# The Business of the Hatch-Waxman Act

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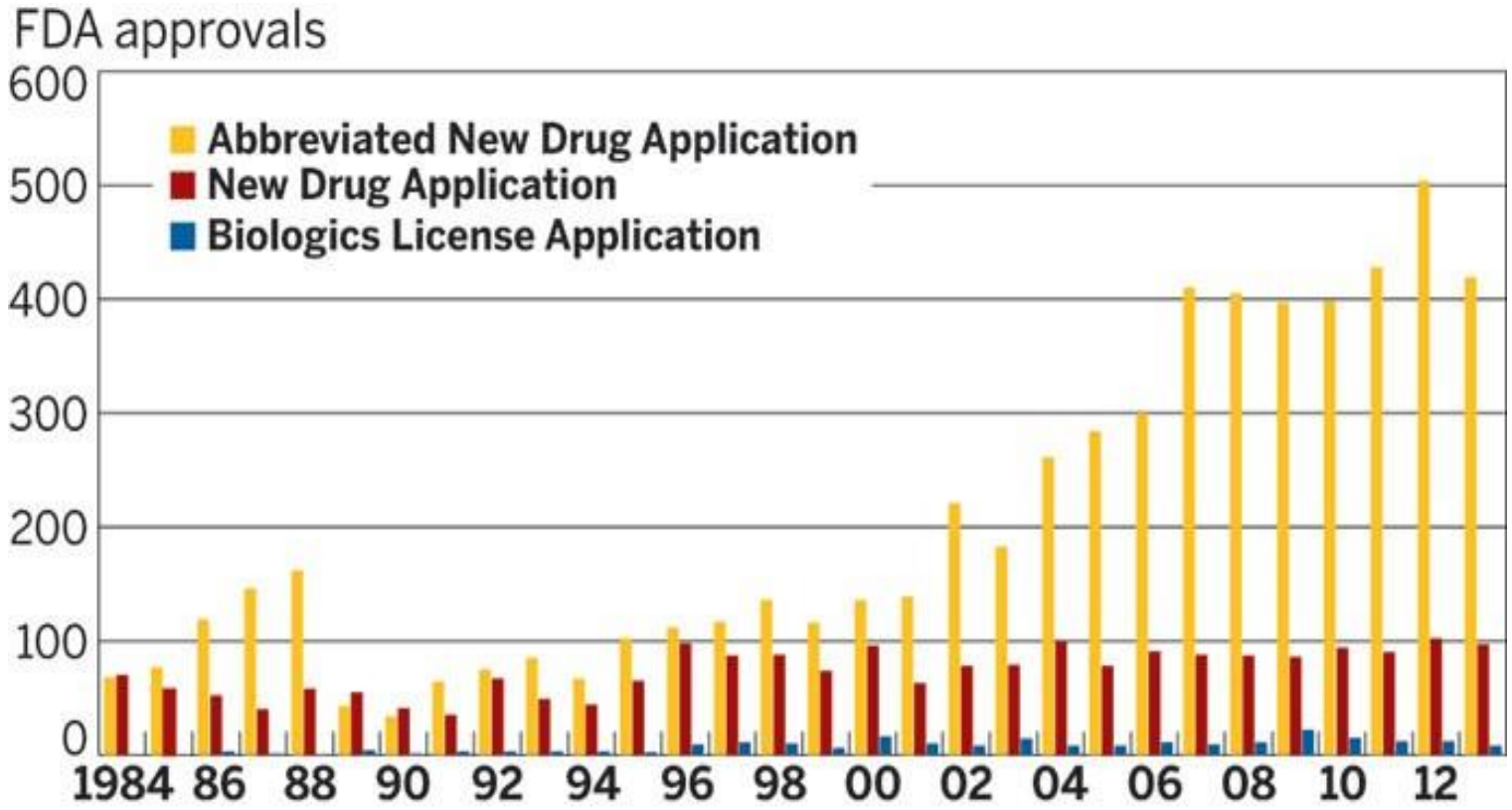
# Impact of Hatch-Waxman Act




Ann M. Taylor, "30 Years of Generics," C&EN, 92(39):8-16 (2014).

