What’s New in Licensing: America Invents Act and Other Recent Developments

September 27, 2012

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Foley Hoag LLP
### 2012 Changes in Funding Sources

Increase due mainly to investments in medical device and diagnostics companies

Drug development / therapeutics remained flat

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#### July 2012 Life Sciences Scorecard (USD M)

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<tr>
<td>Global Venture Capital</td>
<td>7,214</td>
<td>5,809</td>
<td>24.2</td>
<td>5,410</td>
<td>4,355</td>
<td>24.2</td>
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<td>U.S. VC</td>
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<td>IPOs (21 in 2012 v. 35 in 2011)</td>
<td>1,511</td>
<td>3,241</td>
<td>-53.4</td>
<td>771</td>
<td>1,111</td>
<td>-30.6</td>
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<td>U.S. IPOs (11 in 2012 v. 13 in 2011)</td>
<td>771</td>
<td>1,111</td>
<td>-30.6</td>
<td>771</td>
<td>1,111</td>
<td>-30.6</td>
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<tr>
<td>Global PIPEs</td>
<td>3,696</td>
<td>2,400</td>
<td>54.0</td>
<td>947</td>
<td>1,052</td>
<td>-10.0</td>
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<td>Global Follow-ons</td>
<td>4,664</td>
<td>7,673</td>
<td>-39.2</td>
<td>4,165</td>
<td>4,051</td>
<td>2.8</td>
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<td>U.S. Follow-ons*</td>
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<td>Global Other Equity</td>
<td>1,045</td>
<td>482</td>
<td>116.9</td>
<td>928</td>
<td>198</td>
<td>369.9</td>
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<td>U.S. Other Equity</td>
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<td>Global Debt Offerings</td>
<td>14,037</td>
<td>29,004</td>
<td>-51.6</td>
<td>9,734</td>
<td>15,484</td>
<td>-37.1</td>
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<td>Global Other Debt</td>
<td>12,481</td>
<td>9,119</td>
<td>36.9</td>
<td>11,056</td>
<td>3,511</td>
<td>214.9</td>
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<td>Global Partnering</td>
<td>19,585</td>
<td>22,825</td>
<td>-14.2</td>
<td>12,130</td>
<td>14,478</td>
<td>-16.2</td>
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<tr>
<td>Global M&amp;A</td>
<td>78,191</td>
<td>126,311</td>
<td>-38.1</td>
<td>57,296</td>
<td>67,752</td>
<td>-15.4</td>
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Pharma Licensing Trends 2007 - 2011

Number of Licensing Deals

Average Total Value of Licensing Deals

2012 Licensing Activity on the Decline

Aggregate Spend for JVs and Licenses

Products and Platform Technologies

- Milestones: $13.8B (First Half 2011) vs. $8.6B (First Half 2012)
  - 37% decrease

- Upfronts: $1.2B vs. $841.6M
  - 30% decrease

- Size: $14.3B vs. $9.5B
  - 34% decrease

Source: Deloitte Recap Webinar Series, August 14, 2012

But Average Upfronts up 11% from last year
Changes in 2012 Deal Activity by Stage

Licenses & JVs – Products or Platform Technologies

Source: Deloitte Recap Webinar Series, August 14, 2012

1H2011
n=204/304

1H2012
n=160/245

Reformulation 11%
Approved 10%
Registration 4%
Phase III 11%
Phase II 10%
Ph I 4%
Discovery 25%
Lead/Preclinical 20%

Reform. 7%
Approved 13%
Registration 7%
Phase III 9%
Phase II 9%
Ph I 6%
Discovery 30%
Lead/Preclinical 16%
Discovery Platform Technologies or Therapeutic Products – Average Potential Size by Stage at Signing

Source: Deloitte Recap Webinar Series, August 14, 2012
2012 Changes in Deal Size by Therapeutic Area

