

Developing a Successful International Commercialization Strategy for Life Science Technology

ChinaBio® BioBay Investor Forum
Suzhou, China

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Welcome



EYE ON CHINA

■ Speakers (Listed in Alphabetic Order)

- **James F. Ewing**, Partner, Foley & Lardner LLP
- **Linda Ji**, Senior Counsel, Foley & Lardner LLP
- **Guang Yang**, Associate Director, New Products Development, GlaxoSmithKline R&D China



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Overview



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- Commercializing China-originated Technology – What’s Important to the Overseas Partner?
- The Art and Science of Building IPR Value Internationally – Maximizing Investment in Patenting
- Entering the U.S. Market via Strategic Alliances and Collaborations, Joint Ventures, and Direct Investments



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Commercializing China-originated Technology – What’s Important to the Overseas Partner?

Guang Yang
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China's Opportunities



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- Business opportunities in emerging market
- Tap into vast talent pool in the region
- Capitalize on rapid development in life sciences
- Local outsourcing capabilities and unique local resources



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Emerging Rx Market Growing at 19% Annually



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Rank	2002 ¹ (USD Bn)		2004 ¹ (USD Bn)		2006 ² (USD Bn)		2008 ² (USD Bn)		2010 ² (USD Bn)		2011 ² (USD Bn)	
1	USA	198	USA	241	USA	275	USA	309	USA	356	United States	379
2	Japan	53	Japan	65	Japan	63	Japan	67	Japan	72	Japan	75
3	France	20	France	30	France	35	France	37	France	40	Germany	42
4	Germany	20	Germany	29	Germany	33	Germany	36	Germany	40	France	42
5	UK	14	UK	20	Italy	21	UK	24	UK	27	UK	29
6	Italy	13	Italy	19	UK	21	Italy	22	Italy	24	China	26
7	Spain	9	Spain	13	Spain	16	Canada	18	China	23	Italy	26
8	Mexico	8	Canada	12	Canada	15	China	18	Canada	21	Canada	22
9	Canada	8	China	10	China	14	Spain	17	Spain	19	Spain	19
10	China	6	Mexico	8	Brazil	11	Brazil	13	Brazil	15	Brazil	17
11	Brazil	5	Brazil	7	Mexico	11	Mexico	12	Mexico	14	Russian Fed.	16
12	South Korea	5	Australia	6	South Korea	9	South Korea	11	Russian Fed.	14	Mexico	15
13	India	5	South Korea	6	Turkey	7	Russian Fed.	10	South Korea	13	South Korea	14
14	Australia	4	Turkey	6	India	7	India	9	India	12	India	14
15	Turkey	3	India	6	Australia	7	Turkey	9	Turkey	11	Turkey	12

Note: 1. Source: IMS World Review 2007
 2. Source: IMS Market Prognosis 2007-2011
 3. At ex-manufacturer price level



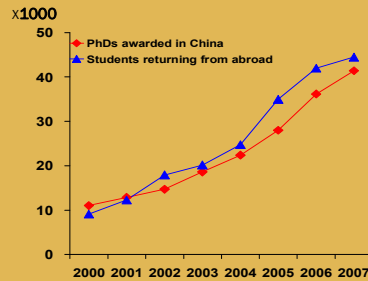
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Talent pool and Life Science in China

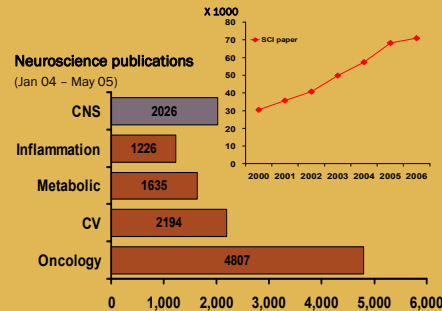


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- Significant burden of CNS disease in China and globally
- Centres of excellence in Neurosciences in China
- Increasing research output as measured by high-quality publications in *Cell*, *Nature*, *Science*, *Neuron*, ...



