

Life Science Deals

Hot Topics in 2018

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Audio

The screenshot displays the Cisco Webex meeting interface. In the top-left corner, an 'Audio Broadcast' window is open, showing a volume slider and a status of '24.7 Kbps'. A red arrow points from the text below to this window. The main meeting area is mostly obscured by a large grey redaction box. On the right side, the 'Participants' panel is visible, showing a list of participants: 'Brian Dolan (Host)' and 'Webinar Guest (me)'. Below the participants list is a 'Q&A' section with a dropdown menu set to 'All (0)'. At the bottom of the interface, there is a text input field for asking questions, with a dropdown menu set to 'All Panelists' and a 'Send' button. The bottom status bar shows the Cisco logo on the left and 'Connected' with a green indicator on the right.

Audio Broadcast

24.7 Kbps

Participant Event Help

Participants Chat Q&A

Speaking:

Panelists: 1

Brian Dolan (Host)

Attendees:

Webinar Guest (me)

Q&A

All (0)

Ask: All Panelists

Select a panelist in the Ask menu first and then type your question here. There is a 256-character limit.

Send

Connected

Audio should stream automatically on entry through your computer speakers

Audio

The screenshot displays the Cisco WebEx Event Center interface. At the top, the title bar reads "Cisco WebEx Event Center" and the menu bar includes "File", "Edit", "View", "Communicate", "Participant", "Event", and "Help". Below the menu bar, there are tabs for "Event Info" and "Webinar Cov...". The main content area is mostly obscured by a large grey redaction box. A red text overlay in the upper left of the main area reads: "If you cannot stream audio, click phone icon and a phone number will be sent to you". A red arrow points from this text to a phone icon in the "Participants" panel on the right. The "Participants" panel shows a list of participants: "Brian Dolan (Host)" and "Webinar Guest (me)". Below the list, there are icons for audio, video, and chat. A "Q&A" panel is also visible, showing "All (0)" questions. At the bottom, there is a "Send" button and a "Connected" status indicator.

If you cannot stream audio, click phone icon and a phone number will be sent to you

Audio Connection

- I Will Call In
- Call Using Computer
[Test computer audio](#)

Participants

Speaking:

- Panelists: 1
 - Brian Dolan (Host)
- Attendees:
 - Webinar Guest (me)**

Q&A

All (0)

Ask: All Panelists

Select a panelist in the Ask menu first and then type your question here. There is a 256-character limit.

Send

Connected

Q&A

Cisco WebEx Event Center

File Edit View Communicate Participant Event Help

Event Info Webinar Cov... x

01

Participants Chat Q&A

Participants

Speaking:

Panelists: 1

Brian Dolan (Host)

Attendees:

Webinar Guest (me)

Q&A

All (0)

