11th Annual Patent Law Institute

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Life Sciences Litigation: Trends and Trajectories (PowerPoint slides)

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Life Sciences Litigation

Trends and Trajectories

PLI's 11th Annual Patent Law Institute
Douglas R. Nemec
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Much of what you are about to read may be moot by the time you receive it.
Overview

• The Trump Administration’s push for repeal of the Affordable Care Act, which includes the Biologics Price Competition and Innovation Act (”BPCIA”), may upend the biosimilar approval and patent challenge framework

• New administration may take more conservative approach to antitrust enforcement

• David Kappos recently called on Congress to abolish § 101 of the Patent Act
Recent Key Biosimilar Litigation

- Interpreting the Biosimilar Act
- Review of Large Molecule Litigation
Overview: Let’s Learn the Lingo

Glossary

- **BLA**: Biologics License Application
- **RP**: Reference Product
- **RPS**: Reference Product Sponsor
- **aBLA**: Abbreviated Biologic License Application
- **BA**: aBLA Applicant
- **Patent Dance**: Pre-litigation, post-aBLA exchange of information between the RPS and the BA
- **First Wave Litigation**: RPS can bring patent infringement lawsuit over negotiated list of patents from patent dance or over violations of BPCIA during dance
- **Second Wave Litigation**: RPS can pursue preliminary injunction after BA’s notice of commercial marketing for patents identified during patent dance but not litigated in First Wave
Overview: Biosimilar Approval Pathway and the “Patent Dance”

**Major Global Impact**

The biosimilar market is expected to play an increasing role in the global economy.

- Large projected market share.
- May alleviate impending small-molecule drug “patent cliff.”
- Cost of biologics can be enormous:
  - Spinraza™, $375,000 per patient for one year of treatment
  - Humira®, $14B global sales in 2015
  - Enbrel®, $5B global sales in 2015
Overview: Biosimilar Approval Pathway and the “Patent Dance”

Abbreviated Licensure for Biosimilar Biological Products

- Licensure pathway laid out in § 351(k) of the Public Health Service Act (“PHSA”), as amended by the BPCIA.

- Biological products may rely on the FDA determinations made for similar, previously licensed biological products.
Overview: Biosimilar Approval Pathway and the “Patent Dance”

FDA shall license a biological product under § 351(k) if:

- The information submitted is sufficient to show the biological product is **biosimilar** or **interchangeable**; and

- The applicant **consents to inspection** of the facility.
Overview: Biosimilar Approval Pathway and the “Patent Dance”

Biosimilarity

- **Definition**: the biological product is
  - Highly similar to the reference product; AND
  - Is not meaningfully different in terms of safety, purity and potency from the reference product.

- **Demonstrating Biosimilarity**:
  - **Analytical study** including structural and functional analysis.
  - **Animal study** including toxicology studies, animal PK and PD measures, and animal immunogenicity assessments.
  - **Clinical study** to demonstrate safety, purity and potency.

Interchangeability

**Definition:** the biological product is:
- Biosimilar;
- Expected to produce the same clinical result as the reference product in any given patient; and
- No increased risk in terms of safety or efficacy from alternating use of the reference product and biological product.

**Demonstrating Interchangeability:**
- Very difficult when first filed.
- No biosimilar has yet been approved as interchangeable.
Overview: Biosimilar Approval Pathway and the “Patent Dance”

Exclusivity Rules for Biosimilars

- **12 year biologic exclusivity**: No approval of biosimilar until 12 years after the licensing of the reference product.

- **4 year submission exclusivity**: No submission of biosimilar application until 4 years after licensing of the reference product.

- **Exclusivity for Interchangeable Biosimilars**: Exclusivity granted for first interchangeable biosimilar.
Overview: Biosimilar Approval Pathway and the “Patent Dance”

The Patent Dance

- FDA accepts abbreviated application.
- Applicant must provide sponsor with access to application.
- Sponsor must provide applicant with list of infringed patents and licensing proposals.
- Applicant must provide sponsor with non-infringement and invalidity contentions and a counter list of infringed patents.
Overview: Biosimilar Approval Pathway and the “Patent Dance”

The Patent Dance (continued)

- **Sponsor must provide applicant with non-infringement and invalidity contentions.**

- **Parties must negotiate to compile a list of patents to litigate.**

- **Parties exchange patent lists within 5 days of notice of applicant’s patent list size.**

