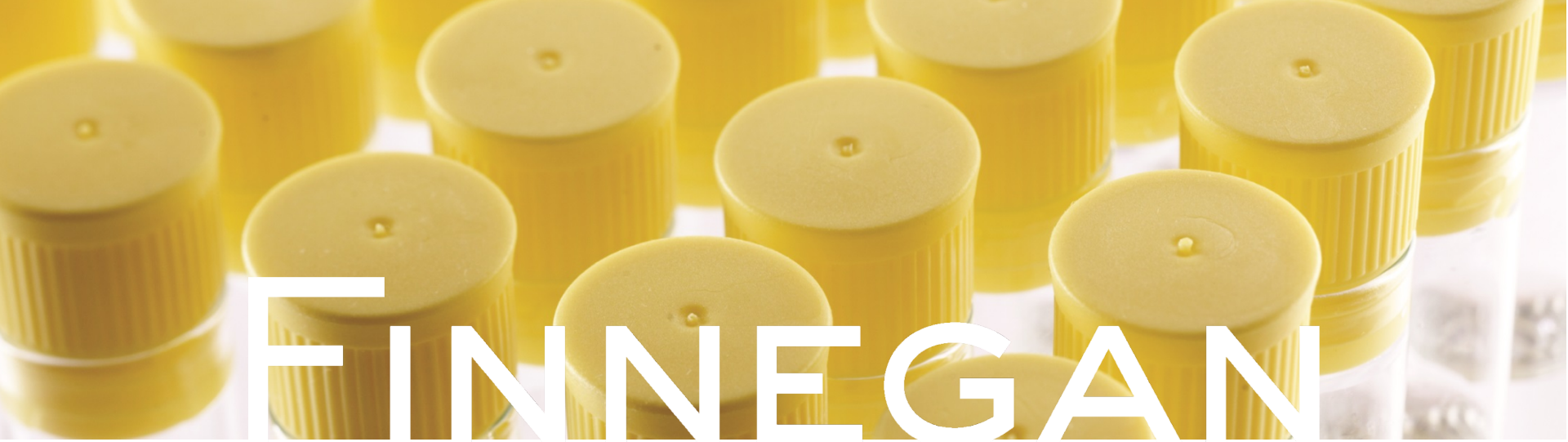


Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

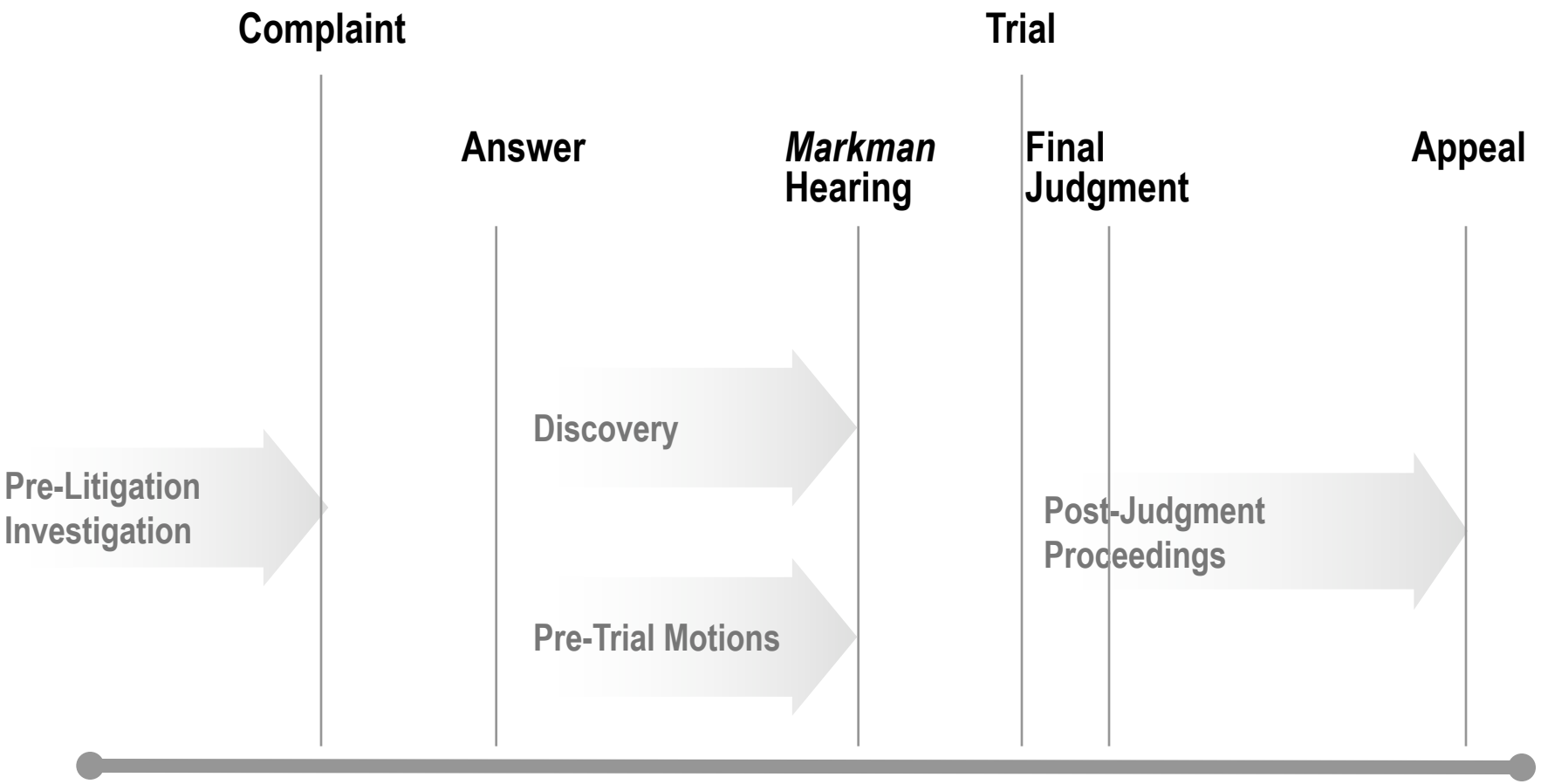
Expert Evidence in Patent Controversies

Presented by:

Eric J. Fues

ASIPI BOGOTÁ 2018

U.S. Patent Litigation



Decision Maker in U.S. Patent Cases

- Most pharmaceutical patent cases are decided by a district court judge – typically no technical training; handles hundreds of cases at a time.
- Some patent cases are decided by a jury — typically no technical or legal training.

What Is The Role of an Expert?

- Explain patented technology
- Explaining meaning of words within a claim
- Explain how accused pharmaceutical/method does or does not infringe
  - Relying on bioequivalence is not enough
- Provide evidence establishing objective indicia of nonobviousness
- Calculate the amount of patent damages

What Is The Role of an Expert?

4. A pharmaceutical dosage form comprising a population of extended release beads, wherein said extended release beads comprise:

an active-containing core particle comprising cyclobenzaprine hydrochloride as the active; and

an extended release coating comprising a water insoluble polymer membrane surrounding said core, wherein said water insoluble polymer membrane comprises a polymer selected from the group consisting of ethers of cellulose, esters of cellulose, cellulose acetate, ethyl cellulose, polyvinyl acetate, neutral