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IP Professionals

Intellectual Property: Recent Developments and Implications

Nichole Gifford, Partner, Rothwell Figg Ernst & Manbeck P.C.

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Overview

Introduction *to Biologics Price Competition and Innovation Act ("BPCIA")*

What's at Stake in the Supreme Court's *Sandoz v. Amgen* ruling and practical implications of the decision

How IPRs can provide a strategic alternative to litigation for key patents

INTRODUCTION TO THE BPCIA

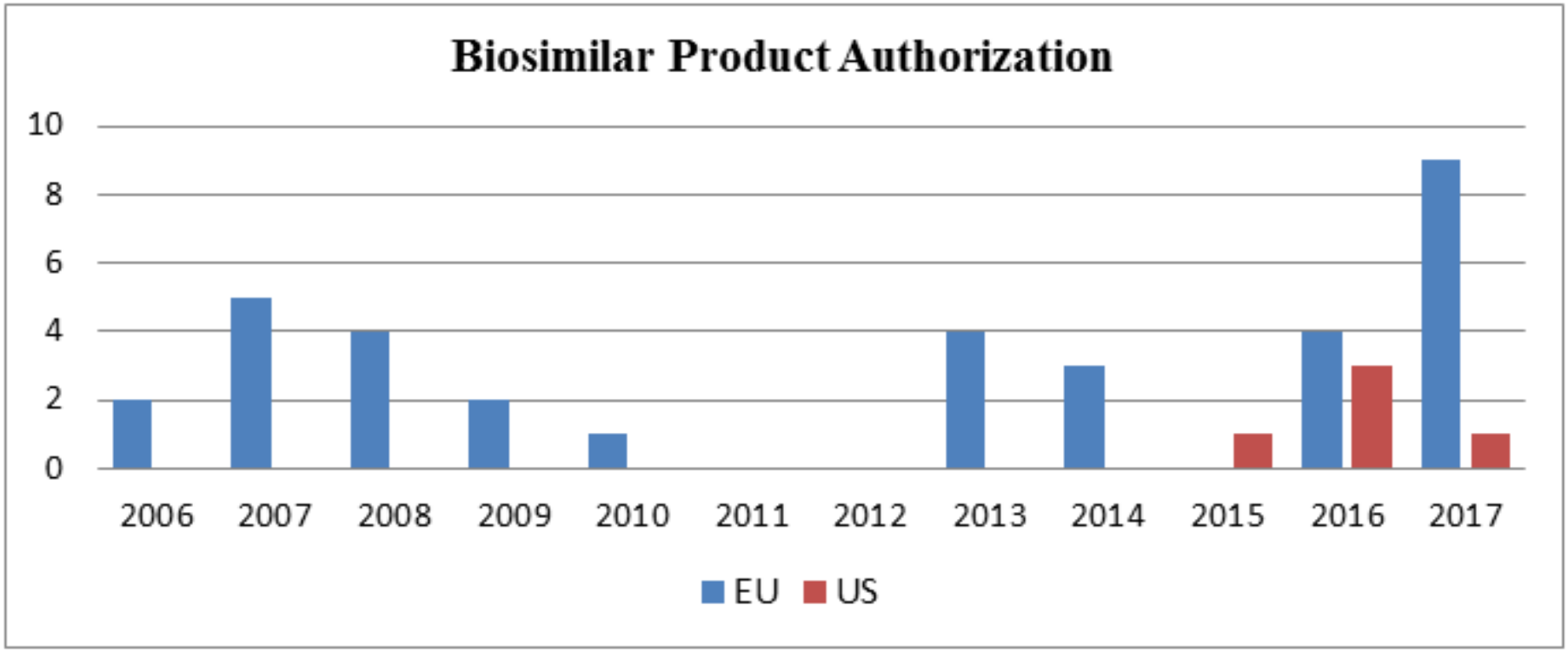
Biologics Price Competition and Innovation Act

