HATCH WAXMAN ACT

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Also known as “The Drug Price Competition and Patent Term Restoration Act”

Enacted in 1984
- Amended the Patent laws
- Amended the Federal Food, Drug, and Cosmetic Act

Before 1962- new drug approved based on safety alone

1962- Proof of efficacy made compulsory for marketing approval of a new drug (Kefauver-Harris Amendments)
There was no provision for patent term extension prior to enactment of the Hatch Waxman Act, to make up for the time lost out of the total patent term during the marketing approval process.

Generic companies required to submit their own comprehensive NDA:
- **Costly**
- **Time consuming**

If drug was covered by patent:
- **Testing could not begin until patent expired**

To overcome the above problems an act was needed to promote generic companies.
OBJECTIVES OF THE ACT

- Reducing the cost associated with the approval of a generic drug
- Allowing Early-Experimental-Use
- Compensating the branded drugs manufacturers for the time lost from the patent term because of the regulatory approval formality
- Motivating the generic drug manufacturers

“HWA strives to strike a balance between the interests of branded drug manufacturers, generic drug manufacturers and the consumers”
Creation of section 505(j)

Section 505(j) established the ANDA approval process

The timing of an ANDA approval depends in part on patent protections for the innovator drug

NDA must include any patent that claims the "drug" or a "method of using [the] drug" for which a claim of patent infringement could reasonably be asserted

On approval of NDA, FDA publishes patent information for drug in Orange Book ("Approved Drug Products with Therapeutic Equivalence Evaluations")
FDA publishes patent information on approved drug products in the Orange Book.

An NDA applicant must submit the following information for each patent:

- Patent no and date on which the patent will expire
- Type of patent, i.e. drug, drug product, or method of use
- Name of patent owner
- The name of an agent of the patent owner or applicant

Brand drugs listed for generics to compare with their proposed products.
When an applicant submits an ANDA to the FDA, the applicant must certify one of four things under section 505(j)(2)(A)(vii):

- that the required patent information relating to such patent has not been filed (Para I);
- that such patent has expired (Para II);
- that the patent will expire on a particular date (Para III);
- that such patent is invalid or will not be infringed by the drug, for which approval is being sought (Para IV – Patent Challenge)
Para IV - Patent Challenge

Generic - Para IV Filing

Generic - Provide Notice to Brand within 20 days of acceptance

Brand - Must bring lawsuit within 45 days

Generic - If sued, automatic 30 month stay granted to Brand
Upon receiving the Para IV challenge, the generic manufacturer warns the brand name manufacturer/innovator that the existing innovator patent is either invalid or will not be violated by the generic.

The innovator can file a patent infringement lawsuit, even if the authentic claim by the generic manufacturer.

- If filed within 45 days:
  - FDA does not grant approval to the generic for a period of 30 months (2.5 years).
- If filed after 45 days:
  - No action by FDA.

After 2.5 years, the USFDA decides if it should grant approval or not.
INCENTIVES AND PROTECTION

180 Day Market exclusivity

- First applicant to submit a substantially complete ANDA (first-to-file)
- May be shared by multiple applicants
- Subject to forfeiture

30-month stay of FDA approval

- If patent owner or NDA holder sues the ANDA applicant for patent infringement within 45 days of receiving notice of the Paragraph IV certification
- Runs from date of notification or expiration of NCE exclusivity
- May be lengthened or shortened by the court
Upon ANDA acceptance for filing, the applicant must notify the NDA holder and patent owner of the ANDA within 20 days. The notice must include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

Upon notification, the NDA holder and patent owners have 45 days in which to initiate an action for patent infringement. If such an action is brought within 45 days, the ANDA is subject to a 30-month stay of FDA approval beginning on the date the notification letter was received.
**ANDA APPROVALS**

![Graph showing ANDA approvals from 1999 to 2009.](image)

*does not include tentative approvals*
Indian companies bagged 33.17% or 139 of 419 original ANDA approvals from US FDA in 2010

The manufacture, use, or sale of a patented drug is not an act of infringement, to the extent it is necessary for the preparation and submission of an ANDA.

The Hatch-Waxman Act provides under 35 U.S.C. § 271(e)(1), generally that:

"It shall not be an act of infringement to make, use, or sell a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs."
HATCH WAXMAN TRADE-OFF

BRANDS

- 30 MONTH STAY
  - Automatic Injunction
  - Notice of generic competition
  - Can be worth $$ mn per day

GENERICS

- 180 DAY EXCLUSIVITY
  - 1st successful Para IV filer
  - A big head start on others
HATCH WAXMAN TRADE-OFF

BENEFITS FOR BRANDED MANUFACTURERS

- Orange Book provides public notice of patents
- Allows for resolution of patent disputes prior to generic entry
- 30-month stay of FDA approval of generic drugs
- Patent Term Restoration
- Allows for Several **Market Exclusivities:**
  - Data Exclusivity
    - 5 years for New Chemical Entity (NCE) Drug
    - 3 years for non-NCE Drug
  - Orphan Drug (7 years)
  - Pediatric (PEDS) (6 months)
HATCH WAXMAN TRADE-OFF

BENEFITS FOR GENERIC MANUFACTURERS

- 180-day market exclusivity for first successful challenger to Orange Book patent
- Allows generics to challenge Orange Book patents without risk of damages
- “Safe Harbor” rule allows generics to perform bioequivalence and other testing relating to regulatory approval without risk of patent infringement

