What Every CEO and GC Needs to Know about the Pitfalls and Obstacles in Working with Non-US Companies

May 10, 2011
Boston, Massachusetts
Speakers

Moderator
- Sven Riethmueller, Partner, Foley & Lardner LLP

Panelists (Listed in alphabetical order)
- Chuck Abdalian, Senior Life Sciences Executive, Former Senior Vice President and Chief Financial Officer of Molecular Insight Pharmaceuticals, Inc.
- Jim Ewing, Partner, Foley & Lardner LLP
- Travis Wilson, CEO, Stealth Peptides Inc. and a member of Morningside

WINNING GENES: How to Create, Grow, and Sustain a Successful Life Sciences Company

Presenter
Jim Ewing, Partner
Foley & Lardner LLP
**Forms of IP**

<table>
<thead>
<tr>
<th></th>
<th>USA</th>
<th>Europe</th>
<th>China</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade Secret</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Copyright</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Trademark</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Patent</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Invention/Utility</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Utility Model</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Design</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Plant</td>
<td>Yes</td>
<td>Limited</td>
<td>No</td>
</tr>
</tbody>
</table>

**Inventor Reward and Remuneration**

- Articles 77 and 78 of the *Rules* provide a statutory scheme for employee-inventor reward and remuneration in the absence of an agreement between the employer-patentee and the employee-inventor.
- All business entities obtaining a granted patent in respect of an invention made by an employee in the course of his employment – or using the employer’s resources, materials or equipment – are legally obliged to engage in the development and management of a remuneration plan for the employee-inventor.
- Article 76 of the *Rules* provides that an employer may specify its reward and remuneration scheme either in an agreement with its employees or in its bylaws. As stipulated under Article 16 of the Patent Law, the terms contained in such agreement or bylaws must be ‘reasonable.’
Inventor Reward

- *Rules* provide that within three months of the date of the grant of a patent for an employee invention, the patentee shall reward the employee-inventor
  - No less than RMB3,000 (approx US$450) for an invention patent
  - No less than RMB1,000 (approx US$150) for a utility model or design patent.
  - Although not specified in the *Rules*, the payment is usually made as a one-off reward (in one lump sum)

Inventor Remuneration

- The *Rules* provide that upon commercial exploitation of an employee invention that is the subject of an invention or utility model patent, the patentee shall pay the employee-inventor no less than 2% of the business profits derived from exploitation of the invention during the term of the patent.
  - For inventions the subject of a design patent, the patentee is required to pay 0.2% of the annual profits derived from exploitation of the patent.
  - Alternatively, the patentee-employer can make a lump sum payment based on the above rates.
  - If the patentee-employer licenses the relevant patent to another entity, the employee is entitled to no less than 10% of the royalty charged
Chinese Technology Import/Export Regulation

- The Foreign Trade Law of the People's Republic of China (PRC) restricts export/import of certain technologies that may involve national security, public interest, or public morality.

- Regulations of the People's Republic of China on Administration of Import and Export of Technologies ( Regulations) formulated by the PRC State Council govern.

- Technology export and import are defined as the transfer of technologies across the border by way of foreign trade, investment, or economic or technological cooperation, and such transfer may include assignment or licensing of patents and/or technical knowledge.

Chinese Technology Import/Export Regulation

- The Regulations categorize the technologies into three groups (free-to-transfer technologies, restrictive technologies, and forbidden-to-transfer technologies).

- Governmental approval is required before the restricted technologies can be exported or imported.

- Failure to comply with this approval requirement may result in confiscation of the profits, fines of up to five times the profits, revocation of the relevant party's foreign trade license, and under certain circumstances even criminal charges.

- The approval procedures for the export of restrictive technologies are similar to those for import.
### Impact of Chinese Subsidies

- China continues to represent a huge market for U.S. exports and investments.
- The total U.S. – China trade during the past three decades has risen sharply, reaching $366 billion in 2009, according to the U.S. government.
- China is the second-largest U.S. trading partner and an extremely important market for U.S. exports.
- The rapid expansion of U.S. – China economic ties also has created tension between the two trading partners, since U.S. imports from China are growing at a much faster rate than its exports to China.
- In 2009, the United States had a trade deficit with China of $227 billion.

