

# Law School For Pharmaceutical And Medical Manufacturer Executives

## Understanding Your Company's Antitrust Exposure While Litigating Or Settling Patent Lawsuits Under Hatch-Waxman

John F. Sweeney  
Dr. Andrea Wayda and  
Pamela A. Kayatta

Morgan & Finnegan, LLP  
New York, New York

The Pharma, Biotech and Device Colloquium  
Princeton, NJ  
June 6-9, 2004

# Overview

---

- OxyContin : A Case Study
- Hatch – Waxman Amendments
  - Medicare Act of 2003

# Balancing Act of Hatch-Waxman

---

- Streamline Generic Approval
  - Safe Harbor
  - Abbreviated New Drug Application (ANDA)
    - “bioequivalence”
    - no clinical testing
  - 180-Day Exclusivity
- Promote Innovation of Brand Drugs
  - Patent Term Extension (PTE)
  - 30-Month Stay

# Hatch-Waxman “Safe Harbor” Provisions

- 35 U.S.C. Section 271(e)(1):
  - “It shall not be an act of infringement to make, use, offer to sell, or sell within the United States a patented invention ... solely for uses reasonably related to the development and submission of information under Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products.”
- Provision insulates generics from infringement suits of activities that are “reasonably related” to FDA submission

# ANDA Filing under Paragraph IV of Hatch-Waxman A Technical Act of Infringement

- 35 U.S.C. Section 271(e)(2):
  - “It shall be an act of infringement to submit –
    - (A) An application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, or . . . .”

# OxyContin: A Case Study

- Purdue's development of OxyContin
  - first patented controlled release oxycodone formulation
  - enormously successful product
    - \$1.4 billion dollars in sales in 2002
    - top 1% of all pharmaceuticals sold in US (2000-2002)

# OxyContin: A Case Study

- Generic entrants into the market
  - NDA : Boehringer-Ingelheim/Roxane-Roxicodone
  - ANDA : Endo (10, 20 and 40 mg generic oxycodone)
  - ANDA : Teva (80 mg generic oxycodone)

# Purdue v. Endo

- Filed in response to Endo's Paragraph IV ANDA filing
- Asserted three patents claiming controlled release oxycodone
  - 5,549,912
  - 5,508,042
  - 5,656,295

# Purdue's Statements Regarding "Reduced Dosages"

It has now been surprisingly discovered that the presently claimed controlled release oxycodone formulations acceptably control pain over a substantially narrower, approximately four-fold [range] (10 to 40 mg every 12 hours— around-the-clock dosing) in approximately 90% of patients. This is in sharp contrast to the approximately eight-fold range required for approximately 90% of patients for opioid analgesics in general.

# Claim 1 of the '912 Patent

A controlled release oxycodone formulation for oral administration to human patients, comprising from about 10 to 40 mg oxycodone or a salt thereof, said formulation providing a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 30 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions.

# Purdue v. Endo

## Claim Construction

- “Controlled release”
  - Claims limited to formulations that control pain over a four-fold dosage range

# Purdue v. Endo

## Inequitable Conduct – The Applicable Law

- Applicant intentionally withheld material information from the Patent office
- Materiality and intent weighed “in light of all the circumstances” to determine if patentee’s conduct sufficiently culpable such that patent should be held unenforceable

# The Court's Ruling

## Purdue Misrepresented A Material Fact

1. Described the surprising discovery (“the result”) in concise, quantified terms
2. Described it as having occurred in the past tense
3. Considered the discovery “absolutely critical to the invention,” and most importantly
4. Used this precisely quantified “discovery” throughout the prosecution of the ‘331, ‘912, and ‘042 patents as a prominent, and, at times, the only argument, in favor of patentability before the PTO

# The Court's Ruling

## Purdue Intended To Mislead The Examiner

- Purdue lacked a set of procedures and methods to prove that Oxycontin was easy to titrate
  - could not prove the benefit of a reduced dosage range
- Even a year after his comments to the PTO, Kaiko considered his “surprising discovery” only a non-qualified “expectation” that needed additional studies and supporting data

# Inequitable Conduct And Antitrust Walker Process

- Finding of inequitable conduct exposes plaintiff to individual and class action federal and state antitrust allegations
  - Clayton Act (Section 16)
  - Sherman Act (Section 2)
  - Relevant state antitrust and consumer protection statutes.