# Before Hatch-Waxman

## Drug Approval Process

- Drug Discovery
- Preclinical Testing → IND
- Phase I – III Clinical Trials
- NDA Application → FDA Review

- 7-10 year timeline

## The Life of a Patent

- Expires 17 years from issuance

# The Problem – Patent Term Distortions

- **FDA approval process cuts short enjoyment of patent term.**
- **Generic drug makers could not engage in premarket testing without liability before the pioneer company's patents expired.**
  - *Roche Prods. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1983)

# The Hatch-Waxman Act (1984)

- **Safe Harbor**
  - 35 U.S.C. § 271(e)(1)
- **Abbreviated approval pathway**
  - 505(b)(2) “paper” NDA
  - 505(j) ANDA
- **Patent Listing/Challenge Procedures**
  - Orange Book
  - 30-month stay
- **Technical Act of Patent Infringement**
  - 35 U.S.C. § 271(e)(2)
- **Patent Term Restoration**
- **Exclusivities**

# The Life of a Patent (Now)

- **First-Inventor-to-File System**
  - Effective filing date of patent application determines who wins the patent race
  - Applies to applications filed after March 16, 2013
  - Encourages early filing

- **Patent Expiration**
  - 20 years from date of filing date of the earliest U.S. or international (PCT) application (excluding provisional applications) to which priority is claimed

- **Prosecution Timeline**
  - Tech. Center 1600 (Biotech): 11.8 months to first office action; 22.8 months pendency
  - Tech. Center 1700 (Chemical and Mats. Eng'g): 16.4 months to first office action; 27.7 months pendency
    - (USPTO, FY 2019 Performance & Accountability Report, Table 4)

# Maintaining Your Market

- **Patent Term Extension**
- **Prosecution Strategy**
- **Exclusivities**

# Patent Term Extension | 35 U.S.C. § 156

- **Accounts for delays associated with regulatory review by extending patent term**

- **PTE = (½ x IND Phase) + NDA Phase – Applicant Delay**
- **Cannot exceed 5 years from patent's expiration**
- **Not to exceed 14 years from NDA approval**
  - Measured from date of regulatory approval to date of expiration with PTE and any PTA

- **PTE election may require considerable strategic thinking and offers great upside.**

# Patent Term Extension | 35 U.S.C. § 156

- **Applies to patents that claim a product, a method of using a product, or a method of manufacturing a product.**
- **Product must have undergone a period of regulatory review; must be first permitted commercial marketing/use of product.**
- **“Product” = active ingredient of drug, antibiotic, human biological product**
  - Including any salt or ester of the active ingredient
  - As a single entity or in combination with another active ingredient
- **Patent must not have been previously extended.**

# Patent Term Extension | 35 U.S.C. § 156

- **Must file for PTE before patent expires.**
- **Patent owner or agent must file application for PTE 60 days from date of FDA approval (no extensions).**
- **Plan in advance; begin drafting well before NDA approval**
- **Multiple applications permitted; elect a single application later.**

# Prosecution / Claiming Strategy

- **Compound**
  - genus; species; pharmaceutically acceptable salts
- **Formulation**
  - X% active; excipients; particle size, dissolution rate, etc.
- **Method of Treatment**
  - Condition; dose; dosing regimen; resulting in PK
- **Polymorph**
  - XRPD graph; characteristic peaks
- **Devices**
  - Autoinjectors; metered dose inhalers

# Method of Treatment Claims

- **Generic Liability for Indirect Infringement:  Inducement, Contributory**

- **Inducement Liability in Court:**
  - **A defendant induces infringement if it:**
    - **(a) knows of the patent;**
    - **(b) encourages another (i.e., doctor, patient, pharmacist) to infringe and intends for them to do so;**
    - **(c) others (i.e., doctor, patient, pharmacist) will actually use the product in an infringing manner if approved.**

- **Prosecution Goals:  Closely Align the Claims & Label**

# Method of Treatment Claims

- **Proving Acts of Inducement:  Based on Label**
- **Proving Specific Intent:  Labels that Instruct Infringement =  Evidence of a Specific Intent to Induce**
- **What Parts of the Label**
  - The label as a whole may be considered.
  - Stronger case for inducement when indication refers to other sections of the label.
    - Dosage/Administration; Clinical Studies; Contraindications; Warnings; Etc.
  - Avoid claims that depend on statements that may describe an infringement use, but do not affirmatively encourage or promote the use.

