PROGRAM MATERIALS
Program #29208
November 18,2019

Navigating Patent Thickets in BPCIA Litigation

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Navigating Patent Thickets in BPCIA Litigation

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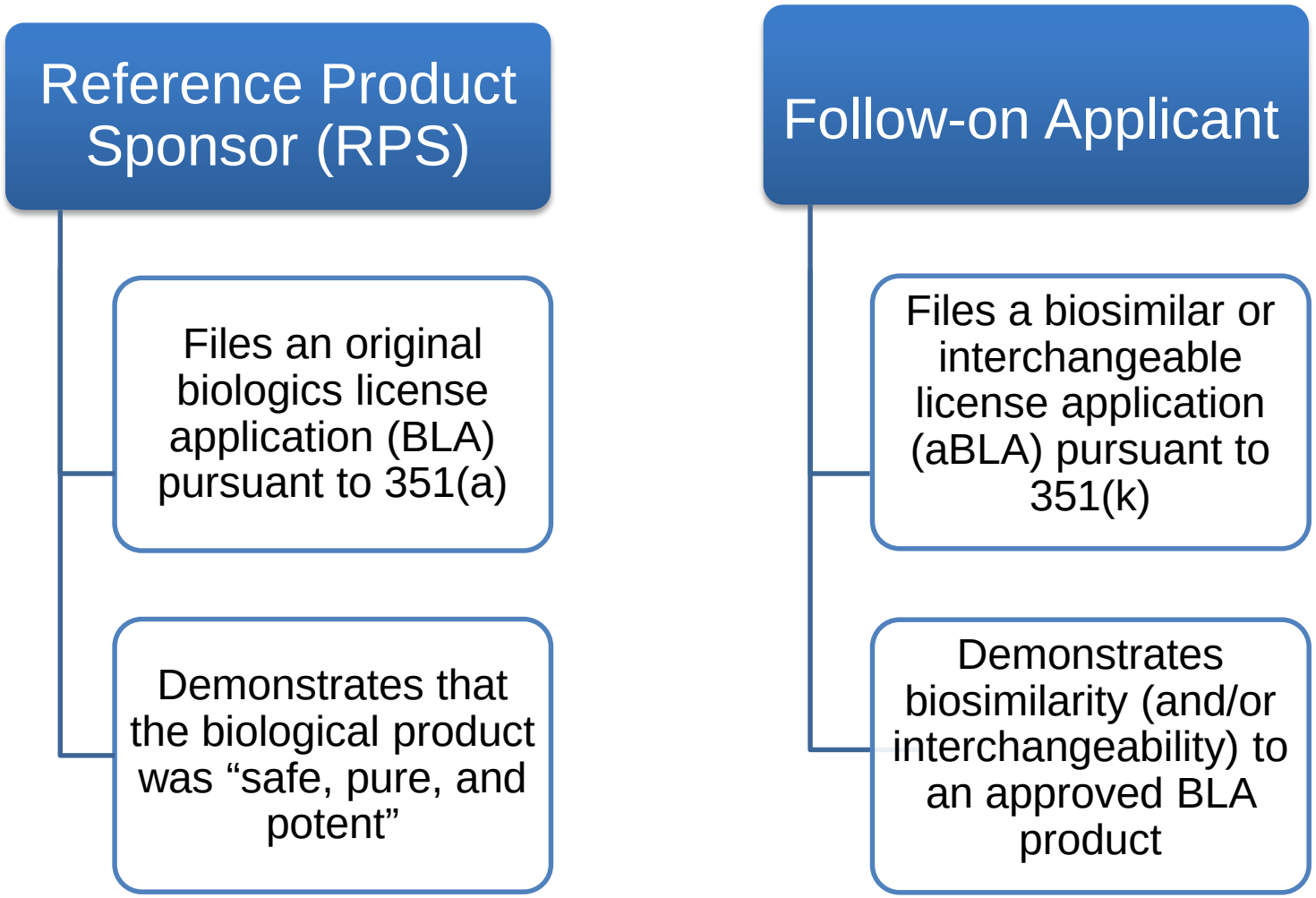
November 18, 2019

What is the BPCIA?

- Biologics Price Competition and Innovation Act of 2009
  - Section 351 of the Public Health Service Act (42 U.S.C. § 262)
  - Passed in March, 2010 as part of the Affordable Care Act
  - The BPCIA provides an abbreviated pathway for companies to bring follow-on biologic drugs to market
    - Biologic drugs are complex molecules (e.g., proteins such as antibodies and vaccines) made from living organisms
    - Relying on clinical studies performed by reference product sponsors of “brand” biologic drugs provides a shorter pathway to approval by the Food and Drug Administration (FDA)
    - Developers of follow-on biologics can seek one of two designations, “biosimilar” or “interchangeable”

Biological Product Definitions, U.S. Food & Drug Administration

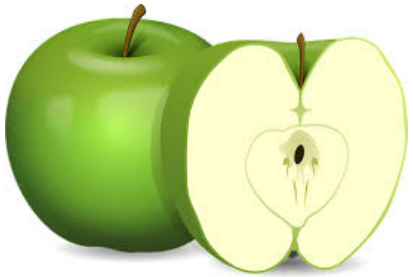
The Players



US Food and Drug Administration, *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product – Guidance for Industry* (April 2015)

Hatch-Waxman and BPCIA

Similar but Different



Hatch-Waxman

- Abbreviated pathway for small molecule pharmaceuticals
- Filing of ANDA creates cause of action
- Notice Letter based on patents identified by Originator and available in the Orange Book

- RPS initially controls number of asserted patents
- Patents limited to product/method of use

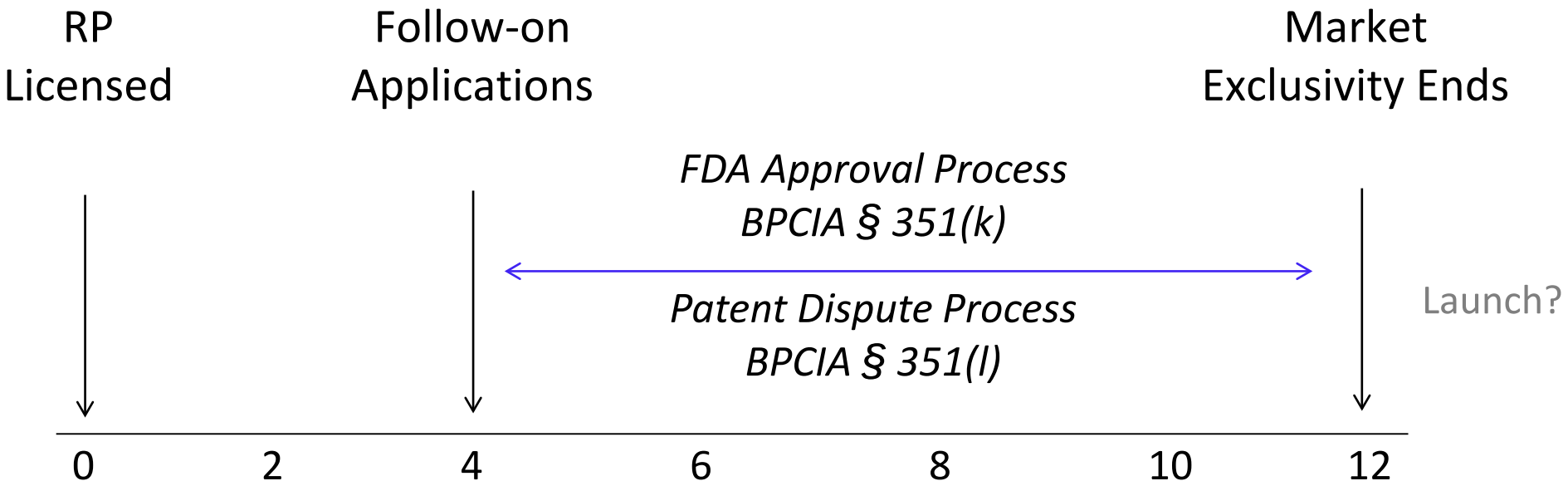
BPCIA

- Abbreviated pathway for follow-on biologics (biosimilars and interchangeables)
- Filing of aBLA creates cause of action
- Detailed Statement based on patents identified by RPS after starting the patent dance

- Follow-on applicant initially controls number and timing of asserted patents
- Manufacturing patents may be litigated

BPCIA "Aspirational" Timeline: Approvals & Patent Disputes

- Applications may not be submitted until 4 years after RP licensed
- Licenses "may not be made effective" until 12 years after RP licensed



Licensure of Biological Products as Biosimilar or Interchangeable

- 42 U.S.C. § 262(k) (or 351(k)) Application (aBLA)
  - Application filed with the FDA when pursuing the abbreviated biologics pathway
  - Demonstrates biosimilarity or interchangeability to a reference biological product
    - Biosimilar:
      - The biological product is **highly similar** to the reference product notwithstanding minor differences in clinically inactive components; and
      - There are **no clinically meaningful differences** between the biological product and the referenced product in terms of the safety, purity, and potency of the product. (42 USC § 262(i)(2).)
    - Interchangeable:
      - The biological product meets the requirements for biosimilarity to the reference product; and
      - Is expected to produce the same clinical result as the reference product in any given patient; and
      - When administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and reference product is not greater than the risk of using the reference product without alternating or switching. (42 USC § 262(k)(4).)

