John M. Garvey, Ph.D., Associate, Greenberg Traurig, Boston, MA

Dr. Garvey works with pharmaceutical and biotechnology clients, primarily those companies engaged in drug discovery, genomics, proteomics, small molecule drug design, immunology and vaccine technologies, drug delivery, gene therapy technologies, stem cell technologies and biomedical devices. His practice includes advising clients on the creation and development of patent portfolios, and their strategic use in corporate collaborations and financial transactions, as well as patent validity, freedom to operate and infringement opinions. He also supports the firm's litigation and patent interference practices.

Dr. Garvey has authored numerous articles on patent law, technology transfer, and the development of intellectual property portfolios for biotechnology companies. Most recently, aspects of his scientific work, originating out of a collaboration with researchers at the University of Birmingham, U.K., were presented at the 9th Annual Human Antibodies and Hybridomas Conference in Berne, Switzerland.

Education

- Ph.D., Molecular and Cellular Biology, Brandeis University, 2000
- J.D., Franklin Pierce Law Center, 1993
- B.S., Fairfield University, 1990

Admitted to Practice

- Massachusetts
- U.S. Patent and Trademark Office

William Lee Ph.D., President & CEO, Cofounder, eMembrane, Inc.

Dr. Lee received his B.Eng., M.Eng. and Ph.D. from the University of Tokyo. Following a post-doctoral program at Harvard Medical School/Massachusetts General Hospital/Shriners Research Center, he joined JAFCO, Japan's largest venture capital firm, as an Assistant Investment Officer for the Life Science Division. Shortly after his career in venture capital, Dr. Lee returned to Boston and cofounded eMembrane, Inc. in Cambridge, MA based on his and his advisors' years of research work. eMembrane is a US company developing a broad spectrum of multi-functional polymeric materials and membranes for chemical and biological applications. The Company's "Made in Japan" technology has been funded by Asian investors to target multiple global markets with diverse applications.

Michel Morency, Ph.D., Shareholder, Greenberg Traurig, LLP, Boston, MA

Dr. Morency works with pharmaceutical and biotechnology clients, primarily those companies engaged in drug discovery, neurobiology, genomics, proteomics, small molecule drug design, immunology and vaccine technologies, drug delivery, gene therapy technologies, stem cell technologies and biomedical devices. Mike advises clients on all aspects of patent strategy, including the creation and management of patent portfolios as well as the evaluation of both client and competitor portfolios, preparation of validity and infringement opinions, and freedom-to-operate opinions. His practice also involves the

acquisition and exploitation of intellectual property rights through licensing and strategic collaboration agreements. In addition, Mike represents companies and investors with regards to intellectual property assets and the formation and funding of ventures built around technology portfolios.

Member, American Bar Association
- Member, Boston Bar Association
- Member, American Intellectual Property Law Association
- Member, Patent and Trademark Institute of Canada

Articles, Publications and Lectures
- Author of several legal and scientific publications

Education
- LL.B. (J.D.), *cum laude*, University of Ottawa in Ottawa, Canada, 1994
- Ph.D., Medical Sciences-Neurosciences, McMaster University in Hamilton, Canada, 1992
- B.S., with honors, Life Sciences, Queen's University at Kingston, Canada, 1984

Admitted to Practice
- Massachusetts
- United States Patent and Trademark Office

Successful Licensing in the Far East

Dr. John M. Garvey, Greenberg Traurig, LLP
Dr. John Prince, Norvartis, Corp.
Dr. William Lee, eMembrane, Inc.

Special Thanks to:
Zack Guarard-Levin– Project Analyst, Johns Hopkins University
John Elliott- Law Clerk, Georgetown University Law Center



Contents

- General Licensing
- Far East Economies and Markets
- Philosophy
- Mechanics



Types of Licensing

- General IP Licensing
- Business Format Franchising
- Technology Licensing
  - "Hard Technology"
  - Solution/Software
  - "Soft Technology"

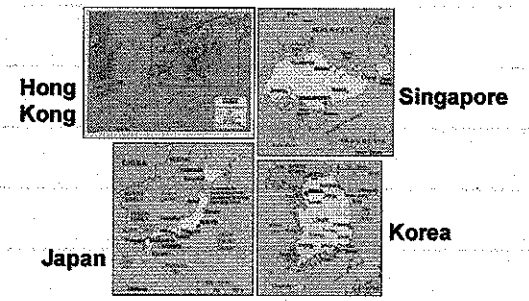


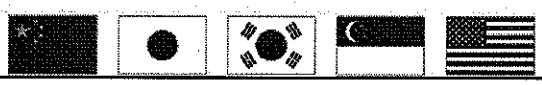
Licensing Factors to Consider

- Distinguish licensable rights
- Protect IP prior to licensing
- Determine basis for valuing IP



