Cooley

May 2025

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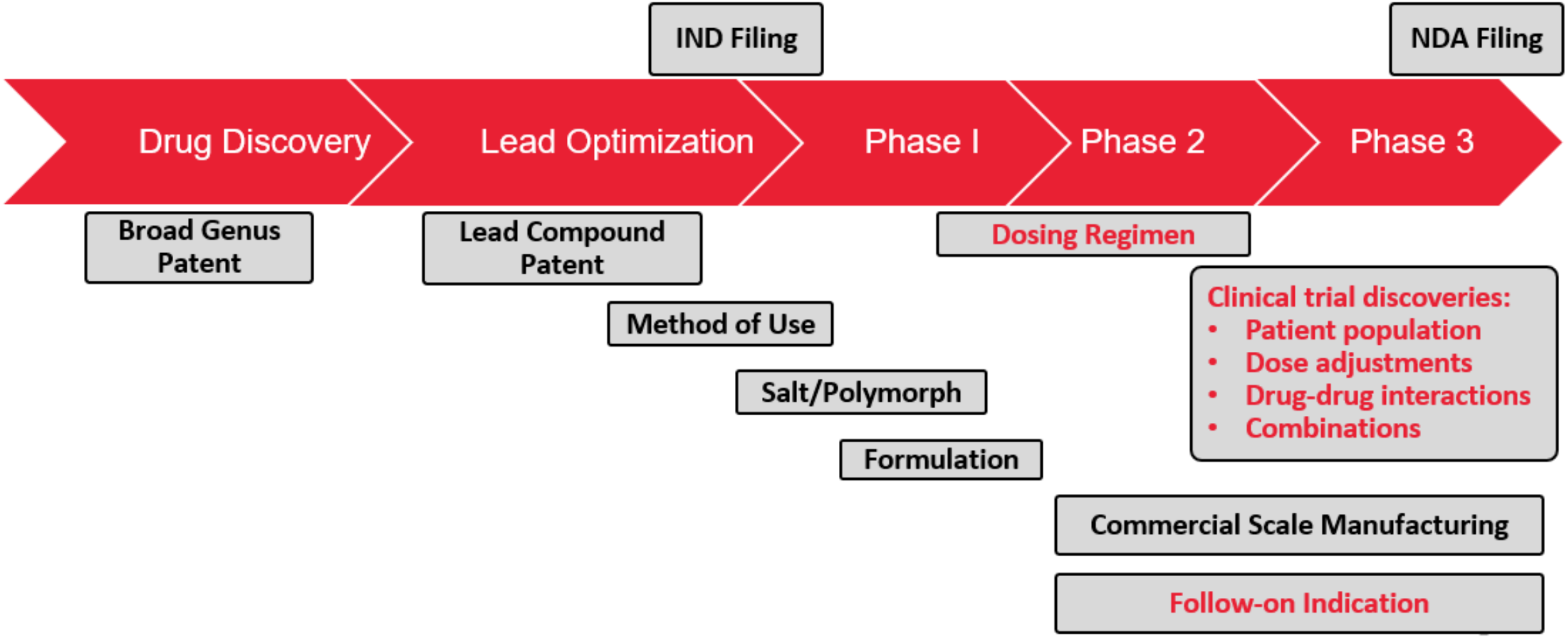
# Cooley Rx:

## Life Sciences Litigation: Clinical Trials and Tribulations – Prosecution and Litigation Implications of Clinical Trial IP and Prior Art

# Agenda

- R&D and patent timeline
- Patentability of clinical trial inventions
- Impacts of different types of indications and drugs
- Sources of prior art
- Best practices and litigation considerations

# R&D and Patent Timeline



# Setting the Stage

Patentability hurdles for clinical trial inventions

- Routine optimization
  - "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)
  - e.g., doses and dosing regimen
- Inherent anticipation
  - "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. IRECO Inc.,* 190 F.3d 1342, 1347 (Fed. Cir. 1999).
  - The Federal Circuit found that a protocol for the administration of ramipril to stroke-prone patients was sufficiently detailed to render claims unpatentable. *In re Montgomery* (Fed. Cir. 2012)
  - e.g., clinical outcomes

# Janssen v. Teva (Fed. Cir. 2024)

- Invega Sustenna, extended-release IM injection of paliperidone palmitate for schizophrenia
- Paliperidone previously formulated as a tablet for daily administration
  - Treatment adherence issues
- Palmitate prodrug provided sustained release profile, allowing for less frequent dosing.
- Faster onset achieved by injecting higher loading doses in deltoid.

