Webinar Series: Biosimilars

Biosimilars: 2018
A Year in Review

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Overview

• Biosimilars Series
  • Introduction to the area of biosimilars
  • Explore key developments and trends

• CLE Credit
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• Materials will be made available
  • fr.com/industries/life-sciences

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Upcoming Fish Webinars

2018 Trademark & Copyright Year in Review
Wednesday, January 23 1:00 p.m. EST
Hatch-Waxman
Thursday, February 7 1:00 p.m. EST
Today’s Topics

- Update on U.S. Biosimilars Market through 2018
- Efforts to Increase Biosimilar Competition in 2018 – Private Party, Regulatory, and Legislative
- Biosimilar Litigation in 2018
- Trends in Biologic IPRs in 2018
- Issues to Watch in 2019
U.S. Biosimilar Market
## 2018 FDA Biosimilar Approvals

<table>
<thead>
<tr>
<th>Biosimilar Drug</th>
<th>Biologic Drug</th>
<th>FDA Approval Date</th>
<th>Launch Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Herzuma® (Celltrion/Teva)</strong></td>
<td>Herceptin® (Genentech)</td>
<td>December 14, 2018</td>
<td></td>
</tr>
<tr>
<td><strong>Truxima® (Celltrion/Teva)</strong></td>
<td>Rituxan® (Roche/ Genentech)</td>
<td>November 28, 2018</td>
<td></td>
</tr>
<tr>
<td><strong>Udenyca™ (Coherus)</strong></td>
<td>Neulasta® (Amgen)</td>
<td>November 2, 2018</td>
<td>January 3, 2019</td>
</tr>
<tr>
<td><strong>Hyrimoz™ (Sandoz)</strong></td>
<td>Humira® (AbbVie)</td>
<td>October 31, 2018</td>
<td>2023 per settlement</td>
</tr>
<tr>
<td><strong>Nivestym™ (Pfizer)</strong></td>
<td>Neupogen® (Amgen)</td>
<td>July 20, 2018</td>
<td>October 1, 2018</td>
</tr>
<tr>
<td><strong>Fulphila™ (Mylan / Biocon)</strong></td>
<td>Neulasta® (Amgen)</td>
<td>June 4, 2018</td>
<td>July 26, 2018</td>
</tr>
<tr>
<td><strong>Retacrit® (Pfizer / Hospira)</strong></td>
<td>Epogen® / Procrit® (Amgen / J&amp;J)</td>
<td>May 15, 2018</td>
<td>November 12, 2018</td>
</tr>
</tbody>
</table>
Biosimilars on the U.S. Market

Biosimilars Launched By Year

- **Retacrit®** (epoetin alfa-epbx)
- **Fulphila™** (pegfilgrastim-jmdb)
- **Nivestym™** (filgrastim-aafi)

<table>
<thead>
<tr>
<th>Year</th>
<th>Zarxio® (filgrastim-sndz)</th>
<th>Inflectra® (infliximab-dyyb)</th>
<th>Renflexis® (infliximab-abda)</th>
<th>Udenyca™ (pegfilgrastim-cbqv)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2016</td>
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<tr>
<td>2017</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
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<tr>
<td>2018</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>2019 to-date</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
Efforts to Increase Biosimilar Competition
Challenges in the U.S. Biosimilar Market

“[Biosimilar] Competition is, for the most part, anemic.”

“The fact is that the biosimilar market isn’t as competitive as many observers hoped it would be after Congress first passed legislation creating the pathway.”

Jan. 11, 2019 6:30 a.m. ET

Samsung’s entry into the U.S. drug market is closely watched because biosimilar treatments have faced slow adoption in the country despite expectations of savings to the U.S. health-care system. Unlike generic pills, biosimilars can’t be easily switched in because they aren’t identical to the branded versions they aim to replace. Regulatory morass and lawsuits among drugmakers have also slowed uptake.
Antitrust Allegations

- **Pfizer v. Johnson & Johnson and Janssen** (No. 17-cv-04180, E.D.Pa)
  - J&J and Janssen maintained their Remicade® (infliximab) market share through a multifaceted scheme of “exclusionary contracts that foreclose Pfizer’s access to an overwhelming share of consumers, coupled with anticompetitive bundling and coercive rebate policies designed to block both insurers from reimbursing, and hospitals and clinics from purchasing, Inflectra or other biosimilars of Remicade despite their lower pricing.”