Source: "High education system in China - An overview" 2006; China Education Yearbook 2001 - 2007



Source: PubMed (Limited search to English language article published between Jan. 1, 2004 and May 31, 2005), WHO website



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GSK RDC Mission and Vision



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A Fully Integrated R&D Center to Develop Products of Value Worldwide

- **Global:** Committed to becoming a leader in neurologic disease modifying therapeutics and to support the GSK global mission in emerging markets
- **Regional:** To lead the GSK R&D network in Asia-Pacific and support GSK productivity by capitalizing on unique local resources and business opportunities

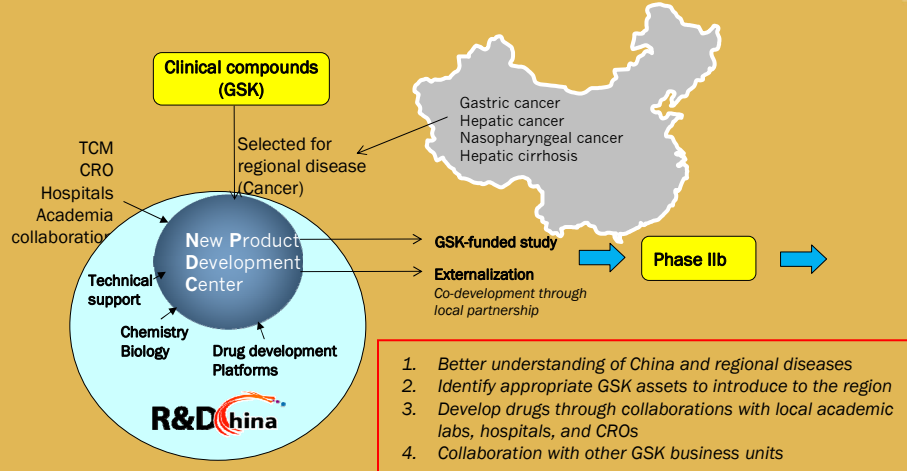


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GSK New Product Development Unit Jan 2011



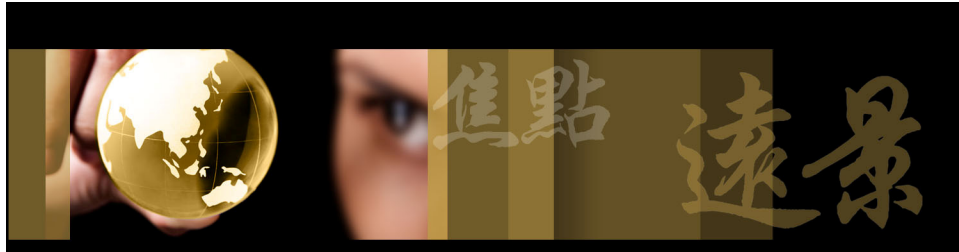
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**THE ART AND SCIENCE OF BUILDING
IPR VALUE INTERNATIONALLY
– Maximizing Investment in Patenting –**

James F. Ewing
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**Acquiring Medical Patents in
the US, Europe and China**

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- Medical Patents Defined
- Patentability Considerations
 - Types of Patents Available
 - Legal Requirements
 - Claiming Strategies
 - Strategies for Accelerating Examination

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Medical Patents Defined



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- A medical patent may refer to:
 - A biotechnology patent (gene patent)
 - A chemical or pharmaceutical patent
 - A medical device patent
 - A medical diagnostic patent



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Types of Invention Protection in the US, Europe and Asia



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- Patents
 - Term of Protection: 20 years
 - Average time between filing and grant: 3-6 years
- Utility Models
 - Term of Protection: 7-10 years
 - Average time between filing and grant: 6-12 months
 - Primarily applies to medical devices



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Key Points for Consideration



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- China is member to international IPR agreements that ensure “national treatment” overseas
- Effective patenting begins with application drafting to international standards – **The first step is critical!**
- Proactive is best in dealing with patent agencies
- Adding value to IPR portfolio requires ongoing reevaluation and revision of patenting strategy



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International Agreements Ensure “National Treatment” Overseas



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- Paris Convention on Industrial Property Rights
 - National treatment principle
 - Right of priority (12-month period)
 - Patent Cooperation Treaty (PCT)
 - Time for further development (30-month period)
 - Foundation for benefits under TRIPS agreement
- National Treatment = “Act local, think global”



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Begin By Preparing Application Draft to International Standards



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- Substantive Requirements Are Universal
 - Inventiveness
 - Operational completeness
 - Conceptual completeness
- Invest Time/Effort Early For Benefits Later
 - The inventors must speak – What is the invention, and why should anyone care?
 - More than working examples – The prophetic dimension



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A Proactive Approach Is Best in Dealing with Patent Agencies