1. A dosing regimen for administering paliperidone palmitate to a psychiatric patient in need of treatment for schizophrenia, schizoaffective disorder, or schizophreniform disorder comprising

(1) administering intramuscularly in the deltoid of a patient in need of treatment a first loading dose of about 150 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;

(2) administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of about 100 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the $6^{th}$ to about 10th day of treatment; and

(3) administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a first maintenance dose of about 25 mg-eq. to about 150 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation a month (±7 days) after the second loading dose.

# Janssen v. Teva (Fed. Cir. 2024)

- Teva's argument
  - Claim are obvious over (1) Phase III clinical study protocol describing four equal injections of 50, 100 or 150 mg paliperidone palmitate, (2) '544 patent describing the injectable formulation and spaced administration schedule and (3) WO '384 further describing aspects of the formulation
    - Unequal dosing was known and a POSA had a reasonable expectation of success using any doses from the Phase III protocol
- Janssen's argument
  - Higher loading doses are contrary to standard "low and slow" titration schedule
  - No recognized problems with the Phase III protocol and no motivation to modify it

# Janssen v. Teva (Fed. Cir. 2024)

- District Court found the claim nonobvious based on lack of efficacy data in clinical trial protocol
- Fed. Cir. remanded to district court to apply proper obviousness analysis

Whatever role safety and efficacy data may play in assessing the strength of a motivation or a lack of motivation to combine, *see Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1360–61 (Fed. Cir. 2017), absence of such safety and efficacy data in the '548 Protocol cannot justify simply discarding that prior art particularly where, as here, the claims do not have any safety and efficacy requirement. In *United Therapeutics Corp. v.*

POSA to alter it.[5] Again, Janssen's narrative that internal information about the PSY-3003 trial's results caused *it* to alter the regimen used for subsequent trials did not prevent Teva from demonstrating a different motivation based on publicly available information. Further, although iden-