Far East Biotech Market





Hong Kong

- Mainly involved in drugs and medicine
- Lack of mainstream R&D sector inhibits commerciality
- Domestic industrial output reached $212 million in 1997
- In 1998, there were over 190 manufacturing establishments with about 2400 employees



Singapore

- Biotechnology market increasing 50% annually up to 2006
- Market projected at $306 million in 2006
- 20,000 scientists involved in R&D
- Wants to be "The Biomedical Science Hub' in Asia



Korea

- Weak infrastructure
- Highly dependent on imports
  - 40%-60% in 1990s
- Market for domestic biotechnology products should reach $7.5 billion by 2005
- Government committed to foster Biotech as nation's strategic industry
- Aims to be world's G-7 level in Biotech by 2010



Japan (1)

- Japan's market expected to reach 5 trillion Yen by 2005 (equiv. to $42.5 billion)
- Opportunities
  - 125 million consumers
  - World's highest per capita income
  - World's highest prices
- Challenges
  - Legal confusion
  - Bureaucratic complications
  - Success rate in West is low



Japan (2)

- Strengths:
  - Enzyme eng., glyco eng., fermentation, metabolic eng., and bioinformatics
  - Domestic market for pharmaceuticals
  - Strong basic research
  - Government support
- Weaknesses:
  - Applied research
  - Lack of experienced TLOs
  - Lack of biotech VCs and Investment Banks
  - Rivalry with ministries



Japanese Governmental Budget on Science and Technology

- FY 2001: 3.469 Trillion Yen
- FY 2002: 3.539 Trillion Yen
- Second S&T Basic Plan (FY 2001-2005): **24 Trillion Yen over 5 years!!**



Japan Budget by Fields FY 2002

Life Sciences, Health and Medical Treatment	436.6 BB Yen
Information and Telecommunication	245.6 BB Yen
Environmental Science	764.3 BB Yen
Nanotechnology and Material Science	123.2 BB Yen
Energy	703.3 BB Yen

1 billion Yen is equivalent to 8.5 million USD



IP in Japan

- 439,175 filings in 2001 (US: 345,732)
- Greatest number of patents worldwide
- Japanese Patent Office (JPO) takes 3 years to examine applications
- 1,088 patent examiners in 2000 (1/3 of US)
- Narrow permissible scope
- Slow adjudication of patent infringement



Philosophy



- Culture differences
- Language barriers
- Different foreign legal systems



Appropriate Introduction

- Formal introduction is most effective
- Introducer plays important role
- Begin relationship correctly



Communicating Concerns

- Be sure both party concerns are well understood
- No written agreements are necessary
- Be polite
- Apologies are important
- Eliminate the word "No"



Understanding Other Viewpoint

- "Think Globally"
- Avoid confrontation
- Develop trust
- Work for a "coexist" (win-win) situation



Goal Setting

- Organization
- Set time references
- Patience
- Always work towards set goals



Consider Future Relationships

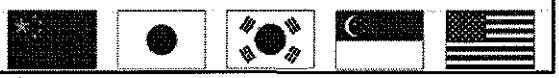
- Establish good line of communication
- Be complete and thorough





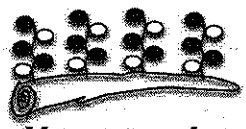
Successful Licensing in the Far East

- Knowledge of foreign market
- Have deep understanding of specific culture
- Open lines of communication
- Build strong relationships for future

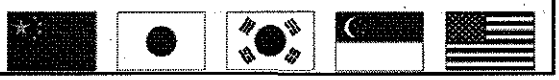


A Case Study

"When East Meets West"



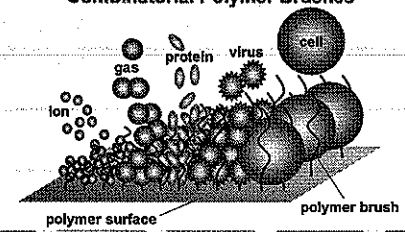
EMEMBRANE, INC.



