The Relationship Between
IP Law and Antitrust Law in
the U.S.

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The Relationship Between Innovators and Generics in the US is Largely Driven by the Statutory Framework

- While many of the basic components of the “tool box” referred to the EC Report are the same for companies operating in the US, how those “tools” are used and the effect they have is different
- Still very limited options for patent challenge (pre- or post-grant) at the US PTO
Statutory framework - Hatch-Waxman

- Established procedures for filing an Abbreviated New Drug Application ("ANDA")
- Benefits for generic manufacturers
  - Ability to launch on "Day 1" after patent expiration
  - 180-day exclusivity for first filer if there has been no forfeiture
Advantages to First Filer

Generic Competition and Drug Prices

- Average Relative Price (avg generic / brand)

Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999-2004, extracted February 2005

Found at: http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm
Patent Portfolio Management

- Types of Claims to Consider
  - New Chemical Entity (NCE)
  - Other forms of the drug (salt, stereoisomer, etc)
  - Method of Use
  - Formulation

- Goal to obtain claims which are “listable” in the Orange Book
Method of Use Claims

- Generic must copy the Innovator’s label
  - But may leave out some indications
- “Off label” use is permitted in the US
- So-called “skinny 8” issues--21 USC 355(j)(2)(A)(viii)
Prosecuting Patents

- Patent Clusters—current scrutiny in the US on double patenting
- Need for care when prosecuting patents in a Patent Cluster
  - Attention to the entire portfolio rather than on a patent-by-patent basis
Overview of Hatch-Waxman Litigation

- Allows Generic to be ready to launch without delay
- Paragraph III vs Paragraph IV certifications
- Manner in which most pharmaceutical patent challenges proceed in the US
Overview of Hatch-Waxman Litigation

- Generic files ANDA with a Par. IV certification and notice to Innovator that listed patents are either invalid or not infringed by proposed generic drug
- Innovator has 45 days from receipt of notice to decide whether to sue Generic
- Filing suit triggers 30 month stay, during which FDA cannot approve generic drug
  - Possibilities for stay to be shortened or lengthened
Subject to forfeiture provisions, subsequent ANDA Paragraph IV filer(s) must wait 180 days after date of first commercial marketing of the drug by any first applicant (21 U.S.C. § 355(j)(5)(B)(iv))
“Threshold” for Paragraph IV certification in the US seems to be dropping
Is a reissue or reexamination warranted?
Generics will often plan ANDA filings with an eye toward expiration of data exclusivity
The 45-day period in which to decide whether to sue is not as long as it seems
  - Issue with Offers for Confidential Access
Once a Notice Letter is Received

- Cost considerations
  - Unequal discovery burdens
  - Possible privacy issues
- Forum considerations
Forum Considerations

- Time to trial
- Patentee vs Generic Win Rate
  - Ex: (2003 to 2009) Delaware—Generics won 10/27
  - C.D. California—Generics won 8/8
- Judges’ expertise with ANDA cases in particular and with pharmaceutical technology in general
Multiple ANDA filers

- Less “up-side” to subsequent filers
- Strategic issues
  - Costs due to multiple suits
  - Possible multiple forums—different outcomes
  - Possibilities for early settlement
Expiration of the 30-month stay
Damage considerations
  - Lost profits
  - Willful infringement
Prevalence of Settlement of ANDA cases

Source: RBC Capital Markets Corp.

Reverse payments - antitrust concerns?

- Sharing benefits of eliminating potential competition?
  - Contract, combination, or conspiracy in restraint of trade
  - Unreasonable restraint on competition
2003 Medicare Modernization Act ("MMA")
Pub.L. No. 108-173

Agreements resolving ANDA litigation must be filed with the FTC and DOJ. § 1112(a)

- Within **10 business days** after execution, **and**
- Prior to the **first commercial marketing** of the generic drug described in the ANDA. § 1112(a)(1); 1113
FTC & DOJ Review of Agreements

- 2003 Medicare Modernization Act ("MMA")
  Pub.L. No. 108-173
  - Agreements between generic companies regarding the 180-day exclusivity period must be filed with the FTC and DOJ. § 1112(b)
    - Within 10 business days after execution, and
    - Prior to the first commercial marketing of either of the generic drugs for which the ANDAs were submitted. § 1112(b)(1); 1113
Must file agreements between Innovator & Generic regarding:

“(A) the manufacture, marketing or sale of the brand name drug that is the listed drug in the ANDA involved;

(B) the manufacture, marketing, or sale of the generic drug for which the ANDA was submitted; or

(C) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to such ANDA or to any other ANDA based on the same brand name drug.”

