Drafting Claims to Survive Hatch-Waxman Litigation

Wednesday, August 9th

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Meet the Speakers

Nitika Fiorella
Principal

302-778-8461
fiorella@fr.com

Michael Kane
Principal

612-337-2502
kane@fr.com

Gwilym Attwell
Principal

302-778-8458
attwell@fr.com

Overview

Housekeeping

- CLE
- Questions
- Materials
- http://www.fr.com/webinars

Agenda

- Background
  - Drug Discovery
  - Hatch-Waxman litigation and the Orange Book
- Surviving Hatch-Waxman Trial
- Claim Drafting Tips

Background

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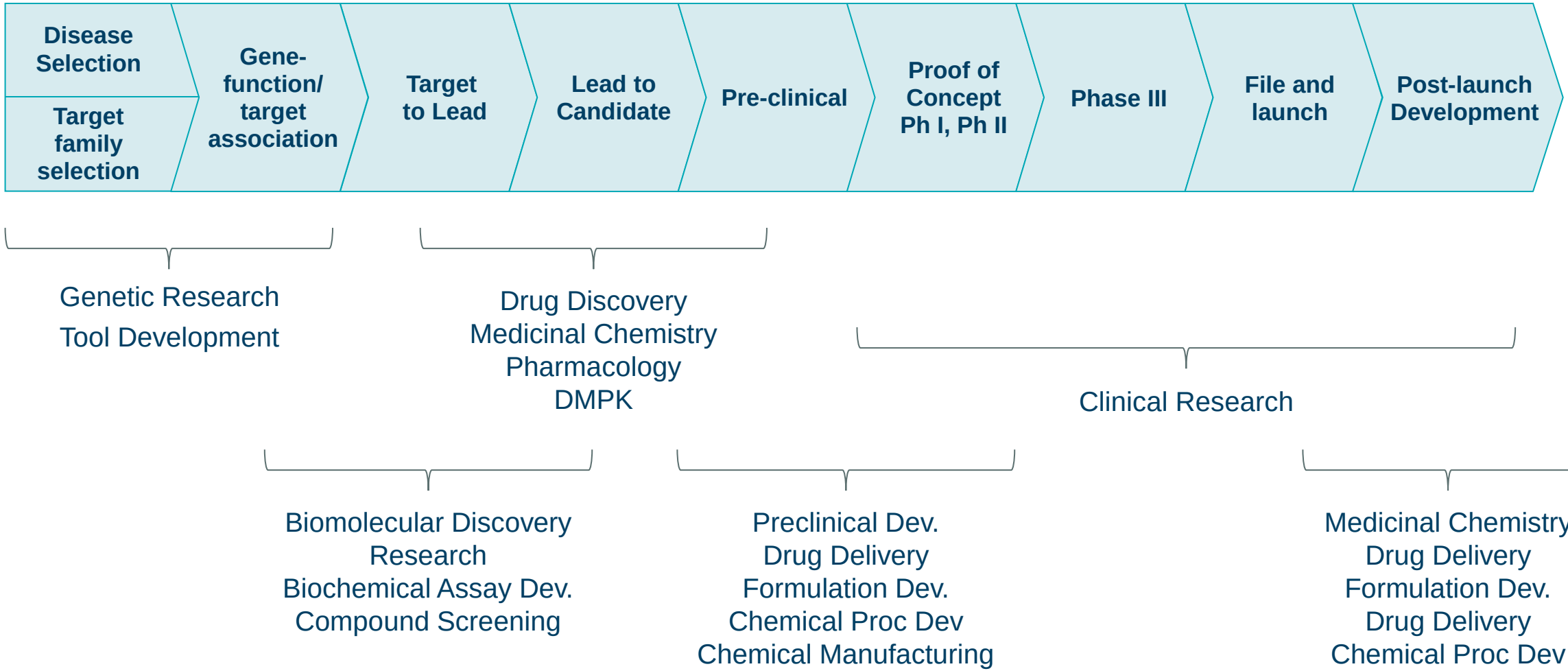
Typical Pharma R&D Process