- Signed into law on March 23, 2010
- Established an abbreviated pathway for regulatory approval ("licensure") of biological products that are demonstrated to be "biosimilar" or "interchangeable" with an FDA-approved product ("reference product")
- Provides two exclusivity periods for the innovator product
  - 4 years of "data exclusivity" – no biosimilar application permitted
  - 12 years of "market exclusivity" – no biosimilar applications may be approved by FDA (regardless of patents)

Biosimilars Approved by FDA

Drug Names/Active Ingredients	Applicant/ Owner	Approval Date and Launch Status	Reference Product	Reference Product Sponsor
ZARXIO® (filgrastim-sndz)	SANDOZ	03/06/2015 (Launched Sept. 2015)	NEUPOGEN® (filgrastim)	AMGEN
INFLECTRA® (infliximab-dyyb)	CELLTRION (sold by Pfizer)	04/05/2016 (Launched Nov. 2016)	REMICADE® (infliximab)	JANSSEN
ERELZI® (etanercept-szzs)	SANDOZ	08/30/2016 (Not launched)	ENBREL® (etanercept)	AMGEN
AMJEVITA® (adalimumab-atto)	AMGEN	09/23/2016 (Not launched)	HUMIRA® (adalimumab)	ABBVIE
RENFLEXIS® (infliximab-abda)	SAMSUNG BIOEPIS	04/21/2017 (Not launched)	REMICADE® (infliximab)	JANSSEN

Approvals in U.S. Compared to Europe



- 34 Biosimilars Approved in Europe since 2006
- 5 Biosimilars Approved in US since 2010 (as of May 25, 2017)

Can You Make a "Patent Dance"?

Shall We Dance? The BPCIA "Patent Dance"

	• Exchange of information "kicks off" when FDA accepts application
20 days	• Applicant provides copy of application and manufacturing information to Reference Product Sponsor. § (2)(A)
60 days	• RPS provides list of patents that could be infringed. § (3)(A)
60 days	• Applicant provides detailed statement and list of patents. § (3)(B)
60 days	• RPS provides response to Applicant's detailed statement § (l)(3)(C)

15 days	• Parties Negotiate on Patents to be included in litigation § (l)(4)
	  • If parties agree, then immediate suit on agreed patents.
	  • If no agreement, applicant sets number and parties exchange lists § (l)(5)