Pub.L. No. 108-173, § 1112(a)(2)
Must also file:

- Contingent and otherwise related agreements (see § 1112(c)(2))
- Oral agreements (see § 1112(c)(3))

But not:

- Agreements that solely concern purchase orders for raw material supplies, equipment and facility contracts, employment or consulting contracts, or packaging and labeling contracts. (see § 1112(c)(1))
Agreements filed with the FTC 2004-2009

- 66/218 agreements involved some form of compensation from the brand name manufacturer to the generic to delay entry
  - 51 were between the brand name and 1st ANDA filer
  - On average, delay generic entry for almost 17 months longer than settlements without compensation
  - Estimated to cost American consumers $3.5 billion per year

The FTC believes all “pay-for-delay” agreements are *per se* illegal

- Cost consumers billions
- Circumvents Hatch-Waxman’s goal of timely entry of generics into the market
- “[B]uy more protection from competition than the assertion of the patent alone provides.”

The FTC’s position

- Stopping pay-for-delay agreements is a “top priority”
- Argues a legislative remedy is needed:
  - Ban on reverse payments, OR
  - Generic forfeits 180-day exclusivity if enters into a reverse payment agreement
Advantages to First Filer

Generic Competition and Drug Prices

Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999-2004, extracted February 2005

Found at: http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm
“The Administration will prevent drug companies from blocking generic drugs from consumers by prohibiting anticompetitive agreements and collusion between brand name and generic drug manufacturers intended to keep generic drugs off the market.”

The DOJ’s position

- In 2008, the DOJ opposed the FTC’s *per se* illegal rule.

- However, after President Obama appointed a new head of the DOJ’s antitrust division, Christine Varney, in 2009, the DOJ is taking a tougher stance against reverse payments.

- July 2009, in amicus brief to *Arkansas*, the DOJ advocated for a *presumption of illegality*:
  - This is a heavier burden on defendants than their previous position.
Many bills have been introduced that would ban reverse payments, but so far none have passed

Currently pending bills:

- H.R. 1706 - Rush Bill – would prohibit pay-for-delay settlements
- S. 369 - Kohl Bill – initially drafted to ban reverse payment agreements, but modified to treat reverse payments as presumptively unlawful
Authorized Generics

- Authorized generics = when the Innovator sells the drug as a “generic”
  - Market drug as both a brand name and private (generic) label
  - Can enter the market prior to/during 180-day exclusivity period of 1st ANDA filer
  - Innovator can agree NOT to market an AG in ANDA litigation settlement
    - FTC believes this may be anti-competitive
  - Reduce incentives of 1st ANDA filers to litigate?
2009 FTC report on Authorized Generics

- Reports only on short term effects of AGs on competition during the Generic’s 180 day exclusivity period – consumers benefit due to increased competition (and lower prices) with AGs.
- With AG, retail prices are on average 4.2% lower than without.
- Sole Generic’s revenues drop 47-51% when AG enters market.
  - Thus, Generic may be more willing to agree to delay entry in return for Innovator agreeing not to market AG.
- 2004-2008, 25% of settlements between 1st ANDA filers and Innovators included an agreement that Innovator would not market AG and Generic would delay market entry, on average, 34.7 months.
- See http://www.ftc.gov/os/2009/06/index.shtm#24
Courts have allowed AGs to compete with generics during the 180 day exclusivity period.

- Agreed with the FDA’s position that nothing in the ANDA statute bans this conduct.
- *Mylan Pharms. v. FDA*, 454 F.3d 270 (4th Cir. 2006)

Current legislation to ban AGs.

- 2009 – S. 501 and H.R. 573
Citizen Petitions at the FDA

- Citizen Petitions, 21 C.F.R. § 10.30
- Alert FDA to scientific and safety issues.
- Any individual or group can file.
- Request the FDA to:
  - issue, amend, or revoke an order, or
  - to take or refrain from taking any other form of administrative action.
  - requires a full statement of factual and legal grounds on which the petitioner relies.
Prior to 2007

- FDA did not review ANDAs until all issues in a citizen petition had been addressed.
- Citizen petitions could be used by Innovators to delay (“block”) approval of generics.
- Possible misuse of system by those wanting to keep generics off the market.
  - Some petitions filed within 6 months prior to generic approval.
  - From 2001-2005, 78% (33/42) of filed petitions re: generics were denied by the FDA.
    - See http://www.fda.gov/NewsEvents/Testimony/ucm161497.htm
Citizen Petitions at the FDA

- 2007 - FDA Amendments Act (“FDAAA”)
  - To remedy perceived abuses of the system
  - 21 U.S.C. § 355(q)
  - FDA must take final agency action on petition within 6 months of petition filing. § 355(q)(1)(F)
  - Approval process of ANDA continues during review of petition (unless delay is necessary to protect public health). § 355(q)(1)(A)
  - Petitioner must certify if they received any payment to file and from whom. § 355(q)(1)(H)
2007 - FDA Amendments Act ("FDAAA")

- 21 U.S.C. § 355(q)
- Petition will be denied if it was submitted with the primary purpose of delaying the approval and does not on its face raise valid or scientific or regulatory issues. § 355(q)(1)(E)

- Does not apply to petitions relating to the 180-day generic exclusivity period. § 355(q)(4)

- Supplemental comments or information filed must:
  - include a verification that filing was not intentionally delayed (and when the information was known), and
  - disclosure of any payments to be received and from whom. § 355(q)(1)(I)
Thank you for your attention