- **In re Remicade (Direct Purchaser) Antitrust Litigation** (No. 18-cv-00303, E.D.Pa.)

- **In re Remicade (Indirect Purchaser) Antitrust Litigation** (No. 17-cv-04326, E.D.Pa.)

- **Walgreen Co. and The Kroger Co. v. Johnson & Johnson, et al.** (No. 18-cv-02357, E.D.Pa)
Citizens Petition re Biosimilar Communication

• Pfizer filed a Citizen Petition on August 22, 2018
  • “Just as there is a need for policies that support innovation, there is also a need for policies that ensure that patients and physicians have truthful and non-misleading information that encourages appropriate uptake of biosimilars so that biosimilars can reach their full potential for patients.”
  • Claims that many RPSs have issued misleading communications about biosimilars and asks FDA to issue guidance
• Novartis and Sandoz’s November 2018 Letter in Support of Pfizer:
  • “[F]urther FDA and HHS action could do more to incentivize the use of biosimilars while still ensuring access to and development of novel biological products.”
  • Claims that originator companies “introduce[e] misinformation about biosimilars into the public domain”
  • Requests FDA guidance as well as partnering with the FTC, issuing a list of companies that disseminate misinformation, and enhancing education
“Without biosimilar competition, U.S. patients and payers will likely see additional price increases on biologics in the years to come.”

“Over the past year, AbbVie entered into global settlement agreements. . . Under the agreements, [the biosimilar manufacturers] will not launch their products in the United States until 2023, but [the] companies will be able to launch their biosimilars into the European market in October 2018. This means that while European patients will benefit from biosimilar competition later this year, Americans may be without access to Humira biosimilars for almost five more years.”

“In light of the importance of biosimilar competition to drive down prices and improve the quality of life for American patients, we urge the FTC to examine global patent settlements relating to biosimilars to ensure they are not in violation of antitrust laws.”
## Humira® Settlements

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Date of Settlement</th>
<th>Date of U.S. Entry</th>
<th>Date of European Union Entry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amgen (Amjevita™)</td>
<td>September 2017</td>
<td>01/31/2023</td>
<td>10/16/2018</td>
</tr>
<tr>
<td>Samsung Bioepis (Imraldi™)</td>
<td>April 2018</td>
<td>06/30/2023</td>
<td>10/16/2018</td>
</tr>
<tr>
<td>Mylan (Hulio™)</td>
<td>July 2018</td>
<td>07/31/2023</td>
<td>N/A</td>
</tr>
<tr>
<td>Sandoz (Hyrimoz™)</td>
<td>October 2018</td>
<td>09/30/2023</td>
<td>10/16/2018</td>
</tr>
<tr>
<td>Fresenius Kabi (MSB11022)</td>
<td>October 2018</td>
<td>09/30/2023</td>
<td>Date of approval from European Medicines Agency</td>
</tr>
<tr>
<td>Momenta (M923)</td>
<td>November 2018</td>
<td>11/20/2023</td>
<td>Date of approval from European Medicines Agency</td>
</tr>
<tr>
<td>Pfizer (PF-06410293)</td>
<td>November 2018</td>
<td>11/20/2023</td>
<td>Date of approval from European Medicines Agency</td>
</tr>
</tbody>
</table>
Legislation to Address Anticompetitive Settlements

• Patient Right to Know Drug Prices Act
  • Signed into law in October 2018.
  • Amends the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.
  • Requires reference biologic and biosimilar manufacturers to report to the FTC and DOJ settlement agreements relating to the “manufacture, marketing, or sale” of biosimilar products for antitrust scrutiny.
  • Brings biosimilar settlement review procedures more in line with requirements for small molecule drugs.

• Biosimilars Competition Act of 2018
  • Contains reporting requirements to FTC and DOJ for any agreements that may keep lower-cost drugs off the market.