# The Court's Decision

## The Immediate Financial Impact

- Teva's Launch of its 80 mg generic equivalent of OxyContin will end Purdue's exclusive control of the controlled release oxycodone drug category and erode Purdue's profit on its sale of 80 mg OxyContin
- Purdue must expend significant economic and legal resources to defend against the 64 (and counting!) antitrust and unfair and deceptive trade practices suits/actions brought against it around the country

# Tips For Avoiding Inequitable Conduct

1. Disclose all research data – don't eliminate data to improve results
2. Disclose all material prior art – if in doubt, disclose it
3. Assess criticality if a numerical range is near the prior art and be sure that any argument for criticality is substantiated
4. Submit prior art from the European Patent Office and other foreign prosecutions promptly

# Tips For Avoiding Inequitable Conduct

5. Confirm proper inventorship before filing the application
6. Scrutinize affidavits to ensure that statements are correct and that the Examiner will not be misled by anything that was not said explicitly
7. Say only what is necessary to respond to the Examiner
8. Establish whether the company is a small entity and review frequently to monitor any change.

# Hatch-Waxman Amendments Medicare Act of 2003

- Notice
- New causes of action
  - Declaratory Judgment
  - Counterclaim to Delist

# Hatch-Waxman Act

## 30-Month Stay

- If the branded company files suit, FDA's approval of the generic application is stayed for 30 months until the earliest of:
  - (1) the date that the patent expires
  - (2) a final determination of non-infringement or patent invalidity by a court in the patent litigation or
  - (3) the expiration of 30 months from the receipt of notice of the Paragraph IV certification

# The Hatch-Waxman Act

## Strategies to Exploit the 30-Month Stay Provision

- Branded companies listed additional patents in the Orange Book after a generic applicant filed its ANDA
  - FDA granted multiple 30-month stays

<b>Drug Product</b>	<b>Total Number of Stays</b>	<b>Total Length of Stays</b>	<b>Net Sales in Year the Second Stay was Issued</b>
Hytrin	3	70 months (The time from the beginning of the first stay until the end of the final stay lasted approximately 70 months, but the stays were not overlapping)	Between \$500 and \$750 million
Paxil	5	65 months	Over \$1 billion
Taxol	2	Potentially 60 months (The actual length of stays were shorter because of court actions)	Between \$750 million and \$1 billion
BuSpar	2	Potentially 30 months (The actual length of stays were shorter because of court actions)	Between \$500 and \$750 million
Neurontin capsules	2	53 months	Between \$250 million and \$500 million
Neurontin tablets	2	37 months	Between \$250 million and \$500 million
Tiazac	2	Potentially 60 months (The actual length of stays were shorter because of court actions)	Between \$100 and \$250 million

## Medicare Act of 2003

### Amendment of the 30-Month Stay Provision

- Branded companies now limited to one 30-month stay

# Hatch-Waxman Act

## 180-Day Exclusivity

- The first generic to file an ANDA with a Paragraph IV certification is entitled to 180-days of generic exclusivity

# Hatch-Waxman Act

## Strategies to Exploit 180-Day Exclusivity

- Anticompetitive Agreements
  - if the first generic agreed not to trigger the 180-day exclusivity, the possibility existed that no other generics could enter the market
  - case example
    - *In re Hoechst Marion Roussel, Inc. & Andrx Corp.*<sup>1</sup>

<sup>1</sup> No.9293 (FTC filed Mar. 16, 2000)

# Medicare Act of 2003

## Amendment of the 180-Day Exclusivity Provision

### Overview of Changes

1. Exclusivity applied on a product basis
2. Shared exclusivity if two ANDAs are filed on the same day
3. District court decision trigger is eliminated
4. Exclusivity period begins upon the generics marketing of either the NDA product or the ANDA product
5. New forfeiture provisions

# Medicare Act of 2003

## Forfeiture of 180-Day Exclusivity

Generic forfeiture of exclusivity occurs if:

(1) The applicant fails to market the drug:

