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Legal and Business Strategies for Generic Companies Filing an ANDA

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Legal / Business Strategies for Local Generic Companies Filing an ANDA

- Considerations for generics prior to filing
- Strategies for limiting jurisdiction and choice of forum
- Defense strategies for generics after initiation of litigation
- Remedies in Hatch-Waxman cases
- Settlement and licensing considerations
- Impact of PTAB on Hatch-Waxman litigation

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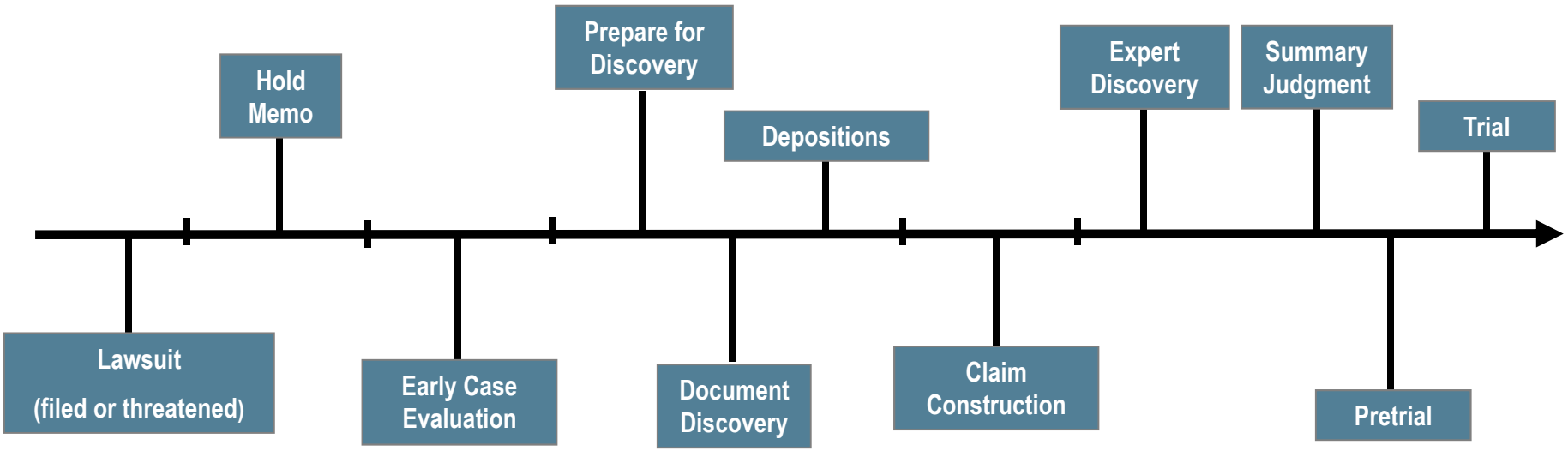
Considerations for Generics Prior to ANDA Filing

- Assess risk
  - Review patent(s)
    - Assess claim scope
    - Assess potential invalidity
  - Review potentially infringing products
    - Assess infringement risk
    - Assess total revenue at risk
  - Assess exposure of corporate entities to U.S. jurisdiction
- Evaluate potential design-around
- Evaluate potential carve-outs
- Evaluate alternatives to district court litigation

Considerations for Generics Prior to ANDA Filing

- Search prior art for invalidating references or statements
  - Consider statements made by patentee in other contexts regarding scope of invention or product
- Obtain Opinion Letters
  - Opinion letters should cover Orange Book patents and other patents that could pose a litigation risk
  - Substance of opinion letters could be basis for paragraph IV certification and detailed statement that accompanies notice letter to innovator
- Prepare Detailed Statement of reasons that Orange Book patents are invalid, unenforceable and/or not infringed
- Structure contacts with United States to limit jurisdictions for lawsuits (more on this issue shortly)

Basic Litigation Timeline



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Duty to Preserve Evidence

- Once there is a reasonable apprehension of a lawsuit, U.S. law requires a litigant to preserve relevant evidence
- Failure to preserve evidence results in discovery sanctions for spoliation (destruction) of evidence
- Relevant evidence includes hard copy documents (of all types) and electronically stored information
- Satisfy the duty to preserve evidence by providing a timely and adequate litigation hold memorandum:
  - Hold memorandum should be prepared once there is a reasonable apprehension of a lawsuit
  - Hold memorandum should be sent to all company personnel that may have relevant information
  - Hold memorandum must specify relevant documents to preserve

Duty to Preserve Evidence

- Some recent patent cases where sanctions awarded for failure to preserve evidence:
  - Rambus was sanctioned and ordered to pay **$250 million** for destroying between 700-800 banker boxes of documents, and keeping no record of what was destroyed.
  - Kolon was sanctioned with an **adverse inference** evidence was produced of screenshots showing explicit instructions to delete nearly 18,000 potentially relevant emails and documents in violation of litigation holds supposedly in effect. The jury found for DuPont and awarded it **$900 million in damages**.

Personal Jurisdiction in Hatch-Waxman Litigation

- There are two ways to assert personal jurisdiction over a defendant:
  - General Jurisdiction – "all purpose jurisdiction"
    - Plaintiff's can assert jurisdiction over a defendant in the defendant's "home" forum for any claims
  - Specific Jurisdiction
    - Plaintiff can assert jurisdiction over a defendant in a forum where the defendant has purposely directed its activities and the plaintiff's claims arise out of those activities.
- In the past, Hatch-Waxman plaintiffs relied primarily on general jurisdiction because:
  - Filing an ANDA was a technical act that was not considered "purposefully directed" at any forum.
  - A defendant's substantial business presence in the forum was typically sufficient to establish general jurisdiction.