• Preserve Access to Affordable Generics and Biosimilars Act
  • Introduced December 2018; reintroduced January 2019.
  • To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, and to prohibit biological product manufacturers from compensating biosimilar and interchangeable companies to delay the entry of biosimilar biological products and interchangeable biological products.
“Our plan is aimed at promoting competition and affordability across the market for biologics and biosimilar products.”

Scott Gottlieb
FDA Commissioner
The FDA will continue to play a critical role in facilitating increased access to biosimilars. The agency is taking steps to more efficiently manage our review and licensure pathways to facilitate biosimilar competition. We are modernizing our policies that govern the development of biosimilars to make it more efficient. We are also educating clinicians, payors and patients about biosimilar products and the rigorous evaluation they must go through. And, we are modernizing regulatory policies to accommodate new scientific tools that can better enable comparison between biosimilars and reference products that may reduce the need for clinical studies.

These actions will help create a more competitive market today, while creating greater incentives for sponsors to make the investments required to support future products that deliver greater benefits to patients and public health after statutory exclusivities have expired.
New FDA Guidance

- June 2018
  - Draft guidance providing recommendations regarding the “nuts and bolts” of meetings with the FDA
- July 2018
  - Final guidance on Labeling for Biosimilar Products
- October 2018
  - Revised draft guidance titled “Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act”
- December 2018
  - “Questions and Answers on Biosimilar Development and the BPCI Act” (Guidance for Industry)
  - “New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2)” (Draft Guidance)
  - “Interpretation of the ‘Deemed to be a License’ Provision of the Biologics Price Competition and Innovation Act of 2009” (Guidance for Industry)
  - “The ‘Deemed to be a License’ Provision of the BPCI Act Questions and Answers Guidance for Industry” (Draft Guidance)
FDA’s Part 15 Hearing – Sept. 4, 2018

- Presentations from reference product sponsors, biosimilar manufacturers, patient advocacy groups, and others
- Topics ranged from technical (e.g., importance of switching studies), to legal (improving the Purple Book), to anecdotal patient stories
- Comment period closed September 21, 2018
Biosimilar Litigation Updates
District Court Biosimilar Litigation in 2018

• 12 newly filed district court patent cases
• Most active districts: District of New Jersey and District of Delaware
• Most active biosimilar litigants: Genentech (8) and Celltrion (6)
  • 3 new cases related to Celltrion’s Herzuma® biosimilar of Genentech’s Herceptin® (trastuzumab).
  • 3 new cases related to Celltrion’s Truxima® biosimilar of Genentech’s Rituxan® (rituximab).
• Most new cases involved 20 to 40 patents (at least initially)
### Pending District Court Litigation

<table>
<thead>
<tr>
<th>Parties</th>
<th>Case No.</th>
<th>Reference Biologic</th>
<th>Current Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>AbbVie v. Boehringer Ingelheim</td>
<td>17-cv-01065 D. Del.</td>
<td>Humira®</td>
<td>Only pending case on Humira® biosimilar; middle of Markman and fact discovery</td>
</tr>
<tr>
<td>Immunex v. Sandoz</td>
<td>16-cv-01118 D.N.J.</td>
<td>Enbrel®</td>
<td>Waiting on opinion re invalidity following bench trial</td>
</tr>
<tr>
<td>Amgen v. Mylan</td>
<td>17-cv-01235 W.D. Pa.</td>
<td>Neulasta®</td>
<td>Claim construction complete; discovery stayed</td>
</tr>
<tr>
<td>Amgen v. Adello</td>
<td>18-cv-03347 D.N.J.</td>
<td>Neupogen®</td>
<td>Motion to dismiss claims vs. Amneal pending; fact discovery closes Aug. 2019</td>
</tr>
<tr>
<td>Amgen v. Apotex</td>
<td>18-cv-61828 S.D. Fla.</td>
<td>Neupogen®/Neulasta®</td>
<td>Motion to dismiss pending; fact discovery closes Jan. 2020</td>
</tr>
<tr>
<td>Genentech v. Amgen</td>
<td>18-cv-00924 D. Del.</td>
<td>Herceptin®</td>
<td>Middle of Markman; motion to dismiss counterclaim of unenforceability</td>
</tr>
<tr>
<td>Genentech v. Samsung Bioepis</td>
<td>18-cv-01363 D. Del.</td>
<td>Herceptin®</td>
<td>Middle of Markman; motion to dismiss counterclaim of unenforceability</td>
</tr>
<tr>
<td>Amgen v. Hospira and Pfizer</td>
<td>18-cv-01064 D. Del.</td>
<td>Neupogen®</td>
<td>Middle of fact discovery</td>
</tr>
<tr>
<td>Janssen v. HyClone Labs.</td>
<td>16-cv-00071 D. Utah</td>
<td>Remicade®</td>
<td>Stayed pending outcome of Celltrion case, now on appeal</td>
</tr>
</tbody>
</table>
Lessons Learned in 2018 District Court Litigation