### Impact of Chinese Subsidies

- The unbalanced nature of the U.S. – China trading partnership escalates trade friction and complicates the bilateral relationship between the two partners.
- Despite China's recent economic and legal reforms, the United States is increasingly concerned about a number of issues, including discriminatory government procurement policies (such as requirements for "indigenous innovation"); inconsistent market access; and inadequate enforcement and protection of U.S. intellectual property rights (IPR).
- The IPR protection regime in China still offers inadequate protection and poses significant obstacles for many U.S. businesses in China.
- China viewed as having increasingly protectionist tendencies.
Impact of Chinese Subsidies

- China transitioning from a major manufacturing country to a major global source of innovation
- Chinese government has implemented many policies and invested huge research and development funds to promote the development of critical industries, including renewable energy and space programs
- "Indigenous Innovation Product Accreditation" system likely will give preferential treatment to locally developed technologies in government procurement and has met with strong criticism from U.S. companies
- Procurement preferences and other measures favoring ‘indigenous innovation' could severely restrict market access for American technology and products.

Example: Impact on Green Energy

- China was not a major player in the solar industry five years ago
- China is on track to produce more than half the world’s solar panels this year
- More than 95 percent of them will be exported to countries like the United States and Germany that offer generous subsidies for consumers who buy solar panels.
- Chinese government has relatively modest solar subsidies for its citizens
- Chinese devoted more money to helping manufacturers, allowing them to cash in on other countries’ consumer subsidy programs.
- Chinese solar panel manufacturers benefit from the government’s imposition of sharp reductions in exports of raw materials, known as rare earths, that are crucial for solar panels
- China mines almost all of the world’s rare earths
- W.T.O. rules ban most export restrictions.
Selecting a CRO

- Expertise: Is there expertise to conduct the type of study needed?
- Reputation: A good laboratory will have a good reputation and work hard to maintain it
- Capacity: How many studies can the CRO conduct at the same time vs. how many they have going on.
- Responsiveness: Service orientation
- Qualifications: Staff qualification and experience

Selecting a CRO

- Cost: Important but not the only consideration
- Reliability: Good record of execution to assure project submission timelines are met
- GLP compliance: Do an audit to see how well the CRO executes in compliance with GLP practices
- Team chemistry
Inventorship in Europe

- Law of inventorship is national law; there is no European law of inventorship
- A person may not be considered an inventor under the laws of one country but may be considered an inventor under the laws of another country
- Inventorship and co-inventorship are defined by national laws in European countries
- Inventorship and co-inventorship can be highly relevant even in Europe (first-to-file systems)
  - May determine (joint) ownership and (joint) commercialization rights
- Need to structure collaborations accordingly to avoid adverse “surprises”
Inventorship in Germany

Patent Act in Germany:


“The inventor or its legal successor has the right to the patent. If multiple persons have jointly made an invention, the right to the patent is held jointly. If multiple persons made the invention independently from one another, the person who first applies for the patent at the patent office holds this right.” Section 6 of the German Patent Act

Inventorship in Certain EU States

Germany:

- Inventor has right to patent. If the same invention is made by different inventors working independently, the inventor who applies first is entitled to the entire patent
- Co-inventors are both entitled to the patent; co-invention arises from the collaboration of two or more natural persons and raises the question of who qualifies as a co-inventor under German law
- In the absence of an agreement to the contrary, the effect of joint ownership is the creation a legal entity that shares undivided interests in the intellectual property right - i.e., each inventor holds a nominal equal share
- Each joint owner can assign his interest to a third party and this party will then replace the former joint owner with respect to the interest
- Any dealings on the patent itself is subject to consent of the other owners
- Specific regulations apply for inventions made by employees
Inventorship in Certain EU States

