You Know It Is Coming:
Preparing for the
Paragraph IV Letter

John Farrell, Fish & Richardson
Matt Onaitis, Somaxon
William Scarff, Allergan
Jonathan Singer, Fish & Richardson
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• Regulatory Context: Timing of the Hatch-Waxman Suit
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• Preparing for Discovery
• The innovator company develops the product, performs or references clinical trials, prepares the reference product label
• Innovator controls the scope and timing of patent filings: seeks to obtain patents that cover the product and products the FDA would find bioequivalent to the product
• By filing an ANDA with a Paragraph IV certification, the generic challenger is proposing to market a proposed product bioequivalent to the innovator product, and certifying that an innovator patent covers the proposed product
• Innovator prepares patent enforcement strategy for Orange Book listed patents in advance of ANDA Paragraph IV certification (short time line)
Timing of the Hatch-Waxman Suit

- Hire corporate intelligence companies to monitor ANDA filings

- For New Chemical Entities (NCE), calculate the “NCE – 1” date to estimate when the first Paragraph IV certification is likely to arrive
  - Pioneer drug companies can get 5 years of data and market exclusivity for a drug substance that has never been approved as a drug in a given country
  - Generics can file ANDAs with Paragraph IV certifications at the end of the 4th year

- If not a NCE, determine if any other market exclusivity would apply
  - An ANDA with a Paragraph IV certification is likely to be filed 18-24 months (but can be filed at anytime) before the expiration of market exclusivity (ANDA approval usually takes 18-24 months)
Timing of the Hatch-Waxman Suit

- Market exclusivities:
  - **Orphan drug exclusivity**: 7 years for a drug that is either unprofitable or is approved to treat diseases or conditions that affect less than 200,000 people in the U.S.
  - **New use/indication exclusivity**: 3 years for new therapeutic uses of an old drug, or labeling changes for which the applicant submitted and obtained approval for a new NDA
  - **New formulation exclusivity**: 3 years for changes in an approved drug product that affect the metabolism of its active ingredient(s)
  - **Pediatric exclusivity**: 6 months added to all other exclusivities, including (effectively) to patent exclusivities, for drugs that are approved for use in children
Regulatory Checklist

• Check Orange Book Listings
• Check Use Codes
  – Breadth/Specificity
• Check and Compare Label
  – Patents
• Pending patent applications
• Regulatory Context: Timing of the Hatch-Waxman Suit
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• Make sure relevant file histories are available
• Verify patent information accuracy for each asserted patent:
  – Assignment
  – Standing
  – Listing
  – Title
  – Check each patent for errors (e.g., spelling errors, numerical errors, etc.) and file for certificate of correction if necessary.
  – If the patented product claims a clinical benefit, ensure that proper clinical data is in the specification
Case Evaluation and Formation

• Validity opinions?
  – Must weigh the costs/benefits of a formal vs. informal evaluation of the patents at issue
  – How will the opinion be used?
  – Will the opinion be discoverable?
  – Should opinion counsel or new counsel be used to litigate the patents?

• Infringement?
  – Identify possible claim constructions
  – Identify the universe of potential products that could infringe
  – Check file histories for disclaimers and potential prosecution history estoppel
Case Evaluation and Formation

• Retain the inventors and other key individuals as consultants, if they are not already obligated to assist with the litigation.

• Identify key witnesses and evidence.
  – Know the invention story
  – Contributions by non-inventors?
  – All potentially relevant lab notebooks
  – Crucial data and publications
  – Any prosecution irregularities?
• Identify potential experts early
  – Precisely identify the technologies at issue
  – Retain the best experts in each field (before the other side can)
  – Test case theories with them

• Identify outside counsel
Case Evaluation and Formation

• Identify and evaluate potential forums
  – Experience with Hatch-Waxman?
  – Local Patent Rules
    • Regular (N.D.Cal.)
    • Hatch-Waxman (D.N.J./E.D.Tx.)
  – Time to trial?
    • 30-month stay
  – Experienced judges?
    • Patent vs. Hatch-Waxman
  – Likelihood of Summary Judgment?
## Case Evaluation and Formation

<table>
<thead>
<tr>
<th>Common Forums</th>
<th>Time to Trial (in Years): 1995-2008</th>
<th>Overall Success Rate by Patent Holders</th>
</tr>
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<tbody>
<tr>
<td>Delaware</td>
<td>1.92</td>
<td>47.7%</td>
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<tr>
<td>New Jersey</td>
<td>2.70</td>
<td>32.1%</td>
</tr>
<tr>
<td>Eastern District of Texas</td>
<td>1.79</td>
<td>51.6%</td>
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</tbody>
</table>
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Preparing for Discovery

• Know your document retention policies
  – Legally reasonable and meets business needs?
  – Has it been properly executed?