Ask: All Panelists

Type question here... Send

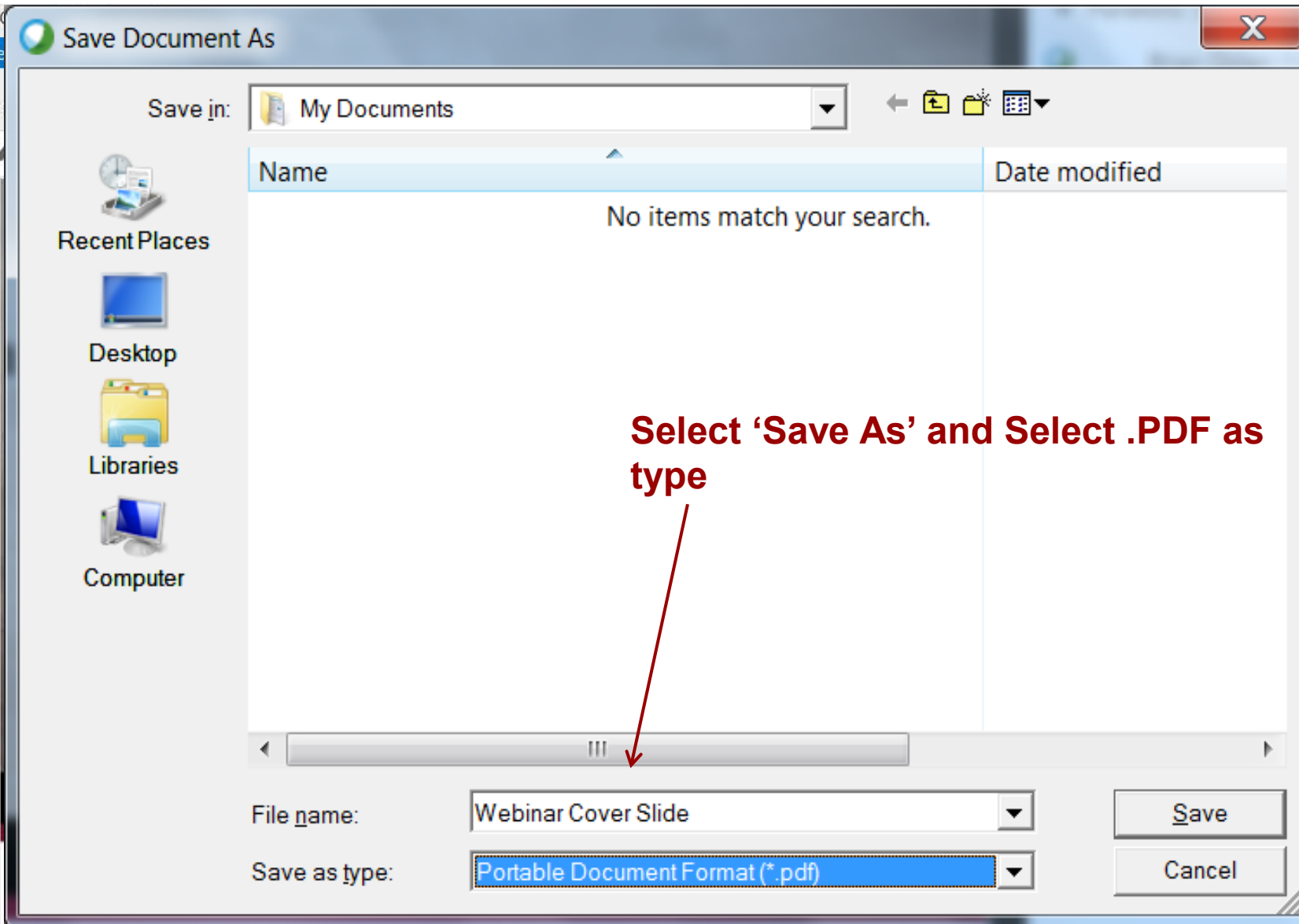
Connected

Send us questions

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The screenshot displays the Cisco WebEx Event Center interface. At the top, the title bar reads "Cisco WebEx Event Center". Below it is a menu bar with "File", "Edit", "View", "Communicate", "Participant", "Event", and "Help". The "File" menu is highlighted with a red arrow and the text "Click 'File'". The main content area shows a slide titled "Pepper Hamilton Webinar". On the right side, there is a "Participants" panel showing "Brian Dolan (Host)" and "Webinar Guest (me)". Below that is a "Q&A" panel with "All (0)" questions. At the bottom right, there is a "Send" button for the Q&A section. The bottom status bar shows "Connected" with a green dot.

