



Dance Dance Dance: Unveiling the Intricacy in Biosimilar Litigation

Peng Sun, Ph.D., J.D.
Foley & Lardner LLP
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Overview



- **Biologics v. Biosimilars**
- **Patent Dance and Pre-Marketing Notice**
 - Why Patent?
 - Patent dispute resolution process under Biologics Price Competition and Innovation Act (BPCIA)
 - Sandoz v. Amgen
- **Alternative Pathway for Resolving Patent Disputes**

Overview



■ **Biologics v. Biosimilars**

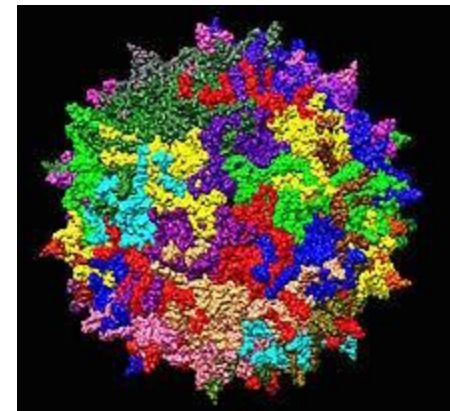
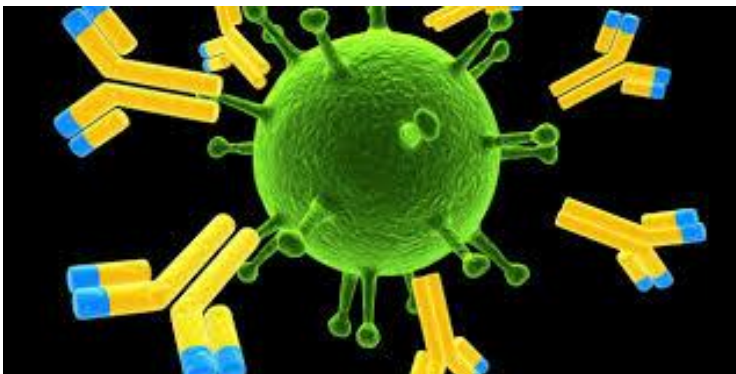
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■ Alternative Pathway for Resolving Patent Disputes

Biologics v. Biosimilars

- **Biologics**: therapeutics derived from, or made by the biological processes of a living organism
 - E.g., polypeptides, vaccines, blood products, cells and tissues, viruses, and toxins.
 - Global market: **\$399.5 Billion by 2025** (by Grand View Research)



Biologics v. Biosimilars



- **Biosimilars**: a product “highly similar” to a reference product
 - No clinically meaningful differences—safety and effectiveness
 - Minor differences in clinically inactive component

U.S. Biosimilar Landscape



- 4 US biosimilars have been approved, none with interchangeable status:
 - Zarxio (Sandoz, biosimilar to Neupogen®), first biosimilar recombinant protein approval (3/6/2015)
 - Inflectra (Celltrion, biosimilar to Remicade®), the first mAb biosimilar to be approved in the US (4/5/2016)
 - Erelzi (Sandoz, biosimilar to Enbrel®), dimeric TNFR fusion protein biosimilar, approved in the US (8/30/2016)
 - Amjevita (Amgen, biosimilar to Humira®) anti-TNF antibody (9/23/2016)

FDA Approval Pathways

- Two main pathways for FDA drug approval

Public Health Service
Act (PHSA)

BLA aBLA

BLA: Biologics License Application
aBLA: Biosimilar Application

Biologic / Biosimilar

Food, Drug, and
Cosmetic Act (FDCA)

NDA ANDA

NDA: New Drug Application
ANDA: Abbreviated New Drug Application

Drug / Generic Drug

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What is Patent?

- A property right to exclude market competitors!
So what?
 - Twenty (20) year term
 - Bringing a drug to market costs innovators big bucks = ~\$800M - \$1B.
 - **They need to recoup costs!**
 - An exclusive right: prevent competitors from practicing invention (selling drug and getting market share)

What is Patent?



