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Preparing Your Company for Hatch-Waxman Litigation

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Meet the Speakers

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Agenda

- Introduction to Hatch-Waxman Act
- Early Patent Considerations and Prosecution Tips
- Company Policies, Procedures, and Training
- Preparing for Hatch-Waxman Litigation
- Discovery Considerations & Best Practices
- Identifying and Retaining Expert Witnesses

The Hatch-Waxman Act

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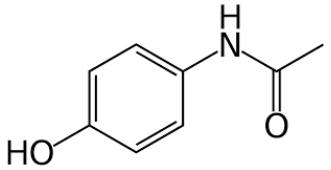
The Hatch-Waxman Act

- Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman Act”)
- Created the U.S. generic drug industry
- Small molecule chemistry
  - Acetaminophen (TYLENOL), Ibuprofen (MOTRIN)
- Compromise!!
  - Innovators: financial incentives (exclusivities, patent extensions)
  - Generics: reduced regulatory burden (ANDA)



“[The Hatch-Waxman Act strikes] a balance between two potentially competing policy interests—inducing pioneering development of pharmaceutical formulations and methods and facilitating efficient transition to a market with low-cost, generic copies of those pioneering inventions at the close of a patent term.”

Novo Nordisk A/S, et al. v. Caraco Pharmaceutical Labs, Ltd., et al., (Fed. Cir., 2010)

Patent Challenge - Litigation

- **Filing of ANDA is an “artificial act” of infringement**
- **NDA sponsor can sue when it receives paragraph IV notice**
- **Infringement suit will thus usually begin before ANDA approval**
- **If suit brought within 45 days of notice, ANDA approval is stayed for 30 months, provided patent tied to stay remains in case**
- **If no suit within 45 days, FDA can approve ANDA at its discretion**
- **If patent tied to stay dismissed, FDA can approve ANDA**

Early Patent Considerations and Prosecution Tips

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Pre-filing Considerations

- **Engage experienced disciplined counsel**
  - You want enforceable patents, not just patents
- **Timing of filing**
- **Be disciplined: carefully manage public disclosures**

Initial Filing Considerations

Communication is key

- Compound claim scope
- Methods of treatment and data

Don’t create your own prior art.

Careful word choice

- Talk to clinicians about how treatment occurs
- Use/Define the right terms

Conduct inventorship analysis early

Manage formalities

Draft a Better Application: Develop Invention Story Early

Talk to inventors early

- What was the problem?
- Inventors' unique appreciation of the problem
- Eureka moment(s)
- Failures and hurdles along the way
- Benefit of invention compared to previous treatments
- You'll draft a better application and be better informed about what they would say at trial

Tell the invention story in the application

- Highlight the problem, hurdles, and benefits of the invention consistent with the inventor's story
- Can support inventor's testimony at trial

Make sure patent claims are consistent with the invention story

- Do the claims require and focus on the key features of the invention?
- Are the patent claims commensurate in scope with what the inventors say they invented?

Invention Story – Why Is It Important?

Finally, the process engaged by the inventors' demonstrates the highly unpredictable nature of the prodrug development approach. The inventors prepared 20 prodrug candidates and evaluated their conversion rates and absorption rates. Pfizer submitted evidence that their **[*40]** experiments yielded unpredictable results. (Tr. 435:10-18, 436:18-19, 437:1-12 (Maag).) The inventors' results, and Dr. Janero's ultimate admission that prodrugs are complicated, are powerful evidence of the unpredictability inherent in prodrug design, a factor that weighs strongly against an obviousness finding. *Procter & Gamble Co. v. Teva Pharm USA, Inc., 566 F.3d 989, 996 (Fed. Cir. 2009)* (highlighting unpredictability seen with a class of compounds in finding nonobviousness). This

Pfizer Inc. v. Mylan Pharms. Inc., 2017 U.S. Dist. LEXIS 125634, *39-40 (D. Del. Aug. 9, 2017)

[20] I find even stronger support for the non-obviousness of claim 16 of the '456 patent in the struggles of the inventors to arrive at rivaroxaban. The plaintiffs describe the fortuitous path the inventors took to arrive at rivaroxaban,

Bayer Intellectual Prop. GmbH v. Aurobindo Pharma Ltd., 2018 US. Dist. LEXIS 116931 *39, n. 20 (D. Del. July 13, 2018)