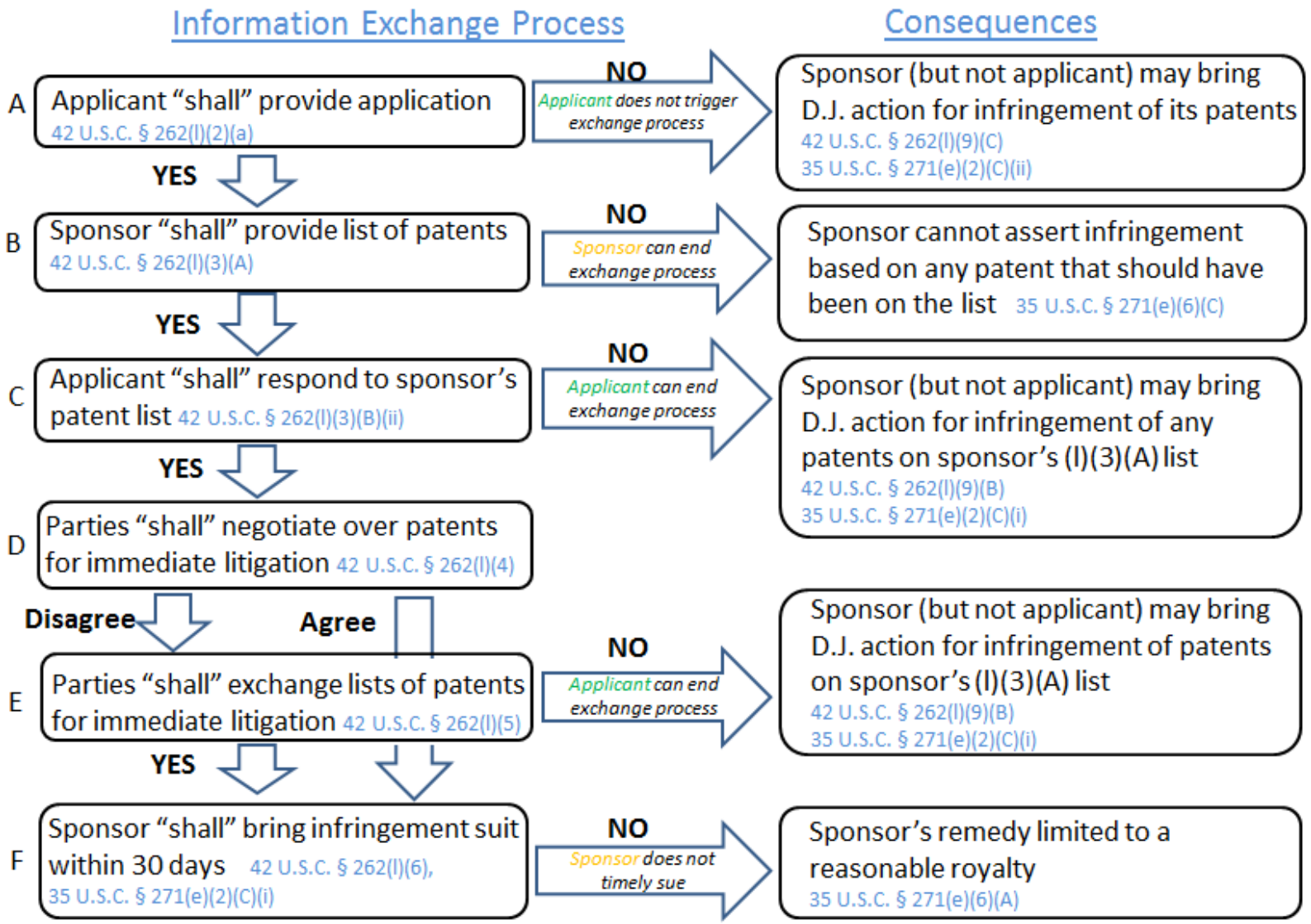
30 days	• Immediate commencement of litigation. Scope varies. § (l)(6)

Notice of Commercial Marketing and preliminary injunction
§ (l)(8)

(A) 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).

(B) After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction….

What are the "Statutory Consequences"



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See Brief for Petitioner at 12, Sandoz, Inc. v. Amgen, Inc., 137 S.Ct. 808 (2017) (No. 15-1039).

Incentives for the Applicant to Participate

- Completing all steps in the "patent dance" allows the **applicant to control the scope and timing** of the initial patent litigation.
- The patent dance could significantly **narrow the parties' dispute**:
- The applicant can use the statutory exchanges to **identify critical patents** and litigate those first.

Incentives for the Sponsor to Participate

- Incentive for RPS to Identify all patents – **loss of right to sue** for infringement
- Inventive for RPS to timely file suit and pursue decision – **limitation on damages** to a "reasonable royalty"

What's at Stake In the Supreme Court's *Sandoz v. Amgen* Decision

Key Issues In Dispute Between the Parties

Question 1: Is the "Disclosure" step of the patent dance optional?

Is a biosimilar applicant required to provide the reference product sponsor with a copy of its biologics license application and related manufacturing information or is the dance optional?

Question 2: When can the Applicant Provide Effective 180-day Notice of Commercial Marketing to the RPS?

Does the biosimilar need to be "licensed" (FDA-approved) before the 180-day notice can be provided by the applicant?

What Did the Lower Courts Decide?

District Court decision March 19, 2015 (N.D. Cal., Judge Seeborg)

- Disclosure of application step of BPCIA is **not mandatory**
- Biosimilar applicant may provide 180-day NCM **prior to FDA approval**

Fed Cir. Decision issued in July 2015, (Split-panel on both issues)

- Disclosure of application step of BPCIA is **not mandatory**. Statute contemplates that applicant may choose not to share its application.
- Notice provision is "stand alone" provision and the 180-day NCM is only effective **after "licensure" (FDA approval)**.

Potential Outcomes and Practical Implications

Practical Effects of Potential Outcomes

If the Supreme Court affirms that disclosure of an application is not mandatory

Substantive litigation could begin immediately after filing of biosimilar application.

