Webinar Series: Biosimilars

Biosimilars 102: Biosimilars Litigation and Strategy

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Principal, Washington DC

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Principal, San Diego
Overview

• Biosimilars Series
  o Introduction to the area of biosimilars
  o 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 Biosimilars Webinars:

Biosimilars & IPR

Thursday, March 24
1:00 PM ET
FDA’s recent approval of Sandoz’s Zarxio as biosimilar to Amgen’s Neupogen® (filgrastim) marked the first approval under the BPCIA.

FDA has received additional biosimilar applications, including:

- Celltrion’s biosimilar to Janssen’s Remicade® (in line to be the first biosimilar monoclonal antibody)
- Apotex’s biosimilar to Amgen’s Neulasta® (the long-acting formulation of Neupogen®)
- Hospira’s biosimilar to Amgen’s Epogen® and Janssen’s Procrit®.
# Significant Patents Will Expire Soon

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Overarching Considerations

• Statute is incredibly confusing.
• Safe Harbor applies.
• No stay of FDA approval pending resolution.
• Preliminary Injunctions will always be a factor to consider.
• Bench trial that may morph into jury trial.
Two Major Aspects of BPCIA

1) An information exchange between the applicant and RPS
   - BPCIA provides that within 20 days after the FDA accepts a biosimilar application for review, the applicant “shall provide to the [RPS] a copy of the application . . . and such other information that describes the [manufacturing process(s)].”
   - Initiates an exchange of information and patent accusations between the applicant and RPS, referred to as the “patent dance.”
   - The purpose is to resolve patent issues before commercialization of an ultimately approved biosimilar, so an applicant may be able to avoid an “at risk” launch.
Two Major Aspects of BPCIA

2) Notice of commercial marketing to be provided by an applicant to the RPS

- An applicant “shall provide notice to the [RPS] not later than 180 days before the date of the first commercial marketing of the biological product licensed under” the Act.
- The RPS can then use this period of time to seek a preliminary injunction based on infringement by the approved biosimilar of any patents that were not on the agreed upon list from the patent dance.
It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product) from abroad if the patentee or the owner of the patent has not brought the action for patent infringement against an infringer of the patent.

The following shall be an act of infringement:

(a) An act of infringement of the United States of America, or the owner of a patent for a drug, or a material for use in the manufacture of a drug, shall be an act of infringement if the patent has not brought the lawsuit against an infringer within the time allowed by section 271 of the Patent Act.

(b) Any person, who after the expiration of the 18-month period described in subparagraph (A), or any other person who has been injured by reason of a patent infringement, shall be held liable for the infringement if the patentee or the owner of the patent has not brought the lawsuit against an infringer within the time allowed by section 271 of the Patent Act.

(c) Any person who, after the expiration of the 18-month period described in subparagraph (A), or any other person who has been injured by reason of a patent infringement, shall be held liable for the infringement if the patentee or the owner of the patent has not brought the lawsuit against an infringer within the time allowed by section 271 of the Patent Act.

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The Act of Infringement

(2) It shall be an act of infringement to submit—

(a) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

(b) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151–158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, or

(C)(i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an application seeking approval of a biological product,

or

(ii) if the application for the patent fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a drug that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,
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(c)(i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a sale that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,
42 U.S.C. § 262 (l)(3) . . . or 351(l)(3)

(3) List and description of patents

(A) List by reference product sponsor

Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

(ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant.
The Act of Infringement

(2) It shall be an act of infringement to submit—

(a) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

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(C)(i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,
42 U.S.C. § 262 (l)(2)(A) . . . or 351(l)(2)(A)

(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 used 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;
The Dance – 42 U.S.C. § 262 (l)(3-9)
The Dance

- FDA Notifies BSA
  - 20 d
  - BSA sends BLA dossier + manuf. info
- BLA provides BSA with list of patents
  - 60 d
- BSA provides BLA with detailed statements + counter-list of patents
  - 60 d
- BLA provides BSA with detailed response
  - 60 d
- Parties to negotiate
  - 15 d

- Agreement
  - 30 d
  - BLA initiates lawsuit

- Simultaneous exchange of patents
- No agreement
  - 5 d
  - BSA informs BLA of max # of patents
  - 30 d
  - BLA initiates lawsuit
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When “Shall” means “May”
Background: **Neupogen**; Sandoz and Amgen failed to agree on confidentiality provisions attendant to exchange of biosimilar application under BPCIA

- Amgen files DJ complaint (October 2014) on Sandoz’s failure to follow the BPCIA disclosure procedures; also asserted a state law cause of action for conversion based on Sandoz's use of Amgen's information related to safety, purity, and potency; alleged patent infringement.