Products and Platform Technologies

<table>
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<tr>
<th>Therapeutic Area</th>
<th>Average Potential Deal Size ($M)</th>
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<tr>
<td>Autoimmune/Inflammatory</td>
<td>300</td>
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<tr>
<td>Cancer</td>
<td>600</td>
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<tr>
<td>Neurology</td>
<td>1100</td>
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<tr>
<td>Endocrine/Metabolic</td>
<td>100</td>
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<tr>
<td>Infectious Disease</td>
<td>50</td>
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Source: Deloitte Recap Webinar Series, August 14, 2012

But Upfronts

Neurology
Infectious Disease
Endocrine/Metabolic
Option-Based Licensing

The Rise and Fall of Option-Based Licensing

Source: Deloitte Recap

*Percentages for Pharma and Biotech Licensing Deals based on licensing deals done between pharma/biotech, pharma/pharma and biotech/biotech

**Percentages for Pharma Licensing Deals based on licensing deals done between pharma/biotech and pharma/pharma
What’s Causing the Decline

Uncertainty in Regulations

Pharma Looking to Academia and VC Collaborations for Drug Discovery
Pfizer CTI Effectiveness By the Numbers

- 4 CTIs: San Francisco, San Diego, New York, Boston
- 20 Academic Centers Involved
- 400 Proposals Reviewed in Last Year
- <5% of Proposals Overlapped with Pfizer Efforts
- 23 Proposals Funded
- 4 Therapeutic Areas (Rare Diseases, Inflammation, Cardiovascular and Oncology)
Trends in Academia – Industry Partnership Models

Emerging in the future
- Risk-sharing
- Competitive grants

Increasingly popular in the present
- Corporate venture capital funds
- Academic drug discovery centers

Commonly used in the past
- Unrestricted grants
- Fee-for-service

Trends in University Sponsored Research Agreements

New default position – industry sponsor will own new IP

- University retains ownership of IP, but
- License terms greatly softened/streamlined
  - Reimbursement of patent prosecution costs
  - $15,000 upfront “administrative fee”
  - 1% royalty on annual sales exceeding $20 million (“home run” clause)
Pharma Partnerships with VCs

- Janssen
- Sanofi
- Polaris Venture Partners
- Third Rock Ventures
- WarpDrive Bio
- Merck
- Flagship Ventures
America Invents Act

A Few Key Provisions

- First inventor to file
- Expanded pool of prior art
- Derivation proceedings
- Third-party submissions
- Post grant proceedings
- Supplemental examination
America Invents Act - Patent Protection or No?

Expansion of Prior Art beyond Publications Globally

New Derivation Proceedings Highlight IP Issues in Early Collaborations

New Post-Issuance Proceedings Cast Doubt on Issued Patents

More Uncertainty in Valuing IP Assets
America Invents Act - Implications for Funding

Filing
• Premium on filing
• But earlier action requires patent funds sooner
• Patent costs higher but 75% cost reduction for microentities

Maintenance
• Post-grant procedures expensive
America Invents Act – Potential Effects

Shift in Landscape
- Lack of Certainty on Patent Coverage
- Preparing for Patent Challenges
- Balancing Patents and Trade Secrets

Implications for Funding
- Early Strategy Key in Light of “First to File” System

CREATE Act
- Impact on Joint Research Agreements
Plan Ahead for Patent Challenges

- Vulnerability of Issued Patents
- Advance Notice
- Penalties or Renegotiation
- "No Challenge" Clause?
Plan Ahead for Patent Challenges

- Notification
- Input or Approval
- Control if Exclusive Licensee

Licensee
Financial Impact of Patent Challenges

Licensor

- Front-load payments
- Status quo on royalty payments during challenges
- Milestone payments after challenge survive
- Separate know-how royalty
Plan Ahead for Patent Challenges

Licensee

- Valid claim excludes patents being challenged
- Reduce/suspend royalty during challenges
- Licensor bears all/some challenge costs
Shifting Balance Toward Trade Secrets?

More vulnerable to challenge

Who decides?

Broader infringement defense

Patents

Trade Secrets
Discussion

Q & A

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- To ask a question, please press *1 on your touchtone phone.

- If you are using a speaker phone, please lift the receiver and then press *1.

- If you would like to withdraw your question, press *1.
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