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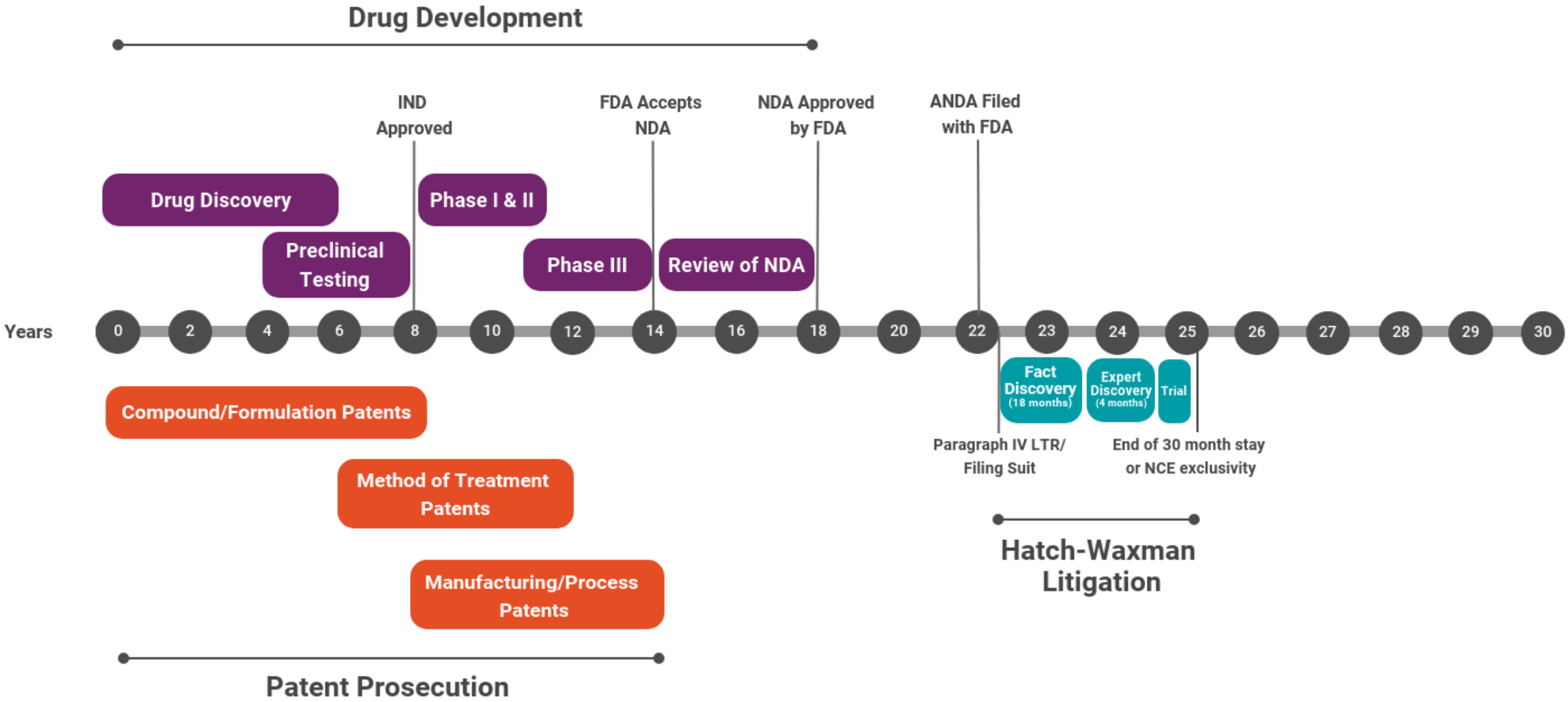
Patents Arising from Pharma R&D Process

- Gene/protein patents
  - Mechanism of action patents
  - Assay patents
    - Compound patents
    - Method of treatment patents

- Chemical process patents / Intermediates
- Formulation, Delivery Device patents
- Compound salt/ester/solvate/polymorph/crystal form patents
- Second Method of Treatment patents
- Dosing regimen / Method of Administration / Treatment Algorithm / Genetic marker association patents / Companion Diagnostics ("Labeling Patents")

Drug Development/ Regulatory/ H-W Timeline



What Are The Challenges?