- **Sponsor must bring litigation on all patents in both lists.**

- **Agreement**
  - **Sponsor must bring litigation on negotiated list.**

- **No Agreement**
  - **30 day max.**
  - **Sponsor must bring litigation on all patents in both lists.**

**Timeline:**
- 60 day max.
- 15 day max.
- 30 day max.
Key Cases Interpreting BPCIA

Key Cases:

- Amgen v. Sandoz, 794 F.3d 1347 (Fed. Cir. 2015)
- Amgen v. Apotex, 827 F.3d 1052 (Fed. Cir. 2016)
Key Biosimilar Litigation: Interpreting the Biosimilars Act

Must We Dance?

No more dancing post Amgen v. Sandoz?

• In Amgen, the Federal Circuit held that the patent dance was not necessary; instead, a patent infringement suit is the sole relief available where an applicant chooses not to dance.

• Under Amgen, an applicant may only give its 180-day notice of commercial marketing after the FDA has approved its product.
No more dancing post *Amgen v. Sandoz*?

- In January 2017, the Supreme Court granted Sandoz’s petition for *cert* and Amgen’s cross-petition.

- Sandoz’s petition asked the Supreme Court to review the Federal Circuit’s interpretation of the “notice of commercial marketing” provision.

- Amgen’s cross-petition asked the Supreme Court to review the holding that the patent dance is optional.
Must We Dance?

No more dancing post *Amgen v. Sandoz*?

- The Solicitor General filed a brief before the Supreme Court granted *cert*, siding with Sandoz on the merits of both issues:
  - Agreed that the “patent dance” disclosure provisions are not mandatory, but with different reasoning than the Federal Circuit
  - Argued that Congress did not intend a further 180-day delay after the biosimilar receives approval, and that failure to comply with this notice provision should not give a right to an injunction
Amgen v. Apotex, 827 F.3d 1052 (Fed. Cir. 2016)

- Notice of commercial marketing effective only after FDA licensing, even where applicant performed patent dance

- Notice provision is enforceable by injunction

- Supreme Court denied cert in December 2016, though it could address these issues in Amgen v. Sandoz—especially considering that the Supreme Court granted Apotex's motion for leave to file a brief as amici curiae in that case
Still More Dancing Around The Dance


- Amgen sought a declaratory judgment that Sandoz violated the BPCIA by refusing to participate in steps of the patent dance.

- Sandoz later reengaged in the patent dance, and the complaint was dismissed.
**Key Biosimilar Litigation: Interpreting the Biosimilars Act**

**Scope of Discovery**


- The District Court held that specific manufacturing information regarding Hospira’s proposed biosimilar need only be produced if it relates to claims already asserted.

- Appeal pending with Federal Circuit, considering:
  - Whether the Federal Circuit has jurisdiction to review orders on such discovery disputes.
  - Whether the ruling on discovery runs afoul of the Federal Circuit’s guidance in *Amgen v. Sandoz* that an RPS “can access the required information through discovery” in an infringement suit when applicants do not make all disclosures in patent dance.
Key Biosimilar Litigation: Large Molecule Litigation

Key Biosimilar Challenges:

- **Amgen v. Apotex**, No. 15-cv-61631 (S.D. Fla.) (Neulasta® (pegfilgrastim) and Neupogen® (filgrastim); decrease infection in patients receiving anti-cancer drugs)

- **Janssen v. Celltrion**, No. 1:15-cv-10698 (D. Mass.) (Remicade® (infliximab); rheumatoid arthritis and other autoimmune disease)

- **Amgen v. Hospira**, No. 1:15-cv-00839 (D. Del.) (Epogen®/Procrit® (epoetin alfa); anemia)

- **Amgen v. Sandoz**, Nos. 3:14-cv-04741, 3:16-cv-02581 (N.D. Cal.) (Neulasta® (pegfilgrastim) and Neupogen® (filgrastim))

- **Immunex v. Sandoz**, No. 2:16-cv-1118 (D.N.J.) (Enbrel® (entanercept); rheumatoid arthritis and other autoimmune diseases)

- **AbbVie v. Amgen**, No. 1:16-cv-00666 (D. Del.) (Humira® (adalimumab); rheumatoid arthritis and other autoimmune diseases)
Key Biosimilar Litigation: Large Molecule Litigation