In contrast, completing the patent dance can take up to 250 days after application is accepted.

If the Supreme Court affirms on the 180-day notice of commercial marketing provision (notice is permitted after FDA-approval only)

Launch of all biosimilars delayed for 180 days after FDA approval

(unless new FDA rules)

Whose Side Are You On?

Amici Curiae in Support of Sandoz

- United States
- Adello Biologics LLC
- Apotex Inc. and Apotex Corp.
- Coherus Biosciences, Inc.
- Mylan, Inc.
- Hospira, Inc. and Celltrion Inc.
- AARP and AARP Foundation
- Citizens Against Gov't Waste
- The UAW Retiree Medical Benefits Trust
- The National Health Law Program and The Coalition to Protect Patient Choice
- America's Health Insurance Plans
- The Biosimilars Council
- Pharmaceutical Care Management Ass'n
- Nat'l Ass'n of Chain Drug Stores and Healthcare Supply Chain Ass'n

Amici Curiae in Support of Amgen

- AbbVie Inc.
- Janssen Biotech, Inc.
- The Biotechnology Innovation Ass'n
- Eleven Professors (who teach and write on patent law and policy)
- Genentech, Inc.

Products Currently in BPCIA Litigation

NEUPOGEN® (FILGRASTIM) INJECTION

Neulasta® (pegfilgrastim)