- **Drug discovery**
  - Find a therapeutic that works (and then file a patent application)
- **Patent Office**
  - Convince the Patent Office that the claimed invention is novel, non-obvious, and satisfies §112
- **FDA**
  - Demonstrate that therapeutic is safe and effective
- **Market**
  - Gain significant market share
- **Generics**
  - Survive Hatch-Waxman litigation and IPR challenges

Types of patent claims – general considerations

- Compound patents (generic/species)
- Method of treatment patents
- Mechanism of action patents
- Label patents
- Formulation patents
- Solvate/polymorph/crystal form patents
- Chemical process patents

Design arounds?

Prior art?

Direct v. indirect infringement?

Orange Book listable?

Surviving Hatch-Waxman Trial

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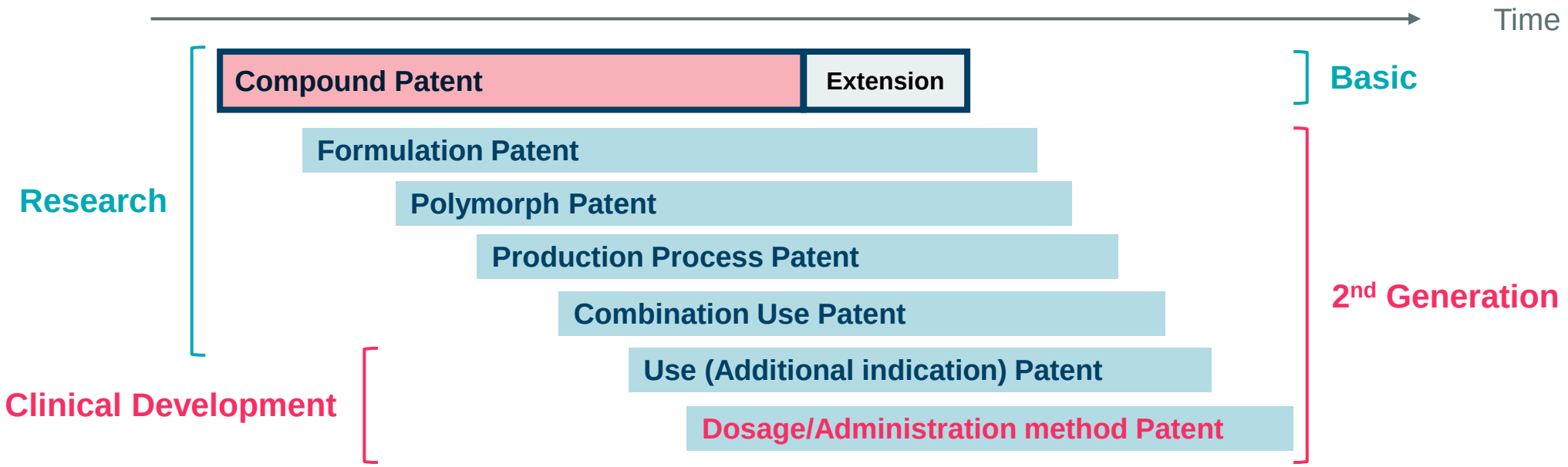
Obtain Patents in All Phases of R&D



- Examples:

Category	Product
Dosage Regimen	Invega Sustenna (Janssen)
Fewer adverse effects at a certain dose	Latuda (Sumitomo Dainippon)
Cyclic administration	Revlimid (Celgene)
Discontinuation in a certain condition	Mulpleta (Shionogi)
Impurity level	Elycys (Excela)