• Likely no declaratory judgment available to biosimilars in the middle of the dance, even if they provide notice of commercial marketing
    • “Allowing an applicant to side-step the BPCIA’s exchange and negotiation requirements and bring suit on any patent simply by filing its notice of commercial marketing would effectively vitiate the BPCIA’s provisions”
  • *Celltrion v. Genentech* (N.D. Cal., May 9, 2018)
    • Celltrion “fails to state a claim for relief … Because Celltrion did not complete its obligations under Section (l)(5), Celltrion may not file actions for declaratory judgment with respect to the patents at issue.”
    • Celltrion may not “satisfy several steps [of the BPCIA dance] at once” by saying it “wished’ to litigate all patents” on the 3(A) list.
    • Notice of commercial marketing did raise the declaratory judgment bar where Celltrion did not complete the dance
    • Appeal dismissed due to settlement
Lessons Learned in 2018 District Court Litigation

• Unclean hands may be a defense
  • *AbbVie v. Boehringer Ingelheim* (D. Del., June 4, 2018)
    • Granting BI’s motion to compel production of relevant documents related to its unclean hands defense, although not deciding viability of defense.
    • BI had alleged that AbbVie engaged in anticompetitive behavior through its development of a “patent thicket” of overlapping and non-inventive patents.

• One biosimilar applicant may be able to obtain information from the RPS on other biosimilar applicants
  • *AbbVie v. Boehringer Ingelheim* (D. Del., Sept. 7, 2018)
    • Granting BI’s motion to compel production of BPCIA patent contention exchanges between AbbVie and third party Amgen, as well as AbbVie’s settlement agreements with other parties concerning adalimumab.
    • “[T]here is sufficient reason to believe that the discovery will produce admissible and relevant evidence regarding several material issues in the case.”
Pending Questions in District Court Litigation

• Whether biosimilars will be successful in using motions to dismiss
  • *Amgen v. Coherus* (D. Del., March 2018) (*Neulasta®*)
    • Granted Coherus’s motion to dismiss Amgen’s complaint.
    • Found Coherus’s protein purification process differed from the process claimed in Amgen’s asserted patent and Amgen was barred by prosecution history estoppel from asserting infringement under the doctrine of equivalents.
    • Now on appeal.
  • *Amgen v. Mylan* (W.D. Pa.) (*Neulasta®*)
    • Mylan is trying to dismiss the same patent as in *Coherus* on similar grounds.
    • Following the court’s claim construction order in November 2018, Mylan stated that it intends to file a renewed motion to dismiss in January 2019.
    • One ongoing dispute is whether Amgen can prove infringement by relying on evidence outside of Mylan’s aBLA.
  • *Amgen v. Apotex* (S.D. Fla.) (*Neupogen®/Neulasta®*)
    • On December 10, 2018, Apotex moved to dismiss Amgen’s complaint based on prosecution history estoppel and issue preclusion.
    • Amgen’s response is due January 23, 2019.
Pending Questions in District Court Litigation

- Whether biosimilar licensing partners should be subject to BPCIA litigation
  - *Amgen v. Adello and Amneal* (D.N.J.) *(Neupogen®)*
    - Amneal is Adello’s licensing partner.
    - On December 5, 2018, Amneal filed a motion to dismiss on two separate grounds.
      - First, Amneal contended that Amgen’s amended complaint failed to state a claim upon which relief could be granted because only Adello, the aBLA applicant, could commit the artificial act of infringement under the BPCIA.
      - Second, Amneal argued that there is no declaratory judgment jurisdiction because Amgen’s allegations of future marketing and sales—if and when FDA approves the biosimilar—do not give rise to a justiciable controversy.
      - Alternatively, Amneal requested that the court decline to exercise declaratory judgment jurisdiction so as not to “upend the carefully crafted BPCIA statutory scheme.”
  - Briefing will be complete in February 2019
2018 Settlements