Germany:
- German Employee Inventor Ownership Act (ArbEG) amended effective October 1, 2009
- Regulates transfer of ownership of an employee's invention to the employer; after transfer, the employer is entitled to prosecute a patent or utility model application and to exploit the invention
- In principle, any invention made by an employee within the framework of his professional activity is attributed to the employer (service invention)
- Employee must immediately notify the employer of the invention; if the employer does not respond, ownership of the invention is automatically transferred to employer upon expiration of 4 months; for employee inventions reported by the employee to the employer before October 1, 2009, the old rules still apply: employee had to immediately notify the employer of the invention and employer had to formally claim the invention within 4 months; otherwise, ownership of the invention remained with the employee
- If the employer does not affirmatively disclaim ownership of the invention (in full or in part) within the 4 month, employer will need to pay reasonable remuneration to the employee
- Lump sum (before or after patent grant) or license model (starting after patent is granted)
- Employer can release the invention even after lapse of the 4-month deadline
- If the employer does not affirmatively disclaim, employer will by default incur various obligations
  - file application and pay remuneration
  - offer IP rights abroad in which the employer is not interested
  - offer employee to acquire the IP right before any abandonment
  - Provide information and render accounts
- Employer can remove or reduce obligations in contracts with employee (post-invention)

France:
- First patent applicant will be deemed to be the inventor; joint ownership is exceptional.
- Joint ownership may be voluntarily agreed upon by the parties
- Use of jointly owned patent may require compensation to other joint owners
- Grant of a non-exclusive license by one joint owner to a third party may require compensation to the other joint owners; each draft license must be notified to the other joint owners
  - Other joint owner may oppose license grant by offering to acquire the share of the joint owner wishing to grant the license
- An exclusive license may only be granted upon consent of all joint owners
- Each joint owner may take action against infringement for its own benefit with compensation limited to the damage it suffered. The joint owner who takes action for infringement must notify the other joint owners of the action
- Freedom to contract on jointly owned patent commercialization to vary rules
Inventorship in Certain EU States

**United Kingdom:**
- The inventor has the right to be granted a patent subject to superior rights to the invention by virtue of an agreement with the inventor or by virtue of law (e.g., the invention belongs to the employer if the invention is made during the course of an employee's duties and those duties are such that an invention may be expected to result).
- If the applicant is different from the inventor, the applicant must prove its right to the patent.
- Where a patent is granted to two or more persons, each of them shall, subject to any agreement to the contrary, be entitled to an equal undivided share in the patent; each of them shall be entitled to use the patented invention itself or through agents, for its own benefit and without the consent of or the need to account to the other co-owner(s)
  - however a co-owner may not, without the consent of the other co-owner(s), grant a license under the patent or assign or mortgage a share in the patent or, in Scotland, cause or permit security interest in it to be granted.

Inventorship in Europe

- National courts in Europe do not have a well developed body of jurisprudence (case law) on inventorship
  - fairness/equity considerations by courts
  - No European patent court as final expert appeals court
- Germany: Co-ownership based on scope of contribution
  - Percentage allocations
  - But: co-ownership of all claims in patent even if the inventor contributed only to some claims
- Germany: Co-inventor may be able to take legal action to obtain co-ownership rights in patent if only one inventor applied for the patent
- Germany: “Joint” scientific/academic publications
  - May be considered by court as “proof” of co-inventorship
Inventorship in Europe

- Need to agree in collaboration/joint research agreement on allocating IP ownership (joint or not joint) to invention — and define which law of inventorship applies
  - To establish (joint) ownership and commercialization rights
  - Also address (joint) ownership and commercialization rights for (co)inventions outside scope of collaboration/joint research project
- Should address ownership issues in contract research agreements even on pre-existing inventions (“background IP”)
- Address actual assignment and specific performance of agreements to ensure agreed-upon allocation of ownership

Inventorship – Sample Clauses

“Ownership of any Inventions discovered, developed, created, made, conceived or reduced to practice in the course of performing the Research Project, and ownership of all Intellectual Property Rights in and to such Inventions, shall vest solely with A, except to the extent B or any of its employees is an inventor or co-inventor of such Invention under the applicable U.S. patent laws governing inventorship, in which case ownership of such Invention shall, and ownership of all Intellectual Property Rights in and to such Inventions shall, vest jointly in the Parties and shall be deemed Joint Intellectual Property.”

“Each Party shall promptly provide the other Party, at the other Party’s expense, with the necessary documents, assignments and inventor assistance to allow each Party to perfect its ownership of Intellectual Property Rights to Inventions consistent with the provisions of this Agreement.”