Remicade® INFLIXIMAB

EPOGEN® EPOETIN ALFA

PROCRIT® EPOETIN ALFA

Enbrel® etanercept

HUMIRA adalimumab

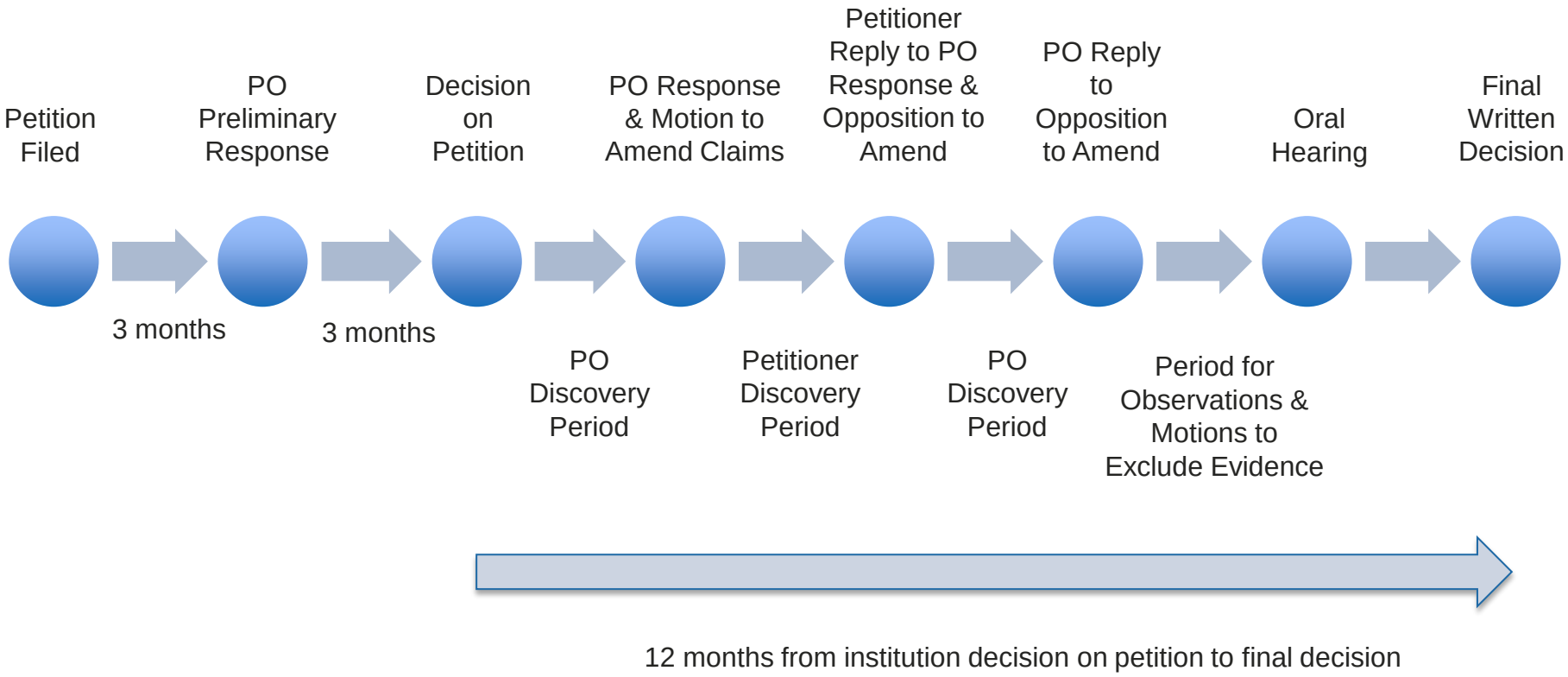
AVASTIN® bevacizumab

IPRs Can Provide A Strategic Advantage for Key Patents

Introduction to IPRs

- *Inter partes* review ("IPR") is one of several post-grant procedures created by the America Invents Act ("AIA") in 2011.
- Provides a mechanism for challenging the patentability of one or more claims of a competitor's issued patent.
- Proceeding is an administrative "trial" conducted by three Administrative Patent Judges ("APJs") from the United States Patent and Trademark Office's Patent Trial and Appeal Board ("PTAB" or "Board").