**Large Molecule Litigation**

*Amgen v. Apotex, No. 15-cv-61631 (S.D. Fla.) (Neulasta® (pegfilgrastim) and Neupogen® (filgrastim))*

- First final judgment and trial under the BPCIA
- After a bench trial in July 2016, the District Court found all claims not infringed
- Federal Circuit appeal pending on judgment of non-infringement
- The patent-at-issue is also the subject of a pending IPR petition
### Key Biosimilar Litigation: Large Molecule Litigation

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<td>• First jury trial under the BPCIA set for February 2017</td>
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<td>• District Court entered partial final judgment of invalidity for double patenting on one of the two patents-in-suit</td>
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<td>• Federal Circuit appeals pending on District Court judgment of double patenting and <em>ex parte</em> reexamination ruling finding patent invalid for double patenting</td>
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<td>• Pfizer announced intention to launch its biosimilar Inflectra® at-risk by November 2016</td>
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Key Biosimilar Litigation: Large Molecule Litigation

**Amgen v. Hospira**, No. 1:15-cv-00839 (D. Del.) (Epogen®/Procrit® (epoetin alfa), anemia)

- Jury trial set for September 2017
- Hospira’s disclosure of manufacturing information during patent dance at issue in pending Federal Circuit appeal, discussed above
- Court denied Hospira’s motion to dismiss Amgen’s request for declaratory judgment that Hospira’s pre-approval notice of commercial marketing is legally ineffective
- Hospira’s biosimilar is not yet approved
Key Biosimilar Litigation: Large Molecule Litigation

**Large Molecule Litigation**

*Amgen v. Sandoz, Nos. 3:14-cv-04741, 3:16-cv-02581 (N.D. Cal.) (Neulasta® (pegfilgrastim) and Neupogen® (filgrastim))*

- Jury trial set for December 2017.

- Sandoz’s conduct during patent dance for biosimilars to these RPs was at issue in the D.N.J. case and the pending Supreme Court case, discussed above.

- One of Sandoz’s biosimilars, Zarxio®, was the first biosimilar approved by the FDA and is on the market. The other biosimilar is not yet approved.
Key Biosimilar Litigation: Large Molecule Litigation

**Immunex v. Sandoz, No. 2:16-cv-1118 (D.N.J.) (Enbrel® (entanercept))**

- Bench trial set for April 2018; *Markman* hearing set for February 2017
- Sandoz agreed to Immunex’s patent list and waived its right to receive statement on infringement/validity, allegedly asserting that the patent dance was complete and that Immunex must bring suit within 30 days
- Sandoz’s biosimilar Erelzi® is approved, but Sandoz stipulated not to launch its product before a date that is not public
Key Biosimilar Litigation: Large Molecule Litigation

AbbVie v. Amgen, No. 1:16-cv-00666 (D. Del.) (Humira® (adalimumab))

- Bench trial set for November 2019
- Amgen identified 61 patents infringed by AbbVie, which the parties narrowed to 10 patents for this First Wave litigation
- Amgen’s biosimilar Amjevita® is approved, but Amgen asserted in its answer that it will not launch its products for 180 days after approval
Potential New Biosimilar Litigation based on FDA Filings

- FDA accepted for review Samsung Bioepis/Merck’s aBLA for biosimilar to Remicade®
- FDA accepted for review Coherus Biosciences’ aBLA for biosimilar to Neulasta®
- Mylan/Biocon submitted aBLA for biosimilar to Herceptin®
- Amgen/Allergan submitted aBLA for biosimilar to Avastin®
Key Biosimilar Litigation

Conclusions

Bounds of BPCIA are Relatively Unsettled

• Supreme Court could provide clarity in its first chance to review BPCIA requirements

• Threat of repeal of the BPCIA by the new administration adds more uncertainty
The Future of Reverse Payment Settlements in ANDA Litigation
Reverse Payment Settlements Disfavored


- Rule of reason applied to pharmaceutical patent settlements even when within the scope of the patent.
Recent Circuit Case Law

- *In re: Nexium® (Esomeprazole) Antitrust Litigation* (1st Cir. 2016)
  - Affirmed first jury verdict on pharmaceutical company settlements since *Actavis*.
  - Found antitrust violation in reverse payment but no injury, because the retailers had not shown that Ranbaxy could have launched its generic sooner.
  - Petition for rehearing and rehearing *en banc* denied in January 2017.
Future of Reverse Payment Settlements in ANDA Litig.