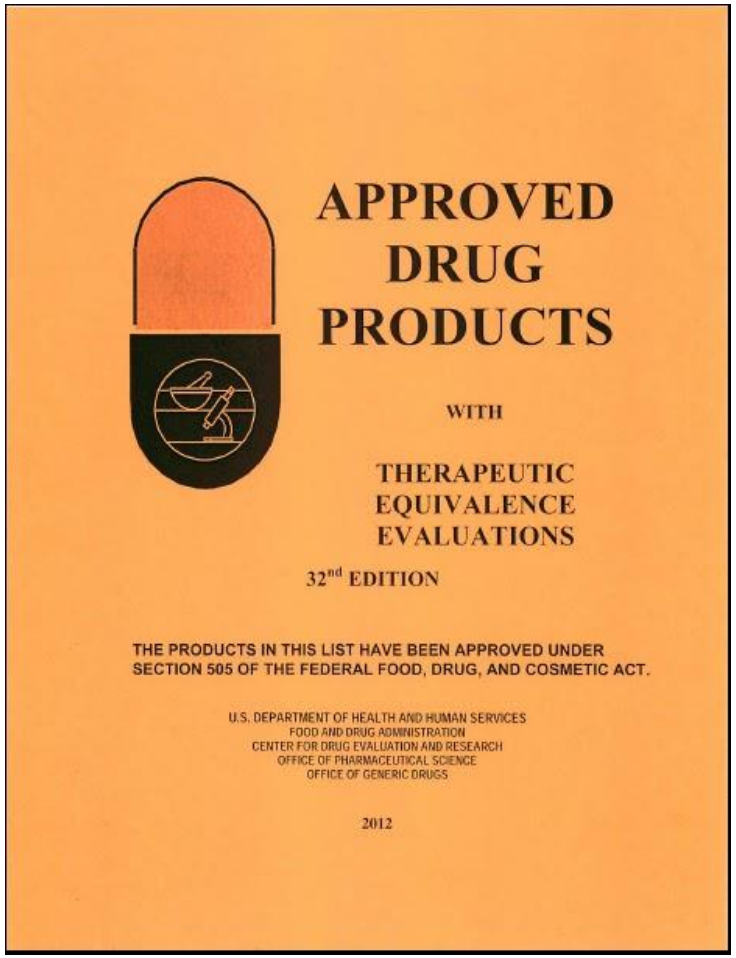
Hatch-Waxman Trial

Types of Patents

- Orange Book-Listed Patents
  - Compound
  - Formulation
  - Methods of treatment
  - Polymorph

Orange Book Listing – Method of Treatment

- Use code
- Identify sections of label



Hatch-Waxman Trial

Types of Infringement

- Direct
- Indirect
  - Inducement
  - Contributory

Types of Defenses

- Non-infringement
- Anticipation
- Obviousness
- Section 112
- Equitable Defenses

Proving Infringement

- **Direct Infringement:**
  - Proof can be relatively simple for claims to the active ingredient
  - Can be more difficult for claims with functional limitations
    - Consider what information the generic defendant will likely submit with the ANDA
- **Indirect Infringement**:
  - Starts with ANDA Label:
    - Contributory: does product as labeled have substantial non-infringing use?
    - Inducement: does it promote and encourage infringement or merely an infringing use?
  - Can consider label as a whole
  - Other acts promoting and encouraging infringement

Defending Against Invalidity Challenges

Prior Art Attacks

- Anticipation/obviousness challenges are highly factual inquiries
- Helpful to have a strong invention story, with support in the specification and the claims
- Be careful claiming ranges, due to obviousness presumption when ranges overlap
- Second-generation patents often more susceptible to prior art attacks
- Difficult to establish nexus for 2nd generation patents

112 Attacks

- Can kill an entire patent quickly
  - Puts settlement pressure on patentees to have a 112 challenge in the case
  - May be decided as early as claim construction
- Appellate courts have signaled their interest in 112 defenses
  - *Amgen v. Sanofi* got SCOTUS attention
  - Multiple Federal Circuit opinions each year on enablement and written description, and many overturn district court opinions on these issues