“Absent an exclusive license granted to A with respect to B’s interest in the Joint Intellectual Property as contemplated above, each of A and B shall be free to use such Joint Intellectual Property and to enter into a license with any other party on any terms it desires with respect to such Joint Intellectual Property in accordance with the laws of the United States governing the use of jointly owned Intellectual Property Rights, irrespective of whether the laws of a country in which the applicable Intellectual Property Rights are recorded or recognized would prohibit such independent licensing.”

Sample clauses showing the interplay between (co)inventorship and joint ownership in cross-border contracts. These are not complete and provided for illustrative purposes only. Actual provisions will need to be tailored to the specific collaboration or joint research project.
IP Rights in Europe

- There is no “European” Bayh-Dole Act equivalent
- Individual EU Member States have enacted similar laws
  - United Kingdom, Germany
- Example: Germany
- Amendment effective January 18, 2002 to the German Employee Invention Owner’s Act
  - Revoked long-standing privilege for employees of universities
- University now can claim ownership of inventions made by its employees with government funding on its campus
- University may retain rights to the invention for commercial exploitation
- Academic employees must receive 30% of the profits from the commercialization of their invention.
- Inventors are allowed to publish their inventions so long as they give their employing institution 2-month notice prior to publication
- Inventors may retain non-exclusive right to use invention as employees

IP Restrictions in Europe

- Prior to Dec. 31, 2006, EU community law did not apply to R&D activities of public, not-for-profit universities or research organizations
- Since Jan. 1, 2007, the COMMUNITY FRAMEWORK FOR STATE AID FOR RESEARCH AND DEVELOPMENT AND INNOVATION (2006/C 323/01) governs
  - Section 3.2 identifies the requirements to be satisfied in order for research collaborations between private companies and publicly funded universities not to be anti-competitive
    - when is research by state funded research organizations for or with private companies not deemed to be involving direct governmental subsidies?
IP Restrictions in Europe

- 2 types of relationships:
  - research services by public research organization for a private company
    - Research organization must receive compensation either at market rate or cost-plus (price that captures all costs plus a reasonable profit)
  - Research collaborations between the research organization and a private company
    - Company must pay all costs of the project or protectable IP rights must be assigned to the research center or the research center receives compensation at market rates for the IP generated from the project and transferred to the private company (less any prior payments to cover university costs already made by the company)

IP Restrictions in Europe

- Commercialization obligations and transfer limitations for IP/research results funded with research grants
- At EU level: Framework Programmes (e.g., 7th Framework Programme) for EU-funded research consortia
- Each Member State imposes its own commercialization obligations and transfer restrictions for IP/research results funded with grants from Member States
  - Example of Member State Research Grant Policies: Germany
  - Research grants available at German Federal and State (Land) levels
  - Popular grant program: federal research grants of the German Federal Department of Education and Research (BMBF)
  - BMBF grant awards are subject to the award terms and the standard additional grant award terms and conditions (BMBF Nebenbestimmungen) (NKBF 98)
  - These terms contain material commercialization obligations and transfer restrictions; failure to comply can result in loss or substantial reduction of IP rights, civil penalties and sanctions and even criminal liability for the company and its officers and directors
  - If the grant is made to multiple recipients, the recipients typically enter into a cooperation agreement which regulates access to their existing IP and the newly developed IP from the funded research, subject to German laws on co-inventorship
IP Restrictions in Germany

- BMBF standard terms and conditions for federal research grants:
  - Grant recipient must commercialize the results from the subsidized research within reasonable period (2 years) or other period specified in its pre-approved plan
    - Failure to do so without good reasons would result in termination of exclusive use right
    - Grant recipient would then have to grant to third parties a non-exclusive, non-transferable use license upon customary market terms for use in Germany or for distribution outside of Germany
  - BMBF is granted an irrevocable royalty-free non-exclusive use right
  - Grant recipient must promptly pursue patent protection of research results
  - BMBF can demand transfer of the subsidized IP back to BMBF (upon reimbursement of costs) if grant recipient abandons IP or fails to defend IP
  - Grant recipient receives only a non-exclusive use right if exclusivity would result in an anti-competitive position (unless grant recipient compensates BMBF for exclusivity at market rates)
  - Patent filings have priority but grant recipient must also publish the research results within 9 months from end of project
  - Grant recipient must disclose research results for research and teaching in Germany upon request subject to confidentiality obligations (and likely grant an non-exclusive royalty free license for these noncommercial uses)