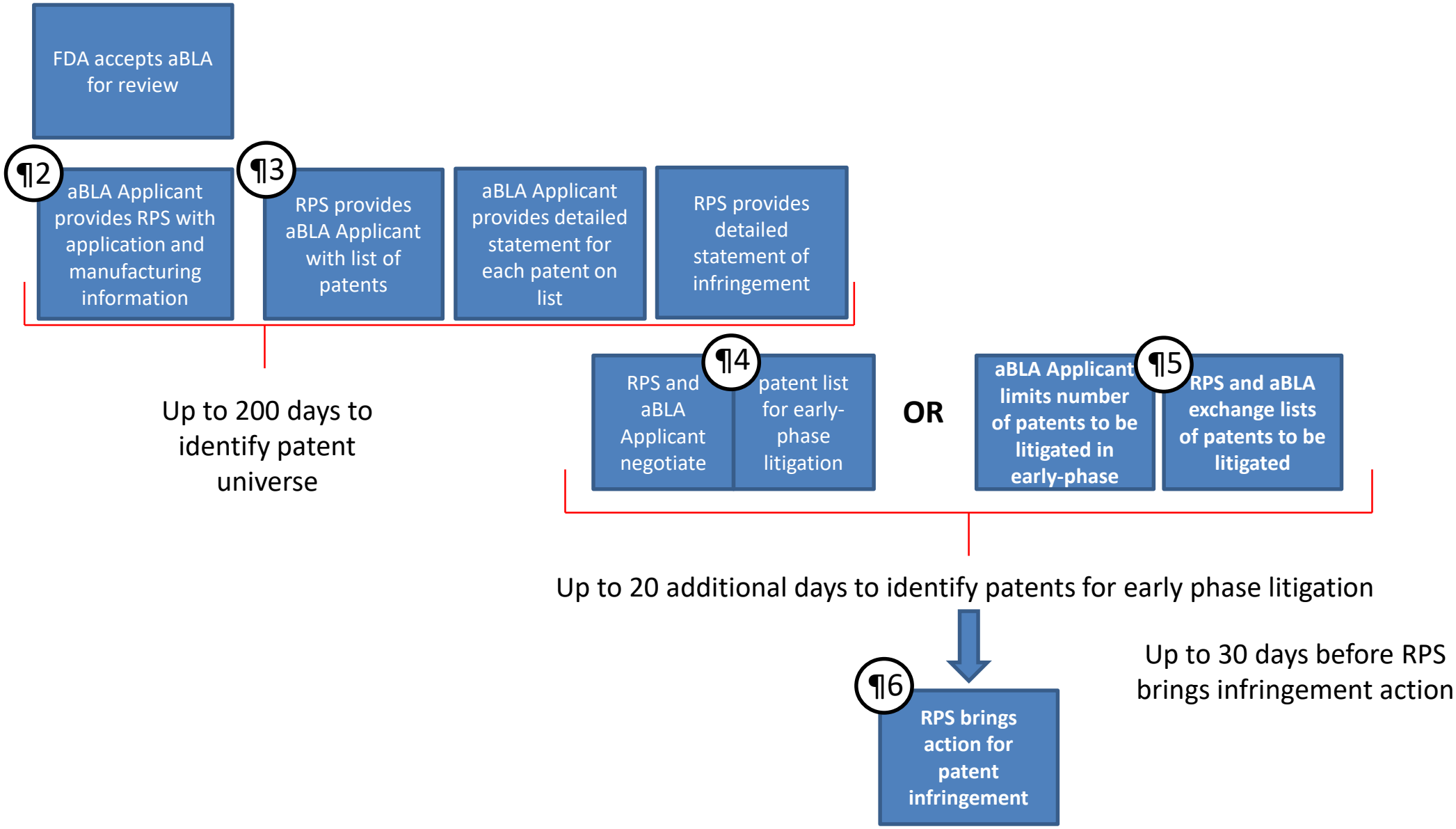
42 U.S.C. § 262(l)
Patents

- 42 U.S.C. § 262(l) (or 351(l)) outlines the steps for resolving patent disputes
  - Patent dispute resolution is divided into two litigation phases
    - Early phase litigation
      - Begins when the aBLA is accepted by the FDA for review, which can constitute a “technical act of infringement”
      - Exchange of patent lists (often referred to as the “patent dance”)
      - Culminates with a Complaint asserting the patents agreed to during the patent dance, which is often a subset of patents that could have been asserted
    - Late phase litigation
      - Typically is triggered by a notice of commercial marketing
        - Litigation of any patents not included in the early phase litigation
        - Litigation of any newly issued or licensed patents

BPCIA SECTION "*l*" PROVISIONS (42 U.S.C. § 262(*l*))

Paragraph	Subsection	
2	(A)	aBLA applicant provides the aBLA "and such other information that describes the process or processes used to manufacture . . . ."
3	(A)	No later than 60 days after, RPS provides list of patents for which infringement could reasonably be asserted
	(B)	No later than 60 days after, Applicant provides detailed statement re: RPS patents listed
	(C)	No later than 60 days after, RPS responds with claim-by-claim infringement contentions
4	(A)	Parties must undertake good-faith negotiating (15 days) on which patents to be asserted in the paragraph 6 litigation
	(B)	If no agreement after 15 days, then paragraph 5 applies
5	(A)	Applicant notifies RPS of number of patents from 3(A) list to litigate
	(B)	Five days after 5(A) number of patents provided, parties simultaneously exchange lists of patents for paragraph 6 (early phase) litigation • (ii)(I) – RPS cannot list more patents than number provided by aBLA applicant per 5(A) • (ii)(II) – If Applicant does not list any patents, RPS can list one patent
6	(A)	If parties reach 4(A) agreement, litigation to be commenced within 30 days
	(B)	If no 4(A) agreement, RPS shall bring action within 30 days on all patents on 5(B) lists
7		Newly issued or licensed patents can be added to the 3(A) list within 30 days of issuance/licensing • Applicant to provide a 3(B) detailed statement 30 days later • New patents can be asserted in suits brought under 8(B).
8	(A)	Applicant shall provide notice no later than 180 days before first commercial marketing of aBLA product
	(B)	After receipt of notice, RPS may seek preliminary injunction • (i) – For patents included on 3(A) & 3(B) lists, *and* • (ii) – Not included on paragraph 4 list *or* paragraph 5(B) list
9	(A)	If Applicant complies with paragraph 2(A) (provides aBLA & mfg info), parties must wait until 8(A) notice is received before bringing a DJ action for any patent described in 8(B)(i)&(ii) [i.e., patents on 3(A) but not asserted in early-phase (6) litigation]
	(B)	If Applicant fails to comply with 3(B)(ii), 5, 6(C)(i), 7 or 8(A), RPS may bring DJ for any patent on 3(A) list + later issued/licensed patents
	(C)	If Applicant fails to comply with 2(A), RPS but not Applicant can bring DJ of any patent claiming the product or use of product

Early-Phase Litigation (42 U.S.C. § 262(l)(2-6))



Late-Phase Litigation (42 U.S.C. § 262(l)(7-8))

- ¶ 7 Newly issued or licensed patents
  - Newly issued or licensed after the RPS provides 3(A) list
  - RPS has 30 days to supplement 3(A) list
  - aBLA Applicant has 30 days to provide a statement in accordance with 3(B)
  - Supplemented patents may or may not be included in early phase litigation
- ¶ 8 Notice of commercial marketing and preliminary injunction
  - Notice of commercial marketing
    - 180 days prior to commercial marketing
    - Notice may be provided prior to FDA approval
  - Preliminary injunction
    - After (8)(A) notice, but prior to Applicant's commercial marketing
    - Patents involved:
      - Patents on (3)(A) list, except those litigated in early phase
      - Patents issued or licensed to RPS after (3)(A) list exchanged

Interpreting the BPCIA
42 U.S.C. § 262(l)

- Answered Questions
  - Is Paragraph 2(A) mandatory?
  - When can an aBLA Applicant serve notice of commercial marketing?
  - When can parties seek a declaratory judgment?

- Unanswered Questions

Interpreting the BPCIA

42 U.S.C. § 262(l)(2) – 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; and
  - (B) **may provide** to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

Is Paragraph 2(A) Mandatory?

- The Supreme Court in *Sandoz Inc. v. Amgen Inc*., 137 S.Ct. 1664, 1674 (2017), avoided the question of whether "shall" means "must" and instead held that an RPS cannot seek enforcement of this section by injunction under federal law.
  - "The flaw in the Federal Circuit's reasoning is that Sandoz's failure to disclose its application and manufacturing information was not an act of artificial infringement, and thus was not remediable under § 271(e)(4)."

- The Supreme Court essentially agreed with the Federal Circuit that the BPCIA provides the exclusive federal remedy for failure to disclose the required information by authorizing an RPS to bring an immediate declaratory-judgement action.
  - The Federal Circuit later held that state law did not provide a remedy because the BPCIA preempted state law.