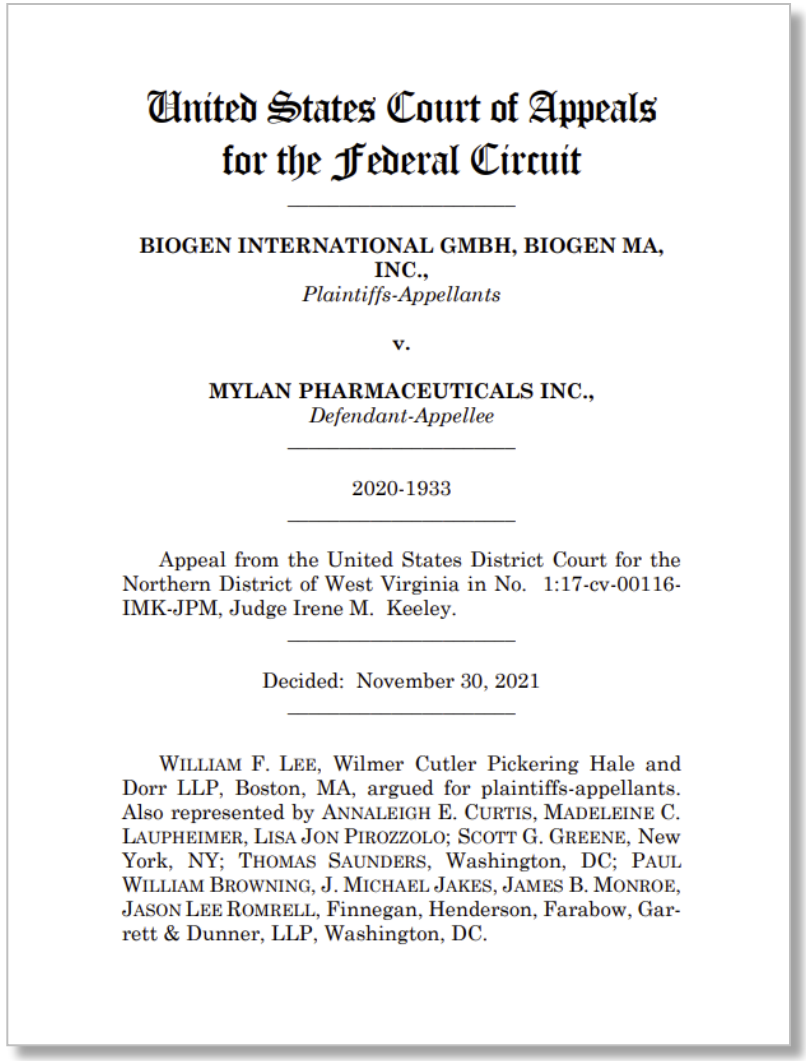
Biogen v. Mylan (Fed. Cir. 2021)

Disclose but not Describe?

1. A method of treating a subject in need of treatment for multiple sclerosis comprising orally administering to the subject in need thereof a pharmaceutical composition consisting essentially of

(a) a therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof, and

(b) one or more pharmaceutically acceptable excipients, wherein the therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof is about 480 mg per day.



United States Court of Appeals
for the Federal Circuit

BIOGEN INTERNATIONAL GMBH, BIOGEN MA, INC.,
Plaintiffs-Appellants

v.

MYLAN PHARMACEUTICALS INC.,
Defendant-Appellee

2020-1933

Appeal from the United States District Court for the Northern District of West Virginia in No. 1:17-cv-00116-IMK-JPM, Judge Irene M. Keeley.

Decided: November 30, 2021

WILLIAM F. LEE, Wilmer Cutler Pickering Hale and Dorr LLP, Boston, MA, argued for plaintiffs-appellants. Also represented by ANNALEIGH E. CURTIS, MADELEINE C. LAUPHEIMER, LISA JON PIROZZOLO; SCOTT G. GREENE, New York, NY; THOMAS SAUNDERS, Washington, DC; PAUL WILLIAM BROWNING, J. MICHAEL JAKES, JAMES B. MONROE, JASON LEE ROMRELL, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, DC.

Biogen v. Mylan (Fed. Cir. 2021)

Disclose but not Describe?