• Know your storage systems
  – Physical document locations
    • Department files
    • Personal files
  – Electronic folders/networks/shared drives
  – Physical archives
  – Electronic archives/back-up tapes
Preparing for Discovery

• When do you “reasonably anticipate” litigation?
  – Very fact specific
  – But, other factors can move this date earlier, e.g. privilege claims. See, *Sanofi-Aventis Deutschland GMBH v. Glenmark Pharmaceuticals Inc.*, USA, 2010 WL 2652412, at 5 (D.N.J.) (Court rejected defendants’ argument that their duty to preserve arose with the filing of the Paragraph IV letter, because it contradicted their claim of work product immunity arising at an earlier date.)
Preparing for Discovery

• Litigation hold
  – “Possibly after October, 2003, when Zulubakte IV was issued, and definitely after July, 2004, when the final relevant Zulubakte opinion was issued, the failure to issue a written litigation hold constitutes gross negligence because that failure is likely to result in the destruction of relevant information.” Pension Committee of Univ. of Montreal Pension Plan v. Banc of America Securities LLC, 685 F.Supp.2d 456, 464-465 (S.D.N.Y. 2010)
Preparing for Discovery

• Litigation hold
  – *Rambus I, 2009-1263 (May 13, 2011)*
    • Destruction of documents as a “litigation strategy” (as opposed to a corporate document retention policy) more likely to result in court finding litigation “reasonably foreseeable”
    • “Knowledge of likely infringing activity” makes litigation more “reasonably foreseeable”
    • Status as plaintiff (who files suit) instead defendant (who is sued) matters (unless the defendant is a d.j. plaintiff)
    • Dispositive requires “bad faith” – i.e., intent to impair a defendant’s ability to defend itself – “prejudice” to other party, and unusually severe conduct
Preparing for Discovery

• Litigation hold
    • Destruction of documents as a “litigation strategy” (as opposed to a corporate document retention policy) more likely to result in court finding litigation “reasonably foreseeable”
    • “Knowledge of likely infringing activity” makes litigation more “reasonably foreseeable”
    • Status as plaintiff (who files suit) instead defendant (who is sued) matters (unless the defendant is a d.j. plaintiff)
    • Dispositive sanction requires “bad faith” – i.e., intent to impair a defendant’s ability to defend itself – “prejudice” to other party (burden depends on resolution of bad faith issue), and unusually severe conduct
Preparing for Discovery

• Litigation hold
  – Identify custodians
  – Identify subject matter
  – Identify timeframe
  – Identify relevant media (paper, local computer, network, etc.)
  – Identify obligations
Preparing for Discovery

- **Cost**
  - Estimate volume of electronic and paper discovery
  - Identify potential vendors to handle discovery
  - Contract attorneys for document review?

<table>
<thead>
<tr>
<th>Electronic Media</th>
<th>Paper Count</th>
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<tbody>
<tr>
<td>1 Megabyte (MB)</td>
<td>Averages 75 pages</td>
</tr>
<tr>
<td>1 Gigabyte (GB)</td>
<td>Averages 75,000 pages</td>
</tr>
<tr>
<td>1 Terabyte (TB)</td>
<td>Averages 75,000,000 pages</td>
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<table>
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<tr>
<th>Media Type</th>
<th>Pages</th>
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<tbody>
<tr>
<td>Email</td>
<td>1-2 pages each</td>
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<tr>
<td>Word Processing</td>
<td>5-8 pages each</td>
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<tr>
<td>Spreadsheets</td>
<td>15-30 pages each</td>
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<tr>
<td>Presentation</td>
<td>12-24 pages each</td>
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<tr>
<td>Graphic</td>
<td>1 page each</td>
</tr>
<tr>
<td>Adobe PDF</td>
<td>35 pages each</td>
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<table>
<thead>
<tr>
<th>Media Type</th>
<th>Pages</th>
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<tbody>
<tr>
<td>CD (640 MB – 800 MB)</td>
<td>48,000-64,000 pages</td>
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<tr>
<td>DVD (4.7 GB – 17 GB)</td>
<td>350,000-1.3 million pages</td>
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<tr>
<td>Firewire USB “flash” drive</td>
<td>10,500,000 pages</td>
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<tr>
<td>(120 GB)</td>
<td></td>
</tr>
<tr>
<td>Hard Drive (20 GB and over)</td>
<td>Over 1.5 million pages</td>
</tr>
<tr>
<td>Back-up Tape (200 GB compressed)</td>
<td>Approximately 17,500,000 pages</td>
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</tbody>
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Questions?