- An RPS may bring a declaratory judgment action if an aBLA Applicant fails to comply with Paragraph (2)(A). 42 U.S.C. § 262(l)(9)(C).

When Can an aBLA Applicant Serve Notice of Commercial Marketing?

- Key provision: 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) [emphasis in opinion]. 42 U.S.C § 262(l)(8)(A).

- Sandoz provided a Notice of Commercial Marketing (NCM) to Amgen prior to obtaining FDA approval.

- District Court: NCM is effective. Sandoz can launch on FDA approval.

- Federal Circuit: NCM can only be given after FDA approves the biosimilar.
  - In other portions of the statute, the biosimilar product is referred to as "the biological product that is the subject of the application," in subsection (l)(8)(A) the statute reads "the biological product licensed under subsection (k)." The change in language indicated to the Federal Circuit that "[i]f Congress intended paragraph (l)(8)(A) to permit effective notice before the product is licensed, it would have used the 'subject of' language."

When Can an aBLA Applicant Serve Notice of Commercial Marketing?

- Key provision: 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). 42 U.S.C § 262(l)(8)(A).

- Supreme Court: The BPCIA does not tie notice to a product having been previously licensed.
  - "[T]he biological product licensed under subsection (k) refers to the term "commercial marketing," not to the "notice" requirement.

- The only timing requirement in Paragraph 8(A) is that notice must be provided 180 days prior to marketing the biosimilar.

- Sandoz's NCM prior to FDA approval was effective.

When Can Parties Seek a Declaratory Judgment?

- An RPS can file a DJ action if:
  - The aBLA Applicant fails to provide its application and manufacturing information under Paragraph 2(A); or
  - The aBLA Applicant serves notice of commercial marketing.

- An aBLA Applicant can only file a DJ if:
  - It complies with Paragraph 2(A); and
  - It serves notice of commercial marketing; and
  - It complies with all of the other steps of the Patent Dance.

When Can Parties Seek a Declaratory Judgment?

- 9(A) Subsection (k) application provided
  - If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).
- 9(B) Subsequent failure to act by subsection (k) applicant
  - If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(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 included in the list described in paragraph (3)(A), including as provided under paragraph (7)
- 9(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

When Can Parties Seek a Declaratory Judgment?

- Case Decisions
  - *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1277 (Fed. Cir. 2014)
    - A follow-on applicant must file an aBLA before seeking a declaratory judgment.
  - *Celltrion Healthcare Co., Ltd. v. Kennedy Trust for Rheumatology Research*, No. 14 Civ. 2256(PAC), 2014 WL 6765996, at *1 (S.D.N.Y. Dec. 1, 2014)
    - FDA must accept the aBLA for review before any “case or controversy” exists.
  - *Celltrion, Inc. v. Genentech, Inc.*, No. 18-CV-00274-JSW, 2018 WL 2448254, at *3 (N.D. Cal. May 9, 2018)
    - An aBLA Applicant cannot use the Declaratory Judgment Act as a procedural means to avoid completing the Patent Dance.
  - *Amgen, Inc. v. Genentech, Inc.*, No. CV 17-7349-GW(AGRx), 2018 WL 718418, at *2 (C.D. Cal. Feb. 2, 2018)
    - Completing the Patent Dance after filing does not cure the defect.

Interpreting the BPCIA – Unanswered Questions

- How much manufacturing information does an aBLA Applicant need to provide to satisfy the requirements of Paragraph 2(A)?

- After notice of commercial marketing, when is it too late for an RPS to seek a preliminary injunction?

Navigating the Patent Thicket

- A patent thicket is “an overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licenses . . . .”
  - Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting, in* Innovation Policy and Economy, Vol. 1 at 119 (Adam B. Jaffe, et al. ed., 2001).

- Can result in multiple gatekeepers blocking commercialization.

- For biologics and pharmaceuticals, typically only a single gatekeeper.

- If licenses are unavailable, an aBLA Applicant must have a strategy to resolve patent disputes.

Navigating the Patent Thicket

- Patent thickets surrounding biologic drugs are typically more dense than the number of patents protecting small molecule drugs.
  - On average, the RPS identifies 80 patents as potentially covering the follow-on biologic.
  - The highest-grossing biologics typically will be the subject of 200+ patent applications.
- The volume of patents protecting biologic drugs require early planning for patent dispute resolution.

Navigating the Patent Thicket

Types of Patents

- Molecule
- Formulation
- Method of Use

- Method of Manufacturing

– Expression system	– Upstream processing	– Downstream processing
• Vectors	• Culture media	• Harvesting protocols
• Cell lines	• Cell culturing protocol	• Purification protocols
		• Filtration
		• Chromatography

Navigating the Patent Thicket

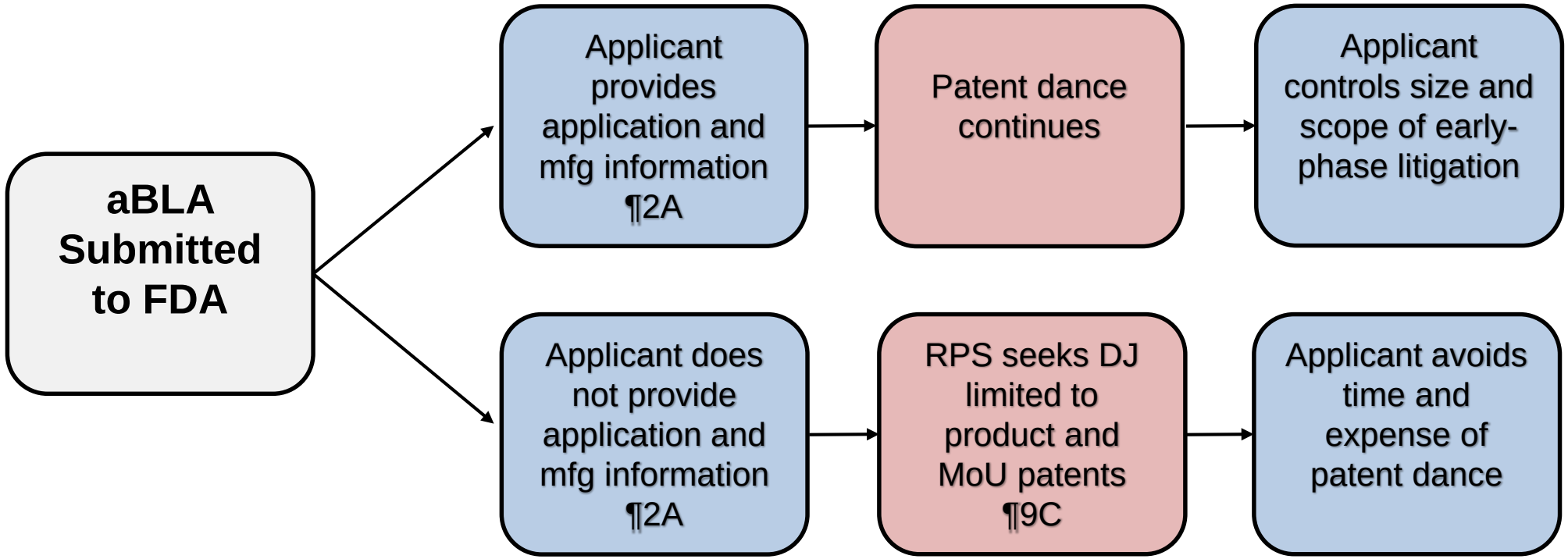
- Assess the patent portfolio
  - No Orange Book
- Collaborate with the product team
- Develop a patent dance strategy

Patent Dance Strategies

• Pros of the Patent Dance	• Cons of the Patent Dance
– More patent certainty (inc. manufacturing patents)	– Time
– Control of early-stage litigation	– Cost
– Option of later filing declaratory judgment action	– Disclosure of manufacturing information

Patent Dance Strategies

The Paragraph 2(A) Decision Tree



When to Give Notice of Commercial Marketing

Providing early notice

- RPS has weak patents (or no patents).
- Applicant seeks early patent resolution.
- Applicant willing to take on more upfront litigation costs.

Reasons to delay notice

- RPS exclusivity blocks early launch.
- Applicant prefers to avoid an early preliminary injunction motion.
- Late phase patents will expire before launch.
- Applicant prefers to spread out litigation spend.
- Applicant seeks to design around the late phase patents.

When to Give Notice of Commercial Marketing

Paragraph 8: Providing Notice of Commercial Marketing

- 8(A) – “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).”
- 8(B) – “After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the RPS may seek a preliminary injunction . . . .”
- 8(C) - If a preliminary injunction is sought, the abbreviated biologics license application (aBLA) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction.