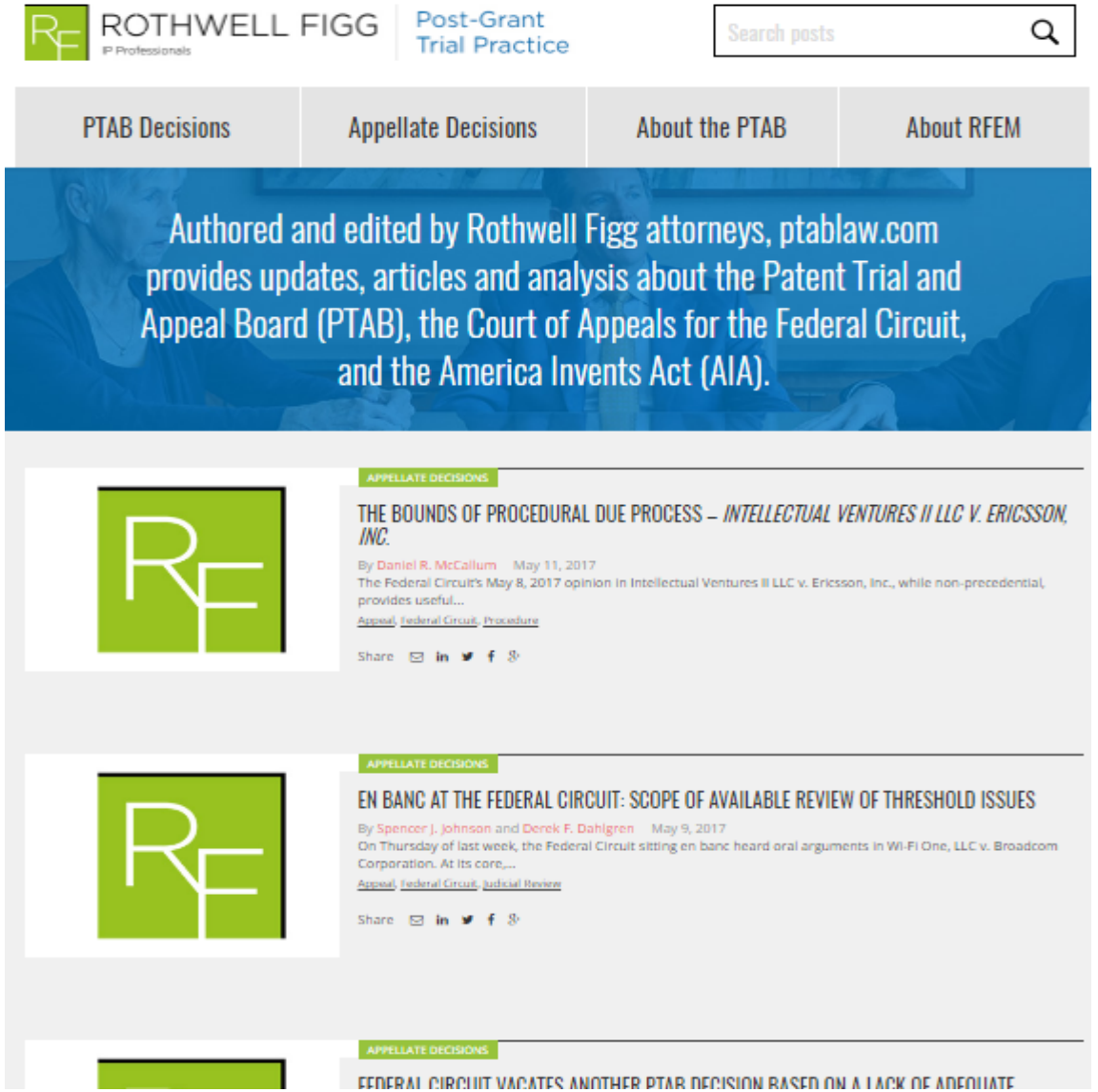
Timeline of an IPR at the PTAB



Potential Benefits of IPRs

- Can be filed earlier in biosimilar development process
- Typically faster and less expensive than district court litigation
- Less stringent legal standards for patent challenger
- Focused proceeding - patentability only
- Patent Judges have technical education
- Other considerations

RFEM's PTAB Website – www.PTABlaw.com



RFEM's IPR Dashboard

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IPR 2017-00737	Patent No. 7,892,549	Hospira	Genentech	Petition: 1/20/17 POPR: 5/2/17 Inst. Dec.: 8/2/17 (est.)	Petition Filed
IPR 2017-00739	Patent No. 7,892,549	Hospira	Genentech	Petition: 1/20/17 POPR: 5/3/17 Hearing: 8/3/17 (est.)	Petition Filed
IPR 2016-01837	Patent No. 7,807,799	Hospira	Genentech	Petition: 9/16/16 Institution: 3/15/17 Hearing: 11/29/17 Decision: 3/15/18 (est.)	Trial Instituted
IPR 2016-1693*	Patent No. 6,407,213	Mylan	Genentech	Petition: 8/30/16 POPR: 12/16/16 Inst. Dec.: 3/10/17	Terminated – Settlement
IPR 2016-1694*	Patent No. 6,407,213	Mylan	Genentech	Petition: 8/30/16 POPR: 12/16/16 Inst. Dec.: 3/10/17	Terminated – Settlement

* The '213 patent is directed to a method of making humanized antibodies. Although the patent does not pertain to particular biologic, Genentech has stated that the method was used for Herceptin® as well as several other products. We have not repeated the listing for this proceeding elsewhere.