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- Prepare application with both strengths and weaknesses of invention in mind – **Tell the whole story!**
- Formalities of a given agency action must not dictate your response priorities or time frame
- Always reach out to the patent examiner
 - Contact examiner directly to clarify his reasoning
 - Examiners often respond to declaration evidence



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Reevaluating and Revising Patent Strategy Over Time Is Critical



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- “Timing is everything!” (part 1) – Make the most of the Paris Convention priority year.
- “Timing is everything!” (part 2) – Coordinate patent, regulatory, and product-cycle time lines.
- Regularly revisit decisions to seek patent protection internationally – Prune your IPR tree!
- Don’t forget patent alternatives and adjuncts.



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Patentability Considerations



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- Patentable Subject Matter
- Novelty Requirements
- Obviousness/Inventive Step Standards
- Enablement/Scope Standards
- Biological Deposit Requirements



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Patentable Subject Matter Overview: Biomedical Inventions



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Patentable Subject Matter			
	Gene Sequences	Pharmaceuticals	Methods of Treatment/Diagnosis
China	Yes	Yes	No/No
U.S.	Yes	Yes	Yes/Yes
Europe	Yes	Yes	No/No



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Claim Formats: Biomedical Inventions



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	Composition Claims	Method of Treatment Claims	Method of Diagnosis Claims	First Medical Use Claims	Swiss-Type Claims
China	Yes	No	No	No	Yes
U.S.	Yes	Yes	Yes	No	No
Europe	Yes	No	No	Yes	No



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Novelty Requirements



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	Novelty Requirement	Grace Period for Applicant's Own Disclosure?	Comments
China	Absolute	6 months (narrow)	Only authorized events.
U.S.	Absolute	One year	
Europe	Absolute	6 months (very narrow)	Exception for abuse or presenting at certified exhibition.



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Inventive Step/Obviousness Standards



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	Legal Standard	Post-Filing Date Data?
China	Not easily made by a person ordinarily skilled in the art to which the invention relates.	Limited circumstances.
U.S.	The differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.	Yes
Europe	Problem-solution approach	Yes



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Biological Deposit Requirements



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	Required?	Timing of Biological Deposit	Other Requirements
China	Yes	Before earliest priority date.	Specific reference to the biological deposit.
U.S.	Yes	Any time before issuance.	Specific reference to the biological deposit.
Europe	Yes	Before earliest priority date.	Specific reference to the biological deposit. Depositor must be Applicant or give authorization to Applicant to file patent app.



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Patent Prosecution Highway (PPH)



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- May 19, 2010, USPTO and SIPO sign memorandum of Understanding on bilateral cooperation on patents
- Focuses on building of work sharing programs, including a bilateral Patent Prosecution Highway (PPH) agreement
- Goal is to improve the administration and effectiveness of the intellectual property systems through the exchange of information.
- The PPH agreement will be SIPO's first, thus driving China onto the Patent Prosecution Highway



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Patent Prosecution Highway (PPH) (cont.)



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- The Patent Prosecution Highway (PPH) speeds up the examination process for corresponding applications filed in participating countries by allowing examiners to reuse search and examination results.
- Under the PPH program, an applicant receiving a ruling from the Office of First Filing (OFF) that at least one claim is patentable may request that the Office of Second Filing (OSF) fast track the examination of corresponding claims in corresponding applications filed in the OSF.



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PPH Benefits



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- Accelerated Examination/Reduced Pendency
 - Examination typically begins within 2-3 months from the grant of a PPH request
- Greater Efficiency
 - More than 90% of PPH cases are allowed. The allowance rate for non-PPH cases is less than 50%



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PPH Benefits



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- Decreased Costs of Prosecution
 - PPH cases have fewer office actions compared to non-PPH cases.
 - 3.4 average actions in a regular case
 - 1.7 average actions in the PPH



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Japan-US PPH Results Timeliness 2009



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- PPH between Japan and the US has made patent decisions much quicker. The time to first action decreases dramatically :

	<u>Regular cases</u>	<u>PPH cases</u>
Japan	28.5 months	1.8 months
US	25.6 months	3 months



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Accelerated/Prioritized Examination in the U.S.