Launches At Risk Under the BPCIA

"Launches At Risk" are commercial launches of a product accused of infringing one or more patents in an active litigation

- Damages exposure can be in the billions of dollars.
- After launch, the case will typically be tried to a jury.
- There's a threat of treble damages for willful infringement.

aBLA Applicants can limit the risk by:

- Maintaining pricing close to the RPS in a given distribution channel
- Prioritize gaining market share in less profitable channels for the RPS
- Cap sales volume until patent litigation is resolved
- Obtain opinion(s) of counsel as a defense to willful infringement

Launches At Risk Under the BPCIA

Case	Status
Epoetin alfa	
Amgen Inc. v. Hospira, Inc., No. 15-CV-00839 (D. Del. filed Sep. 18, 2015)	• Jury: Hospira made commercial quantities of RETACRIT • Jury: Biosimilar infringed and awarded $70M (Sep. 25, 2017) • Finding of infringement appealed (*Amgen Inc. v. Hospira, Inc.*, No. 19-1067, 1002 (CAFC)) – oral argument Sep. 30, 2019
Infliximab	
Janssen Biotech, Inc. v. Celltrion Healthcare Co., Ltd, No. 17-CV-11008 (D. Mass. filed Mar. 6, 2015, refiled May 31, 2017)	• Celltrion launches INFLECTRA Nov. 28, 2016 • D. Mass. held no infringement on Aug. 23, 2018 • Appeal is pending (*Janssen Biotech, Inc. v. Celltrion Healthcare Co., Ltd*., No. 18-2321 (CAFC))

Launches At Risk Under the BPCIA (con't)

Case	Status
Trastuzumab	
Genentech, Inc. v. Amgen Inc., No. 18-CV-00924-CFC (D. Del. filed July 2, 2018)	• Genentech's motion for a temporary restraining order and preliminary injunction - denied July 18, 2019 • Amgen launched • Genentech filed interlocutory appeal (*Genentech, Inc. v. Amgen Inc.*, No.19-2156 (CAFC)) - pending • District Court litigation - pending
Bevacizumab	
Genentech, Inc. v. Amgen Inc., No. 17-CV-01407-CFC (D. Del. filed Oct. 6, 2017) and No. 17-CV-1471-CFC (D. Del. filed Oct. 18, 2017) (consolidated)	• Genentech's motion to enforce statutory prohibition on commercial marketing and motion for temporary restraining order - denied July 18, 2019 (*Genentech, Inc. v. Immunex Rhode Island Corp.*, No. 19-CV-00602-CFC (D. Del. filed Mar. 29, 2019) • Amgen launched • Genentech filed interlocutory appeal (*Genentech, Inc. v. Immunex Rhode Island Corp.*, No.19-2155 (CAFC) - pending • District Court litigation - pending

Launches At Risk Under the BPCIA (con't)

Case	Status
Filgrastim/Pegfilgratism	
Amgen Inc. v. Coherus Biosciences, Inc., No. 17-CV-00546 (D. Del. filed May 10, 2017)	• Final judgment against Amgen entered Apr. 18, 2018 • Amgen appealed May 21, 2018 (*Amgen Inc. v. Coherus BioSciences Inc.*, No. 18-1993 (CAFC)) • UDENYCA launched Jan. 3, 2019 • CAFC affirmed district court decision July 29, 2019
Amgen Inc. v. Hospira, Inc., No. 18-CV-01064-CFC (D. Del. filed July 18, 2018)	• NIVESTYM launched Oct. 1, 2018 • Final judgment against Amgen entered Apr. 18, 2018 • Amgen appealed (18-1993)

Launches At Risk Under the BPCIA

Timeline in *Genentech, Inc. v. Amgen Inc.*, Civ. No. 18-924-CFC (D. Del.)

- May 2018: Amgen provides notice of commercial marketing.
- Feb. 2019: Genentech learns that Amgen filed a "resubmission" with FDA in Dec. 2018.
- Apr. 2019: Genentech learns that Amgen plans to launch in July 2019.
- Apr. – June 2019: Amgen witnesses testify re: planned July 2019 launch.
- May 16, 2019: Genentech informs the Court that it was not seeking a preliminary injunction.
- June 13, 2019: FDA approves Amgen's biosimilar.
- July 10, 2019: Genentech files motion for preliminary injunction.
- July 22, 2019: Court denies Genentech's motion.

Patents Issued After Launch Under the BPCIA

- After launch of a biosimilar, RPS will likely maintain continuation applications from which new claims will issue.
  - New claims may be novel and, while the patent expiration date may be same as the parent, a patent term adjustment could lengthen patent term.
  - New claims may be considered the same as earlier issued claims requiring a terminal disclaimer.
- Is there a relationship between the patent lists provided by the RPS under 42 U.S.C. § 262(l)(3) and (7) and “new” patents that issue after launch?

Patents Issued After Launch Under the BPCIA

- 42 U.S.C. § 262(l)(3)(A)
  - RPS shall provide "a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted …."
- 42 U.S.C. § 262(l)(7)(A) and (B)
  - For patents that are "issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product sponsor provided the" patent list under ¶ 3(A); and
  - The reference product sponsor "reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted," the reference product sponsor has 30 days after issuance or licensing to supplement the ¶ 3(A) list.
    - Neither ¶ 3 nor ¶ 7 require the identification of claims.
    - What does "could have reasonably been asserted" mean?
- 35 U.S.C. § 271(e)(6)(C)
  - "The owner of a patent that should have been included in the list…but was not timely included in such list, may **not** bring an action…for infringement of the patent with respect to the biological product"
  - What does it mean to be "timely?"
    - Is it not timely if new claims could have issued in a prior patent?

Patents Issued After Launch Under the BPCIA

- If asserted claims of post-launch patent could have issued earlier in prior patent(s):
  - RPS may be barred under 35 U.S.C. § 271(e)(6)(C) from bringing an action based on asserted claims of “new” patent.
    - **Scenario 1**

      Post-launch claims could have earlier issued in a patent that was listed because the RPS believed it “could reasonably be asserted” thus, post-launch claims may not be “timely.”
    - **Scenario 2**

      Post-launch claims could have earlier issued in a patent that was not listed because the RPS did not believe it “could reasonably be asserted” thus, post-launch claims may not be “timely.”

Purple Book

- The BPCIA does not require the RPS to provide a list of patents as part of its biologic license application
  - Different from Hatch-Waxman (i.e., the Orange Book)
  - Purple Book
    - Voluntarily created by the FDA
    - Lists RPs and follow-on biologics approved by FDA
      - Identifies first date of licensure
  - Purple Book Continuity Act of 2019 (H.R. 1520 - unanimously passed the House)
    - Patents disclosed in Purple Book: patents listed under ¶ 3(A) or supplemented under ¶ 7
  - Biologic Patent Transparency Act of 2019 (S. 659 – introduced 3/5/2019)
    - 'Patent required to be disclosed' is any patent for which the holder of a biological product license … believes a claim of patent infringement could reasonably be asserted by the holder, or by a patent owner that has granted an exclusive license to the holder.

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Axinn IP Update: U.S. Supreme Court Ruling Leaves On-Sale Bar Unchanged

Chad Landmon, Stacie Ropka, PhD, and Alex Alfano

January 23, 2019

On January 22, 2019, the U.S. Supreme Court held that the America Invents Act ("AIA") did not change the scope of the on-sale bar. *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 139 S.Ct. 628 (2019). In a unanimous decision authored by Justice Thomas, the Supreme Court held that the sale of an invention to a third party who is contractually obligated to keep the invention confidential places the invention "on sale" within the meaning of 35 U.S.C. § 102(a)(1) (barring a person from receiving a patent on an invention that was "in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention").

The issue at the center of this case involves the execution of a supply agreement for the marketing and sale of a patented product. The District Court held that the AIA's on-sale bar did not apply to the public disclosure of the sales agreement because the sales agreement did not disclose the claimed invention to the public. *Helsinn Healthcare S.A. v. Dr. Reddy's Labs. Ltd.*, 387 F. Supp. 3d 439, 505 (D.N.J. 2016). Although the District Court acknowledged that secret sales precluded patentability under the pre-AIA on-sale bar, it concluded that the language "or otherwise available to the public" following the on-sale bar in the AIA modified the on-sale bar. *Id.* at *497. The Federal Circuit reversed, holding that the AIA's on-sale bar applied even though "the details of the invention" were not made public in the sales agreement (*Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356, 1371 (2017)), and Helsinn petitioned the Supreme Court for cert.

The Supreme Court affirmed the Federal Circuit opinion, and more than a century of Supreme Court and Federal Circuit precedent on the meaning of "on sale," holding that an invention is "on sale" when it is subject to a commercial offer for sale and ready for patenting even when the sale does not make the details of the invention available to the public. *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 139 S.Ct. 628, 633-34 (2019). In addressing the added language in the AIA, the Supreme Court stated that "[t]he addition of 'or otherwise available to the public' is simply not enough of a change for us to conclude that Congress intended to alter the meaning of the reenacted term 'on sale.'" *Id.* at 634.

Although the Supreme Court reaffirmed the rule that has largely been in place for quite some time, this decision highlights that companies need to be extremely diligent in filing patent applications very early in the product development process. This is particularly important for life sciences companies, who often rely on partners and contract manufacturers throughout the research and development process.