- Amgen files PI motion (February 2015) to block commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States:
  - BPCIA says “shall” disclose application (42 U.S.C. § 262(l)(2)).
  - Sandoz’s 180-day notice of commercial marketing is premature because the notice was not “before” being “licensed” by FDA (42 U.S.C. § 262(l)(8)).
  - Provide a copy of the application, complete patent exchange process, provide notice of commercial marketing.
Amgen Inc. v. Sandoz Inc.

- Sandoz’s opposition to MTD
  - as remedies exist for failure of applicant to provide biosimilar application, BPCIA does not mandate disclosure.
  - Amgen is still able to assert its patents and can do so immediately.
  - 180 day notice of commercial manufacturing does not first require FDA approval.
- No irreparable harm
  - Sandoz offered application with “industry standard” confidentiality obligations but Amgen refused.
  - Amgen had right to sue immediately after expiration of 20 day period to disclose application but instead waited 3 months.
  - Any economic harm can be compensated with monetary damages.
Amgen Inc. v. Sandoz Inc.

NDCA denies Amgen’s PI

- Disclosure of biosimilar application is optional
  - “Shall” does not always mean mandatory particularly where the law provides remedies for failure to comply.
- 180-day notice can be provided before FDA approval
  - “Licensed” does not require FDA approval prior to 180-day notice.
  - “Before” modifies “first commercial marketing” not “licensed” thus must give notice “before” marketing.
  - Waiting until FDA approval will give RPS an additional 6 months exclusivity not intended by BPCIA.

- PI Denial
  - Amgen only raised “speculative” notions of irreparable harm.
  - Amgen did not provide any proofs of infringement.
Federal Circuit

A divided panel ruled:

1) the information exchange and “patent dance” procedures were optional and that a biosimilar applicant could choose not to engage in them; but

2) the 180-day notice requirement was mandatory, at least for applicants who had opted out of the patent dance, and that only a notice given after FDA approved the aBLA would be effective to start the 180-day clock.

- According to the Court, Sandoz’s opt-out did not violate the BPCIA or constitute unfair competition, leaving patent infringement as Amgen’s only remedy, but Sandoz’s July 8, 2014, notice was ineffective since its application was unapproved at that time.

- Federal Circuit denied rehearing.
The Dance is currently optional ... despite the use of “shall” . . . But that is not the only way that you can get into Court.
(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.

(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.
Amgen v. Apotex (SD FL)

- Amgen brought preliminary injunction motion.
- Parties stipulated to 3 of the 4 preliminary injunction elements:
  1. Irreparable Harm
  2. Balance of Hardships
  3. Public Interest Served by an Injunction
- The only contested issue was likelihood of success on the merits.
- The only issue actually before the Court was whether the BCPIA requires a company like Apotex, who shared its aBLA pursuant to 262(l)(2), to give Amgen, the BLA, 180 day notice of commercial marketing after FDA licensure.
- The Court ruled that Apotex is required to give Amgen 180-day notice of its intent to market after FDA approves its application.
- Practical result – BLA’s get an additional 180-day market exclusivity.
Limitation on DJ Actions

• If Biosimilar applicant provides confidential access to application, no DJ can be brought by either party before the 180 days notice of commercial marketing is received; DJ can only be brought on “PI patent list.”

• If Biosimilar applicant fails to provide (1) claim by claim statement on initial pioneer list (or newly issued patent) within 60 day (or 30 day) time frame; (2) notice of number of to be exchanged patents; (3) notice of complaint to FDA; (4) or 180 day notice prior to marketing, Pioneer can bring DJ on any patent on “initial Pioneer list” and on any newly issued patent.