Limiting Personal Jurisdiction

Daimler A.G. v. Bauman, 134 S. Ct. 746 (2014)

- District Court (N.D. Cal.)
  - Plaintiff Argentinian residents brought suit against Defendant Daimler A.G., a German public stock company, for actions committed by an Argentinian subsidiary, alleging claims under the Alien Tort Statute, the Torture Victim Protection Act of 1991, and California and Argentinian law.
  - Personal jurisdiction was asserted based on contacts of a second subsidiary of Daimler, which was incorporated in Delaware and had its principal place of business in New Jersey.
  - Daimler moved to dismiss for lack of personal jurisdiction, which the district court granted.
- Ninth Circuit
  - Reversed the district court.
  - The court held that Daimler's U.S. subsidiary was Daimler's "agent" for jurisdictional purposes, and general personal jurisdiction existed.

Limiting Personal Jurisdiction

Daimler A.G. v. Bauman, 134 S. Ct. 746 (2014)

- Supreme Court
  - Granted Daimler's petition for *certiorari* and reversed, finding that no general personal jurisdiction existed.
  - Held that, even if U.S. subsidiary's contacts could properly be attributed to Daimler, this would not warrant exercise of general personal jurisdiction, as U.S. subsidiary was neither incorporated in nor had its principal place of business in California.
  - The Court distinguished the language in *International Shoe* regarding "continuous and systematic" contacts, clarifying that this applies only to specific personal jurisdiction. For general personal jurisdiction, the defendant must be "essentially at home" in the forum, such as when the defendant is incorporated or has its principal place of business there.

Filing, Jurisdiction, and Venue: Personal Jurisdiction

Daimler A.G. v. Bauman, 134 S. Ct. 746 (2014)

Application in patent infringement cases

- Cases relying on *Daimler* to dismiss defendant in patent infringement case:
  - *Kolcraft Enterprises, Inc. v. Artsana USA, Inc.*, No. 13 C 4863, 2014 WL 3865814, at *6 (N.D. Ill. Aug. 6, 2014) (dismissing defendant parent corporation from case because subsidiary's contacts could not be attributed to parent under *Daimler*)
  - *Leachman Cattle of Colorado, LLC v. Am. Simmental Ass'n*, No. 14-CV-01040-RBJ, 2014 WL 4458893, at *6 (D. Colo. Aug. 29, 2014) (holding annual meetings in forum state was not sufficient for general jurisdiction under *Daimler*, as this did not make the defendant "at home" in the forum when principal place of business and state of incorporation were not in forum, and no specific jurisdiction existed where there was not sufficient evidence of infringement in the forum state)
  - *Intellectual Ventures I LLC v. Ricoh Co., Ltd.*, No. CV 13-474-SLR, 2014 WL 4748703, at *3 (D. Del. Sept. 12, 2014) (dismissing claims against Japanese parent corporation for lack of personal jurisdiction under *Daimler*, where parent sold various accused products to a Japanese subsidiary, which then imports accused devices into the U.S.)

Filing, Jurisdiction, and Venue: Personal Jurisdiction

Daimler A.G. v. Bauman, 134 S. Ct. 746 (2014)

Application in patent infringement cases

- Cases relying on *Daimler* and not dismissing defendant from patent infringement case:
  - *Loyalty Conversion Sys. Corp. v. Am. Airlines, Inc.*, No. 2:13-CV-655, 2014 WL 4352544, at *9 (E.D. Tex. Sept. 2, 2014) (general personal jurisdiction did not exist under *Daimler*, but specific jurisdiction did exist where defendant's allegedly infringing activity took place in ecommerce via defendant's website)
  - *Google Inc. v. Rockstar Consortium U.S. LP*, No. C 13-5933 CW, 2014 WL 1571807, at *8 (N.D. Cal. Apr. 17, 2014) (general jurisdiction did not exist under *Daimler* for declaratory judgment suit, but specific jurisdiction existed where evidence that defendant's majority shareholder was a competitor of plaintiff, and defendant filed "scare the customer and run" cases in E.D. Tex., supported conclusion that defendant had "created continuing obligations with a forum resident to marshal the asserted patents," which were purposeful enforcement actions in the forum), *motion to certify appeal denied*, No. C 13-5933 CW, 2014 WL 4145506 (N.D. Cal. Aug. 20, 2014)
  - *AstraZeneca AB v. Mylan Pharmaceuticals, Inc.*, No.14-696-GMS, slip op. (D. Del. Nov. 5, 2014) (general jurisdiction did not exist under *Daimler,* as defendant did not consent to jurisdiction although it was licensed to do business and had registered agent in the forum, but specific jurisdiction existed in patentee's home forum in ADNA suit)

Limiting Personal Jurisdiction

Analysis of *Daimler*'s application in patent infringement cases

- How does *Daimler* affect decision of where to sue?
  - The best chance of surviving a personal jurisdiction challenge after *Daimler* is by suing in a forum state where either
    - (1) general jurisdiction exists because the defendant: (a) is incorporated in the forum, or (b) has its principal place of business; or
    - (2) specific jurisdiction exists because: (a) the defendant committed allegedly infringing acts in the forum, (b) in an ANDA case, the patent-holder resides in the forum, or (c) in a declaratory judgment case, the defendant has directed purposeful enforcement actions toward forum residents.
- How does *Daimler* affect decision of when to move to dismiss for lack of personal jurisdiction?
  - *Daimler* has not changed the test for specific jurisdiction, so if there is a good case for specific jurisdiction, *Daimler* does not warrant a motion to dismiss
  - If there is no ground for specific jurisdiction, and defendant is neither incorporated in nor has its principal place of business in the forum, a motion to dismiss is likely to succeed