Documents Supporting Inventorship and the Invention Story

Lab Notebooks

- Help prove that a particular event happened on a particular date, and show the inventor appreciated the importance
- Record failures as well as successes
- Countersign for corroboration
- Do not include privileged information (e.g., other companies' patents, discussions of prior art, notes of meetings with lawyers, or efforts to design around a patent)

Regular Project Reports and Gating Documents

- Often present the bigger picture of the inventors' and team's work
- Can show the scope of the work, hurdles overcome by the team, and how the team learned of things that were (or were not) working
- Gating documents often show why this particular drug candidate was selected, often among multitudes of other candidates, for clinical studies

Make Sure These Documents Are Preserved and Easy to Find!!

- Don't just stick them in a filing cabinet and assume the litigation team will later find them

Initial Filing Considerations: Listable or Not Listable?

Orange Book-Listable Patents

- 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
  - graph; characteristic peaks
- Devices
  - Autoinjectors; metered dose inhalers

Non-Orange Book-Listable Patents

- Process of manufacture
- Metabolites
- Intermediate
- Other solid forms
- Potential design-arounds
- Packaging/Container

Prosecution Tips

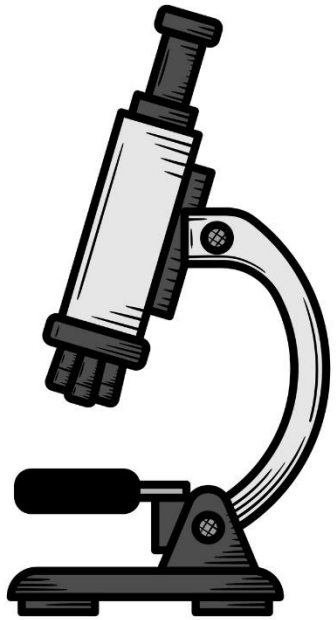
- **Keep a clean record (say less)**
- **Interview practice**
- **Closely align claims with the label**
- **Closely track worldwide prosecution**
- **Duty of disclosure, candor, and good faith**

Prosecution Tips: Prepare Clinical and Commercial Themes

- **Applications are filed/issued – you're not done!**
- **IP group needs to coordinate with clinical, commercial and regulatory teams from development through marketing to ensure consistent messaging**
- **Avoid creating bad documents that can later be spun by an opponent in litigation**
- **Commercial documents**
  - "Evergreening"/line extensions
  - Informal pricing discussions
- **Clinical documents**
  - Make sure that regulatory documents are consistent with patents and the invention story
    - State of the art/standard of care
    - Indications

Prosecution Tips

- **Re-analyze issued claims against final drug label**
- **Keep a continuation pending**
- **Track One applications**



Are the Current Claims Sufficient?

- **Do you have a "picture claim" to the formulation or specific claim to the compound?**
  - **More valuable in Hatch-Waxman than other types of cases because of FDA issues – generics have incentive to copy rather than design around**

- **Do you have claims that incorporate any unexpected results set forth in the specification?**
  - **Generics will argue inherency, but law is unsettled**
  - Recitation of results saved method claim in *Allergan v. Sandoz*, 726 F.3d 1286 (Fed. Cir. 2013)

- **Do you have method claims that track the label?**
  - **Easier to show inducement if claims are close to label**
  - *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1319 (Fed. Cir. 2012) makes it hard to show inducement if claim does not recite approved indication

- **Do your claims have correctable errors?**
  - **Consider if you need a certificate of correction before asserting**
  - Example – case where issued patent recited 0.2% compound A/0.5% compound B where the actual formulation was 0.2% compound B/0.5% compound A

Company Policy and Procedures

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Considerations for Branded Companies

- **Best IP Protection**
  - Patent
    - 20 year right to exclude (if valid)
    - Public disclosure of IP
  - Trade Secret
    - No public disclosure
      - NDAs/Confidentiality agreements
    - No right to exclude
    - Lost if IP becomes public
- **Inventor Disclosures**
  - Consult In-House IP counsel prior to any public disclosures
    - Journal articles, conference presentations, grant applications
    - Have disclosure and documentation system in place for inventors
    - Logging system for Lab Notebooks

Considerations for Generic Companies

- **Evaluate Branded Patent Portfolio**
  - Orange Book Patents
  - Manufacturing Patents
  - Soon-to-issue applications
- **Decide on Paragraph IV Strategy**
  - Which patent(s) to certify first
  - Infringement, Invalidity, or Both
- **Evaluate Commercial Conditions**
  - Exclusivity expirations
  - Settlements with other generic competitions
  - Number of potential generics entering the marketplace
  - Carve-out opportunities
  - Risk of “Product Hop”

Written Communication as Evidence

Written Communication:

- Email
- Slack/Chat/Messages
- Lab Notebooks
- Presentations

All can be “documents” discoverable as evidence in litigation.