• If Biosimilar applicant fails to provide access to confidential information Pioneer can bring DJ or any patent that claims biological product or use of product (but not manufacture of product).
Practical Application
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<td><strong>9.8</strong></td>
<td>Celltrion (Rensima)</td>
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<td></td>
<td><strong>Rituxan (rituximab)</strong>; CD20-directed cytolytic antibody</td>
<td>2018</td>
<td><strong>7.8</strong></td>
<td>Novartis/Sandoz</td>
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<td>Non-antibody biologics</td>
<td><strong>Aransep (darbepoetin alfa)</strong>; Erythropoiesis-stimulating agent</td>
<td>2024</td>
<td>1.9</td>
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<td></td>
<td><strong>Enbrel (etanercept)</strong>; TNF blocker</td>
<td>2028</td>
<td><strong>8.9</strong></td>
<td>Sandoz</td>
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<td></td>
<td><strong>Epogen (epoetin alfa)</strong>; human erythropoietin</td>
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<td>Hospira</td>
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<td></td>
<td><strong>Neulasta (pegfilgrastim)</strong>; Leukocyte growth factor</td>
<td>2015</td>
<td>5.8</td>
<td>Apotex</td>
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<tr>
<td></td>
<td><strong>Neuprogen (filgastim)</strong>; Human erythropoietin</td>
<td>Expired</td>
<td>2.0</td>
<td>Sandoz (Zarxio); Apotex; Hospira</td>
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<tr>
<td></td>
<td><strong>Lantus (insulin glargine)</strong>; Insulin</td>
<td>Expired</td>
<td><strong>7.9</strong></td>
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</tr>
</tbody>
</table>
AbbVie’s Strategy

ABBVIE LONG-TERM STRATEGY

Richard Gonzalez
Chairman and Chief Executive Officer

October 30, 2015
On-market Brands Offer Significant Growth by 2020

2020 Sales: >$18BN
- Anticipate continued growth by driving biologic penetration, increasing market share leadership, and expanding to new indications (HS, Uveitis) with >$1BN in peak sales
- Assume launch of OUS biosimilar in 4Q 2018

2020 Revenue: ~$5BN
- Hematological oncology market $27BN in 2014, growing to ~$50BN by 2020
- 3 diseases (4 indications) FDA approved; front-line CLL under regulatory review
- ~25% of growth from approved indications, 35% from first-line CLL and MCL, remaining from other new hematological indications and other indications (GVHD)
- Potential upside if effective in treating solid tumors in combination with immunology agents, early-stage studies underway

2020 Sales: ~$3BN
- HCV affects 160MM worldwide
- 1st generation successfully established foothold for future innovations
- Highly effective once-daily RBV free regimen for GT1b recently approved in Japan (2nd largest market); GT4 HCV approved in the US under priority review
- 2017 introduction of once-daily, pan-genotypic, RBV-free, ≤12-week regimen based on new protease inhibitor (ABT-493) and next-generation NSSA inhibitor (ABT-530)

2020 Sales: >$1BN
- US Parkinson’s disease population of ~1MM, of which ~190K may be eligible for therapy
- Intestinal gel for advanced Parkinson’s disease affords more consistent drug levels
- Significant efficacy beyond levodopa-carbidopa tablets
- Developing next-generation enhancements with more compact pump

Continued Durable Sales
- Creon, Lupron, Synagis and Synthroid provide steady and durable sales over our long-range plan

Note: Sales for new indications of on-market brands presented on risk-adjusted basis
AbbVie’s Strategy

Strategic Actions Have Positioned AbbVie to Achieve Sustainable Top-Tier Performance

AbbVie’s Mission: Create an innovation-driven, patient-focused specialty biopharmaceutical company capable of achieving sustainable top-tier performance through outstanding execution and consistent stream of innovative new medicines

Our actions:

• Accelerated Humira growth and developed comprehensive strategy in anticipation of biosimilar entry
• Delivered outstanding performance from our promoted portfolio
  • Accelerated Humira growth and developed comprehensive strategy in anticipation of biosimilar entry
• Built strong R&D engine with both biologic and small molecule expertise that has generated above-industry success rate
• Acquired Pharmacyclics, providing a major new growth platform in a key strategic area
• Driven significant operating efficiencies
• Built shareholder value and confidence with investors based on consistent strong performance
• Delivered strong return of capital to investors
• Positioned AbbVie to achieve top-tier performance starting in 2015; current guidance mid-point projects EPS growth of 28.6% in 2015
### AbbVie’s Comprehensive Strategy