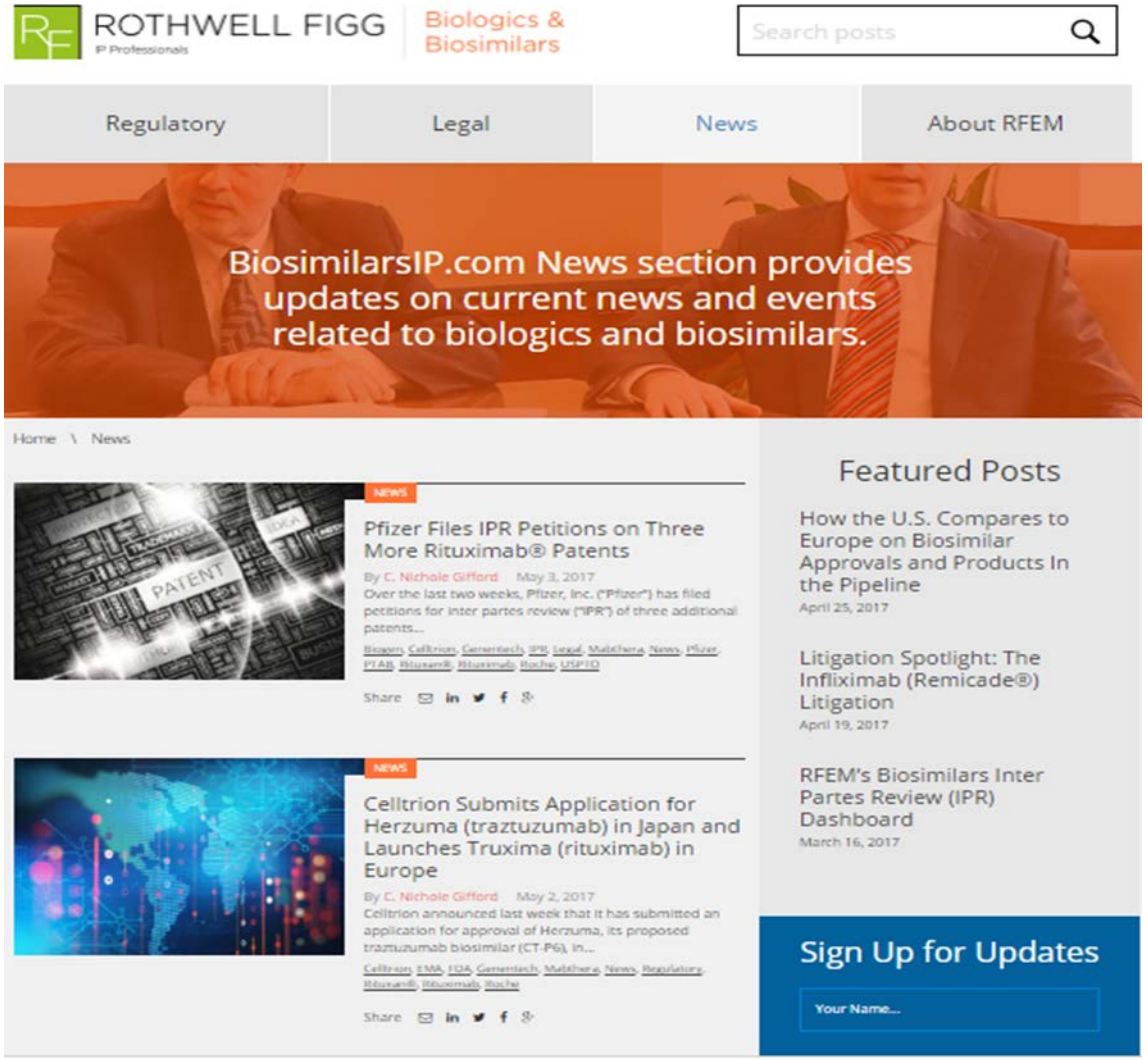
AVASTIN® (Bevacizumab)

IPR Case No.	Patent	Petitioner	Patent Owner	Schedule	Status
IPR 2016-01771	Patent No. 7,622,115	Hospira	Genentech	Petition: 9/9/16 POPR: Waived 12/9/16 Institution: 3/16/17 Hearing: 11/29/17 Decision: 3/16/18 (est.)	Trial Instituted

RITUXAN® (Rituximab)

IPR Case No.	Patent	Petitioner	Patent Owner	Schedule	Status
IPR 2017-01166	Patent No. 8,329,172	Pfizer	Biogen	Petition: 4/21/17 POPR: 7/21/17 (est.) Inst. Dec.: 10/19/17 (est.)	Petition Filed
IPR 2017-01167	Patent No. 8,557,244	Pfizer	Biogen	Petition: 4/27/17 POPR: 8/8/17 Inst. Dec.: 11/8/17 (est.)	Petition Filed

RFEM's Biologics and Biosimilars Site www.BiosimilarsIP.com



Questions?

Nichole Gifford

Partner

ngifford@rfem.com

202.624-1593