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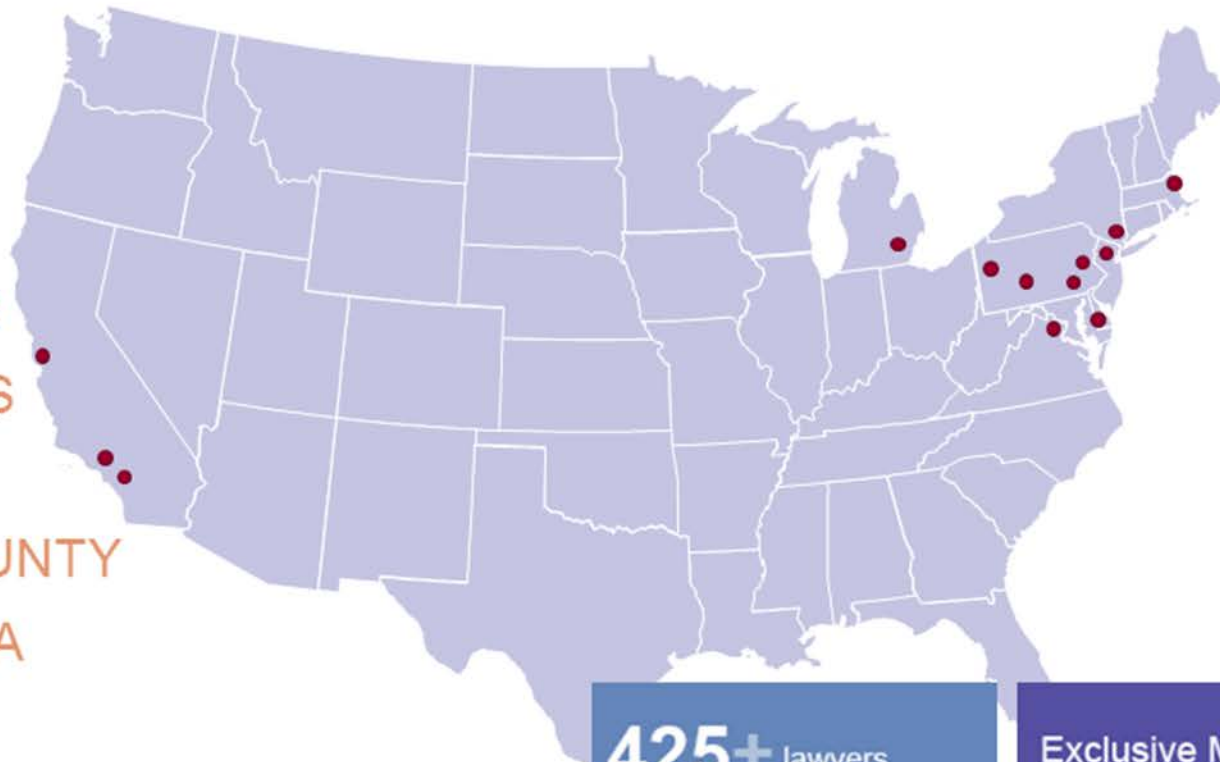
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HEALTH SCIENCES
HIGHER EDUCATION
INVESTMENT FUNDS
LIFE SCIENCES
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PHARMACEUTICAL AND MEDICAL DEVICE
RETAIL
TECHNOLOGY
TRANSPORTATION

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We will be starting at 12pm ET. There is currently no audio until we start.

**Email dolanb@pepperlaw.com for a
CLE form if interested**

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- ▶ Counsels clients in strategic transactions, disclosure and governance issues and regularly handles complex commercial transactions, including strategic alliances, technology licenses and acquisitions, supply distribution and manufacturing agreements.



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- ▶ Works with well-established and nascent companies, universities, and independent inventors to identify and protect their intellectual property
- ▶ Concentrates her practice in strategic patent and trademark preparation and prosecution of domestic and international applications, preparation of patentability and clearance opinions, trademark clearances, life science transactions, and other intellectual property related counseling
- ▶ Technology practice includes work in the molecular biology, nutritional supplement, pharmaceutical, organic chemistry, diagnostic, vaccine, immunology, medical, mechanical, medical device, software and business method areas.