#### Broad U.S. Humira Patent Estate

<table>
<thead>
<tr>
<th>Approved Indication</th>
<th>Rheumatoid Arthritis</th>
<th>Gastro Indications</th>
<th>Psoriasis</th>
<th>Psoriatic Arthritis</th>
<th>Ankylosing Spondylitis</th>
<th>Juvenile Idiopathic Arthritis</th>
<th>Hidradenitis Suppurativa</th>
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<td>Composition of Matter</td>
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<td>Formulation</td>
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<td>Manufacturing</td>
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<tr>
<td>Other (Device, Diagnostics, etc.)</td>
<td>15 patents Expire 2024–2032</td>
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</tbody>
</table>
AbbVie’s Comprehensive Strategy . . .

Litigation Process

- Litigation
  - The average time to trial of a patent action in courts hearing 10 or more patent cases was approximately 3.35 years\(^1\)
  - Appeals to the Federal Circuit usually take about a year
- Total Litigation Timing: 4 to 5 years
- Would seek preliminary injunction against at-risk launch

\(^1\) Docket Navigator, Year in Review 2014 at 29
AbbVie’s Comprehensive Strategy…

**AbbVie Immunology Long Range Plan Built Around Achievable Assumptions; Pipeline Represents Significant Potential**

**Key Assumptions**

**International**
- International markets grow mid-single-digits over long range plan
- Plan assumes some limited erosion impact upon Enbrel biosimilar launch starting in 2016
- Biosimilar Humira entry in European markets in **Q4 2018** (assumes no benefit of international IP)

**Biosimilar intellectual property and litigation protect Humira from biosimilar entry until 2022**

- U.S. market grows mid- to high-single-digits over long range plan, driven by ~4-point increase in biologic penetration
- Humira market share remains relatively constant, despite increased competition
- Biosimilar intellectual property and litigation protect Humira from biosimilar entry until **2022**

**Immunology Pipeline**
- Successful penetration of new indications (>$1BN incremental global sales from HS and uveitis)
- Non-Humira Immunology pipeline begins to contribute in 2019, with introduction of selective JAK-1 inhibitor ABT-494
- Total Immunology pipeline expected to contribute nearly $8BN in nominal sales by 2024; ABT-494 represents roughly half of the expected contribution
Amgen Filed an aBLA on Nov. 25, 2015
“The Dance”
Patent “Dance”

• Biosimilar applicant “required” to provide Pioneer with confidential access to Biosimilar application including manufacturing process within 20 days of FDA “acceptance for review.”

• Within 60 days of confidential access Pioneer required to provide Biosimilar applicant with list of patents that could reasonably be asserted; and a designation of patents available for license (“initial Pioneer list”).
The Patent Dance Framework Under BPCIA

Biosimilar files Application

Biosimilar Application accepted by FDA

Biosimilar provides confidential info to RPS

RPS provides patent list to Biosimilar

Biosimilar provides RPS with patent list and detailed statement

RPS & Biosimilar negotiate final list of patents to litigate

15 days

YES

Agreement Reached

30 days

RPS files complaint

NO

Biosimilar identifies number of patents that can be asserted

5 days

Simultaneous exchange of patent lists

30 days

RPS files complaint

180 days before Biosimilar commercialization must notify RPS

~45 days

20 days

60 days
The AbbVie Dance

• AbbVie receives the *aBLA*.
• AbbVie then has 60 days to provide a list of those patents for which an infringement claim could reasonably be made.
• It’s AbbVie . . . They are going to list *ALL 77 patents*.
• In the event that they don’t, Amgen can add patents to the list.
• Amgen then has 60 days to lay out non-infringement and/or invalidity positions.
The Patent Dance Framework Under BPCIA

- Biosimilar files Application
- Biosimilar Application accepted by FDA
- 20 days
- Biosimilar provides confidential info to RPS
- 60 days
- RPS provides patent list to Biosimilar
- 60 days
- Biosimilar provides RPS with patent list and detailed statement

- RPS & Biosimilar negotiate final list of patents to litigate
- 15 days
- RPS provides Biosimilar with detailed statement
- 60 days

- YES
  - Agreement Reached
  - 30 days
  - RPS files complaint

- NO
  - Biosimilar identifies number of patents that can be asserted
  - 5 days
  - Simultaneous exchange of patent lists
  - 30 days
  - RPS files complaint

