



March 2025

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## Cooley Rx:

Life Sciences Litigation: IP Diligence – The  
Submarine Deal Killer (Practical Approaches and  
Strategic Lessons to Avoid Common Pitfalls)

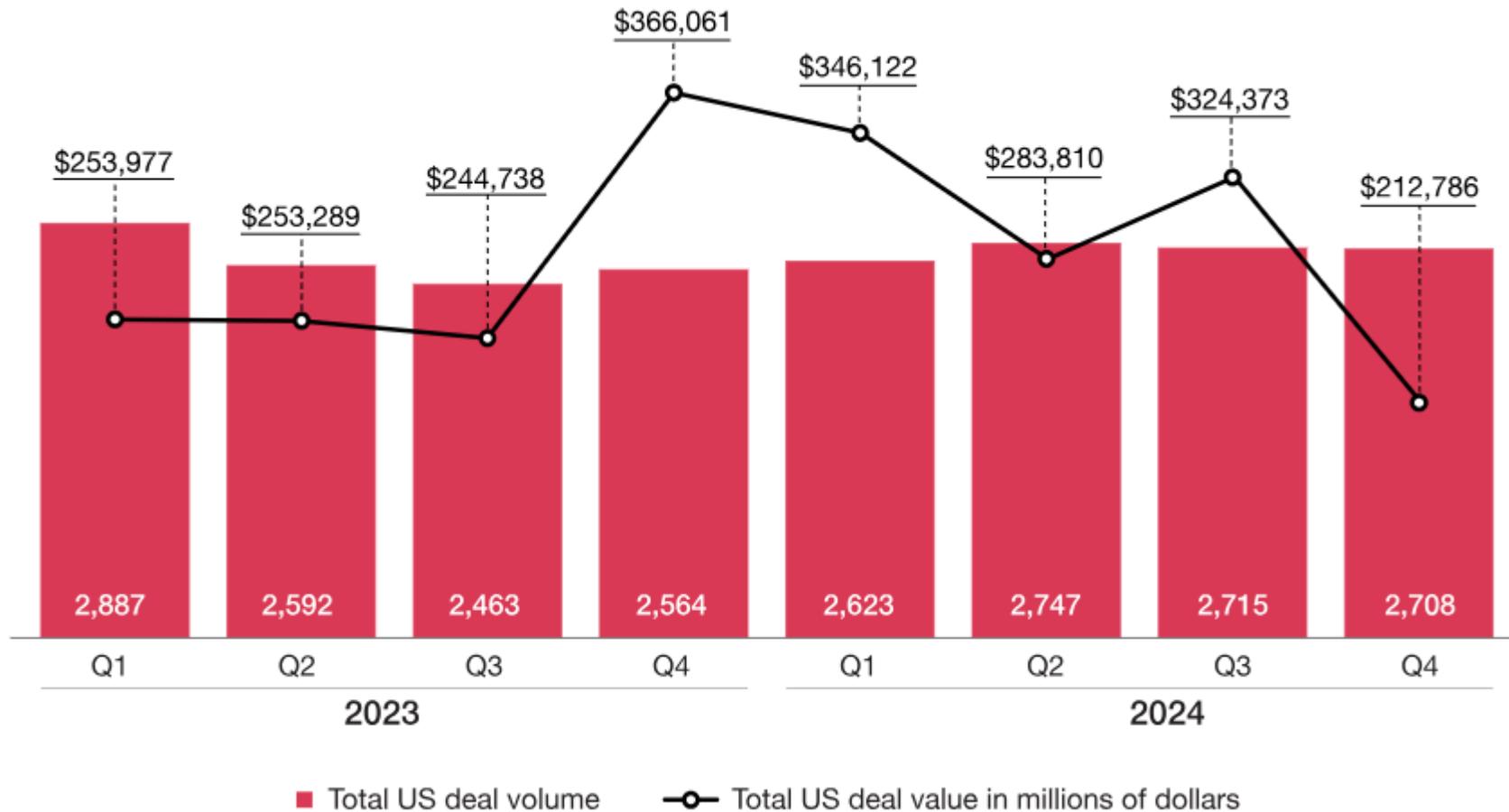
# Agenda

- Background
- IP due diligence overview
- Issues unique to the target
- Issues unique to the stakeholders