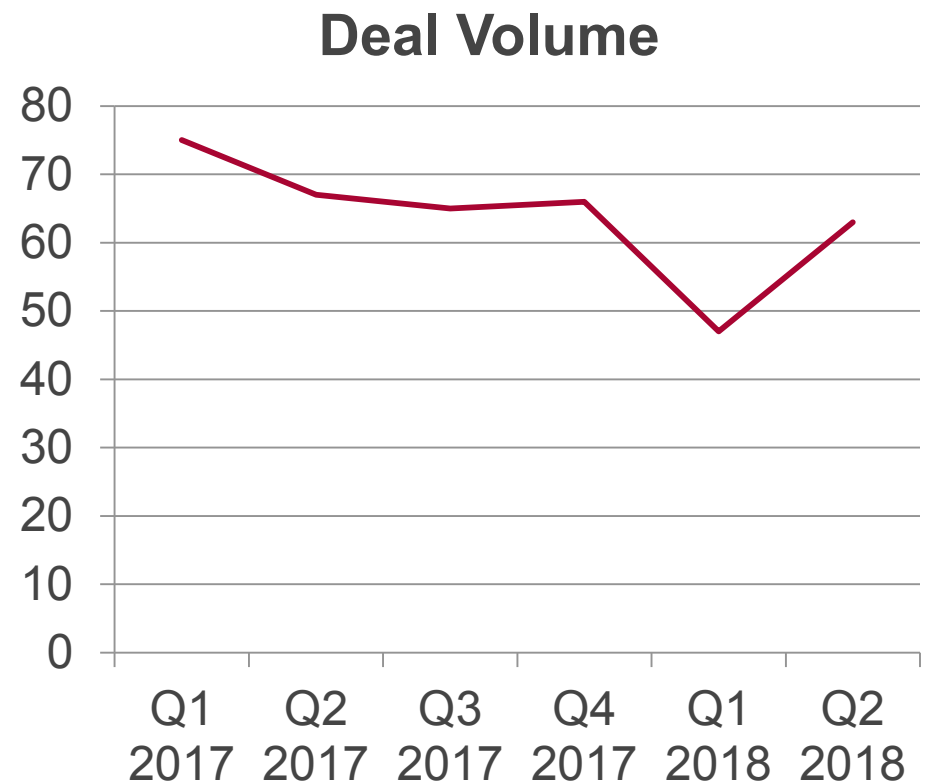


Overview

- ▶ Life Sciences Deals in 2018
 - Year-to-date performance
 - Trends
 - Structuring Considerations
- ▶ Intellectual Property Diligence
 - Importance of IP
 - Seller Considerations
 - Purchaser Considerations
- ▶ Mitigating Risks

2018 – The Deal Landscape

- ▶ Deal market growing in 2018
 - Top 10 2018 deals valued over \$170 billion
 - Value and Volume up on Q2 2018



2018 – The Deal Landscape

- ▶ What are the drivers?
 - Tax reform & favorable repatriation rate
 - Patent cliff
 - Price Pressure
 - Technology Entrants

2018 – The Deal Landscape - Trends

- ▶ Divestitures
- ▶ Consolidation
- ▶ Growth areas: Oncology & Specialty Therapies
- ▶ Customer-Centric Products/Marketing

Transaction Structuring Considerations

▶ License

- Allows separate transactions for various fields/territories to maximize value
- Easier for licensor to regain control after termination of a license (compared to exercising reversion rights over transferred IP)
- Allows licensor a mechanism to control conduct of licensee
- Parties connected in the public eye

▶ Collaborate

- Risk (and reward) shared with partner
- Obtain a stake in asset with low up-front investment
- Parties connected in the public eye

▶ Buy/Sell

- Can be a complete exit for the seller and maximum control for the buyer

Transaction Structuring Considerations

▶ Consideration Structure

- Upfront
- Deferred – 75% of Life Sciences M&A Transactions have a deferred component
 - Milestones
 - Royalties
 - Sublicense Revenue/ Sales Proceeds

Deferred Consideration Pros and Cons

▶ Pros:

- Can bridge the valuation gap
- A form a financing for the buyer
- Allows seller to participate in upside

▶ Cons:

- Increased complexity, especially if public company
- Increased litigation risk
- Seller is exposed to buyer's credit risk

Deferred Consideration Pros and Cons

- ▶ Most Litigated Issue = “Commercially Reasonable Efforts”
 - Typically focused on buyer’s usual efforts
 - *“Those reasonable, diligent, good faith efforts consistent with usual practices of the Buyer in respect of researching, developing, or commercializing its own compound or product, or one to which it has rights, that is of similar scientific and commercial potential, and is at a similar stage in its development, in each case taking into account all relevant factors including issues of safety and efficacy, the patent, and other proprietary position of the Compound or a Product, the likelihood of Regulatory Approval, the then-current competitive environment, the profitability and commercial potential of the Compound or a Product, and other relevant scientific, technical, legal, commercial, financial, and medical factors”*
 - For more certainty, consider specific diligence requirements