Protect your property

Collect license fee



Patents are Serious Business



- 1) \$2.5 Billion Idenix v. Gilead (2016)—Hepatitis C treatment
- 2) \$1.673 Billion Centocor v. Abbott Lab (2009)—Arthritis drugs
- 3) \$1.52 Billion Alcatel-Lucent v. Microsoft (2007)—MP3
- 4) \$1.169 Billion Carnegie Mellon v. Marvell (2012)—Noise \$ reduction technology
- 5) \$1.049 Billion Apple v. Samsung (2012)—Smartphone software
- 6) \$1.0 Billion Monsanto v. E.I. du Pont (2012)—Genetically modified soybean seeds.

Biologics Price Competition and Innovation Act of 2009

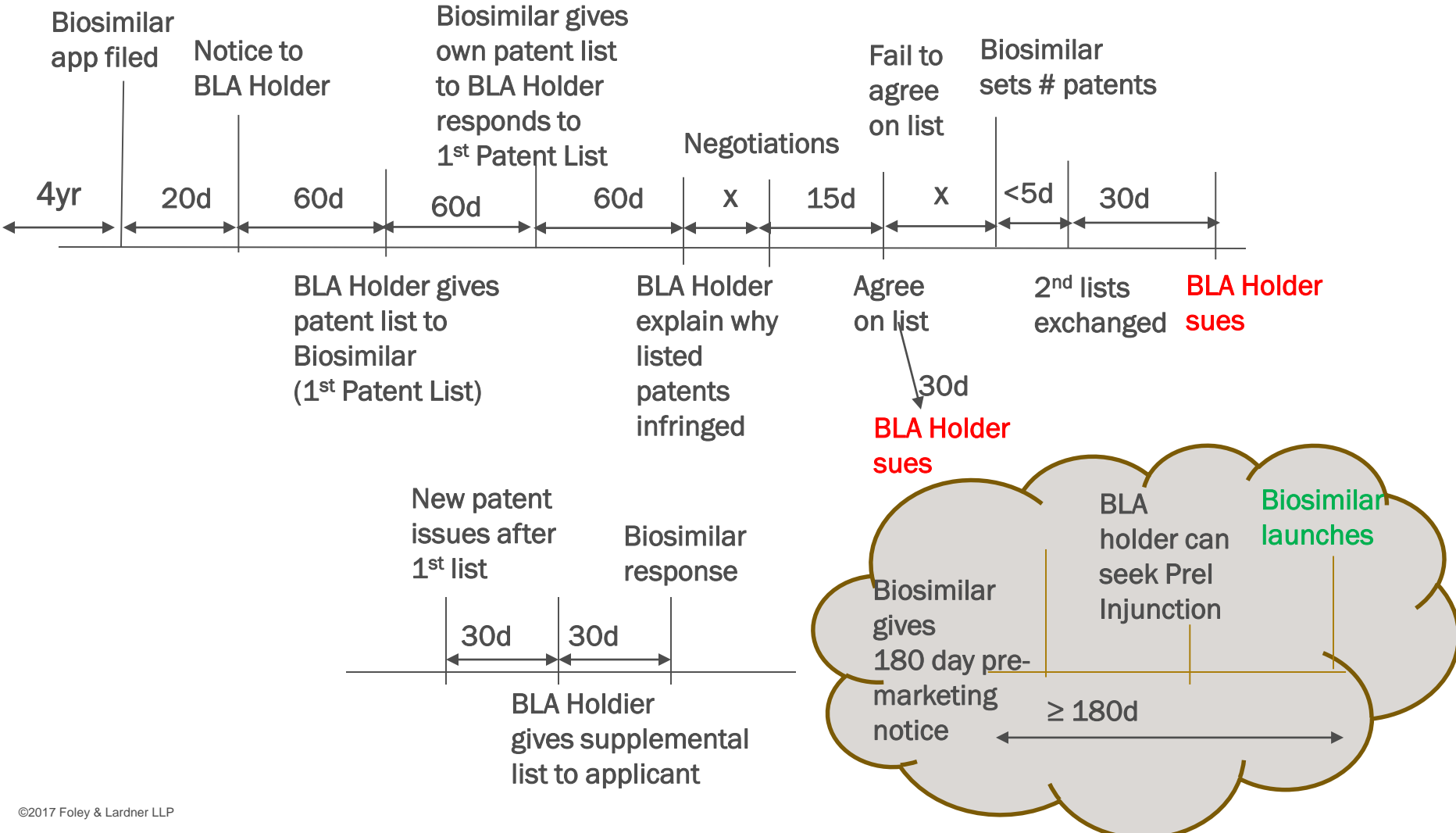
- **Biologics Price Competition and Innovation Act of 2009 (“BCPIA”)**
 - Part of “Obamacare”
- **42 USC 262(l): biosimilar patent disputes**
 - 42 USC 262(l)(2)(A): “Patent Dance” provision
 - 42 USC 262(l)(8)(A): 180-day premarketing notice
- **35 USC 271 (e)(2)(C):**
 - biosimilar patent infringement