- Even when sent only internally
- Even if deleted
- No expectation of privacy
- Restriction for attorney-client privilege for legal advice.
    - However, including attorneys systemically on emails clearly not seeking legal advice likely will lack privilege.

Be Mindful of Written Communication When In-Person or Video Call is More Appropriate

- **Written Communication is helpful when:**
  - Communicating facts
  - Messaging simple answers
  - Asking clarifying questions of fact
  - Arranging in-person or video call

- **Other Communication should be considered when:**
  - There is a highly charged or sensitive issue at hand
  - Inconsistent or confusing data or outcome
  - Unclear of facts or speculating (try not to troubleshoot over email)
  - Opinion or conclusion about facts is desired to be shared

For sensitive IP topics, pick up the phone or have a face-to-face meeting

If you must write something, preface with: *"My personal, technical view of this is…"*

> ***"Never write if you can speak, never speak if you can nod, never nod if you can wink."***
>
> — Attributed to the 19th century Boston political boss Martin Lomasney.

Do Not Put Conclusions About IP in Writing

> *"Just found this patent; **I think it's a problem.**"*

> *"Sure we infringe, **but their patent is invalid.**"*

> *"Look at this patent—**this is what we do.**"*

> *"I've looked at their new model. **I don't think it practices our patent.**"*

Use Language Carefully

- Written communication in litigation could be reviewed years later, and taken out of context
- Avoid using legal terms of art (instead, use science-based or technical language)
  - Can be considered admissions on the record
  - Require legal analysis and are not facts on their face

- **Invention**
  - Instead use, for example, “Project,” or “Data” since that provides clarity from a technical perspective

- **Enablement**
  - Instead use, for example, “Implementation” or “Supporting Data”

- **Novelty or Obviousness (especially in the negative)**
  - Instead use, for example, “Differences between X and Y”

- **Infringe/Infringement or Freedom to Operate**
  - Instead use, for example, “Potential Technical Overlap”

- **Prior Art**
  - Instead use, for example, “Reference(s),” “Citation(s),” “Article(s),” or even just “Art”

Document Retention Policies

- **Considerations:**
  - How long until emails/messages are automatically deleted?
  - How long after employee leaves is their data retained?
  - Are hard copies held off-site?
  - Who all is subject to the policy?

- **Liberal policies of deletion (short time, overinclusive) can lead to allegations of spoliation**
  - May also prevent access to useful data/records for your invention story

Discovery Considerations & Best Practices

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Hatch-Waxman Litigation

- **Themes**
  - Invention story
  - Clinical benefits
  - Commercial impact
- **Fact Witnesses**
  - Inventor(s)
  - Face of the company/clinician
  - Commercial witness
- **Bench Trial**
  - No Jury
  - Judge Trier of Fact and Law
    - Decreased chance of excluding evidence

Hire Experienced Counsel

- **Hatch-Waxman Litigation can involve collecting, reviewing, and producing *millions* of documents**
  - Often during only several months

- **Hiring experienced counsel is critical to managing discovery**
  - Developing your invention story requires early (pre-suit) interviews of potential fact witnesses and early document collection
  - Can include management of contract reviewers for first-level review, quality control
  - Review of highly confidential technical and privileged information is crucial
  - Managing multiple discovery disputes, additional document collection
  - Preparing fact witnesses for defensive depositions

Document/Litigation Hold Notices

- **When should policy be in place?**
  - When litigation is reasonably foreseeable, no later than filing of lawsuit

- **Who should be subject?**
  - Inventors of all relevant patents
  - Anyone listed on Rule 26 initial disclosures
  - Other potentially relevant persons (patent prosecutors, possibly CEO)

- **Ensure automatic deletion through retention policies are deactivated**
  - And that person subject to the hold knows not to manually delete anything

Protective Orders

- **Govern the handling and disclosure of confidential and sensitive documents**

- **Access Limitations**
  - In-house counsel
  - In-house IP advisors

- **Considerations**
  - Prosecution bars
  - Enforcement/Violations
    - Submitting to Court's jurisdiction

What Kinds of ESI are Potentially Discoverable?