- (a) Within 75 days of approval or 30 months after submission of the ANDA (whichever is earlier) or
- (b) Within 75 days after the final U.S. Court of Appeals decision that each of the patents that earned the applicant the exclusivity is invalid or not infringed, whichever is later

(2) The applicant withdraws the ANDA or amends or withdraws all Paragraph IV certifications that qualified the drug for exclusivity

# Medicare Act of 2003

## Forfeiture of 180-Day Exclusivity

- (3) The applicant fails to obtain tentative approval within 30 months after the filing of the ANDA
- (4) The applicant enters into an agreement with another applicant, or with the NDA holder or patent owner, that is found by the FTC or a U.S. Court of Appeals to be in violation of the antitrust laws or
- (5) All of the patents that earned the applicant exclusivity have expired

# Medicare Act of 2003

## FTC and Justice Department Review

- Effective Jan. 8, 2004
- If a generic that has filed a Paragraph IV ANDA and enters into an agreement with a branded company regarding the
  - manufacturer, marketing, or sale of either the reference listed drug or the generic, or
  - regarding the 180-day exclusivity of any generic,
- Then both parties must file the agreement with the FTC and DOJ.

Public Law 108-173, Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Title XI, Section 1112-13, 1118 (Dec. 8, 2003).

## Medicare Act of 2003

### FTC and Justice Department Review

- If two generic applicants each file a Paragraph IV certification to the same reference listed drug, and enter into an agreement regarding the 180-day exclusivity period with each other, both must file the agreement.
- In either case above, any agreement (written or oral) must be filed with the FTC and DOJ within 10 business days after it is signed or face penalties up to \$11,000 per day.

# New Strategies

---

## Authorized Generics

- Branded companies are now licensing patent to a generic, which launches the authorized equivalent drug during another generics 180-day marketing exclusivity period for the same product
- The generic with the authorized product then splits the sales with the brand firm

# New Strategies

---

## Authorized Generics

- Example
  - Barr Laboratories awarded 180-day exclusivity for the drug Ortho-Tricyclen™, an oral contraceptive
  - When Barr launched, J & J struck a deal with Watson Pharmaceutical to make authorized copies and share some of its revenues
  - Watson's authorized generic drove down prices during the exclusivity period and Barr lost hundreds of millions

# New Strategies

## A Legal Challenge to Authorized Generics

- *Mylan Pharmaceuticals Inc. v. The Proctor and Gamble Co., Watson Pharmaceuticals and Does 1—100*
  - Filed March 23, 2004 in Superior Court of California
  - Alleges violation of California Business & Professions Code Section 17200 et seq., 17500 et seq. for acts related to Watson's sale of an authorized generic for P&G's Macrobid

# New Strategies

---

## The Threat of Unlisted Patents

- A provision in the new law may let branded companies delay generic competition by simply not listing all of their patents in the Orange Book
- Branded companies could then use the threat of a later-filed infringement lawsuit on the unlisted patents to keep generic firms from launching in the first place

# New Strategies

---

## The Threat of Unlisted Patents

- If a generic firm is found to have infringed a patent after it has launched the product, the generic could be liable for crippling financial damages

# New Strategies

---

## The Threat of Unlisted Patents

- Although the new patent rules require brand firms to list their patents in the Orange Book and sign an FDA declaration that they have listed all applicable patents, there is no specific FDA penalty for brand firms that do not list all of their patents
- Even though the new law allows a generic to file a declaratory judgment action, it does not apply to unlisted patents in the Orange Book

# Morgan & Finnegan®

## INTELLECTUAL PROPERTY LAW

### NEW YORK

345 PARK AVENUE  
NEW YORK, NY 10154  
(212) 758-4800  
FAX (212) 751-6849

AS OF JULY 30<sup>TH</sup>  
THREE WORLD FINANCIAL CENTER  
NEW YORK, NY 10285  
(212) 758-4800  
FAX (212) 751-6849

### WASHINGTON

1775 EYE STREET, NW  
WASHINGTON, DC 20006  
(202) 857-7887  
FAX (202) 857-7929

### CALIFORNIA

44 MONTGOMERY STREET  
SUITE 2550  
SAN FRANCISCO, CA 94104  
(415) 676-5820  
FAX (415) 676-5816