# Investment in life sciences

- Average investment in medical devices: \$30–40 billion per year
- Average investment in biotechnology: \$200 billion
- Average investment in pharmaceuticals: \$200–250 billion per year

# Life sciences deal volume



# IP due diligence overview

- An evaluation of the risks associated with the target's IP position.
- Different scope of diligence for different transactions.
- Substantive issues typically identified 75% of the time.
- Identification of significant issues may lead to:
  - Deal not closing
  - Altered deal value
  - Altered deal terms

Issues unique to the target

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# Issues unique to the target

- Let your lawyers do the talking
- Data room issues
- Confidentiality agreements and compartmentalization
- Privilege issues
- Diligence timing, costs and preparation

# Let the lawyers do the talking

- Inventorship traps
- Trade secret traps
- Disclosure traps

# Data room issues

- What is a data room?
- Only exchange materials through the data room
- Control access and maintain a log
- Decommissioning a data room

# Confidentiality agreements and compartmentalization issues

- One vs several
- Obligations
- Penalties
- Access

# Privilege issues

- Tension between pressure to close the deal and waiver of privilege
- Freedom to operate
- Patent strategy
- Ongoing litigation

# Diligence timing and cost

- Timing/costs depends on:
  - the attorneys hired to perform the diligence
  - number of products and/or technical features to be analyzed
  - complexity of issues
- In financings, target typically pays fees out of round
- Average timing:
  - 2 to 4 weeks for venture financings/collaborations
  - 4 weeks to many months for mergers/acquisitions
- Be prepared in advance!

# Diligence preparation: Getting your information together

- Business plan
- Description of structure, function, and use of products
- List of competitors
- Lists of patents/applications and their status
- Unpublished patent applications
- Prosecution histories of key patents/applications
- FTO and patentability searches and results
- List/copies of relevant third-party patents/applications
- Prosecution histories
- Warning letters and responses
- Licenses and assignments
- Consulting agreements
- Any other agreements affecting IP (e.g., security interests, joint development agreements, etc.)
- **Don't be deceptive!**

Issues unique to stakeholders

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# Issues unique to stakeholders

- Timing concerns/cost
- Substantive diligence issues that affect financial models
  - Exclusivity
  - Freedom to operate
  - Litigation
  - Ownership

# Timing concerns/cost

- Give yourself enough time
- Hope for the best, plan for the worst
- Size of team
- Expense is relative

# Substantive diligence issues that affect financial models

- Exclusivity (patent term and scope)
- Freedom to operate concerns
- Litigation
- Ownership issues

# Substantive diligence issues: Exclusivity

- How strong is the patent protection?
  - Do the patents cover the key products or key aspects of the products?
  - How much protection is provided?
  - Is it easy to prove infringement?
  - Are the patents valid (art, description, eligibility)?
- Loss of exclusivity
  - Does not necessarily equate to patent term
  - Possibility of additional term or extension?
  - Trade secrets?

# Substantive diligence issues: Freedom to operate

- Is there a risk of third-party infringement?
  - Invitation to license
  - Cease and desist letters
  - Active litigation
  - Searching and analysis
  - Written Opinions
- What is the likelihood potentially problematic patents will issue?

# Litigation

- Stepping into shoes of target
  - Potential or ongoing litigation
  - Preserving privilege
- Assessing the risk
- Options
  - Walk away
  - Alter deal price or terms
  - Escrow

# Substantive diligence issues: Ownership

- Does the company own all the IP?
  - Do the inventors have the right to assign?
  - Have the inventors assigned to the company?
  - Have the assignments been recorded?
  - Is the company name correct?
  - Are there university relationships, consultant relationships, previous employer relationships, or government rights at play?
  - Are there any encumbrances (e.g., security interests)?

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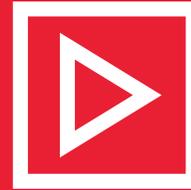
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