- Specification referred to 480 mg dose, but was a passing reference in the context of a large range
- The Federal Circuit affirmed (2-1) finding that the specification ***did not provide written description support*** for the claimed dosage
  - Court noted that MS was just one of the many neurological disorders mentioned in the specification
  - Assumed disclosure of connection between treatment of MS and use of DMF but still found claims invalid for WD
  - Court focused on the fact that the 480 mg/day was mentioned only once and the specification's focus was on drug discovery and basic research
  - So district court did not clearly err in finding that a POSITA would not have recognized based on the passing reference that 480 mg of DMF would have been efficacious
- Three judges later voted to take the case *en banc* (four too few)

Novartis v Accord (Fed. Cir. 2022)

Can Silence be Disclosure?

- Novartis markets Gilenya® (fingolimod) for treatment of a certain type of MS

- Novartis filed suit against other ANDA filers
  - Each claim requires administering "a daily dosage of 0.5 mg, ***absent an immediately preceding loading dose regimen***."

- Specification makes no mention of loading doses
  - Describes a mouse study and a prophetic human clinical trial, which support 0.5 mg daily dosing
  - No suggestion for either study that a loading dose was given prior to the daily dosing
  - No mention of the pros and cons of including or excluding a loading dose

Novartis v Accord: Original Fed Circuit Decision

Can Silence be Disclosure?

- Affirms district court finding of ***no lack of written description*** for "absent an immediately preceding loading dose regimen."
- Majority opinion by Judge O'Malley (joined by Judge Linn)
  - Skilled person would recognize that Novartis had possession of a method of treatment with no loading dose
  - Silence can serve as disclosure if it would convey to the skilled person that the inventor was in possession of the claim element
  - Based on expert testimony, the court agreed that the "EAE model and the Prophetic Trial . . . both indicate to a person of ordinary skill that the claimed invention did not include the administration of a loading dose."
- Dissent by Chief Judge Moore
  - "Silence is not disclosure"
  - "Negative claim limitations are adequately supported when the specification describes a reason to exclude the relevant limitation, such as by listing the disadvantages of some embodiment."
  - "The patent is silent, eerily silent" on a loading dose.

Novartis v Accord: Reversal on Rehearing

Can Silence be Disclosure?

- HEC petitioned for a panel rehearing on the decision in February
  - Just a few weeks later, Judge O'Malley retired.
  - Judge O'Malley was replaced on the panel by Judge Hughes
- New panel grants rehearing and reverses, finding claims ***lack written description support***
- Chief Judge Moore wrote new opinion (joined by Judge Hughes) very similar to the original dissent
  - "Silence is *generally* not disclosure."
  - "While silence will not generally suffice to support a negative claim limitation, there may be circumstances in which it can be established that a skilled artisan would understand a negative limitation to *necessarily be present* in a disclosure."
  - On this record, there is no evidence that a skilled artisan would understand silence regarding a loading dose to necessarily exclude a loading dose."
- Judge Linn dissented in line with the original majority opinion

Claim Drafting Tips

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Claim Drafting Tips

- The *more* claims, the better
- Build a *complex* claim set
  - Varying scope (broad – intermediate – narrow)
  - Diverse language and type
  - Picture claims (many)
  - Nested dependent claims
- Describe your invention in different ways
  - Try to make sure your claims are consistent with the invention story you'll want to tell at trial
- Keep an application alive in each family
- Make sure any negative limitations have support in specification

Claim Drafting Tips – More Advanced

- Track the drug label and updates to label (or try to cover what you reasonably believe will be on the drug label)
  - Promote and encourage v. simply describe infringing use
- Individual patient vs. patient population
- Incorporate unexpected results
- Include safety related limitations
  - Impurities/side effects
- Talk to scientists/clinicians and identify subject matter for second generation claims
- Avoid method of treatment limitations which might appear in clinical trials descriptions but cannot be proven for individual patients
- Identify other ways of practicing your invention
- Non-Orange Book claims (process of making, metabolites, product-by process)

Nitika Fiorella
Principal
fiorella@fr.com

Michael Kane
Principal
kane@fr.com

Gwilym Attwell
Principal
attwell@fr.com

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