Limiting Personal Jurisdiction

Analysis of *Daimler*'s application in patent infringement cases

- Federal Rule Civ. P. 4(k)(2):
  - *Federal Claim Outside State-Court Jurisdiction.* For a claim that arises under federal law, serving a summons or filing a waiver of service establishes personal jurisdiction over a defendant if:
    - (A) the defendant is not subject to jurisdiction in any state's courts of general jurisdiction; and
    - (B) exercising jurisdiction is consistent with the United States Constitution and laws.
- Foreign entities should direct contacts to a single jurisdiction to have the best chance of limiting lawsuits to that jurisdiction
- Take into account subsidiary or affiliate contacts in analysis to avoid *alter ego* theories of jurisdiction

Forum Considerations: Fastest Districts
Time to Termination by Any Contested Judgment
(Excluding consent and default judgments)

1. E.D. Va. (12.2 mo.)
2. W.D. Wis. (19.4 mo.)
3. C.D. Cal. (19.6 mo.)
4. S.D. Fla. (20.6 mo.)
5. W.D. Wa. (21.2 mo.)

Source: Legal Metric Top 5 Report Fastest To Judgment, Feb. 2014, available at http://www.legalmetric.com/patent/

Forum Considerations: Most Favorable to Accused Infringers

Contested Patentee Win Rates

(Excluding consent and default judgments)

1. S.D. Tex. (3.8 %)
2. E.D. Mich. (9.5 %)
3. C.D. Cal. (9.8 %)
4. N.D. Cal. (10.4 %)
5. N.D. Ill. (10.4 %)

Source: Legal Metric Top 5 Report Most Favorable to Accused Infringer, Feb. 2014, available at http://www.legalmetric.com/patent/

Forum Considerations: Most Favorable to Patentees
Contested Patentee Win Rates
(Excluding consent and default judgments)

1. D. NJ. (38.2 %)
2. E.D. Tex. (37.0 %)
3. N.D. Ohio (35.0 %)
4. D. Del. (31.9 %)
5. S.D. Fl. (29.0 %)

Source: Legal Metric Top 5 Report Most Favorable to Accused Infringer, Feb. 2014, available at http://www.legalmetric.com/patent/

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Early Case Assessment: Develop Defenses

- Contest personal jurisdiction over foreign entities
  - Must be raised at start of litigation
- Consider and assert non-infringement defenses
  - Direct infringement
  - Inducement of infringement
    - Is this a method of treatment claim?
    - Is this a method of manufacturing claim?
  - Contributory infringement
- Consider and assert invalidity and unenforceability defenses

Defense Strategies: Non-infringement

- Determination of whether a product or process infringes a patent claim is a two-step process:
  - First, the meaning of the patent claim is construed in light of the specification and prosecution history.
  - Second, the construed claim is compared with the accused product to determine if each and every element of the claim covers the product or process.
- Three types of patent infringement:
  - Direct infringement
  - Inducement of infringement – some action to encourage direct infringement
  - Contributory infringement – component of a patented article and supplying it knowing it is made for use in the patented invention

Defense Strategies: Anticipation

- In order to be patentable, an invention must be novel, i.e., not anticipated by the prior art.
- A claim is anticipated if all the elements are disclosed in a single prior art reference.
- "Old rules" : In the US, applicant for a patent must be the *first person to have invented* the subject matter for which protection is sought.
- "New rules" (as of March 16, 2013): the patent holder must only have been the *first to file* new invention (generally)

Defense Strategies: Obviousness

- If not all the elements of a claim have been described in a single prior art reference, a claim is still invalid if a "person of ordinary skill in the art" would find the invention "obvious" in light of the prior art as a whole.
- How is non-obviousness determined?
  - The scope and content of the prior art
  - The difference between the prior art and the invention
  - The level of ordinary skill in the art
  - "Secondary considerations," such as:
    - A long-felt need for the invention
    - Commercial success
    - Acceptance in the marketplace

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Remedies in Hatch Waxman Litigation

- Order delaying FDA approval until expiry of Orange Book patents
- Declaratory judgment
- Permanent injunction preventing commercial manufacture and sale until patent expiry
- Monetary damages
  - If there is an at-risk launch after the end of 30 month stay
- Preliminary Injunctions have been granted in some ANDA cases to prevent an at-risk launch
  - Innovator needs to demonstrate irreparable harm
- Attorney's fees
  - In exceptional cases

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Settlement and licensing considerations

- Reverse payment
  - Payment from brand manufacturer to generic in exchange for agreement by generic to delay its entry into the market
- Potential consequence
  - FTC investigation
  - Civil suits under state and federal anti-trust law

Scrutinizing Settlements
FTC v. Actavis (June 17, 2013) (cont.)

- Question before the Court was whether Hatch-Waxman Act settlements are generally legal as long as they don't exceed the scope of the patent
- FTC urged that all pay-for-delay" settlements should be blocked
- Other side urged "scope of the patent" test
  - Settlements are fine as long as they
    - Don't exceed the substance of the patent
    - Don't extend the duration of the patent
    - Result from sham litigation
    - Protect patents obtained through fraud

Scrutinizing Settlements
FTC v. Actavis (June 17, 2013) (cont.)

- Original Hatch-Waxman Litigation
  - The case settled in September 2006
    - Claim construction was fully briefed
    - Motions for partial judgment (not case dispositive) were filed
    - Discovery was underway
  - Terms of the settlement
    - Cases dismissed
    - License to enter market for all defendants in August 2015
      - This was five years prior to the expiration of the last to expire patent

Scrutinizing Settlements
FTC v. Actavis (June 17, 2013) (cont.)