Axinn IP Update: *Hikma Pharmaceuticals USA, Inc. v. Vanda Pharmaceuticals, Inc.*

Stacie L. Ropka, PhD, Thomas K. Hedemann, and Jonathan M. Knowles

March 18, 2019

Today the Supreme Court took the relatively uncommon step of calling for the views of the solicitor general as to the petition for certiorari in *Hikma Pharmaceuticals USA, Inc. v. Vanda Pharmaceuticals, Inc.*, Docket No. 18-817. Whereas the Court grants certiorari to only about one percent of petitions generally, it grants around one third of the petitions for which it has called for the views of the solicitor general. If the Court grants certiorari here, it will address the question "[w]hether patents that claim a method of medically treating a patient automatically satisfy Section 101 of the Patent Act, even if they apply a natural law using only routine and conventional steps." The petition was an appeal from a decision by a split Federal Circuit panel that a method for treating a patient with schizophrenia, which involved analyzing the patient's DNA and adjusting the dosage of a drug accordingly, was patent eligible because it was not directed to a law of nature under step one of the *Mayo/Alice* two-step subject matter eligibility test. *Vanda Pharmaceuticals, Inc. v. West-Ward Pharmaceuticals International Limited*, 887 F.3d 1117, 1133-36 (Fed. Cir. 2018). Any decision could have a significant impact on patents directed to methods of treatment in the pharmaceutical and biologics industries.

Axinn IP Update: No Collateral Estoppel after PTAB Ruling on IPR

Ted Mathias, Stacie Ropka, and Rebecca Clegg

October 9, 2019

On October 2, 2019, Judge Chesler in the District of New Jersey denied a motion for summary judgment of invalidity seeking to bar the patentee from relitigating invalidity. The Patent Trial and Appeal Board ("PTAB") had found two patents asserted in the litigation invalid as obvious in an inter partes review ("IPR"), but Judge Chesler concluded that collateral estoppel did not apply because the PTAB applied a different legal standard for proving obviousness than required in district court cases. *Sanofi-Aventis U.S. LLC v. Mylan GmbH*, No. 17-9105 (D.N.J. Oct. 2, 2019).

Several months after Mylan filed IPR petitions challenging the validity of U.S. Patent Nos. 7,476,652 and 7,713,930 ("the asserted patents"), Sanofi-Aventis filed a complaint alleging that Mylan infringed those same patents. While litigation was ongoing, the PTAB found the asserted patents invalid as obvious. Mylan moved for summary judgment based on collateral estoppel.

Collateral estoppel, also called issue preclusion, prevents parties from contesting issues that have already been decided in a prior proceeding. Collateral estoppel applies "when an issue of fact or law" was "actually litigated [by the parties] and determined by a valid and final judgment, and the determination is essential to the judgment." *Id.* at 2.

The Court concluded that collateral estoppel did not apply where the prior proceeding applied a different legal standard for evaluating the disputed issue. *Id.* Judge Chesler found persuasive the Supreme Court's statement in *B&B Hardware* that "[i]ssues are not identical if the second action involves application of a different legal standard, even though the factual setting of both suits may be the same." *Id.* (quoting *B&B Hardware, Inc. v. Hargis Indus., Inc.*, 135 S. Ct. 1293, 1306 (2015)). In federal district court, a patent challenger is required to demonstrate that the asserted patents are invalid by clear and convincing evidence. In IPR proceedings, however, a petitioner must only prove that the challenged patents are obvious by a preponderance of the evidence. Collateral estoppel was inappropriate in this case because the proceedings required different burdens of proof and consequently different issues.

The PTAB's decision is currently on appeal to the Federal Circuit. Judge Chesler did not address what would happen if the Federal Circuit were to affirm the PTAB's decision while the district court action remains pending. Although the "different standards of proof" rationale would still apply even after a Federal Circuit affirmance, the PTAB's determination will become binding on the district court if affirmed by the appellate court. *XY, LLC v. Trans Ova Genetics*, 890 F.3d 1282, 1294 (Fed. Cir. 2018) ("[A]n affirmance of an invalidity finding, whether from a district court or the [PTAB], has a collateral estoppel effect on all pending or co-pending actions."). Thus, even though the different burdens of proof applied by the PTAB and federal district court initially prevents application of collateral estoppel, patent invalidity findings will have preclusive effect on pending actions if affirmed by the Federal Circuit.

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BPCIA Litigations Pending in District Court[1]

Case	Allegations & Status
Trastuzumab	
Genentech, Inc. v. Amgen Inc., No. 18-CV-00924-CFC (D. Del. filed July 2, 2018)	**Pre-litigation** • Genentech alleges Amgen failed to comply with 42 U.S.C. § 262(l)(2)(A) • Genentech claims it provided a list of 37 patents pursuant to 42 U.S.C. § 262(l)(3)(A) • Genentech claims it suggested litigating 18 of the 37 patents but that Amgen wanted to litigate each of the 37 patents • Genentech claims agreement was reached to litigate all 37 patents, later Amgen stipulated to dismiss with prejudice 19 of the 37 patents • Genentech alleges Amgen purported to provide a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A) **Early Phase Litigation** • Genentech brings action for infringement pursuant to 35 U.S.C. § 271(e)(2) based upon Amgen's submission of its aBLA • Genentech brings action for infringement pursuant to 42 U.S.C. § 262(l)(6)(A) based upon patent negotiations pursuant to 42 U.S.C. § 262(l)(4)(A) • Genentech also seeks a declaratory judgment pursuant to 42 U.S.C. § 262(l)(9) • Expert discovery ongoing as of October 30, 2019 **Late Phase Litigation** • Genentech's motion for a temporary restraining order and preliminary injunction was denied on July 18, 2019 – decision appealed to Federal Circuit (*Genentech, Inc. v. Amgen Inc.*, No.19-2156 (CAFC)) o CAFC denied Genentech's motion for an emergency stay pending appeal (August 7, 2019)
Bevacizumab	
Genentech, Inc. v. Amgen Inc., No. 17-CV-01407-CFC (D. Del. filed Oct. 6, 2017) and No. 17-CV-1471-CFC (D. Del. filed Oct. 18, 2017) (consolidated)	**Pre-litigation** • Genentech alleges Amgen failed to comply with 42 U.S.C. § 262(l)(2)(A)

[1] As of October 16, 2019

	• Genentech claims it provided a list of patents pursuant to 42 U.S.C. § 262(l)(3)(A) and § 262(l)(7) • Genentech alleges Amgen did not comply with 42 U.S.C. § 262(l)(4) or (5) • Genentech alleges Amgen purported to provide a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A) **Early Phase Litigation** • Genentech brings action for infringement pursuant to 35 U.S.C. § 271(e)(2)(C) based upon Amgen's submission of its aBLA; asserts 26 patents • Opinion regarding claim construction – 6/17/2019 **Late Phase Litigation** • Genentech's emergency motion to enforce statutory prohibition on commercial marketing and motion for temporary restraining order denied July 18, 2019 (*Genentech, Inc. v. Immunex Rhode Island Corp.*, No. 19-CV-00602-CFC (D. Del. filed Mar. 29, 2019, D.I. 42) - decision appealed to Federal Circuit (*Genentech, Inc. v. Immunex Rhode Island Corp.*, No.19-2155 (CAFC)) o CAFC denied Genentech's motion for an injunction pending appeal (August 16, 2019)
Filgrastim/Pegfilgratism	
Amgen Inc. v. Kashiv Biosciences, LLC (formally Adello Biologics, LLC), No. 18-CV-03347-CCC (D.N.J. filed Mar. 8, 2018)	**Pre-litigation** • Amgen alleges Adello refused to provide its aBLA or manufacturing information under 42 U.S.C. § 262(l)(2)(A) • Amgen alleges Adello purported to provide notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A) **Early Phase Litigation** • Amgen brings action for infringement pursuant to 35 U.S.C. § 271(e)(2)(C)(ii); asserts 4 patents • Amgen's motion to amend infringement contentions granted October 24, 2019
Amgen Inc. v. Hospira, Inc., No. 18-CV-01064-CFC (D. Del. filed July 18, 2018)	**Pre-litigation** • Amgen alleges Hospira failed to comply with 42 U.S.C. § 262(l)(2)(A) • Amgen claims it provided a list of 6 patents pursuant to 42 U.S.C. § 262(l)(3)(A) • Amgen claims the parties agreed to litigate 1 patent pursuant to 42 U.S.C. § 262(l)(4)(A)

	Early Phase Litigation • Amgen brings action for infringement pursuant to 35 U.S.C. § 271(e)(2)(C) and 35 U.S.C. § 271(g); asserts 1 patent • Discovery Conference set for December 6, 2019
Amgen Inc., v. Accord (formally Apotex Inc.), No. 18-CV-61828-WPD (S.D. Fla. filed Aug. 7, 2018)	**Pre-litigation** • Amgen claims it supplemented its 42 U.S.C. § 262(l)(3)(A) patent list pursuant to 42 U.S.C. § 262(l)(7); 1 patent was added • Amgen alleges Apotex provided its statements pursuant to 42 U.S.C. § 262(l)(3)(B) thus committing an act of infringement under 35 U.S.C. § 271(e)(2)(C)(i) with respect to the supplemented patent **Early Phase Litigation** • Amgen brings action for infringement pursuant to 35 U.S.C. § 271(e)(2)(C)(i); asserts 1 patent • Joint status report due November 1, 2019 (filed under seal)