- **Genentech v. Pfizer** (17-cv-01672 D. Del.) and **Genentech v. Celltrion** (18-cv-00095, 18-cv-01025 D. Del.)
  - Disputes concerning biosimilars of Genentech’s Herceptin® (trastuzumab)

- **Genentech v. Sandoz** (17-cv-13507 D.N.J.)
  - Dismissed after Sandoz announced it would not be pursuing its current submission for a Rituxan® (rituximab) biosimilar after receiving a Complete Response Letter from FDA earlier this year

- **Genentech v. Celltrion and Teva** (18-cv-00574, 18-cv-11553 D.N.J.)
  - Dispute concerning a biosimilar of Genentech’s Rituxan® (rituximab)

- **AbbVie v. Sandoz** (18-cv-12668 D.N.J.)
  - Dispute related to Sandoz’s biosimilar of AbbVie’s Humira® (adalimumab)
  - Settlement allowed Sandoz to enter the U.S. market in 2023
BPCIA Appeals Decided in 2018

- *Janssen v. Celltrion* (17-1120) and *In re Janssen Biotech, Inc.*, 880 F.3d 1315 (Fed Cir. 2018)
  - Related to U.S. Patent No. 6,284,471 (the “’471 Patent”), a patent covering Janssen’s Remicade® (infliximab).
  - The first action was filed under the BPCIA in the District of Massachusetts and resulted in a ruling that the ’471 Patent was invalid for obviousness-type double patenting.
  - In a separate proceeding at the USPTO, the PTAB also found all claims of the ’471 Patent invalid for obviousness-type double patenting.
  - Janssen subsequently appealed both decisions to the Federal Circuit.
BPCIA Appeals Decided in 2018

- **Janssen v. Celltrion** (17-1120) and *In re Janssen Biotech, Inc.*, 880 F.3d 1315 (Fed Cir. 2018)
  - In January 2018, the Federal Circuit affirmed the PTAB’s ruling.
  - Dismissed Janssen’s arguments that obviousness-type double patenting was inapplicable because the safe-harbor provision of 35 U.S.C. § 121 protected the ‘471 Patent claims.
  - The Federal Circuit held that Janssen could not retroactively amend its continuation-in-part application and re-designate it as a divisional application subject to the safe harbor.
  - The appeal from the district court ruling was then dismissed as moot.
BPCIA Appeals Pending in 2018

- **Janssen v. Celltrion (18-2321 and 18-2350)**
  - Janssen alleged that the cell culture media used by Celltrion to produce its Remicade® biosimilar infringes U.S. Patent No. 7,598,083 (the “’083 Patent”) under the doctrine of equivalents.
  - In July 2018, Judge Wolf of the District of Massachusetts granted Celltrion’s motion for summary judgment of non-infringement.
  - In August 2018, Janssen appealed the non-infringement ruling to the Federal Circuit, and Celltrion cross-appealed.
• **Janssen v. Celltrion (18-2321 and 18-2350)**
  - Janssen filed its opening brief on December 10, 2018, arguing the district court erred by
    1. impermissibly using hindsight to find that a hypothetical claim covering Celltrion’s cell culture medium would have been obvious;
    2. failing to find Celltrion’s arguments regarding ensnarement legally baseless where Celltrion failed to offer any motivation to choose and modify the prior art references; and
    3. failing to draw reasonable inferences in Janssen’s favor (e.g., teaching away from using ferric ammonium citrate and evidence of copying) in its summary judgment analysis.