- The Case Itself
  - Terms of the settlement (cont.)
    - Watson agreed to market Andro-Gel through its sales force to urologists
      - Watson would receive share of profits equal to est. $20-30 million/year
    - Par would promote Andro-Gel to general practitioners
      - From 2006 – 2012 Solvay would pay Par $10 million/year
    - Paddock would provide back-up manufacturing capacity
      - From 2006-2012 Solvay would pay Paddock $2 million/year
  - FTC alleged that these arrangements were not arms length and exceeded the value of the services provided

Scrutinizing Settlements
FTC v. Actavis (June 17, 2013) (cont.)

- Supreme Court Opinion
  - Majority
    - Rejected both positions
      - Scope of the patent test is too narrow
      - Reverse payment settlements are not presumptively anticompetitive
        - Agreements analyzed case by case under a rule of reason

Scrutinizing Settlements
FTC v. Actavis (June 17, 2013) (cont.)

- Supreme Court Opinion
  - Considerations
    - The "potential for genuine adverse effects on competition.“
    - Whether "these anticompetitive consequences [are] unjustified.“
    - Where a reverse payment threatens to work unjustified anticompetitive harm," large reverse settlement payments may be "a strong indicator of market power" by the patentee
    - Whether a "large" payment suggests that the patentee has serious doubts about the patent's survival
    - Whether there were "other ways" for the parties to settle that did not include a reverse payment

The District Courts Apply *Actavis*

- Numerous decisions from U.S. District (trial) Courts have recently attempted to apply the *Actavis* "reverse payment" analysis to Hatch-Waxman settlments
- Some courts have held that *only cash* payments from the brand to the generic are subject to antitrust scrutiny
- Other courts have held that non-cash consideration may be sufficient under *Actavis*
- The divergent approaches of the District Courts applying *Actavis* to patent settlements will certainly lead to review by Courts of Appeals, and possibly another review by the Supreme Court
- Justice Roberts, in dissent, said "good luck to the district courts" applying the majority's *Actavis* standard and the rule of reason. The lower court cases since *Actavis* have confirmed this view of the Supreme Court's majority decision

Cases Holding that Only Cash Consideration is Subject to *Actavis* Scrutiny

In re Lamictal Direct Purchaser Antitrust Litigation (D.N.J., Jan. 24, 2014)

- GSK sued Teva for infringement of patents on its Lamictal® (lamotrigine) product
- Parties settled just after the trial judge indicated that he would rule that a key patent claim was invalid as anticipated, but before a full decision
- The settlement included "early entry" for Teva as to chewable and tablet products
- GSK also agreed that it would *not* launch an authorized generic ("AG") during Teva's 180-day exclusivity period
- "In sum, in exchange for dropping its challenge to GSK's patents, the settlement allowed Teva to market generic lamotrigine before the relevant patent expired and ensured that once it did so, its generic tablets and chewables would not face competition from GSK's own 'authorized generic' for a certain period of time."

Cases Holding that Only Cash Consideration is Subject to *Actavis* Scrutiny

In re Lamictal Direct Purchaser Antitrust Litigation (D.N.J., Jan. 24, 2014) (cont.)

- After dismissing the plaintiffs' case before *Actavis*, the court reconsidered its dismissal in light of the new *Actavis* standard
- Judge Walls held that "*Actavis* applies only to 'reverse payments' of money"
- "That Teva was allowed early entry, that there was no payment of money and that the duration of the "No-AG" Agreement was relatively brief all serve to persuade this Court that the settlement was reasonable and not the sort that requires *Actavis* scrutiny."
- Direct Purchasers appealed to the Court of Appeals for the Third Circuit, which heard arguments on Nov. 19, 2014

Cases Holding that Only Cash Consideration is Subject to *Actavis* Scrutiny

In re Loestrin 24 FE Antitrust Litigation (D.R.I. Sept. 4, 2014)

- Watson filed Paragraph IV certification against Warner Chilcott's '394 patent; litigation ensued.
- At approximately the expiration of the 30-month stay, the parties entered into a settlement agreement.
- Watson agreed to delay launching a generic Loestrin 24 generic until about 6 months before patent expiry.
- In return, Warner Chilcott (1) agreed not to launch an AG within Watson's first 180 days on the market; (2) agreed not to license other generics to market Loestrin 24 during the same period; (3) granted Watson a license to market the product worldwide beginning about 6 months before patent expiry; (4) agreed to pay Watson annual fees and a percentage of sales for co-promotion of another product; and (5) gave Watson the exclusive right to earn brand sales of yet another Warner Chilcott contraceptive product.

Cases Holding that Only Cash Consideration is Subject to *Actavis* Scrutiny

In re Loestrin 24 FE Antitrust Litigation (D.R.I. Sept. 4, 2014) (cont.)

- In a related case, Warner Chilcott settled with Lupin on similar terms
- Direct Purchasers and End Payors sued for antitrust violations alleging an illegal reverse payment
- On defendants' motion to dismiss, the District Court found that "the discussion of patent settlements in *Actavis* fixates on one the one form of consideration that was at issue in that case: cash."
- "All of [the five *Actavis*] factors can be reasonably measured when the reverse payment is a cash payment; a non-cash settlement, particularly one that is multifaceted and complex . . . is almost impossible to measure against these five factors."
- The defendants did not seriously dispute that they received substantial value; however, "merely because a settlement is of some value (even of great value) does not mean that it constitutes a reverse payment."

Cases Holding that Only Cash Consideration is Subject to *Actavis* Scrutiny

In re Loestrin 24 FE Antitrust Litigation (D.R.I. Sept. 4, 2014) (cont.)

