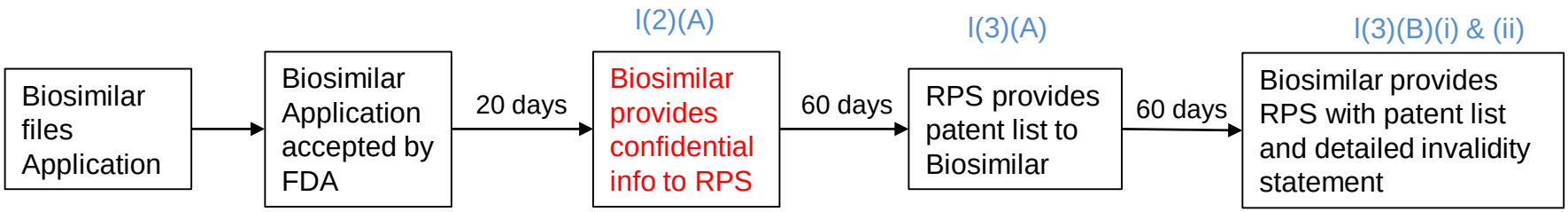
- Disclosures during Patent Dance (2(A))
- Skipping Parts of the Patent Dance
- Scope of Discovery in BPCIA Litigation

The BPCIA Patent Dance-First Wave



Scope of Information Provided under 2(A)

- § 262(l)(2)(A):
  - 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 **shall provide to the [RPS] a copy of the** [abbreviated biologic license application (**aBLA**)] 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 the [aBLA.]



Scope of Information Provided under 2(A)

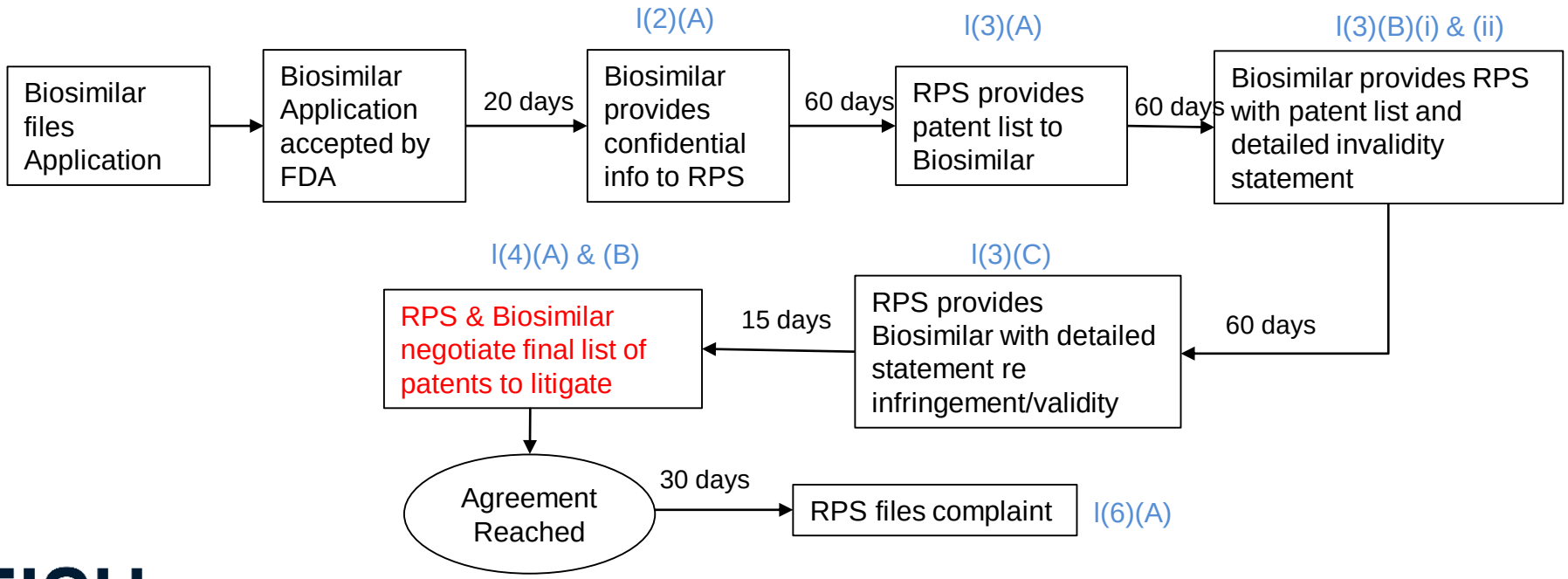
- What constitutes sufficient disclosure?
  - The type and amount of information disclosed has varied between BPCIA cases
- Type of access to aBLA submissions
  - File transfer links to electronic files in eCTD format
  - Remote access to a Sandoz-hosted database of TIFF images, modified to include added confidentiality designation

Scope of Information Provided under 2(A)

- Manufacturing Information
  - Celltrion provided Janssen with a copy of its entire aBLA for an infliximab biosimilar, but refused to disclose additional information relevant to the manufacture of its biosimilar.
  - Hospira provided Amgen its entire aBLA for an epotetin alfa biosimilar
    - Over 507 native files as well as 747,000 additional pages of information concerning Hospira's product and the process employed to make it
    - Amgen not satisfied
  - Genentech sought a declaratory judgment and an accompanying order that Amgen's § 262(l)(2)(a) disclosure of its aBLA for a bevacizumab biosimlar (which omitted manufacturing information) was insufficient.