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- Accelerated Examination Program
- Green Technology Pilot Program
- Project Exchange Program
- Applicants Age or Health
- Three-Track Proposal



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Leahy-Smith America Invents Act



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- Substantive patent law
 - Sec. 3: First Inventor to File
 - Sec. 15: Best Mode Requirement
- Contentious issues
 - Sec. 8: Preissuance Submissions
 - Sec. 5: Prior Commercial Use Defense
 - Sec. 6: Post-grant Review of Patents and Inter Partes
- Review
 - Sec. 12: Supplemental Examination
 - Sec. 16: Marking



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Practice Tips



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- Prepare application drafts to international standards
- Draft multiple dependent claims to provide intermediate generalizations between the main claim and the examples. In other words, provide as many fall-back positions in the specification as possible
- Carefully consider potential advantages to programs that accelerate prosecution



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Practice Tips (cont.)



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- Make similar statements in a few different ways in the description to provide basis for a range of amendments during examination
- For the sake of translation costs, page fees, etc, try not to draft specifications which are unnecessarily long



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Practice Tips (cont.)



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- Make the most of the Paris Convention priority year
- Coordinate patent, regulatory, and product-cycle time lines
- To support enablement and inventive step, when drafting the EP and Asian applications:
 - Clearly state advantages of the invention
 - Include as much data as possible
 - Emphasize surprising/unexpected results



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Practice Tips (cont.)



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- Choose your countries wisely
- Verify that the subject matter is patentable in the jurisdictions you file
- Consider selecting a single foreign associate in each country to manage similar technologies in your IP portfolio
- Consider the use of a reputable translation service to consolidate all patent translations to reduce expensive translation costs



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Practice Tips (cont.)



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- Make foreign filing decisions, and provide instructions to your counsel as soon as possible before the 12 month Paris Convention deadline.
 - Ensures enough time to address any specific national requirements and account for time zone or national office closings.
 - Can prepare any country-specific modifications to the specification or claims to put the application in better condition for examination.



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Practice Tips (cont.)



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- Periodically review your portfolio to ensure your assets align with your business objectives
- Abandon or monetize IP that you do not need or that is not core to your commercial position
- A proactive approach is best in dealing with patent agencies
- Consider adjuncts to patent protection



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Questions & Answers



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Entering the U.S. Market via Strategic Alliances and Collaborations, Joint Ventures, and Direct Investments

Linda Ji
Foley & Lardner LLP



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Introduction - Doing Business in the U.S



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- Legal Framework
- Trends



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Legal Framework



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- Contractual Arrangements
- Business Entities –corporations, limited liability companies, partnerships
- Foreign Investments in the US
 - In general, no approval required for forming a company
 - Profits and dividends can freely flow abroad (subject to US taxes)
 - Interest and royalty payments can freely flow abroad (subject to US taxes)
 - Financing arrangements are flexible

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Legal Framework (cont.)



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- Special Industries and Considerations
 - Highly regulated sectors – domestic air transport, banking and broadcasting, national defense, insurance, shipping, mineral rights, energy & utilities - require licenses, citizenship, etc.
 - Exon-Florio Law – permits President of the US to block otherwise legal foreign acquisitions that would threaten national security
 - US Patriot Act – requires financial institutions to establish anti-money laundering programs

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Legal Framework (cont.)



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- Intellectual Property Protection
- Anti-Trust and Competition
 - law designed to provide consumers with the benefits of competition.
 - The law protects competition not competitors
- Product Distribution
 - Distributors, Resellers, Sales Representatives
 - Franchising – system of marketing and distribution where one person is given the opportunity to market and sells goods pursuant to an established system and practice in exchange for a fee



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Trends



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- Foreign Investment including by Chinese investors is growing rapidly. China's investment in greenfield projects and acquisitions in the US in 2010 reached \$5.35 billion, rose 132% from 2009 levels (Asia Society May 2011 Special Report). FDI in the US is expected to grow 50% in 2011 (MOFCOM).
- Joint ventures are challenging – “*Tong chuang yi meng*”



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Trends (cont.)



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- Strategic imperatives, large, recovering markets and strong balance sheets have resulted in a return to M&A as a primary corporate growth and market entry strategy.
- In 2010, Chinese spent \$4.87 billion on acquisitions in the US (Asia Society May 2011 Special Report). In the same year, Chinese companies purchased or announced the purchase of over 50 US companies (*CNN Money*).