- Transfer of IP by grant recipient to permitted third parties only upon express agreement by acquirer that it will comply with all of these obligations (inc. commercialization obligation)
- Contracts with third parties for commercialization of research results outside of the EU requires prior consent of BMBF
  - Need to obtain consent from BMBF, may require payment to BMBF
  - Transfer of IP to affiliates (e.g. subsidiary) outside of EU requires prior consent of BMBF
  - Commercialization or use of IP (e.g. manufacturing of protected product) outside EU requires prior consent of BMBF
  - Change of control or significant influence by a non-EU company (e.g. US venture fund) over grant recipient where IP is used predominantly outside of the EU requires prior consent of BMBF
    - Same applies for any sale of asset transaction which involves the IP to a non-EU purchaser
IP Restrictions in Germany

- BMBF standard terms and conditions for federal research grants:
  - Obligations and restrictions continue indefinitely except as specified in award
  - Grant recipient may seek to amend research and commercialization plan subject to approval by BMBF
  - Consequences for failure to comply include – in addition to the loss of rights or exclusivity (as discussed above)
    - Revocation of award/grant (incl. retroactively)
    - Repayment of grant and all other benefits received (e.g., royalties) – unjust enrichment theory
    - Criminal liability for company and its officers/directors for subsidies fraud (intentional misconduct or gross negligence)

IP Restrictions in Europe

- EU: 7th Framework Programme
  - Operates through Grant Agreement and Consortium Agreement
  - Contains similar commercialization obligations and transfer restrictions as BMBF Terms
  - Contains default regime on joint ownership of IP (and right to grant licenses by joint owners) absent express agreements by research consortium parties

- Approvals must be obtained from the EU Commission
- Contract penalties for failure to comply
- Company can be debarred from all EU grants for period of 2 years
- Criminal liability for company and its officers and directors depending on Member State (e.g. Germany)
IP Restrictions in Europe

- Transfer of ownership of IP funded by a 7th Framework Programme grant:
  - EU Commission may object to transfer of IP to third party in non-EU country if it considers the transfer detrimental to European competitiveness or inconsistent with ethical principles of security considerations
  - Transfer of ownership shall not take place until Commission’s approval
  - Commission may require notification of transfer to non-EU persons under terms of the Grant Agreement

- Other European organizations may have their own IP policies/regulations in connection with technologies funded or licensed by European organizations (e.g., ESA - European Space Agency, EMBL – The European Molecular Biology Laboratory)

**Due diligence in licensing, acquisitions or collaborations/joint ventures is key as significant life science technologies in Europe have often been funded by EU or Member State research grants**

Bayh-Dole Act in USA

- Bayh-Dole allows US universities to elect ownership of federally funded research
- Applies to all US federally-sponsored research, in whole or in part
- The vast majority of US university-licensed inventions result from research funded by the US federal government
- Assignment of IP is not permitted (waivers available) under Bayh-Dole
- Provides for license to US government
- Licensing preference to small business
- Universities have obligation to commercialize federally funded inventions
- March-in rights by US government if no commercialization in reasonable time
- For exclusive licensees US sales requires US manufacture
- Revenue must be shared with inventors (faculty)
- Net revenue from licenses to support research or education
- University tech transfer offices are permitted to recoup only patenting and licensing expenses
Follow-up Information

Sven Riethmueller  
Partner  
Foley & Lardner LLP  
111 Huntington Avenue  
Suite 2600  
Boston, MA 02199  
617.342.4043  
sriethmueller@foley.com

James F. Ewing  
Partner  
Foley & Lardner LLP  
111 Huntington Avenue  
Suite 2600  
Boston, MA 02199  
617.342.4088  
jfewing@foley.com

WINNING GENES: How to Create, Grow, and Sustain a Successful Life Sciences Company

What Every CEO and GC Needs to Know about the Pitfalls and Obstacles in Working with Non-US Companies

May 10, 2011  
Boston, Massachusetts