Recent Circuit Case Law

- *In re Loestrin 24 Fe Antitrust Litigation* (1st Cir. 2016)
  - Holding *Actavis* controls a settlement agreement which allows delayed entry of a generic in return for favorable promotional deals and the brand maker’s promise not to introduce a generic.

- *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.* (3d Cir. 2015)
  - Holding consideration in the form of an agreement by the brand not to launch an “authorized generic” during the generic’s 180-day exclusivity period can be a reverse payment under *Actavis*
  - Petition for *cert* denied November 2016
Future of Reverse Payment Settlements in ANDA Litig.

Statistics Following Actavis*

21 Settlements potentially involving pay for delay
- 20 different branded products.
- 10 include compensation solely in the form of cash.
  - 9 purportedly covering litigation fees.
  - 1 in the form of debt forgiveness.
- 6 include compensation in the form of a side business deal.
- 5 include brand manufacturer's promise not to market an authorized generic for some period of time.

111 of the 160 final settlements restrict the generic manufacturer's ability to market its product but contain no explicit or possible compensation.

*Statistics cover FY 2014, the most recent data from the FTC
Future of Reverse Payment Settlements in ANDA Litig.

Two Cases in the Third Circuit May Clarify Pleading Standards

- In re: Wellbutrin XL Antitrust Litigation, Nos. 15-2875 15-3559, 15-3591, 15-3681, and 15-3682
  » Deal allowed patent dispute to continue and generics makers to launch products either whenever the generics makers prevailed in the patent suit or by a set date

- In re: Effexor XR Antitrust, No. 15-1342
  » “No-authorized generic” deal
Future of Reverse Payment Settlements in ANDA Litig.

President-elect Trump’s appointees may signal relief on pay-for-delay policy:

- Selected former FTC commissioner Joshua Wright to lead the transition on antitrust and the FTC

- Wright has criticized the FTC's approach to pay-for-delay settlements and suggested he would take a more conservative approach
Future of Reverse Payment Settlements in ANDA Litig.

Conclusions

Available reverse payment settlements:

- Payments to reimburse attorneys’ fees.

- Early entry by the generic without any payment.

N.B. Variations of both of these scenarios may give rise to antitrust scrutiny.
3 Facts and Strategies for Life Sciences IPRs
Facts and Strategies for Life Sciences IPRs

Life Sciences IPRs Are Growing More Common

- Over 530 life sciences IPRs have been filed in total since the post-grant opposition procedures took effect.

- ~170 of these life sciences IPRs were filed in 2016, and ~190 were filed in 2015.
Facts and Strategies for Life Sciences IPRs

Anatomy of Life Sciences IPRs

• 94% filed by pharmaceutical and biological companies

• 6% filed by hedge funds
  – Nearly all filed by Coalition for Affordable Drugs (hedge fund created by Kyle Bass).
  – Only three successful challenges from Bass:
    » Shire's patent covering Gattex®; on appeal in the Federal Circuit
    » Two Celgene patents covering three Orange Book Drugs: Thalomid®, Pomalyst®, and Revlimid®; requests for rehearing pending
  – Last IPR filed by Bass in Sept. 2015.
Facts and Strategies for Life Sciences IPRs

Conclusion

Takeaways

• Life sciences IPRs are heating up.

• Hedge funds are not dominating life sciences IPRs in general; Kyle Bass has been the prime driver behind hedge fund initiated life sciences IPR petitions.

• Statistics show that life sciences IPRs are less likely to be instituted and claims, once instituted, are more likely to survive.
Recent Key Life Sciences Litigations
Recent Key Life Sciences Litigations

The U.S. has led the world in global medical innovation.

- **Ranked first** in contributions to global life-sciences innovation.

- More than ½ of IP related to the world’s new medicines was invented in America between 1997 and 2012.

- In the 2000s, U.S. biopharmaceutical companies introduced more new chemical entities than companies from the next five nations combined.
Recent Key Life Sciences Litigations

The § 101 Trend May Spell Trouble

Recent judicial decisions on § 101 may alter this trend
Recent Key Life Sciences Litigations

The Shift Toward Strict Application of § 101

Mayo Collaborative Services v. Prometheus Laboratories, Inc. (U.S. 2011)

- Patented method for optimizing treatment of certain gastrointestinal diseases by adjusting the amount administered based on the medicine's interaction with the body.