- While dismissing the case, the District Court commented that the decision to apply *Actavis* only to cash settlements was "vexing" for several reasons: first, there is "tension" between *Actavis* and the pleading standard established by the Supreme Court in *Twombly* ("pleading facts sufficient to glean the monetary value of non-cash settlements is a tall task, one that would typically require considerable discovery to achieve."); second, "Even prior to *Actavis*, trends in the pharmaceutical industry suggested that, increasingly, patent settlements were taking unconventional, non-cash forms."
- The District Court felt constrained by *Actavis*, but clearly expressed reservations that the issue of its applicability to non-cash settlements remains unclear at best, and that the issue will surely be the subject of appeals to higher courts.

Cases Holding that Non-Cash Consideration Can Constitute an *Actavis* Reverse Payment

In re Nexium (Esomeprazole) Antitrust Litigation (D. Mass., Sept. 11, 2013)

- AstraZeneca ("AZ") settled patent infringement suits against Ranbaxy, Teva and Dr. Reddy's ("DRL").
- Direct Purchaser and End Payor plaintiffs sued for violation of the antitrust laws, alleging illegal reverse payments to keep generic versions of Nexium® out of the market; defendants moved to dismiss.
- AZ sued first ANDA filer Ranbaxy, and the parties settled before the trial court ruled on the merits.

Cases Holding that Non-Cash Consideration Can Constitute an *Actavis* Reverse Payment

In re Nexium (Esomeprazole) Antitrust Litigation (D. Mass., Sept. 11, 2013) (cont.)

- AZ/Ranbaxy settlement in April 2008
  - Consent judgment on same day 30-month stay expired
  - Ranbaxy admitted that the asserted patents were valid, enforceable and infringed
  - Ranbaxy agreed to delay generic launch until May 27, 2014
  - AZ agreed not to market an AG during Ranbaxy's 180-day exclusivity period, which plaintiffs alleged to be worth $1 Billion to Ranbaxy; AZ and Ranbaxy would argue that this was a license agreement permitted under the antitrust laws

Cases Holding that Non-Cash Consideration Can Constitute an *Actavis* Reverse Payment

In re Nexium (Esomeprazole) Antitrust Litigation (D. Mass., Sept. 11, 2013) (cont.)

- AZ/Teva settlement in January 2010
  - Teva admitted that all Orange Book listed patents were "enforceable and valid as to certain products"Ranbaxy admitted that the asserted patents were valid, enforceable and infringed
  - Teva admitted that it would infringe certain of the Orange Book patents
  - Teva agreed to delay launching generic until May 27, 2014
  - AZ forgave a significant portion of potential damages owed by Teva due to Teva's at-risk launch of generic Prilosec® (omeprazole), which plaintiffs alleges was "tantamount to a payment from AstraZeneca to Teva" worth tens of millions of dollars

Cases Holding that Non-Cash Consideration Can Constitute an *Actavis* Reverse Payment

In re Nexium (Esomeprazole) Antitrust Litigation (D. Mass., Sept. 11, 2013) (cont.)

- AZ/DRL settlement in January 2011
  - AZ dismissed infringement action against DRL
  - DRL agreed to delay launching generic until May 27, 2014
  - AZ agreed to forgive DRL's contingent liability for at risk sales of generic Accolate®, which plaintiffs alleged constituted a reverse payment by AZ to DRL

Cases Holding that Non-Cash Consideration Can Constitute an *Actavis* Reverse Payment

In re Nexium (Esomeprazole) Antitrust Litigation (D. Mass., Sept. 11, 2013) (cont.)

- Applying Actavis, District Court denied defendants' motions to dismiss
- "Taking all intendments in the light most favorable to the [plaintiffs], then, the no-authorized generic agreement between AstraZeneca and Ranbaxy and AstraZeneca's forgiveness of Teva's and Dr. Reddy's contingent liabilities related to the infringement of non-Nexium-related patents sufficiently implicate reverse payment anticompetitive consequences to allow [plaintiffs'] claims to proceed
- The Court declined to read *Actavis* as applying only to cash payments: "Adopting a broader interpretation of the word "payment" . . . serves the purpose of aligning the law with modern-day realities."

Cases Holding that Non-Cash Consideration Can Constitute an *Actavis* Reverse Payment

In re Nexium (Esomeprazole) Antitrust Litigation (D. Mass., Sept. 11, 2013) (cont.)

- The Court further held that the fact that the various settlements were implemented via consent judgments by the judge in the patent cases did not create immunity from antitrust scrutiny under *Noerr-Pennington* (doctrine which can give parties "petitioning the courts" immunity from antitrust liability)
- The case proceeded to a jury trial in October 2014; no verdict as of the date of this presentation

Cases Holding that Non-Cash Consideration Can Constitute an *Actavis* Reverse Payment

In re Niaspan Antitrust Litigation (E.D. Pa. Sept. 8, 2014)

- Multiple lawsuits by Kos against Barr for infringement of patents covering Niaspan®
- Barr received tentative FDA approval in May and June 2003, and expected final ANDA approval shortly after March 2005
- Barr began stockpiling product for at-risk launch, driving Kos's stock price down 13%
- Kos began preparations for AG launch

Cases Holding that Non-Cash Consideration Can Constitute an *Actavis* Reverse Payment

In re Niaspan Antitrust Litigation (E.D. Pa. Sept. 8, 2014) (cont.)