• Cross-appellant Celltrion’s brief is due on February 11, 2019.
• **Amgen v. Sandoz (18-1551 and 18-1552)**
  - Amgen asserted U.S. Patent Nos. 8,940,878 (the “’878 Patent”) and 6,162,427 (the “’427 Patent”) were infringed by Sandoz’s biosimilars of Neupogen® (filgrastim) and Neulasta® (pegfilgrastim).
  - After claim construction, Amgen and Sandoz stipulated to non-infringement of the ’427 Patent.
  - In December 2017, the Northern District of California granted summary judgment of non-infringement regarding the ’878 Patent because the asserted protein purification method required separate washing and eluting steps, but Sandoz’s process involved a single, simultaneous washing and eluting step.
  - The court also denied Amgen’s Rule 56(d) motion to deny or continue the motion for summary judgment until Sandoz submitted its intended new purification method to FDA, since the revised method would not materially change the infringement analysis.
Amgen v. Sandoz (18-1551 and 18-1552)

- As framed by Amgen, the questions in the consolidated appeals are:
  1. whether the district court properly construed the “washing” and “eluting” elements of claim 7 of the ’878 patent,
  2. whether the district court properly granted summary judgment of non-infringement of claim 7 of the ’878 patent with respect to Sandoz’s current process for manufacturing its biosimilar products,
  3. whether the district court properly denied Amgen’s motion for additional discovery pursuant to Rule 56(d), and
  4. whether the district court properly construed terms in the ’427 patent.
- The issues have been briefed and the Federal Circuit will likely hear oral argument in the first quarter of 2019.
Amgen v. Coherus (18-1993)

- In March 2018, the D. Del. granted Coherus’s motion to dismiss Amgen’s complaint over Coherus’s Neulasta® (pegfilgrastim) biosimilar.
  - The court found that Coherus’s protein purification process differed from the process claimed in Amgen’s asserted patent and Amgen was barred by prosecution history estoppel from asserting infringement under the doctrine of equivalents. Amgen thus failed to state a claim for patent infringement.
- Amgen’s appeal centers around two issues:
  1. whether dismissal of Amgen’s complaint based on prosecution history estoppel was proper, and
  2. whether dismissal of Amgen’s complaint based on disclosure-dedication doctrine was proper.
- The parties have fully briefed the appeal, and the Federal Circuit will likely hear oral argument in the second quarter of 2019.
**BPCIA Appeals Pending in 2018**

- **Amgen v. Hospira (19-1067 and 19-1102)**
  - In September 2017, a jury awarded Amgen $70 million in reasonable royalty damages based on Hospira’s infringement of U.S. Patent No. 5,856,298 (the “‘298 Patent”) in relation to a biosimilar of Amgen’s Epogen® (epoetin alfa).
  - The jury also found that Hospira did not infringe U.S. Patent No. 5,756,349 (the “‘349 Patent”).
  - In ruling on post-trial motions, Judge Andrews of the District of Delaware upheld the jury verdict.
  - Hospira appealed the district court’s judgment of infringement and validity of the ’298 Patent and the court’s award of approximately $80 million. Amgen cross-appealed.
  - Hospira filed its opening appeal brief on December 10, 2018.
Post-Grant Activity
Post-Grant Activity

**Biologic IPRs by Year**

- 2015
- 2016
- 2017
- 2018
Hatch-Waxman Integrity Act

- Proposed legislation to modify the IPR process for pharmaceuticals under Hatch-Waxman and the BPCIA.
  - “[T]o restore the careful balance the Hatch-Waxman Act struck to incentivize generic drug development.”
- Would apply to both generic and biosimilar drug applicants, requiring anyone wishing to challenge a pharmaceutical patent to choose between Hatch-Waxman/BPCIA litigation and an AIA challenge (IPR).
- The legislation is currently under consideration.
Looking Forward
Looking Forward

• Launch of more biosimilars
  • 16 approved to date, but only 7 launched

• Legislative and regulatory review of the balance between competition and innovation

• Resolution of pending anti-trust issues

• Guidance from courts regarding, for example:
  • Role of licensing partners in BPCIA litigation
  • Scope of safe harbor in biosimilar manufacturing
  • Unclean hands in biosimilar litigation
Thank you!

SPECIAL THANK YOU TO PHILIP CHEN

Please send your NY CLE forms or questions about the webinar to marketing at lundberg@fr.com.

A replay of the webinar will be available for viewing at www.fr.com.
Additional Resources


https://www.fr.com/fish-litigation/