- Under § 101, a process which merely applies a natural law without an inventive concept is patent ineligible.
Recent Key Life Sciences Litigations

The Shift Toward Strict Application of § 101

Association for Molecular Pathology v. Myriad Genetics (U.S. 2013)

- Patented isolated forms of genes that indicate a high risk of developing breast cancer.

- Under § 101, naturally occurring gene sequences are not patent eligible; however, molecules that do not occur naturally are patent eligible.
Recent Key Life Sciences Litigations

The Shift Toward Strict Application of § 101

**Ariosa Diagnostics, Inc. v. Sequenom, Inc. (Fed. Cir. 2015) (en banc)**

- Patented methods of making a prenatal diagnosis based on non-invasive testing using cell free fetal DNA.

- Under § 101, the application of a well-known method used for a new purpose does not contain the inventive concept required under the *Mayo-Alice* framework.

- Judge Lourie warns: "a crisis of patent law and medical innovation may be upon us."

- Supreme Court denied *cert* in June 2016.
The Shift Toward Strict Application of § 101

**Genetic Technologies Ltd. v. Merial LLC** (Fed. Cir. 2016)

- Patented method of analyzing sequences of genomic DNA by amplifying the exon DNA and then analyzing the linked intron region.

- Under *Mayo, Alice* and *Ariosa*, using a well-known method in a new context based on discovery of exon-intro linkages was insufficient to add the inventive concept required to satisfy § 101 patent eligibility.
Recent Key Life Sciences Litigations

The Trend May Be Slowing

*Rapid Litigation Management LTD v. Cellzdirect, Inc.* (Fed. Cir. 2016)

- Patented method of an improved process of preserving hepatocytes (liver cells).

- Reversed district court’s finding of patent ineligibility—*first eligibility finding* since *Alice* on claims relating to a "law of nature" or "natural phenomenon."

- Held claims were not directed to ineligible law of nature, but rather “a new and useful laboratory technique.” Further, the claims reflected a “significant” improvement that was not routine or conventional given unpredictability in field.
Recent Key Life Sciences Litigations

Beware The Slippery Slope

Recent judicial opinions at the district level signal the situation Judge Lourie warned might ensue—but *Cellzdirect* and computer-based § 101 precedent suggest courts are tapping the brakes.

[Image of caution and slippery slope sign]

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Recent Key Life Sciences Litigations

**District Courts**

**Cautious**

**Bristol-Myers Squibb Co. v. Merck & Co., Inc. (D. Del. Mar. 17, 2016) (Sleet, J.) (Keytruda® (pembrolizumab))**

- Patented method of cancer treatment using the body’s immune system via the PD-1 pathway.

- Denied the 12(b)(6) motion to dismiss upon finding that “[w]hen the factual allegations . . . [are] read in the light most favorable to [the plaintiff], there are . . . material factual disputes . . . .”

- Nonetheless, the court held that the patent failed step one of the *Alice* test “conclud[ing] that . . . the [patent] touches upon a natural phenomenon by using T cells to activate the immune system.”
Recent Key Life Sciences Litigations

District Courts

Cautious

Vanda Pharms., Inc. v. Roxane Labs., Inc. (D. Del. Aug. 26, 2016) (Sleet, J.) (FANAPT® (iloperidone))

- Includes patented personalized medicine method claims directed to diagnosing certain genetic polymorphisms and treating those with particular polymorphisms with specific dosages of iloperidone.

- Entered judgment for patentee after bench trial, including a finding of patent eligibility.

- Found that method of treatment claims were directed to laws of nature.

- But drawing on Cellzdirect, found that “using this genetic test to inform the dosage adjustment recited in the claims was not routine or conventional” and passed step 2.
Recent Key Life Sciences Litigations

District Courts Cautious


- Patented “kit” and “method” claims relating to TB tests. “Kit” claims cover kits for diagnosing TB infection comprised of a specific panel of peptides, and “method” claims cover methods of using these kits in vitro.