- After preliminary injunction hearing, but before Court decision, parties entered into settlement
  - Kos and Barr drop all claims and counterclaims
  - Kos gives bar license for all relevant patents on condition that Barr not launch generic until Sept. 2013
  - Kos agrees not to launch AG after Barr entered with generic
  - Parties entered into co-promotion agreement under which Kos would pay Barr (as long as it kept its generic off market) a royalty on all of Kos's sales of Niaspan® and Advicor®, and Barr agreed to co-promote those products

Cases Holding that Non-Cash Consideration Can Constitute an *Actavis* Reverse Payment

In re Niaspan Antitrust Litigation (E.D. Pa. Sept. 8, 2014) (cont.)

- After preliminary injunction hearing, but before Court decision, parties entered into settlement (cont.)
  - Royalty to Barr was based on overall sales of both products, regardless of whether Barr generated the sales
  - Parties entered into a license and manufacturing agreement; Kos paid Barr lump sum or investment in developing FDA-approved manufacturing processes for both products
  - Kos would make quarterly payments to Barr for each quarter that Barr remained ready to manufacture Niaspan and Advicor, and Barr agreed to provide ready back-up supplies of both to Kos; obligation would terminate if Barr sold generic Niaspan before Sept. 20, 2013

Cases Holding that Non-Cash Consideration Can Constitute an *Actavis* Reverse Payment

In re Niaspan Antitrust Litigation (E.D. Pa. Sept. 8, 2014) (cont.)

- Direct Purchaser and End Payor plaintiffs file antitrust actions; defendants file motions to dismiss; court denies the motions
- Court agreed with the *Nexium* decision that reverse payments are not limited to cash payments
- Court concludes that the no-AG provision is a reverse payment
- Court concludes that the three Kos-Barr agreements cannot be "dismembered" and must be read in conjunction with each other
- "The plausibility of plaintiffs' allegations concerning the true nature and purpose of these payments is bolstered by the fact that these agreements were expressly contingent on Barr's promise to delay generic entry."
- Payments "did not reflect traditional settlement considerations, but rather the desire to ensure that Barr would not market its generic version of Niaspan or otherwise challenge the validity of Kos's Niaspan patents."

Cases Holding that Non-Cash Consideration Can Constitute an *Actavis* Reverse Payment

In re Lipitor Antitrust Litigation (D.N.J. Sept. 12, 2014)

- Pfizer and Ranbaxy engaged in worldwide patent litigation over Pfizer's Lipitor® patents
- Direct Purchasers and End Payors file antitrust complaints
- After dismissing the initial complaints, the Court permitted plaintiffs to file an amended complaint after *Actavis*
- The parties' June 2008 settlement resolved U.S. litigation concerning Lipitor®, Accupril® and Caduet®, as well as more than 20 foreign Lipitor® litigations
- Plaintiffs' main reverse payment allegation was that Pfizer accepted $1 million to settle its Accupril® litigation with Ranbaxy, while Ranbaxy was potentially liable in that case for hundreds of millions of dollars after Ranbaxy's infringing sales and the trial court's preliminary injunction ruling

Cases Holding that Non-Cash Consideration Can Constitute an *Actavis* Reverse Payment

In re Lipitor Antitrust Litigation (D.N.J. Sept. 12, 2014) (cont.)

- "In short, the Plaintiffs contend that this Settlement Agreement was Pfizer and Ranbaxy's purposeful intent to restrain and monopolize trade by extending the Lipitor patent duration until November 30, 2011, when Ranbaxy's amorphous version would not have infringed the Lipitor process patents." Ranbaxy then changed its product to a crystalline form
- "Plaintiffs allege that this was accomplished by Pfizer forgiving its claim for infringement damages by settling the Accupril claim for $1 million when the value of the Accupril claim was far higher; and allowing the defendants to market generic Lipitor in foreign markets. As a result, Ranbaxy agreed to delay entry of its generic until November 30, 2011."
- Applying the pleading standards of *Twombly* and *Iqbal*, the Court held that plaintiffs did not plausibly plead a reverse payment

Cases Holding that Non-Cash Consideration Can Constitute an *Actavis* Reverse Payment

In re Lipitor Antitrust Litigation (D.N.J. Sept. 12, 2014) (cont.)

- First, the Court found that "a payment may refer to a transfer of something other than money."
- However, the Court held that under the plausibility standards of *Twombly* and *Iqbal,* plaintiffs failed to plead sufficient facts in support of their reverse payment claim
- Focusing mainly on plaintiffs' allegations concerning the Accupril settlement, the Court stated that "the non-monetary payment must be converted to a reliable estimate of its monetary value so that it may be analyzed against the *Actavis* factors such as whether it is 'large' once the subtraction of legal fees and other services provided by generics occurs."
- "Where a non-monetary payment is alleged in an antitrust suit, the pleading must demonstrate the reliable foundation showing a reliable cash value of the non-monetary payment through the use of more facts upon which Plaintiff depends."

Cases Holding that Non-Cash Consideration Can Constitute an *Actavis* Reverse Payment

In re Lipitor Antitrust Litigation (D.N.J. Sept. 12, 2014) (cont.)

- The Amended Complaint failed to show a "reliable foundation used within the industry to convert the non-monetary payment to a monetary value."
- Court found that the amount of the injunction bond posted by Pfizer in the Accupril case ($200 million) was not a reliable surrogate for the value of Pfizer's contingent claim for damages in that case
- The Court also commented that parties' view of the true settlement value of the Accupril case was subject to change as the litigation progressed, and that the Amended Complaint did not take into account the parties' assessment of trial risk, etc.
- The Court also found that the Amended Complaint was also "devoid of any discussion about saved litigation costs by either party," another consideration in assessing the reasonableness of a patent settlement

Cases Holding that Non-Cash Consideration Can Constitute an *Actavis* Reverse Payment

In re Lipitor Antitrust Litigation (D.N.J. Sept. 12, 2014) (cont.)