# Impacts of Different Types of Indications / Drugs

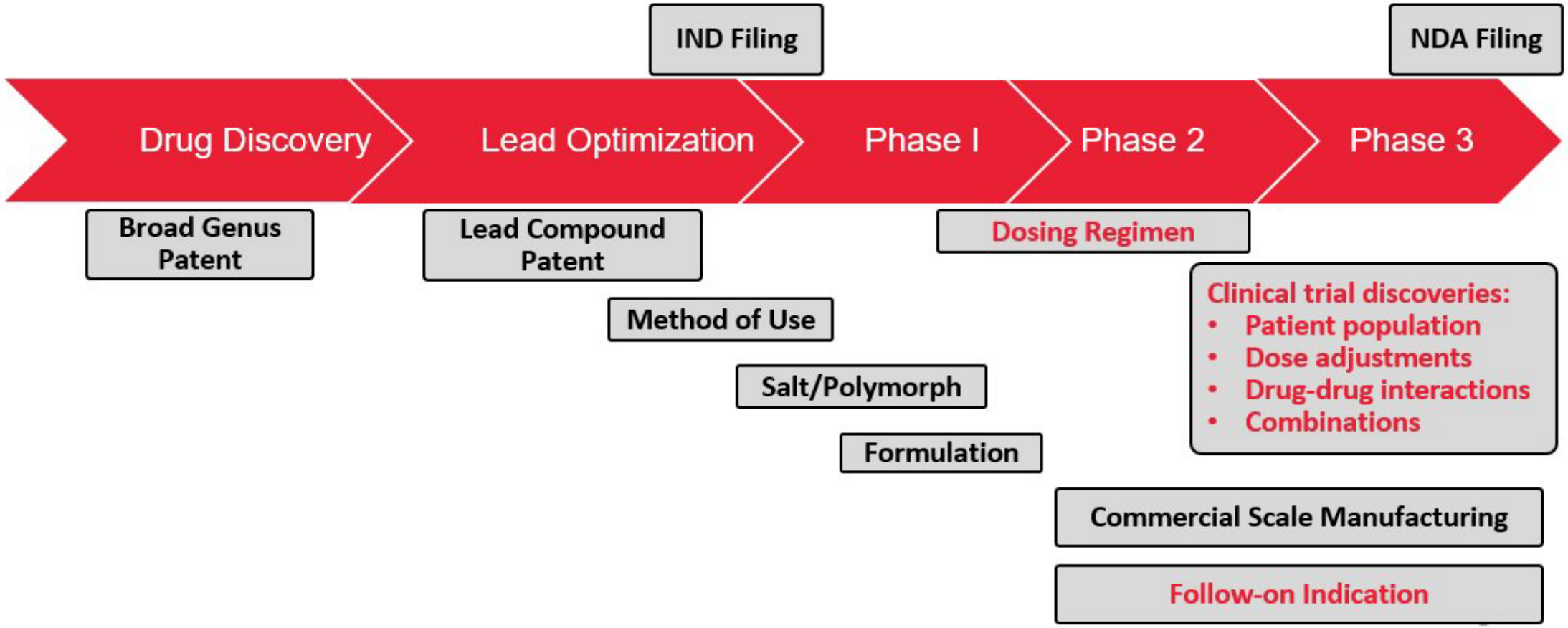
- First indication versus later indications
  - Potentially greater prior art risk for the later indications
- New drug versus old drug
  - Potentially greater prior art risk for old molecule

# Potential Sources of Prior Art

- Clinicaltrials.gov
- Clinical study documents, including protocols, Investigator Brochures, and patient disclosures
- Company press releases and investor calls
- Earlier patents and patent applications
- Scientific posters and presentations
- Off-label use
- Investigator initiated studies / retrospective clinical studies

# Prosecution Best Practices

- Balance of prior art versus staggering filings for longer term



# Prosecution Best Practices

- Consider not disclosing target clinical indication in earlier composition of matter filings
  - Typically, don't have human efficacy data at time of filing composition of matter application
    - Establish utility using target engagement/inhibition data
    - File on initial indication before publication with during US grace period
  - Scope of disclosure turns on predictability and business considerations
    - Are all indications “validated” by know MOA?
    - Does company need to disclose indication in fundraising efforts?

# Prosecution Best Practices

- Application timing considerations
  - Phase II protocol – generally first disclosure of treating diseased subjects
    - Protocol includes expected efficacious doses and dosing regimen
  - Recommendations
    - File before protocol with doses/dosing regimen publishes
    - Hopefully get preliminary data within year of provisional application filing. If not, convert and new application with data.

# Prosecution Best Practices

- Control level of disclosure on clinicaltrials.gov
  - Use generic chemical names as long as possible
    - Rules allow for masking compound name until INN is assigned
  - Mask dosing details
    - Use general descriptions, like "ascending doses"
    - Overcome inherency issues with dosing details that will be on label instructions and rely on unexpected results
      - e.g., tablet; administer in the morning after a meal

# Litigation Considerations

- Infringement
  - Timing of lawsuit
    - Before competitor launch (e.g. Hatch-Waxman, BPCIA litigation)
    - After competitor launch
  - Nature of the likely defendant
    - ANDA generic, 505(b)(2), branded competitor
  - Sources of direct infringement evidence
  - Sources of induced infringement evidence

# Litigation Considerations

- Validity
  - Prior art
    - Obviousness
    - Anticipation / inherent anticipation
    - Prior public use / sale
  - 112 and priority claims
  - Inventorship

# Strategy Considerations for Follow-on Indications

- Unexpected results
  - Clinical outcomes
- Differentiated dosing
  - Avoid off-label use by pursuing dose that cannot be made from prior approved use (dividing or combining tablets)
- Different formulation
- Additional safety considerations
  - New drug-drug interactions