What is Patent Dance?



- **42 USC 262(I) prescribes a schedule for exchanging information, particularly patent information**

Patent Dance and Premarketing Notice



Sandoz v. Amgen



- In July, 2014, FDA accepted Sandoz's aBLA for Zarxio® (filgrastim-sndz)
 - biosimilar of Amgen's Neupogen® (filgrastim)
- Sandoz refused to share its aBLA
 - No “patent dance”
- Sandoz gave pre-marketing notice prior to approval

Sandoz v. Amgen



- Is patent dance mandatory?
- Must a premarketing notice be given after FDA approval?

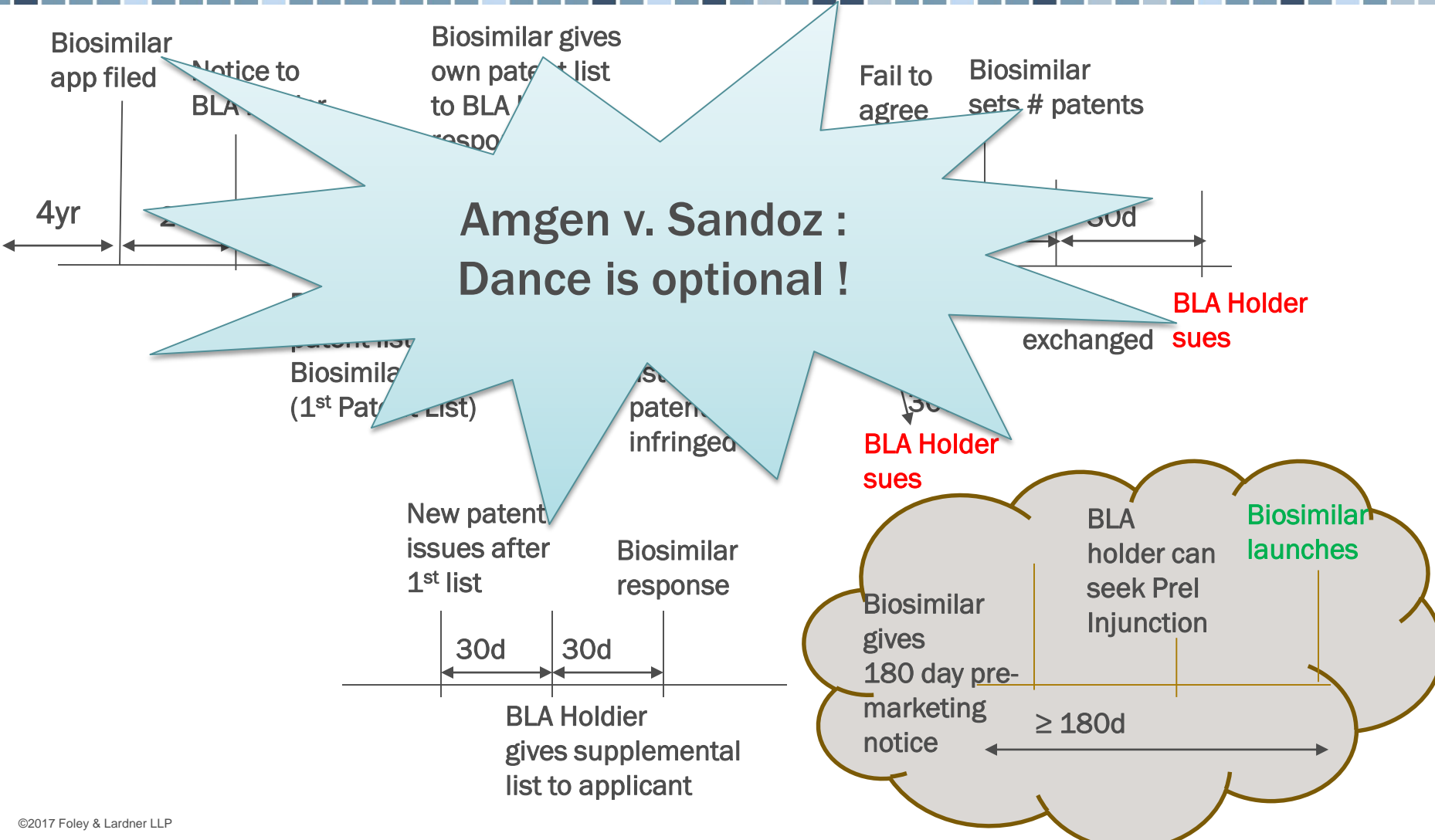
Sandoz v. Amgen



■ Holdings:

- Patent dance is optional
 - When no “dance,” the only federal remedy is being subject to an immediate infringement action brought by the reference product sponsor.
- Biosimilar applicant does not have to wait for FDA approval before giving pre-marketing notice

Patent Dance and Premarketing Notice



BLA Holder Patent Strategies



- **Early diligence during 4 year exclusivity period (before biosimilar application can be filed)**
 - Create/maintain lists of all patents
 - Know which products covered by which patents
 - Know relative strength of patents
 - Use market intelligence to identify likely aBLA filers
- **Retain counsel and scientific experts early**

Biosimilar Patent Strategies

■ Early diligence

- Research patents held by/licensed to BLA holder
- Consider IPR strategies to eliminated/reduce patents to be litigated

