Pay For Delay
How Drug Companies Collude to Keep Generics Off the Market

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Hatch-Waxman Act

- Established in 1984
- Purpose was to enable generic drug companies to bring cheaper versions of brand drugs to the market while recognizing the investment in R&D by the brand company
- Before Hatch-Waxman generics could not obtain FDA approval without repeating expensive clinical trials that brand companies had already performed
Generics are Cheaper than Brand drugs

- A generic drug is typically 20% to 90% less expensive than the brand name original.
Generics Promote Competition

- Competition from generic rivals forces brand drugs to reduce their own prices after — or even before— patent expiration
- Graph shows antiretroviral drugs, used to treat HIV before and after generic

Source: libertatianstandard.com
Reaction of Brand Companies Since Hatch-Waxman - U.S R&D

Source: Compiled by PRIME Institute, U of Minnesota, based on data in PhRMA Annual Survey 1998.
Brand Company Files NDA With FDA

- To come to market a Brand Company files a New Drug Application ("NDA")
- FDA Determines:
  - Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks.
  - Whether the drug's proposed labeling (package insert) is appropriate, and what it should contain.
  - Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.
To come to market a Generic Company files a Abbreviated New Drug Application (“ANDA”).

Abbreviated

Not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness.

Instead, generic applicants must scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manner as the innovator drug).
### Difference Between NDA and ANDA

Table 1. Components of Applications for Innovator Drugs (NDA) and Generic Drugs (ANDA)

<table>
<thead>
<tr>
<th>NDA</th>
<th>ANDA</th>
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<tr>
<td>1. Labeling</td>
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<td>2. Pharmacology/toxicity</td>
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<td>3. CMC</td>
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<td>4. Microbiology</td>
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<td>5. Inspection/testing</td>
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<td>6. Preclinical (animal) studies</td>
<td>6. Bioequivalence studies</td>
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<td>7. Clinical (human) studies</td>
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<td>8. Bioavailability</td>
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Hatch-Waxman Requirement - Provide Patent

- Brand company must provide the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.
Orange Book

- FDA Publishes a list of all FDA-approved drugs
- Each drug listing lists all patents Brand company has identified in the NDA
- Designed to allow generic companies to identify drugs eligible for abbreviated NDAs and certain types of patents relating to those drugs.
- List of Approved Drugs is called the “Orange Book”
ANDA Filing Requirements

- In its ANDA filing, the generic manufacturer must refer to a drug listed in the Orange Book.
- Generic manufacturer must include information to show that:
  - (1) the generic drug has the same route of administration, dosage form and strength as the brand drug; and
  - (2) the generic drug’s labeling will be the same as the labeling of the brand drug.
As part of the ANDA, generic manufacturers are required to file one of the following four certifications for each patent listed in the Orange Book relating to the listed drug:

- (I) patent information has not been filed with FDA;
- (II) the patent has expired;
- (III) the date that a relevant patent will expire; or
- (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which the application is submitted.
Paragraph IV Certification

- Most common certification
- Generic must send a detailed letter notifying the brand company why they believe their product will not infringe the patent or why the patent is invalid

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After receiving notice, the NDA holder has 45 days to bring a patent infringement action against the ANDA applicant.

If the NDA Holder brings a patent infringement action against the ANDA applicant the FDA may not approve the ANDA for **30 months** from the date of the receipt of the notice or if a court rules that the patent is invalid or not infringed the FDA may approve the ANDA.
1st Generic to file ANDA

- Receives 180 day market exclusivity, once approved by FDA
- Brand Company is allowed to compete with Generic by creating an Authorized Generic
Settlement of Patent Lawsuit

- The majority of the time the patent infringement lawsuit settles just as the 30 month stay is set to expire.
Reverse Payment

- Patent Holder agrees to make a payment to potential competitors who have threatened to enter the market and challenge the patent holders' right to the patent, thereby delaying the point at which the competitor enters the market.

- Reverse Payment - payment moves in the opposite direction compared to what would ordinarily be expected in a lawsuit (here the patent holder who is plaintiff in lawsuit pays the potential infringer to “settle” the patent litigation and not enter the market).

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Appellate Court Split - Reverse Payment

- Prior to June 2013
- Some Courts Said - Absolutely Illegal Under Antitrust Laws
  - Antitrust Law can pierce shield of Patent Law
- Other Courts Said - Legal if Within Scope of the Patent
  - Prioritized Patent Law over Antitrust Law
FTC v. Actavis

- June 2013
- The Supreme Court rejected the “scope of the patent test”
- Antitrust Law - “Rule of Reason” Analysis can pierce the shield of patent rights

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Rule of Reason Analysis

- The "rule of reason" test has three parts:
  - The plaintiff must show that the challenged conduct has produced **anti-competitive effects** within the market. If yes, then:
  - Defendant must show that the challenged conduct **promotes a sufficiently pro-competitive objective**.
  - The plaintiff can rebut defendant's pro-competitive justification by showing that the restraint is **not reasonably necessary** to achieve the pro-competitive objective.
- Supreme Court advised that: Courts should look at the size of the payment
Recent Litigation

- Since Actavis, there has been a flurry of litigation by Direct Purchasers, Third Party Payors and Consumers to recover for overcharges.

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What Can You Do?

- Get involved with Litigation
- File claims when litigation is successful