E-mails

Word Docs

Excel Files

Slide Decks

Chat messages, such as Slack, Skype, etc.

Text Messages

Digital Images

Video Files

What Sources of ESI are Potentially Discoverable?

Personal or Work Computer

Networks

The Cloud

Smart Phones

Tablets

Cameras

GPS Systems

Wearable Technology

Non-Email Communication is Increasing

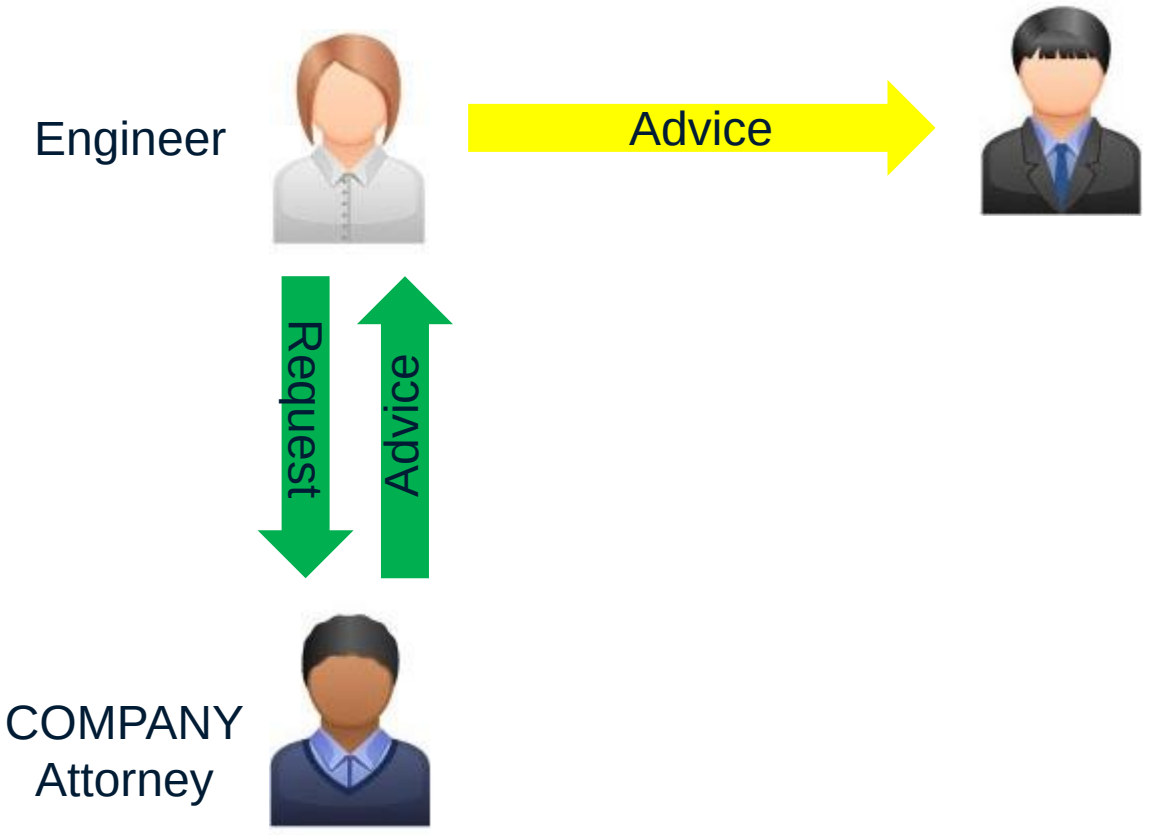
- Other types of messaging and electronic communication are becoming more common.
- Communications from less formal systems are discoverable and can be just as damaging in litigation.

Messaging – Many Forms, Increased Complexity

Depending on the type of message system, there are potential concerns and issues surrounding storage and archiving of messages

- Are message logs saved? For how long? Backups?
- Where are they saved and who has access? Internal only? Cloud? Encryption?
- Privilege issues? Export Control? Trade secret?