- 180 days before Biosimilar commercialization must notify RPS
Detailed Statement - Applicant

(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)—

(I) a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

(Further text or details regarding the detailed statement and the process of providing such information)
**The Patent Dance Framework Under BPCIA**

- **Biosimilar files Application**
  - **Biosimilar Application accepted by FDA**
    - **20 days**
    - **Biosimilar provides confidential info to RPS**
      - **60 days**
      - **RPS provides patent list to Biosimilar**
        - **60 days**
        - **Biosimilar provides RPS with patent list and detailed statement**
          - **~45 days**

- **RPS & Biosimilar negotiate final list of patents to litigate**
  - **15 days**
  - **RPS provides Biosimilar with detailed statement**
    - **60 days**

- **Agreement Reached**
  - **YES**
    - **30 days**
    - **RPS files complaint**
      - **180 days before Biosimilar commercialization must notify RPS**
  - **NO**
    - **Biosimilar identifies number of patents that can be asserted**
      - **5 days**
      - **Simultaneous exchange of patent lists**
        - **30 days**
        - **RPS files complaint**
Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).
Where the Wheels Really Come Off the Rails . . .

Biosimilar files Application

~45 days

Biosimilar Application accepted by FDA

20 days

Biosimilar provides confidential info to RPS

60 days

RPS provides patent list to Biosimilar

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5 days

Simultaneous exchange of patent lists

30 days

RPS files complaint

180 days before Biosimilar commercialization must notify RPS
I. 2nd Wave Litigation

Biosimilar Notice of Commercial Marketing and Preliminary Injunction Procedure

• Biosimilar applicant must provide Pioneer with 180 day notice of intent to market commercially.

• Pioneer may seek preliminary injunction (PI) on any patents on the “initial Pioneer list” or “initial Biosimilar list” that are not also included on the “negotiated list” or the “exchanged lists.”

• Both parties required to reasonably expedite discovery in any infringement action seeking PI.
Why Dance?

- Current uncertainty re: notice of commercial marketing.
- Potential for negotiated settlement with rational players.
- Preliminary injunction factors.
INJUNCTIVE RELIEF
Preliminary Injunction

- Two types of Preliminary Injunctions:
  - Those that maintain the status quo.
  - Those that alter parties’ positions.

- Four factors weighed in assessing whether to issue a preliminary injunction:
  1. Irreparable Harm.
  2. Balance of Hardships.
  3. Public Interest Served by an Injunction.
  4. Likelihood of Success on the Merits.
Preliminary Injunction

Motion Success

<table>
<thead>
<tr>
<th>Type of court document</th>
<th>Motion/Application for Preliminary Injunction</th>
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<tr>
<td>Court/Agency</td>
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<td>75.0%</td>
<td>50.0%</td>
<td>55.6%</td>
<td>55.6%</td>
</tr>
</tbody>
</table>

FISH.
Statutory Injunction

of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the licence or sale is conditioned.

statutory injunction may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or import into the United States a patented invention other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 2, 1953 which is set forth in section 35(q)(2) (1953 U.S.C. (as added by section 14 of the Magna Carta Act of 1948 and the Act of March 2, 1953) which is set forth in section 35(q)(2) (1953 U.S.C. (as added by section 14 of the Magna Carta Act of 1948)

of the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(k) of such Act, and the biological product has not yet been approved because of the biological product involved in the infringement.

(3) If the court finds that the biological product involved in the infringement is not a new animal drug or veterinary biological product as those terms are used in the Federal Food, Drug, and Cosmetic Act, and the Act of March 2, 1953, the court may not enter a permanent injunction unless the court finds that the biological product involved in the infringement is not a new animal drug or veterinary biological product and that the biological product, if not provided on the market, is not a new animal drug or veterinary biological product.

(4) The court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed.

(5) A declaratory judgment may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale of a new animal drug or veterinary biological product involved in the infringement.
Injunctive Relief

• Duration
• Products
• Parties
• Irreparable Harm
• Did you ask for it in the *beginning*?????
• *MAKE YOUR RECORD!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!
Questions?
Biosimilars Webinar Series

Mark your calendar!

Upcoming Webinars: Biosimilars & IPR

Thursday, March 24
1:00 pm EST
Thank you!

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 fr.com/industries/life-sciences.