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DECLARATORY JUDGMENT STRATEGY UNDER THE BIOLOGICS PRICE COMPETITION AND INNOVATION ACT

by Stacie Ropka, Ted Mathias and Drew Hillier

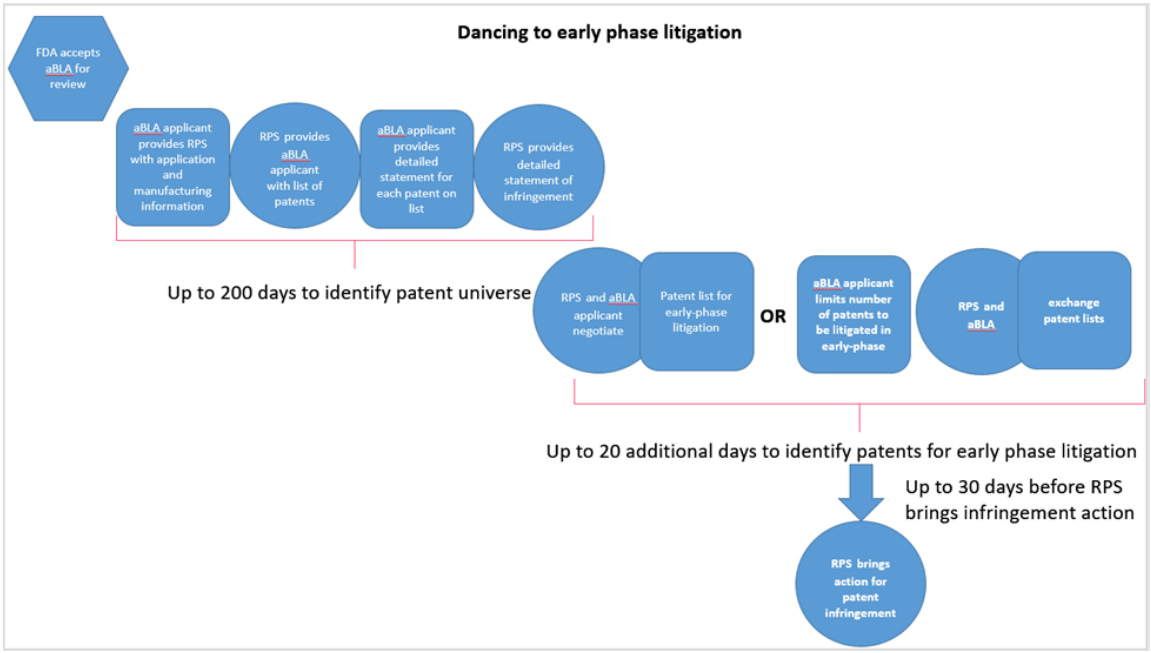
Much like the Hatch-Waxman Act provides a pathway for approving generic small-molecule drugs and litigating patent disputes about those drugs, the Biologics Price Competition and Innovation Act ("BPCIA") provides the same for follow-on biologic drugs. Although the BPCIA was enacted in 2010, to date only a handful of biologics have been the subject of BPCIA litigation. Much of that early litigation has focused on the availability of declaratory judgments as a mechanism to resolve patent disputes concerning follow-on biologics. In addressing those issues, courts have affirmed the primacy of the BPCIA's processes for framing patent disputes, commonly known as the "patent dance," and limited the use of declaratory judgments to avoid the patent dance. Below we discuss why these decisions leave applicants filing abbreviated biologics license applications ("aBLAs") with a clear strategic choice that they must make soon after filing their applications.

I. PATENT DANCE BASICS

The patent dance consists of a series of exchanges between a Reference Product Sponsor ("RPS") who owns an FDA-approved biologic and an aBLA applicant who seeks approval to market a follow-on biologic. After the aBLA applicant provides some initial information, the RPS provides a list of patents it might assert, and the parties provide detailed statements explaining why the patents do or do not cover the aBLA product.[1] The parties then negotiate the scope of a "phase I" or "early phase" litigation, with the aBLA applicant controlling how many, and to some extent which, patents are included.[2]

[1] *See* 42 U.S.C. § 262(*l*)(2)-(*l*)(3).
[2] *See* 42 U.S.C. § 262(*l*)(4)-(*l*)(6).

Just getting to phase I litigation, however, takes substantial time. Even after FDA has accepted the aBLA for review, the exchanges can result in delaying phase I litigation for up to 250 days. Figure 1 illustrates how this timing works.



”Phase II” or “late phase” litigation is triggered after the aBLA applicant notifies the RPS that it intends to commercially market its aBLA product in 180 days.[3] The aBLA applicant may provide this notice prior to FDA approval of the aBLA product.[4] Once the aBLA applicant serves notice of commercial marketing, the RPS may seek a preliminary injunction at any time prior to the aBLA applicant’s commercial launch.[5] In phase II litigation, the RPS can assert (1) patents that it initially identified during the patent dance but not included in phase I litigation, and (2) newly-issued or -licensed patents.

[3] 42 U.S.C. § 262(*l*)(8)(A).
[4] *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1677, 198 L. Ed. 2d 114 (2017).
[5] 42 U.S.C. § 262(*l*)(8)(B).

II. THE BPCIA'S LIMITATIONS ON DECLARATORY JUDGMENT ACTIONS

The BPCIA limits the circumstances under which the parties may file declaratory judgment actions. There are three distinct bars to seeking a declaratory judgment: (1) where an applicant does not provide manufacturing information concerning its aBLA product; (2) where an applicant fails to complete specified steps of the patent dance, such as identifying the number and identity of patents it would include in phase I litigation, and (3) where the aBLA applicant has not served a notice of commercial marketing.[6] But the BPCIA also refers to the Declaratory Judgment Act, which affirmatively allows the courts to issue judgment in "a case of actual controversy."[7]

III. COURT DECISIONS ADDRESSING LIMITATIONS ON DECLARATORY JUDGMENTS

aBLA applicants have sought to take advantage of uncertainty regarding the interplay between the BPCIA and the Declaratory Judgment Act by filing declaratory judgment actions rather than completing the patent dance. In response, courts have rejected arguments that the Declaratory Judgment Act provides a mechanism to sidestep the patent dance.

A. FDA Acceptance of an aBLA Is a Prerequisite

In *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274,(Fed. Cir. 2014), the plaintiff filed a declaratory judgment action before submitting an aBLA. The district court dismissed the action on two grounds. First, because the plaintiff planned to avail itself of the BPCIA's expedited pathway for regulatory approval, "it had to follow the BPCIA's patent-related procedures applicable to aBLA applicants – which it had not done."[8] Second, the district court concluded

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[6] *Celltrion, Inc. v. Genentech, Inc.*, No. 18-CV-00274-JSW, 2018 WL 2448254, at *7 (N.D. Cal. May 9, 2018), appeal docketed, No. 18-2160 (Fed. Cir. July 16, 2018).
[7] 28 U.S.C. § 2201(a).
[8] *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1277 (Fed. Cir. 2014)

that there was no actual controversy as the Declaratory Judgment Act requires.[9] The Federal Circuit affirmed the dismissal on the second ground and did not reach the district court's rationale under the BPCIA.[10] The Federal Circuit explained that because the aBLA applicant could not "lawfully enter the market now anyway," absent FDA approval, there was "no question of its taking immediate action that risks building up infringement liability."[11] Indeed, it seems unlikely that a justiciable controversy could exist before a plaintiff has even submitted the aBLA required to market the follow-on biologic.

In *Celltrion Healthcare Co., Ltd. v. Kennedy Trust for Rheumatology Research*, Celltrion sought a declaratory judgment that three of the Kennedy Trust's patents were invalid, with the goal of clearing a path to market the biosimilar Remsima.[12] When it filed suit, Celltrion had filed its aBLA but FDA had not accepted the application for review. Nor had the Kennedy Trust communicated any intent to sue Celltrion in the United States. Similar to the district court's approach in Sandoz, the court in Celltrion dismissed the action because there was no actual controversy.[13] It also explained that even if an actual controversy did exist, it would have declined to hear the case because Celltrion did not follow (and indeed had not even begun) the patent dance.[14] The court disapproved of "Celltrion's attempts to skirt the BPCIA's dispute resolution mechanisms while reaping the benefits of its approval process" and declined to exercise jurisdiction outside of the Congressional framework.[15]

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[9] *Id.* at 1276.
[10] *Id.* at 1282
[11] *Id.* at 1282.
[12] *Celltrion Healthcare Co., Ltd. v. Kennedy Trust for Rheumatology Research*, No. 14 Civ. 2256(PAC), 2014 WL 6765996, at *1 (S.D.N.Y. Dec. 1, 2014).
[13] *Id.* at *3-*4.
[14] *Id.* at *4.
[15] *Id.* at *4-*5.