“Dr Reddy’s was the first Indian company to get the 180-day exclusivity for marketing Fluoxetine (Eli Lilly’s Prozac) 40 mg capsule in August 2001”
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<th>Types</th>
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<td>New chemical entity</td>
<td>5 years</td>
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<td>New Clinical study</td>
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<td>Pediatric exclusivity</td>
<td>6 months</td>
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<td>180-day generic market exclusivity</td>
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NEW CHEMICAL ENTITY EXCLUSIVITY

- Hatch-Waxman Act, 1984
- Granted: to drug products containing a New Chemical Entity
- Blocks: submission of 505(b)(2) or ANDA
- Length: five years (or four years if para. IV)
NEW CHEMICAL ENTITY

DEFINITIONS

- **New Chemical Entity**: “a drug that contains no active moiety that has been approved by FDA in any other application submitted under section 505(b) of the act”

- **Active Moiety**: “the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance”
Federal Drug Administration Amendments Act, 2007 ("FDAAA")

Under strict conditions, an enantiomer can qualify as a NCE:

- The single enantiomer has not been previously approved except in the approved racemic drug
- The NDA includes full new clinical investigations
- The clinical studies were not used for the racemate
- The enantiomer indication is not in the same therapeutic category as the racemate

Three-year exclusivity available:
e.g., Lexapro (escitalopram); Nexium (esomeprazole)
Orphan Drug Act, 1983

Granted: to drugs intended for treatment of a “rare disease or condition”
- Affects < 200,000 people in the U.S., or
- No reasonable expectation of recouping dev. costs

Blocks: approval of 505(b)(1), (b)(2), or ANDA directed to the same drug, for same disease

Length: seven years

Additional rewards: tax credits; grants; fees waived
Food and Drug Administration Modernization Act, 1997 ("FDAMA")

Granted: to applicants who successfully complete FDA-requested clinical trials of a drug in a pediatric population

Blocks: approval of 505(b)(2) or ANDA

Length: six months beyond any existing marketing or patent exclusivity

gov’t funding of pediatric studies if no exclusivity
Hatch-Waxman Act, 1984

Granted: to first ANDA applicant who submits a “substantially complete” ANDA containing a paragraph IV certification

- Substantially complete = sufficient to permit review

Blocks: approval of subsequently-filed ANDA containing a paragraph IV certification

Length: 180 days, from commercial marketing
Medicare Modernization Act, 2003 ("MMA")

Six ways to forfeit:

1. failure to market
2. withdrawal of application
3. amendment of certification
4. failure to obtain tentative approval within 30 mos.
5. improper agreement with another applicant, the listed drug application holder, or a patent owner
6. expiration of all patents
Reverse Payment Agreements
Sham Litigations (30 months stay)
Sham Citizen’s Petitioning
Walker Process Fraud
Product Hopping
REVERSE PAYMENT AGREEMENTS

Side deals

- Intellectual property licenses
- Distribution agreements
- Co-promotion arrangements
- Development agreements
- Supply agreements
- No authorized generic
REVERSE PAYMENT AGREEMENTS

CASE STUDY

FTC vs. Cephalon (E.D. Pa.) (filed Feb. 13, 2008)

- Provigil - $800 million brand sales
- 6 years delayed entry
- Complaint alleges that Cephalon unlawfully induced four first filers to refrain from marketing generic Provigil until 2012 by entering into over 13 side deals that transferred substantial value to the generics
FTC V. CEPHALON, INC.

Settlements Allegedly Delay Entry By 6 Years
FTC v. Cephalon, Inc.
Settlement Terms and Timeline

- **4 side deals**
  - Payments of $XXX million

- **2 side deals**
  - Payments of up to $XX million

- **2 side deals**
  - Payments of $XX million, plus upside

- **5 side deals**
  - $X million to Barr, plus substantial potential value
  - Payments of $XX million to Chemagis

**Timeline**
- **Dec 4**: Teva Settlement
  - IP license ($125 million)
  - API supply
  - Bars non-infringing versions of Provigil, Nuvigil, and Sparlon

- **Dec 22**: Ranbaxy Settlement
  - API supply
  - IP license
  - Bars non-infringing versions of Provigil

- **Jan 9**: Mylan Settlement
  - 2 product development deals
  - Bars non-infringing versions of Provigil, Nuvigil, and Sparlon

- **Feb 1**: Barr/Chemagis Settlement
  - Settlement of unrelated litigation (Actiq)
  - API supply
  - Co-development deals
  - Bars non-infringing versions of Provigil
Settlements at Issue
- Original Settlement – FTC did not approve because included provision that BMS would not launch authorized generic
- Revised Settlement – Did not include authorized generic provision, but BMS orally represented it would not launch authorized generic

Both Settlements Submitted to FTC
- Required under prior BMS consent, which required FTC approval
- Required under MMA filing requirement
- Apotex submitted letter with MMA filing noting oral terms
- BMS signed FTC certification confirming no oral terms

Ramifications for BMS
- DOJ Criminal Investigation and Plea Agreement with BMS (two felony counts and criminal fine of $1 million)
- BMS Senior VP Andrew Bodnar ($100,000 fine, one year jail time, required to write book on experience)
- State Attorneys General ($1.1 million fine for misleading States regarding settlement (violation of 2003 Order with States))
- FTC ($2.1 million in civil penalties for misleading FTC regarding settlement (violation of 2003 FTC Order and MMA violation))
LOOPHOLES IN THE HATCH-WAXMAN ACT

- Authorized generics
- 30 month stay
- Warehousing patents
- Reverse payments
- Citizen’s petitions
THANK YOU