Skipping Parts of the Dance

- Waiving negotiation process of 262(l)(4) and (5)
  - *E.g., Immunex v. Sandoz* (Enbrel®); *Amgen v. Hospira* (Epogen®); *Janssen v. Celltrion* (Remicade®)
- What are the ramifications?



Skipping Parts of the Dance

- § 262(*l*)(6)(A): 30 day window for filing a complaint under the BPCIA
- § 271(e)(6)(B): if a suit is brought later than 30 days or dismissed without prejudice, then "the sole and exclusive remedy" is a reasonable royalty

- *Janssen v. Celltrion*
  - Standing issues
  - Celltrion short-circuited the patent dance by skipping the negotiation steps of § 262(*l*)(4)(A) and (5)
  - District Court: only the list of patents that emerge from the properly completed BPCIA "are potentially subject to the reasonable royalty damages limitation."
    - The 30-day clock was never triggered.
    - Janssen can cure standing without being limited to a reasonable royalty.

Scope of Discovery in BPCIA Litigation

- Sandoz's Neulasta® (pegfilgristam) biosimilar not yet FDA approved
- Amgen seeks discovery into Sandoz's projected sales and marketing strategies for pegfilgristam and when it intends to enter the market
- Sandoz opposes:
  - No monetary damages available until FDA approval
  - Discovery not needed for an injunction, especially because "the likelihood of future harm is not in dispute"
- Amgen's response:
  - Current PO adequately protects Sandoz
  - The issue is whether the information is relevant, not the merits of an injunction
- Magistrate Judge sided with Amgen, unless there is a bifurcation of liability and injunction issues
- Sandoz has moved to bifurcate and stay discovery order

Scope of Discovery in BPCIA Litigation

- Sandoz received a CRL for its pegfilgrastrim biosimilar application
- Amgen sought discovery into "existing and proposed changes to the manufacturing and purification process" used by Sandoz
- Sandoz wanted only limited discovery into the accused "anion exchange" step
- Magistrate Judge sided with Sandoz – discovery is limited to the anion exchange step.
  - Broader discovery not "proportional to the needs of this case."

Scope of Discovery in BPCIA Litigation

- Amgen (biosimilar applicant) moved to compel validity/invalidity information disclosed during AbbVie's patent dances with other biosimilar applicants:
  - Validity/Invalidity positions are not confidential
  - That fact that aBLAs were filed is likely not confidential, and regardless, protected by the PO
  - Patent dance exchanges are not akin to "settlement negotiations"
- AbbVie opposed:
  - 3B and 3C statements protected under the BPCIA
  - AbbVie proposes "notice and opportunity for any third party to object and intervene," not a court ordering production
  - Exchange materials are only marginally relevant ("Such materials would not be evidence generated by percipient witnesses of the parties. They would be prepared by and exchanged between counsel.")
  - Amgen does not need to "piggyback"– it has access to the same materials.
- Decision unknown at this point

IPRs

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IPR Petitions Filed

IPR PETITIONS FILED

Drug	2013	2014	2015	2016	2017	Total by Drug
Avastin (bevacizumab)	0	0	0	1	0	1
CroFab (crotalidae polyvalent immune fab)	0	1	1	0	0	2
Dupixent (dupilumab)	0	0	0	0	3	3
Elaprase (idursulfase)	0	0	1	0	0	1
Enbrel (etanercept)	0	0	1	0	1	2
Epogen / Procrit (epoetin alfa)	1	0	0	0	0	1
Gattex (tedeglutide)	0	0	2	0	0	2
Herceptin (trastuzumab)	0	0	0	2	17	19
Humira (adalimumab)	0	0	7	1	8	16
Kadcyla (ado-trastuzumab emtansine)	0	2	0	0	0	2
Myozyme / Lumizyme (alglucosidase alfa)	3	0	0	0	0	3
Neulasta (pegfilgrastim)	0	0	0	1	0	1
Orencia (abatacept)	0	0	1	0	0	1
Rituxan (rituximab)	0	3	2	2	10	17
Tysabri (natalizumab)	0	0	0	3	0	3
Cabilly Patent	0	0	2	4	0	6
CSL830	0	0	0	0	1	1
Lantus (insulin glargine)	0	0	0	0	2	2
Unknown product	0	0	0	1	5	6
Total by Year	4	6	17	15	47	89

IPR Stats

- Most challenges: Herceptin®, Humira®, and Rituxin®
  - 17 Herceptin® patent challenges in 2017 alone
- IPR petitions so far in 2017 have tripled all of 2016
- Common for multiple petitions by the same challenger
  - E.g., Hospira brought 6 IPRs on Herceptin patents (4 were instituted, 2 were denied)
  - Hospira has also filed IPRs related to other biologics
- Of those IPRs with a final written decision:
  - Roughly a quarter upheld as valid
  - Roughly three quarters invalidated

Questions?

FISH.

Thank you!

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