B. Full Compliance with the Patent Dance Is a Condition Precedent for Declaratory Relief

Celltrion's suit against Genentech on a different drug, Herceptin, addressed issues left unanswered in its prior case against Kennedy Trust. Here, FDA had accepted Celltrion's aBLA, and the parties started the patent dance. After the parties exchanged detailed statements regarding their infringement and invalidity positions as the BPCIA requires, they failed to reach agreement on the patents to litigate in Phase I. Celltrion then severed negotiations, served notice of commercial marketing, and filed a declaratory judgment action.[16]

There was little question that Celltrion's action satisfied the Declaratory Judgment Act's "case or controversy" requirement. Genentech had identified patents that, in its view, would be infringed by marketing Celltrion's aBLA product and communicated an intent to sue. As for the BPCIA, Celltrion argued that its declaratory judgment action should proceed because, by declaring its intention to litigate all of the patents Genentech issued in phase I, it had effectively satisfied its obligations leading to Phase I litigation. The court rejected this argument and dismissed the case, however, in view of the BPCIA's bar on an aBLA applicant seeking declaratory relief where it failed to complete the entire patent dance, including completing the fifteen day negotiation period and formally exchanging the list of patents it wished to litigate in Phase I.[17]

In one final case, *Amgen, Inc. v. Genentech, Inc.*, the court faced a similar but closer issue. The parties exchanged information pursuant to the patent dance and took the required fifteen days to negotiate the scope of Phase I litigation.[18] After the negotiation period, the aBLA

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[16] *Celltrion, Inc. v. Genentech, Inc.*, No. 18-CV-00274-JSW, 2018 WL 2448254, at *3 (N.D. Cal. May 9, 2018), appeal docketed, No. 18-2160 (Fed. Cir. July 16, 2018).
[17] *Id.* at *5-*7.
[18] *Amgen, Inc. v. Genentech, Inc.*, No. CV 17-7349-GW(AGRx), 2018 WL 910198, at *1 (C.D. Cal. Jan. 11, 2018) (tentative ruling).

applicant, Amgen, issued its notice of commercial marketing and filed a declaratory judgment action. Nevertheless, the parties completed the patent dance by exchanging lists of patents to be included in Phase I litigation.[19]

Completing the dance made no difference. The court in *Amgen* held that the BPCIA barred the suit because the BPCIA's limitations on declaratory judgments specifically refers to the negotiation and exchange provisions. The court explained that it would not "hear a case where [the applicant] effectively attempted to bypass the BPCIA's scheme for negotiations and eventual litigation."[20] Accordingly, completing each step of the dance is a condition precedent for an aBLA applicant to seek declaratory relief.[21]

IV. THE CONTINUING AND IMPORTANT ROLE OF DECLARATORY JUDGMENTS IN THE BPCIA FRAMEWORK

Although courts to date have curtailed use of declaratory judgment actions, they remain an important option for aBLA applicants. The BPCIA does not bar aBLA applicants who have completed the patent dance and provided notice of commercial marketing from filing declaratory judgment actions where a case or controversy exists. This right is particularly important in the case of later-issuing patents. The BPCIA provides that an RPS may add patents to its list that issue after the patent dance begins.[22] The BPCIA does not place any kind of time limit, however, on when the RPS must assert later-issuing patents. The existence of such patents could cause an aBLA applicant to refrain from launching its product because of the possibility that it could later be held liable for patent infringement. In cases where the RPS elects not to

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[19] *Id.* at *2.
[20] *Amgen*, 2018 WL 910198, at *4.
[21] *Amgen, Inc. v. Genentech, Inc.*, No. CV 17-7349-GW(AGRx), 2018 WL 718418, at *2 (C.D. Cal. Feb. 2, 2018) (final ruling).
[22] 42 U.S.C. § 262(*l*)(7).

assert its patents, an aBLA applicant can file a declaratory judgment action and seek some measure of patent certainty prior to product launch.

In addition, an aBLA applicant with a generous tolerance for risk can seek to indirectly use the BPCIA's declaratory judgment provisions by inducing an RPS to file an early declaratory judgment. In the first stage of the patent dance, an aBLA applicant provides its application and manufacturing information about its product to the RPS.[23] If the aBLA applicant declines to provide that information, the RPS can elect to file a declaratory judgment action asserting patents claiming the product itself or a method of using it.[24] Triggering a declaratory judgment action affords the aBLA applicant two potential benefits. First, the applicant avoids the delay associated with the patent dance. Second, for the applicant who values the secrecy of its manufacturing processes, this approach could at least put off disclosure of those processes. Because the BPCIA limits the RPS to asserting patents covering the product or its method of use, the RPS cannot assert patents directed to manufacturing processes. Although the RPS may seek discovery on the manufacturing processes anyway, the aBLA applicant at least increases its chances of successfully opposing such a request.[25]

Pursuing this "triggering" strategy comes with risks. The RPS could choose not to file a declaratory judgment action at all, leaving the aBLA applicant without any means of obtaining

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[23] 42 U.S.C. § 262(*l*)(2)(A).

[24] 42 U.S.C. § 262(*l*)(9)(C). The Federal Circuit has considered in dictum whether this provisions permits action for a manufacturing patent but did not reach a clear consensus. *See Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1356 n.3 (Fed. Cir. 2015) (J. Lourie); *id.* at 1634-45 (J. Newman, dissenting in part). The Supreme Court reversed in part and vacated in part without reaching the issue. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664 (2017).

[25] To be sure, protective orders typically would bar the RPS's outside counsel from sharing the secret manufacturing process with RPS personnel. Nevertheless, manufacturing processes can be sufficiently valuable that companies place a premium on delaying their disclosure. And experienced lawyers also recognize, that come trial, courts are reluctant to seal courtrooms to avoid public disclosure of information even though that information has been covered by a protective order through discovery.

patent certainty prior to launching its aBLA product. Even if the RPS does file suit on the product and method of use patents, the aBLA applicant would risk exposure to damages for infringing the manufacturing process patents that the RPS could assert closer to or after launch. Of course, if the RPS does not hold any manufacturing process patents or the patents it holds are weak, the aBLA applicant's damages exposure could be inconsequential.

What recent court decisions make clear is that aBLA applicants cannot pursue their own declaratory judgment actions while seeking to induce an RPS to file an early suit and skip the patent dance. Applicants must decide which strategy to pursue. An applicant that discloses its aBLA and manufacturing information commits to follow the patent dance. An applicant that declines to provide that information cannot file a declaratory judgment action and allows the RPS to dictate the manner and timing of litigation. Applicants must decide early on which mutually-exclusive strategy to pursue and live with the consequences of its choice.

CONCLUSION

Courts have established a sequence that aBLA applicants must follow to pursue a declaratory judgment. This leaves aBLA applicants with a clear choice that requires careful strategic planning by applicants and their counsel.

AXINN

PATENT DANCE DEVELOPMENTS: A TALE OF TWO ANTIBODIES

by Ted Mathias, Stacie Ropka and Nisan Zaghi, Axinn, Veltrop & Harkrider LLP

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) outlines a series of steps, commonly referred to as the "patent dance," for resolving patent disputes involving biologic drugs. The patent dance is similar in some respects to the now-familiar Orange Book listings and notice letters that precede a Hatch-Waxman litigation for small molecule drugs. The patent dance is different, however, in that parties face more strategic choices. Whereas the pre-suit Hatch-Waxman process is essentially mandatory, an abbreviated biologic license application (aBLA) applicant might elect to forgo the patent dance.[1] For parties that do engage in the patent dance, recent litigations for the antibodies trastuzumab and adalimumab point to the different approaches parties can take.

The Patent Dance

The BPCIA provides for a patent dance and, potentially, two phases of litigation. Participating in the patent dance allows an aBLA applicant to both trigger an early-phase litigation that can provide some patent certainty and control the number of patents that are litigated.

The patent dance begins when an aBLA applicant sends the reference product sponsor (RPS) its aBLA and information regarding its manufacturing processes.[2] The RPS then has 60 days to provide a list of patents (the Paragraph 3(A) list) it potentially will assert.[3] The aBLA applicant may respond with a detailed statement, similar to a Hatch-Waxman notice letter, as to why the listed patents are either not infringed, invalid and/or unenforceable.[4] After receiving the aBLA applicant's statement, the RPS has 60 days to respond with its own detailed statement explaining, on a claim-by-claim basis, why the aBLA product will infringe the listed patents.[5]

With the patent list and detailed statements in hand, the parties spend fifteen days negotiating the number and identity of patents to be asserted in the early-phase litigation.[6] If the parties reach an agreement, the RPS has 30 days to file suit.[7] Absent an agreement, the aBLA applicant informs the RPS of the number of patents it wants to litigate in the early-phase. This triggers a simultaneous exchange where the parties each identify the specific patents to be litigated.[8] The RPS's list of patents to litigate cannot exceed the number that the aBLA applicant agreed to litigate.[9] The patents identified in the simultaneous exchange might, but do not necessarily, overlap. Therefore, the total number of patents litigated in the early-phase cannot be more than twice the limit that the aBLA applicant sets. The parties then proceed to litigate the patents on their respective lists.

Late-phase litigation occurs after the aBLA applicant provides notice to the RPS that it intends to commercially market its aBLA product in 180 days.[10] In this second phase, the RPS is limited to asserting those patents listed but not litigated in the early-phase.[11] The aBLA applicant thus indirectly controls the late-phase litigation's scope. It can choose to litigate a relatively small percentage of the patents on the RPS's list in the early-phase, increasing the likelihood that the RPS will assert a larger number of patents in the late-phase. Alternatively, the aBLA applicant can force the RPS to assert most or all of its patents in the early-phase, and narrow or eliminate the second litigation.