- Finally, the Court found that the Amended Complaint had not considered the settlement agreement as a whole, and essentially ignored the Caduet and foreign litigation settlements, instead focusing almost exclusively on "guesswork" regarding the true value of the Accupril case

Cases Holding that Non-Cash Consideration Can Constitute an *Actavis* Reverse Payment

In re Effexor XR Antitrust Litigation (D.N.J. October 6, 2014)

- Same New Jersey District Judge (Sheridan) as in the *Lipitor* case
- Judge applied much of the same reasoning from his *Lipitor* decision in dismissing *Effexor* case
- In December 2002, Teva filed the first ANDA with a Paragraph IV Certification as to Effexor XR®
- Main claim term in dispute throughout the litigation was "extended release formulation"
- Wyeth lost its claim construction argument on this key term 2005
- Approximately one month after the claim construction ruling, Wyeth and Teva agreed to settle the litigation, and also agreed that the claim construction ruling would be vacated

Cases Holding that Non-Cash Consideration Can Constitute an *Actavis* Reverse Payment

In re Effexor XR Antitrust Litigation (D.N.J. October 6, 2014) (cont.)

- The parties' settlement
  - Wyeth permitted Teva to sell generic Effexor IR before the original compound patent expired in 2008
  - Wyeth agreed to launch an AG of Effexor IR during Teva's sales period
  - Plaintiffs alleged that Wyeth also agreed not to sell an AG of Effexor IR until the expiration of a key patent, thus giving Teva at least a year and a half of being the only IR generic on the market; plaintiffs alleged that this was worth $100 million to Teva
  - Plaintiffs also alleged that Teva agreed not to sell its approved Effexor XR generic until as late as July 2010, two years after the expiration of the original compound patent
  - "According to Plaintiffs, to induce Teva to agree to the delay period, Wyeth promised Teva that Wyeth would not market an authorized generic of Effexor XR during Teva's 180-day exclusivity period," which plaintiffs alleged to be worth over $500 million.

Cases Holding that Non-Cash Consideration Can Constitute an *Actavis* Reverse Payment

In re Effexor XR Antitrust Litigation (D.N.J. October 6, 2014) (cont.)

- The parties' settlement (cont.)
  - The parties submitted their agreement to the trial judge, who solicited the FTC's comments on the settlement; FTC responded that "you may advise the Court that we will not file an objection bsased on the joint stipulation of the parties," but "reserved the right to take such further action as the public interest may require."
  - Judge Sheridan allowed plaintiffs to amend their complaint after *Actavis,* and defendants moved to dismiss
  - Like in *Lipitor,* Judge Sheridan focused on the pleading and plausibility standards of *Twomby* and *Iqbal*, and found that the complaint lacked the required specificity and reliability
  - Although the plaintiffs alleged, by way of comparison of sales of a similarly popular product, the Court rejected that comparison because it did "not specifically value the monetary amount of the no-authorized generic agreement" between the parties

Cases Holding that Non-Cash Consideration Can Constitute an *Actavis* Reverse Payment

In re Effexor XR Antitrust Litigation (D.N.J. October 6, 2014) (cont.)

- The parties' settlement (cont.)
  - "Plaintiffs' calculation of the no-authorized generic agreement is vague and amorphous" and lacked a "reliable foundation to show that a reverse payment was actually entered into and present facts showing how the alleged non-monetary payment was calculated."
  - Addressing the *Actavis* requirement of a "large" payment, the Court also found plaintiffs' allegations insufficient
  - Plaintiffs' counsel argued that "$500 million may not be an awful lot of money to Wyeth. I'll bet it's a lot of money to Teva." The Court found that this sort of "betting" had no reliable foundation based on facts
  - The Court also rejected amicus FTC's "reservation" of a right to object to the settlement on antitrust grounds
  - "When a governmental agency receives an invitation from the Court to intercede in a matter by way of an Order, that agency should respond appropriately, not simply reserve that right for the future."