■ Biosimilar controls the initial pace of patent disputes.

- But if biosimilar opts out of “patent dance,” BLA sponsor decides when to bring suit.

■ Weigh benefits/drawbacks of participating in “patent dance”

- Early resolution of patent issues
- Risks of sharing information
- Risks if product/method of manufacture change during approval process

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Post Grant Challenges at USPTO



■ *Inter Partes* Review (IPR)

- Patent challenge based on patents and printed publications (35 USC §§ 102, 103, double patenting)
- Any US patent can be challenged

■ Post Grant Review (PGR)

- patent challenge based on *any* ground of patentability (§ 101, § 102, § 103, § 112)
- Only US patents examined under the first to file system can be subject to a PGR (claim priority post 3/2013)

Humira IPR proceedings

- Humira® (adalimumab) for treating autoimmune diseases
 - \$16 billion revenue in 2016
- Coherus successfully challenged three Humira® patents in IPR proceedings
 - U.S. Patent No. 8,889,135, 9,017,680, 9,073,987
 - Claims directed to methods of treating rheumatoid arthritis with a TNF alpha antibody.
- But **“Humira real estate”!**
 - Abbvie owns more than 100 patents related to Humira

Thank You & Questions



Contact Information:

Peng Sun, Ph.D., J.D.

202-295-4072

psun@foley.com

www.foley.com/peng-sun/