Caution: Privilege Can Be Waived



- COMPANY's ability to keep a communication privileged is risked when the advice is repeated to others.
- Risk to "privilege" depends on the facts of dissemination

- **Best practice**: Continue to "CC" the Attorney on any advice forwarded by "Engineer" within COMPANY
  - If not possible, consult with COMPANY Attorney in order to determine best way to proceed.

How to Avoid Inadvertently Waiving Privilege

LIMIT

emails to attorneys when seeking legal advice

AVOID

forwarding emails from attorneys—better to start a new email giving instructions or issuing requests to the appropriate people

NEVER

forward emails from an attorney to anyone else outside the organization, e.g. a consultant, without first getting permission from your in-house attorneys

Identifying and Retaining Expert Witnesses

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Types of Expert Witnesses

- Consulting

- Testing

- Testifying

Consulting Experts

- **Primary Role:**
  - Provide advice on technical issues/strategy without needing to be disclosed to other side
  - Can provide a useful “check” on other experts
- **Key requirements:**
  - Need not be a POSA
  - Subject matter expertise
- **Things to investigate:**
  - Can consulting expert stay walled off from other experts (colleagues, etc.)?

Testing Experts

- **Primary Role:**
  - Provide testing in support of infringement/validity (including inherency and indefiniteness)

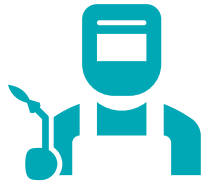
- **Key requirements:**
  - Do not need to be a POSA
  - Subject matter expertise, credentials less critical than testifying expert
  - Certifications and access to appropriate testing facilities/equipment

- **Things to investigate:**
  - Testing often requires tight turnarounds, does the expert have the bandwidth?
  - Any issues with GMP/facilities?

Testifying Experts

Primary Role:

Provide testimony (including declarations) for claim construction, infringement, validity, and damages



Key requirements:

Must be at least a person of ordinary skill in the art (“POSA”) (except damages experts)

Subject matter expertise, credentials (publications, awards, societies) prior experience testifying

Substantial bandwidth (expert reports, depositions, and trial prep take significant time)

Things to investigate:

Impeachment material

- Prior testimony / depositions? Has the expert written any articles/given talks that contradict their testimony or undermine your positions?
- Has the expert been subject to a successful *Daubert* motion before or been discredited by a court?

How to Identify Potential Experts

- **Client (Scientific Advisory Boards, Clinical Trial Sites, Consultants)**
  - Benefits: Likely very familiar with the technology, willing to help
  - Costs: Connection to client can be fodder for cross-examination/credibility

- **Internet Searches (Westlaw, Lexis, PubMed, Google)**
  - Benefits: More likely to find “independent” expert
  - Costs: May need to contact many potential experts, difficult to contact, unknown conflicts

- **Expert Consulting Networks**
  - Benefits: Initial legwork done by search firm, more likely expert has testifying experience
  - Costs: search firm usually takes a cut of fees, expert rates are generally higher

- **Law firm (internal recommendations)**
  - Benefits: Prior experience working with firm, usually proven testifier
  - Costs: Significant work with the same law firm can be fodder for cross-examination/credibility

When to Identify and Retain

- **ASAP!**
  - Pre-suit, no later than fact discovery
  - Before the other side can retain them
    - Niche fields can have few qualified experts, or broader fields can have few prominent experts, so competition can be high
      - Especially for experts with prior (good) testifying experience
  - Retaining an expert does not ultimately mean they submit a report, go to trial

- **Finding experts, running diligence/conflicts, and bringing them up to speed can take significant time (months)**

Other Considerations

- **Using the same expert for infringement and validity**
  - More continuity on the case if issues overlaps (e.g., infringement and indefiniteness)
  - Usually limited deposition time (single deposition must cover all issues)

- **Using multiple experts on validity**
  - Different patents can require different experts
    - Method of treatment/administration (Clinicians)
    - Formulation (Pharmacists)
    - Method of manufacture (Industry consultants, chemical engineers)
    - Delivery devices (medical engineers)
    - Drug substance (chemists, crystallographers)
  - Different issues can require different experts
    - Anticipation/obviousness
    - Written Description/Enablement (especially post-*Amgen*)
    - Indefiniteness
    - Section 101

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Thank You!

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