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Strategic Alliances and Collaborations



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- Definition – a cooperative effort whereby each party is involved in the development and sale of a technology, product or service under its own name and logo. There is no separate legal entity formed.
- When are these useful?
 - One time opportunity.
 - “Dating” – companies desire a business relationship but do not want to make a serious commitment.



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Strategic Alliances and Collaborations (cont.)



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■ Examples

- Joint collaboration agreement where two companies come together to jointly research and develop a new technology or product.
- Joint marketing effort where two companies come together to market a solution which includes the products of both parties.
- Joint bid for a project – technology development and integration.
- Licensing arrangement.
- Distribution arrangement.



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Strategic Alliances and Collaborations (cont.)



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■ Issues

- Objectives
- Duties of the parties
- Compensation
- Financial commitment
- Post-termination competition
- Cross-border tax considerations
- government regulation on outbound technology movement



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Joint Ventures



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- Definition - an arrangement involving two or more companies or individuals in a partnership for a particular purpose. Each contributing member provides capital, expertise, technology, or other special resources to the venture.



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Joint Ventures (cont.)



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- Difference between JVs and Strategic Alliances?
 - JVs typically require a greater financial and other commitment
 - A new entity is formed
 - Tend to be longer term
- When are these useful?
 - Larger market opportunities as opposed to a single project
 - When each party possesses something the other party needs creating synergy



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Joint Ventures (cont.)



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■ Issues

- Objectives
- Duties of the parties
- Compensation
- Financial commitment
- Competition during and after the life of the JV
- Dispute resolution
- Exit strategy
- Cross-border capital movement



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Greenfield Investment



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- Definition – typically refers to a direct investment with an equity injection to establish a new overseas subsidiary
- Issues
 - Identify objectives
 - Pick the right form of entity
 - Pick the right state to form the subsidiary
 - Global structuring – corporate, IP and tax planning and considerations



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Strategic Investment



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- Definition – Where one party seeks to obtain an equity interest in another in exchange for capital injection
- When is this useful?
 - When the deployment of capital creates the opportunity for financial return
 - When the investor see an opportunity but does not have the desire or commitment to acquire the entire company
 - When combined with cooperation on R&D, product distribution or similar objectives



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Strategic Investment (cont.)



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- Process
 - Identify objectives
 - Identify the type of investment desired
 - Establish investment criteria – team, traction, technology, market opportunity
 - Establish a means to attract deal flow
 - Valuation methodology
 - Establish size of initial investment and follow-on
 - Establish the investment process – including deal flow, due diligence, legal, tax, accounting, monitoring and assistance



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Mergers and Acquisitions



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- Most common way for foreign companies to enter the US market
- When is this useful?
 - Buyer wants to enter the market quickly
 - Buyer wants have a “head start”
 - Buyer wants to acquire something it does not have such as new products or distribution channels



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Mergers and Acquisitions (cont.)



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- Process
 - Identify objectives
 - Identify the type of target company desired
 - Establish purchase criteria – industry sector, size, customer quality, management quality
 - Establish a means to attract acquisition opportunities
 - market research, engage an investment banker
 - Valuation methodology



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Mergers and Acquisitions (cont.)



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- Process (cont.)
 - Establish the acquisition process – including due diligence, legal, tax, accounting, monitoring and assistance
 - Establish an integration plan – products/services, sales forces, IT systems, accounting and finance and culture



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Takeaways



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- “One size fits all” does not apply
- Careful and smart analysis and planning goes a long way
- Thoughtful corporate, IP and tax structuring outside and inside China is critical
- IP protection outside and inside China is vital
- Be mindful of and attentive to the differences in culture, laws and business practices



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Questions & Answers



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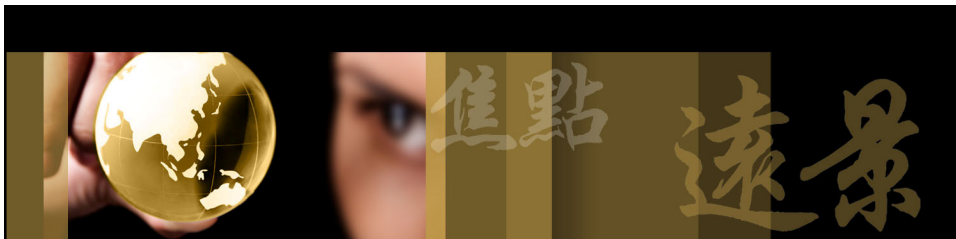
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