# Method of Treatment Claims

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    - ***(c) others (i.e., doctor, patient, pharmacist) will actually use the product in an infringing manner if approved.***

- **How many people carry out the claimed method? It matters!**
  - No underlying infringement if multiple actors perform the method's steps and no on entity directs or controls all the others

- **Prosecution Goals: Talk to Clinicians About How Treatment Occurs Before Drafting the Claims; Use/Define the Right Terms (Administering, Providing, Supplying, Taking); Consult Label**

# Prosecution / Claiming Strategy

- **Always keep a CON pending.**
- **Re-analyze issued claims against final drug label; write better ones.**
- **File new cases when new or improved methods of treatment, uses for the drug, and formulations arise.**

# Regulatory Exclusivities

- **FDA Rewards Pioneers with Exclusivities that Protect the Brand Apart Separate from the Patent System**

- **Types of Exclusivity**
  - New Chemical Entity
  - Marketing
  - Pediatric
  - Orphan Drug

- **Knowing how these exclusivities apply is necessary for business modeling and timelining.**

# The Value of NCE (Data) Exclusivity

- Applies to FDA's first approval of an active ingredient
- Limits timing of submission of ANDA's / 505(b)(2)'s for same active moiety
- ANDA's / 505(b)(2)'s must wait 5 years after NDA approval to submit application if no Paragraph IV Certification
- ANDA's / 505(b)(2)'s must wait 4 years after NDA approval to submit application if it includes Paragraph IV Certification
- 30-month stay runs from expiration of 5 years after NDA approval

# The Value of Marketing Exclusivity

- **Applies when pioneer conducts new clinical studies essential to FDA's approval of the application**
- **Applies to, e.g., new indications, new patient population, and new formulations**
- **Applies to the drug use investigated by the new clinical study**
- **Prevents final FDA approval of ANDA's / 505(b)(2)'s for that use for 3 years after NDA / sNDA approval**

# The Value of Pediatric Exclusivity

- Adds six months of exclusivity to all other exclusivities
- Adds six months to term of listed patents
- Requires clinical studies in pediatric populations on written request from FDA

# The Value of Orphan Drug Exclusivity

- **Applies to drugs for rare conditions (<200,000 affected in U.S.)**
- **Prevents final FDA approval of ANDA's / 505(b)(2)'s for the orphan indication for 7 years after NDA / sNDA approval**
- **Upside for generics?**

# The Value of Priority Review Vouchers

- **Awarded by FDA following approval of a drug for a neglected tropical disease, rare pediatric disease, material threat medial countermeasures, and other enumerated diseases (e.g., Zika, rabies, Ebola, Chagas)**
- **Used to speed up FDA approval (from 10 to 6 months) of another drug**
  - Voucher's user must pay FDA ~$2 million
- **May be sold (and often for tens of millions of dollar)**
  - 9 awarded in 2019

# Planning for Generic Competition

- **Litigation Readiness**
- **Generic Entry Scenarios**

# Litigation Readiness

- **Devise a plan based on your exclusivity.  Do not wait for a PIV letter!**
- **Take advantage of time – build your case early.**
  - Invention story.
  - Clinical benefits.
  - Commercial impact.
- **Proofread.**
  - Can you draft better claims?
  - Do you need a certificate of correction?
- **Internal License Needed?**
  - Entity injured from lost sales must be a named party to recover lost profits.

# Generic Entry

- **Create Timelines for:**
  - Exclusivities
  - 30-month stays
  - Appeal
  - IPR/PGR

- **Understand inflection points for the business.**
  - Value of an authorized generic?
  - Upcoming transition to second generation product?

# Thank You!

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