copolymers based on ethyl acrylate and methyl methacrylate, copolymers of acrylic and methacrylic acid esters with quaternary ammonium groups, pH-insensitive ammonio methacrylic acid copolymers, and mixtures thereof;

wherein the total amount of cyclobenzaprine hydrochloride in the pharmaceutical dosage form is 15 mg;

wherein following a single oral administration of the pharmaceutical dosage form, the pharmaceutical dosage form provides a maximum blood plasma concentration (C_{max}) of 8.315±2.1635 ng/mL of cyclobenzaprine HCl and an $AUC_{0-\infty}$ of 354.075±119.8037 ng·hr/mL.

Patent Owner Construction:

Material or materials on the surface of another material or materials that delay the release of a drug in order to maintain the drug at a therapeutically effective concentrations over an extended period of time.

Accused Infringer Construction:

A continuous outer film applied onto the surface of the active containing core to provide an extended release of an active core.

What Is The Role of an Expert?

1. The magnesium salt of S-omeprazole trihydrate, wherein the compound is characterized by the following major peaks in its X-ray diffractogram:

d-value / Å	Relative Intensity
2.67	m
2.79	m
3.27	m
3.52	s
3.82	s
3.96	vs
4.14	m
5.2	m
5.6	m
6.7	vs
6.9	s
8.3	w
16.6	vs

Patent Owner Construction:

Identifiable by reference to an x-ray diffractogram that includes the major peaks below.