Structural Considerations-IP

- ▶ Key provisions:
 - Definition of Intellectual Property
 - Conveyance: license vs. assignment, boundaries of agreement, Term
 - Collaboration—how is joint IP handled? Prosecution? Litigation?
 - License—royalty obligations and milestones, Field of Use, Territory

Importance of IP

- ▶ IP is often a company's strongest asset
 - provides market exclusivity
 - protects the revenue stream and may provide a direct revenue source (license royalties)
 - leverage against competitors
 - furthers company goals
 - contributes to value of a company
- ▶ Risks of issues with IP diligence
 - Value of deal may decrease
 - Purchaser may ask you to fix issues, thereby delaying the deal
 - May need to negotiate with another part to fix joint ownership, license, assignment of IP, etc.
 - Purchaser may abandon deal altogether

Intellectual Property Diligence

- ▶ Types of IP to be considered
 - Patents
 - Chain of title and encumbrances
 - Scope of claims, coverage of commercial embodiment, and likelihood of patentability
 - Consider validity and freedom-to-operate searches
 - Patent life left in relation to when product will hit the market
 - Trademarks
 - Protection at federal, state, or common-law
 - Ownership, current use, and licenses
 - Field of Use restrictions or coexistence agreements
 - Domain Names
 - Copyrights
 - software—assignments, licenses, goodwill
 - Trade Secrets
 - Policies in place to protect trade secrets
 - confidentiality agreements with third parties
- ▶ IP Litigation search, opinions, cease and desist letters
- ▶ IP Agreements— indemnification, representations and warranties

Seller Considerations of IP

- ▶ Prepare for diligence by reviewing IP portfolio
 - Correlate patent claims with commercial embodiment, improvements, as well as potentially competitive products (blocking patents or defensive patents)
 - Understand strengths of patents (patentability, scope, covers design-arounds; worldwide coverage)
 - Review issues with inventorship, ownership and license rights of IP; identify relevant documentation
 - Review software licenses and company owned code
 - Review opinions, searches, and issues directed to patentability, validity, and FTO
- ▶ Fix potential errors and oversights (clean house)
- ▶ Prepare responses for questions on IP litigation, cease & desist letters, and other IP issues
- ▶ Gather all necessary documentation
- ▶ Review your confidentiality agreements and review trade secret protocols



Purchaser Considerations for IP

- ▶ Study all issued patents and prosecution histories
- ▶ Study all pending patent applications and prosecution histories
- ▶ Ask for and review results of any patentability, validity, and FTO searches
- ▶ Conduct independent searches of IP assets
- ▶ Assess patent scope, commercial embodiments, and design arounds
- ▶ Assess FTO issues
- ▶ Understand competitive landscape and ability of IP to block competitors
- ▶ Have a plan to record all IP transferred in deal in a timely manner (e.g. IP assignment documents)



IP Trends

- ▶ Considerations for Small Molecules and Biologics
 - Regulatory exclusivity (e.g. NCE, CI, ODE, PED, or BLA)
 - When and how easily will generics/biosimilars come onto the market
 - Patents listable on the Orange Book (small molecules)
 - Patent term extension
- ▶ Considerations for Healthcare IT
 - Software and AI: ownership (employees, consultants) of past and future IP
 - Open source software
 - Storage of data

Compliance Considerations for Life Sciences Deals

DOJ Fraud Section Guidance February 2017

- Due Diligence Process
- Integration of Compliance in the M&A Process
- Process Connecting Due Diligence to Implementation

Compliance Considerations for Life Sciences Deals

Due Diligence Process

- Who conducts and how accomplished?
- Self Disclosure, cooperation and individual liability

Some Considerations

- FCPA
- Pricing & Reimbursement
- Incentive Compensation
- Anti-Kickback
- Third Party Relationships
- Trade Secrets

Compliance Considerations for Life Sciences Deals

Integration of Compliance in M&A Process

- “How has the compliance function been integrated into the merger, acquisition and integration process?”

Compliance Considerations for Life Sciences Deals

Process Connecting Due Diligence to Implementation

- Process for tracking and remediating misconduct or risks identified in due diligence
- Process for implementing compliance policies and procedures at new entity

Questions & Answers

For more information, visit

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