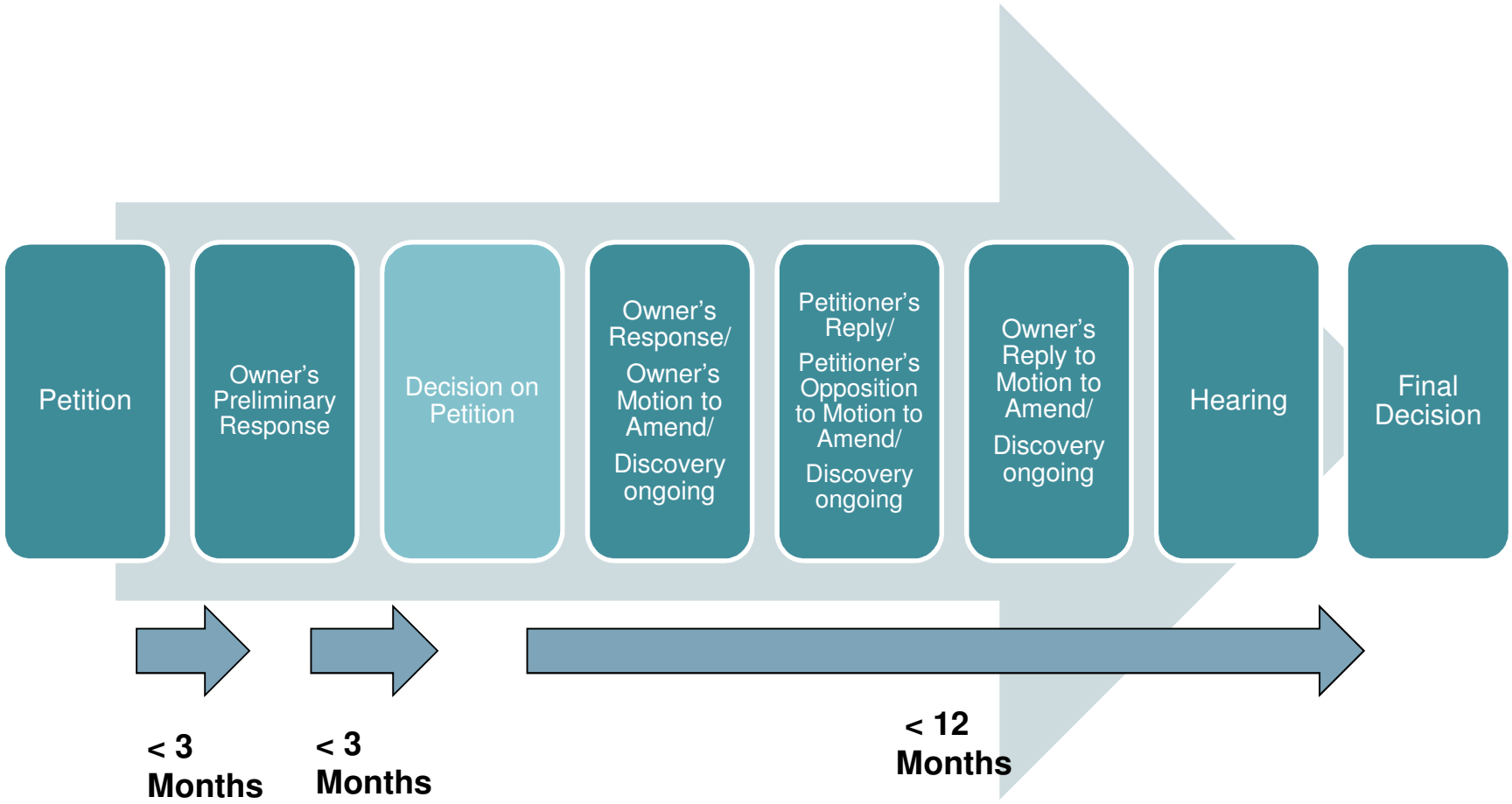
Legal / Business Strategies for Local Generic Companies Filing an ANDA

- Considerations for generics prior to filing
- Strategies for limiting jurisdiction and choice of forum
- Defense strategies for generics after initiation of litigation
- Remedies in Hatch-Waxman cases
- Settlement and licensing considerations
- **Impact of PTAB on Hatch-Waxman litigation**

Alternatives to Litigation in District Courts: Patent Trial and Appeal Board (PTAB) Proceedings

- Types of Proceedings pursuant to the America Invents Act (AIA)
  - *Inter Partes* Review (IPR)
  - Post Grant Review (PGR)
- Comparison to district court proceedings
  - Costs are reduced because of the speed of the proceeding and limitations on discovery
  - Proceedings are heard by a panel of Administrative Law Judges, who may have more technical background than the average district court judge
  - The PTAB has been invalidating the claims at issue in these proceedings at a much higher rate than district courts
    - The standard of review is lower than in district courts
  - Disadvantage is that any surviving claims may be stronger in subsequent proceedings

Timeline for IPR and PGR



Inter Partes Review

Advantages	Disadvantages
Invalidity arguments assessed by the USPTO with no presumption of validity	Estoppel
Likelihood of litigation stay	Risk of "gold plating" the patent
Claim amendments remove past damages or can invoke intervening rights	Claims can be amended
90% petition grant rate	Only available within a year of being served with a complaint for patent infringement
Speed (1 year from date of acceptance)	Only available nine months or more after patent issuance (for first-to-file patents)
Preserve §§ 101, 112, etc. defenses for litigation	
Decision by patent experts rather than district court judge or jury	
High likelihood of some clarification/file history estoppel	
Some discovery	
Direct appeal to Federal Circuit	

Most useful when…

- ***recently charged with infringement of a very broad patent***
- ***challenger has strong prior art reference(s)***
- ***anonymity is not a concern***
- ***challenger wants to stay co-pending district court litigation***

Post Grant Review

Advantages	Disadvantages
Broad grounds of attack, including §§ 101, 112 grounds	Broad range of estoppel including , including §§ 101, 112 grounds
Can be filed immediately after patent grant	Must be filed within nine months after patent issuance
Invalidity arguments assessed by the USPTO with no presumption of validity	Cannot file subsequent requests
Likelihood of litigation stay	Risk of "gold plating" the patent
Speed (1 year from date of acceptance)	Risk of countersuit by patentee (cannot file anonymously)
Decision by patent experts rather than district court judge or jury	Claims can be amended
High likelihood of some clarification/file history estoppel	
Some Discovery	
Direct appeal to Federal Circuit	

Most useful when…

- ***co-pending litigation is filed in the ITC or district court "rocket docket" immediately after patent grant***
- ***co-pending litigation is filed in patentee-friendly jurisdiction***
- ***patent(s)-in-suit susceptible to multiple grounds of attack***

Some Considerations for Instituting PTAB Proceedings in ANDA Context

- If you are a “First-to-File” generic…
  - PTAB proceedings could clear the path to entry of all generics at once, depriving you of the 180-day exclusivity
  - PTAB proceedings could slow down court litigation

- If you are not a “First-to-File” generic….
  - PTAB proceedings are faster and less expensive
  - PTAB proceeding could clear path to faster generic entry

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Questions?