Let's Rumble: The Trastuzumab Litigation

In the trastuzumab litigation concerning biosimilars to Genentech's Herceptin® antibody, the aBLA applicants opted in the early-phase to litigate a relatively large percentage of the patents that Genentech identified on its Paragraph 3(A) list. Defendant Amgen declined Genentech's offer to limit the early-phase litigation to 18 patents and the parties instead agreed that Genentech would assert all 37 patents on its list. Defendant Samsung agreed to include 21 patents in its early-phase litigation.

The trastuzumab defendants thus opted for a larger early-phase litigation in exchange for more patent certainty and the prospect of narrowing or, in Amgen's case, potentially avoiding late-phase litigation entirely. One additional benefit to an "all in" approach to early-phase litigation is that, at least in trastuzumab, Amgen's strategy resulted in the RPS dropping a number of patents. Within weeks of filing its complaint asserting all of the patents on its Paragraph 3(A) list, Genentech withdrew about half of the asserted patents with prejudice. Had Amgen agreed to limit its early-phase litigation as Genentech had proposed, Genentech could have asserted those now-withdrawn patents in later-phase litigation after Amgen provided notice of commercial marketing. Through its dance strategy, Amgen substantially reduced the number of patents it might ultimately be required to litigate.

Another trastuzumab defendant, Celltrion, similarly opted for a large early-phase litigation but took a different approach. Celltrion provided its aBLA and manufacturing process information, Genentech provided a Paragraph 3(A) patent list and the parties then exchanged detailed statements. During the negotiation period that followed, Celltrion provided notice of commercial marketing and filed a complaint for declaratory judgment of patent non-infringement and/or invalidity of all patents from Genentech's Paragraph 3(A) list.[12] After filing the declaratory judgment action, Celltrion did not continue with the patent dance.

The district court granted Genentech's motion to dismiss because a BPCIA provision, 42 U.S.C. § 262(*l*)(9)(B), bars an aBLA applicant from filing a declaratory judgment action where it fails to comply with various patent dance steps.[13] Celltrion maintains that a different section of the statute, 42 U.S.C. § 262(*l*)(9)(A), authorizes an aBLA applicant to file a declaratory judgment action after providing its aBLA application, manufacturing process information and notice of commercial marketing.[14] That issue is currently on appeal.

Let's Not Get Ahead of Ourselves: The Adalimumab Litigation

The adalimumab defendants adopted a different strategy in the patent dance leading up to their litigation.[15] They sought to sharply limit the number of patents to be litigated in the early-stage litigation. AbbVie had listed between 61 and 84 patents on its Paragraph 3(A) lists for the various aBLA applicants. The parties did not reach agreement on the number and identity of patents to be included, and AbbVie ended up asserting as few as two and as many as twelve patents against the various aBLA applicants.

Sharply limiting the number of patents in the early-phase litigation allows aBLA applicants to defer or avoid litigation costs and can be particularly useful where the applicants can identify a limited number of patents for which getting an early decision is particularly important. A cost-conscious aBLA applicant can also take a calculated risk that some of the Paragraph 3(A)

patents will expire before the applicant is ready to launch its aBLA product and thus avoid the expense associated with litigating those patents.

A Future Patent Dance Battleground?

It remains to be seen whether either of the two approaches that the aBLA applicants adopted in trastuzumab and adalimumab will prove to be the dominant strategy that others will follow or, alternatively, an anomaly driven by unique case-specific facts. What does seem clear is that RPS plaintiffs will aggressively police aBLA applicants' compliance with BPCIA requirements for the patent dance. Genentech alleged that Samsung-Bioepis failed to comply with the BPCIA by providing only "a tiny fraction of its entire aBLA."[16] Similarly, AbbVie alleged that Boehringer did not provide "any 'other information that describes the process or processes used to manufacture' the Boehringer aBLA product."[17]

The allegations of noncompliance with the BPCIA's initial disclosure requirements point to issues that present strategic opportunities for litigants on both sides. The BPCIA provides a remedy for an aBLA applicant's failure to make those initial disclosures: the RPS may bring an immediate declaratory judgment action against the aBLA applicant seeking to have its patents adjudged infringed, valid and enforceable.[18] Filing such an action allows an RPS to control the number of patents it asserts. In an early-stage litigation that follows the patent dance, by contrast, the aBLA applicant largely controls the number of patents asserted. The downside for an RPS is that it can only assert patents claiming the biological product or its use in the declaratory judgment action, whereas in the early-stage litigation that follows the patent dance it can assert manufacturing process patents.[19] Depending on the type of patents in its portfolio and their expiration dates, the inability to assert manufacturing process patents could be a substantial issue for an RPS.

The limitation on the scope of declaratory judgment actions for failure to comply with BPCIA disclosure requirements also presents an opportunity for an aBLA applicant. The applicant might want to put off disclosing its manufacturing processes to improve its settlement position. Or, the aBLA applicant might consider its manufacturing process to be a particularly valuable trade secret that it does not want to disclose, even under the standard confidentiality obligations that attach when an aBLA applicant provides information to an RPS. For example, an aBLA applicant might be concerned that its trade secret would be publicly disclosed during an early-stage trial, as courts are reluctant to limit public access to trials. An aBLA applicant reasonably could decide to put off risk of public disclosure until a later trial.

Despite their allegations that aBLA applicants failed to comply with their BPCIA disclosure requirements, neither AbbVie nor Genentech elected to immediately file a declaratory judgment action and instead continued with the patent dance. Their reluctance to abandon the patent dance is perhaps attributable to the absence of any court decision determining the precise scope of the disclosure requirements. If, for example, a court were to find that the aBLA applicant did in fact comply with its disclosure requirements in the face of an RPS allegation to the contrary, and the RPS had filed a declaratory judgment action rather than providing its Paragraph 3(A) list and continuing with the patent dance, the RPS would risk losing its ability to bring suit against the aBLA applicant.[20] Although it seems doubtful that an RPS would take that risk in order to limit an aBLA applicant's ability to control the scope of early-phase litigation through the patent dance, the emphasis that they have placed in their complaints on aBLA

applicants' alleged failures to comply suggest that they consider the opportunity to file an immediate declaratory judgment action to be a particularly attractive option.

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[1] In Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664 (2017), the Supreme Court held that the exclusive federal remedy for an aBLA applicant's failure to provide information specified in the BPCIA was to file an "immediate" declaratory judgment action. There is an open question whether state law permits other remedies. Given the current state of the law, however, an aBLA applicant reasonably could decide to skip the patent dance. We discuss why an aBLA applicant might choose to do so later in this article.

[2] 42 U.S.C. § 262(*l*)(2)(A).

[3] 42 U.S.C. § 262(*l*)(3)(A). The BPCIA permits the RPS to add newly-issued patents to its original list. See 42 U.S.C. § 262(*l*)(7).

[4] 42 U.S.C. § 262(*l*)(3)(B).

[5] 42 U.S.C. § 262(*l*)(3)(C).

[6] 42 U.S.C. § 262(*l*)(4).

[7] 42 U.S.C. § 262(*l*)(6)(A).

[8] 42 U.S.C. § 262(*l*)(5)(B)(ii)(I).

[9] If the aBLA applicant is unwilling to litigate any patents in early-phase litigation, the BPCIA contains a provision that allows an RPS to assert one patent from its Paragraph 3(A) list. See 42 U.S.C. § 262(*l*)(5)(B)(ii)(II).

[10] 42 U.S.C. § 262(*l*)(8)(A).

[11] 42 U.S.C. § 262(*l*)(8)(B).

[12] Celltrion, Inc. v. Genentech, Inc., No. 18-CV-00274-JSW, 2018 WL 2448254, at *3 (N.D. Cal. May 9, 2018).

[13] Celltrion, Inc. v. Genentech, Inc., No. 18-CV-00274-JSW, 2018 WL 2448254, at *8 (N.D. Cal. May 9, 2018).

[14] See Opp'n to Mot. to Dismiss at 5, Celltrion, Inc. v. Genentech, Inc., No. 18-CV-00274-JSW, 2018 WL 2448254, (N.D. Cal. May 9, 2018).

[15] The reference product at issue in the adalimumab litigation is Humira®.

[16] Compl. at ¶ 22, Genentech Inc. v. Samsung Bioepis Co., No. 1:18-CV-01363-GMS (D. Del. Sept. 4, 2018).

[17] Compl. at ¶ 53, AbbVie Inc. v. Boehringer Ingelheim Int'l GmbH, No. 1:17-CV-01065-MSG (D. Del. Aug. 2, 2017).

[18] 42 U.S.C. § 262(*l*)(9)(C).

[19] Id.

[20] Although no court has addressed the issue, both the early-stage and post-notice of commercial marketing litigations permitted under the BPCIA are limited to patents included on the Paragraph 3(A) list. See 42 U.S.C. § 262(*l*)(6) (early-stage litigation); 42 U.S.C. § 262(*l*)(8)(B)(i) (litigation following notice of commercial marketing). Similarly, Section 271 actions appear to be limited to patents that "should have been included" in the Paragraph 3(A) list. 35 U.S.C. § 271(e)(6)(C).