Accused Infringer Construction:

Having each of the referenced peaks in its x-ray powder diffractogram ***within normal experimental error***

Typical Experts in Pharma Cases

- **Chemist**
  - Similarity of structure or composition (infringement/validity)
  - Synthesis routes
  - Properties
- **Pharmacologist**
  - Bioavailability
  - Unexpected/superior effects
- **Economist**
  - Objective indicia of non-obviousness (market need)
  - Damages
  - Economic harm (injunctive relief)

Finding the Right Expert

- Look for experts with good reputation in industry (e.g. professors, industry experience)
- Work with client to identify potential experts
- Meet in person before engaging
  - Good listener
  - Knowledgeable but not arrogant
- Ensure expert has not given conflicting testimony (e.g., previous testimony, publications or patents)
  - May be used to impeach at trial/deposition

Finding the Right Expert

Who May Testify As An Expert?

- An individual may testify as an expert witness if:
  - Their **scientific, technical, or other specialized knowledge will help** the trier of fact to understand the evidence or determine a fact in issue
  - Their testimony is based on **sufficient facts or data**
  - The testimony is the product of **reliable principles and methods**, and
  - They **have reliably applied the principles and methods** to the facts of the case.

Fed. R. Evid. 702

Ensuring Expert Testimony Will Be Helpful

- Engage expert early on in the case
- Have expert work cooperatively on their reports
- Ensure all methods used are accepted in industry
- Ensure expert has not given conflicting testimony (e.g., previous testimony, publications or patents)
- Prepare adequately for deposition/trial cross-examination

Expert Reports

- A complete statement of all opinions the witness will express and the basis and reasons for them
- Facts or data considered by the witness in forming opinions
- Any exhibits that will be used to summarize or support opinions
- Expert qualifications, including a list of all publications authored in the previous 10 years
- List of all other cases in which, during the previous 4 years, witness testified as an expert
- Statement of the compensation to be paid for the study and testimony in the case

Typical Expert Testimony in Pharma Cases

- Testing of accused samples to show it meets the claim limitations (e.g., API, excipients, properties)
- Testimony on label and off-label uses for relevant pharmaceutical
  - Dosages
  - Off label use - alone or with other prescriptions
- Understanding/explaining clinical studies
- Impact of generic entering the market on branded pharmaceutical
- Skilled artisan view on prior art

Challenging Reliability -- *Daubert*

- Is the expert sufficiently qualified?
- Has theory been tested?
- Has theory been peer reviewed?
- What is the error rate?
- Has theory been generally accepted by scientific community?

Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 589 (1993).

Germany

- Court may appoint experts but often asks parties to suggest experts. Experts provide independent, impartial advice to the court.
- Parties can submit a written expert's opinion, but those opinions are considered part of the pleadings, not independent evidence
- Parties have right to reply to court-appointed expert testimony and can request the opportunity to question expert in court

UK

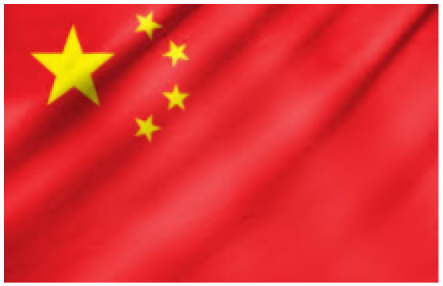
- Parties each submit experts; court will not appoint an expert
- Experts submit evidence in a written report prior to trial. At trial, the parties call their expert witnesses to confirm written evidence
- Witnesses are cross-examined and may be asked about any document or issue in the case

Japan

- Parties may request that the Court appoint neutral, third-party experts
- Party appointed experts are rarely used. Must file a request to have an expert witness testify along with brief summary of testimony.
- Parties may cross-examine the court's experts and have right to reply to written opinions

China

- Parties can submit expert witness reports. More commonly, court will appoint expert.
- If a party disagrees with expert's opinion, expert must testify in court.



Turkey

- Usually, a panel of independent experts (e.g., academic, lawyer, patent lawyer) is appointed by the court to examine the technical and legal facts, the costs of which are paid by the plaintiff
- The experts or their reports can be challenged by either party on reasonable grounds, which then leads to the preparation of a second final report

Questions?

Contact Information

+1 202 408 4245
eric.fues@finnegan.com

Eric Fues leads Finnegan's chemical and metallurgical practice group. His practice focuses on patent and trade secret litigation in federal courts and at the U.S. International Trade Commission (ITC). He has been involved in more than 50 district court matters and ITC investigations, including many pharmaceutical cases. He also represents clients before the U.S. Court of Appeals for the Federal Circuit and provides client counseling services.

+1 202 408 4253
clara.jimenez@finnegan.com

Clara N. Jiménez works closely with clients of all sizes to develop business-sound intellectual property solutions. She has experience with a broad range of technologies including consumer, industrial, and pharmaceuticals products; polymers, catalysts, advanced materials and oil and gas. Her practice encompasses patent prosecution, client counseling, post-grant practice, and patent litigation.

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