- Denied the 12(b)(6) motion to dismiss for both “kit” claims and “method” claims (overruling magistrate’s recommendation to grant motion as to “kit” claims)

- Distinguished “kit” claims from Myriad because “they are alleged to be chemically different than the naturally occurring amino acids.” “Method” claims survived as they “improve on the current testing methods for tuberculosis.”
Recent Key Life Sciences Litigations

Recent Federal Circuit § 101 Precedent on Computer-Based Claims May Protect Life Sciences Patents


- Patented test for assessing cardiovascular disease risk by analyzing inflammation of the blood vessels
- Found three of four patents invalid under § 101 at motion to dismiss stage (and found infringement pleading insufficient for fourth patent)
- Appeal pending in the Federal Circuit (No. 16-1766), with the patentee drawing from arguments in *McRO* and *BASCOM* in addition to analogizing patent claims to *Cellzdirect*
Recent Key Life Sciences Litigations

Takeaways on Subject Matter Eligibility

The weakened § 101 framework has deep effects on the life sciences industry.

- Life sciences are particularly reliant on patent protection due to enormous innovation costs, long R&D timescale, relatively low cost of copying and, unlike most industries, the presence of both statutory and market incentives to copy.

- Life sciences patents are more likely to resemble naked applications of scientific discoveries.

Though the most recent cases suggest the trend is slowing, § 101 may still hinder U.S. contributions to medical innovations, and therefore global medical innovation.
Recent Key Life Sciences Litigations

Recent Jurisdiction & Venue Caselaw

- The Supreme Court declined to review the Federal Circuit’s holding that a generic’s plan to nationally market a proposed generic drug is sufficient for minimum contacts for personal jurisdiction in *Acorda Therapeutics, Inc. v. Mylan Pharms., Inc.*, 817 F.3d 755 (Fed. Cir. 2016).

- In *TC Heartland* the Supreme Court may change the long-standing test that cases can be brought anywhere a defendant is subject to personal jurisdiction. *TC Heartland LLC v. Kraft Food Brands Grp. LLC*, No. 16-341.
Recent Changes to Hatch-Waxman Act Regulations
Recent Changes to Hatch-Waxman Act Regulations

The FDA issued new regulations, effective December 5, 2016

- New regulations apply to new NDAs, ANDAs, and 505(b)(2) applications, and to existing submissions in certain circumstances

- NDA holders must provide **specific use codes** for their drugs that describe only the specific method of use claimed by the patent in the Orange Book

- Third parties can **challenge patent information** in the Orange Book by submitting a written request to the FDA to dispute the accuracy or relevancy of patent information
Recent Changes to Hatch-Waxman Act Regulations

The FDA issued new regulations, effective December 5, 2016

- **Marketing notice requirement**: First applicant is required to notify the FDA within 30 days of first commercial marketing, or risk losing some of the 180-day exclusivity.

- NDA holders must submit “amendment to the description of the approved method(s) of use claimed by the patent [] within 30 days of a decisions by the USPTO, or by a Federal District Court, the . . . Federal Circuit, or the U.S. Supreme Court that is specific to the patent and alters the construction of a method-of-use claim(s)” to avoid being considered late-listed—could extend to claim constructions.
Recent Changes to Hatch-Waxman Act Regulations

Clarification on Availability of 30-Month Stay

- Intention is to encourage NDA holders to move for PIs in advance of expiration of 30-month stay
- If PI entered prior to expiration: FDA will extend stay until court decides infringement and validity
- If court order requires termination of 30-month stay, application may be approved
- Voluntary agreement not to market will not have same effect as PI and will not require stay beyond 30 months
- Voluntary agreement consenting to approval will terminate 30-month stay
Recent Changes to Hatch-Waxman Act Regulations

Paragraph IV Notice Letters

- A paragraph IV notice letter must be sent no later than twenty days after the defined postmarked date of a “paragraph IV acknowledgment letter” (as defined in regulations)

- Paragraph IV recertifications are required after certain amendments, such as to indications or conditions of use or adding new strengths—and recertifications do not forfeit 180-day exclusivity
Recent Changes to Hatch-Waxman Act Regulations

Takeaways

- Long due updates change responsibilities for both brand and generic companies

- New regulations on specific use codes provide opportunities for ANDA and 505(b)(2) applicants to target indications that do not infringe

- Companies with pending submissions must carefully review new obligations

Conclusion
Questions or Comments?

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