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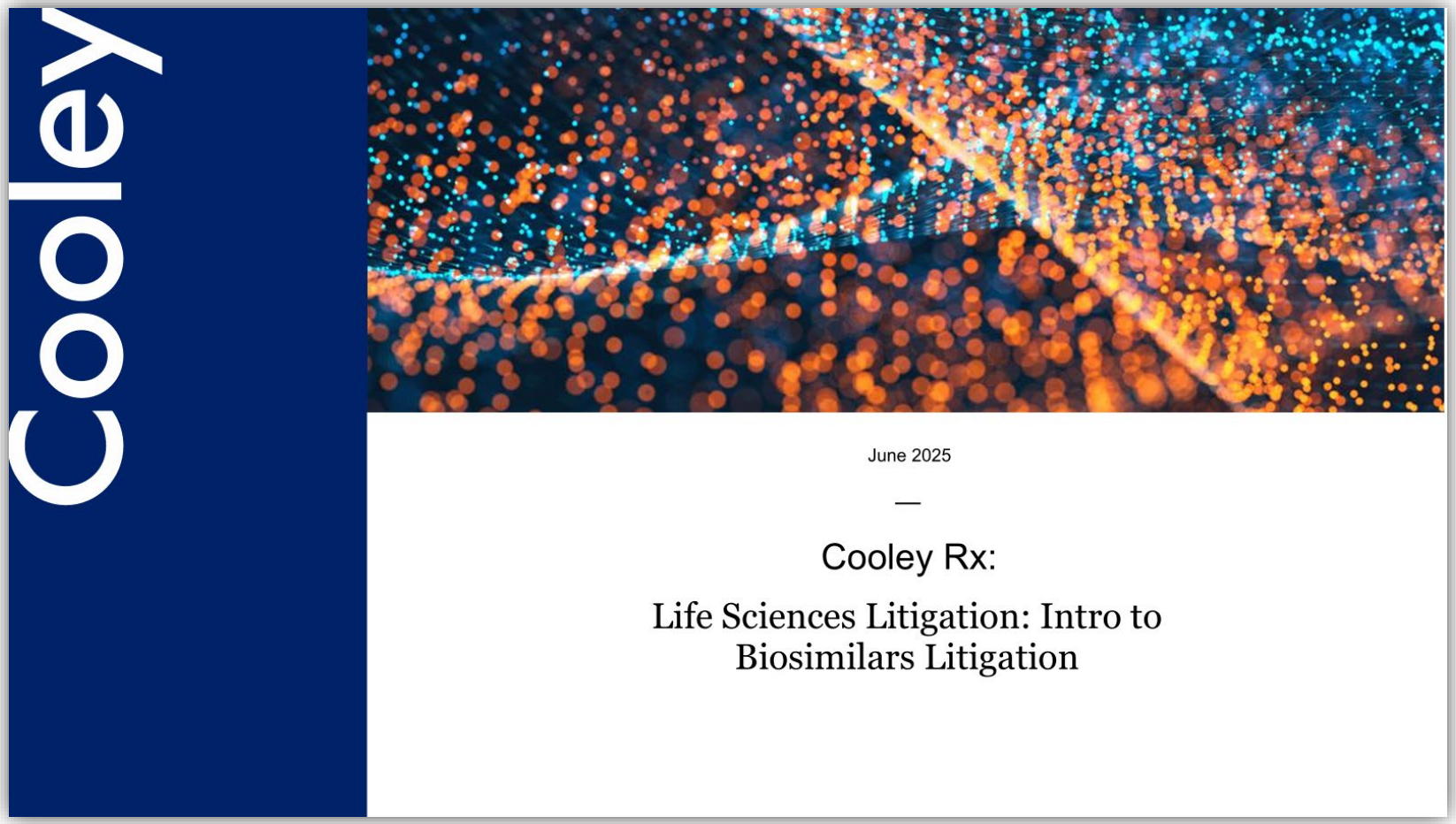
# Upcoming Webinar

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