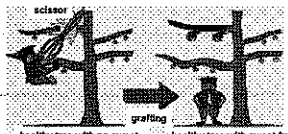
The Company

A Multifunctional Polymeric Materials and Membranes Company

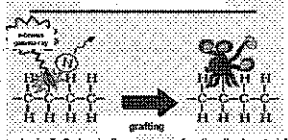
Electron-Beam-Induced Grafting (eBIG) of Combinatorial Polymer Brushes



Electron-Beam-Induced Grafting (eBIG)

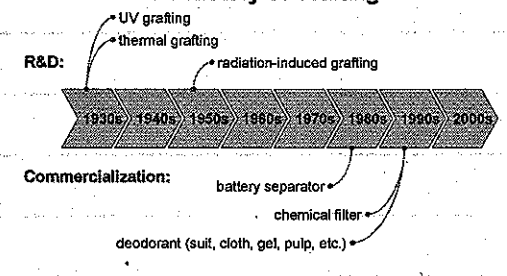


by Gardener



by Chemist

The History of Grafting



Radiation-induced grafting IP: > 150 Japanese patents, > 40 foreign patents } owned by JAERI

Three Principles for Licensing Japanese Government-Owned Patents

Regular license:

- **Non-exclusive**
- **Non-discrimination**
- **Proper license fee**

Priority license



Structuring the Licensing Relationship

Priority license

JAERI **KJK** **eMembrane**

- Patents are not available from the government on an exclusive basis (JAERI)
- Patents already licensed (back) to the Inventor (KJK)
- Typically no rights given to a licensor to sublicense the patents



Cultural Considerations

- A "Western" style agreement would be overwhelming
  - Provisions would be ignored
  - Would never be signed
- Formal agreements are counterproductive
  - Culture of trust
  - Relationships



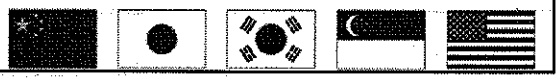
Solutions

- First, a Letter of Intent
  - Binding
  - Vague terms but specific obligations
- Follow with a Western-style agreement
  - Appease the lawyers
  - Typical for doing business with the U.S.



Grant of Rights

- *Grant*. KJK hereby grants to eMembrane a license under the KJK Patent Rights and a sublicense under the JAERI Patent Rights, in all cases in the Field, throughout the Term of this Agreement, to make, have made, use, sell and import the XXXX Products within the Territory.



Downside Protection (Exclusivity-1)

- *Priority of this Agreement*. In the event KJK seeks to grant any license under the KJK Patent Rights or any sublicense under the JAERI Patent Rights to any manufacturer or seller of XXXX Products (a "Third Party License"), and where the Third Party License may permit such third party licensee to manufacture or sell XXXX Products within the scope of the license granted in this Agreement, then KJK will:
  - promptly provide written notice to eMembrane that it is negotiating such Third Party License, such notice detailing the proposed royalty rates and terms of the Third Party License, and
  - extend to eMembrane the opportunity to negotiate with KJK, in good faith, for a similar license (a "Supplemental License"), such that the Supplemental License taken in combination with this Agreement shall afford eMembrane rights of equivalent scope and equivalent terms with respect to the Third Party License.



Downside Protection (Exclusivity-2)

- *Equivalency of Terms*. If any royalty rates or terms in the Third Party License are more favorable to the third party licensee than the royalty rates or terms in this Agreement are to eMembrane, then irrespective of whether eMembrane obtains such Supplemental License, KJK shall extend to eMembrane under this Agreement the more favorable royalty rates or terms, effective as of the date on which they became effective with respect to the Third Party License. For the avoidance of doubt, this includes the royalties or terms applicable to any Project Plans.



Downside Protection (Exclusivity-3)

- KJK shall not enforce any KJK Patent Rights or JAERI Patent Rights against eMembrane, its Affiliates, or any third party manufacturer of XXXX Products if eMembrane elects to manufacture or have manufactured any XXXX Products under Section 3.1 or 3.2, and will indemnify and hold harmless eMembrane, its Affiliates or third party manufacturers from any such infringement suit brought by JAERI to enforce the JAERI Patent Rights.



Japanese-Style Provisions-1

- *Dispute Resolution*. The Parties recognize that disputes as to certain matters may from time to time arise which relate to either Party's rights and/or obligations hereunder. The Parties hereby agree that they will attempt in good faith to resolve any controversy, claim or dispute (collectively, a "Dispute") arising out of or relating to this Agreement promptly by negotiations. Any such Dispute which is not settled by the Parties within fifteen (15) days after notice of such Dispute is given by one Party to the other in writing shall be referred to a senior executive of eMembrane and of KJK who are authorized to settle such Disputes on behalf of their respective companies ("Senior Executives") and who, if possible, are not involved in the Dispute. The Senior Executives will meet for negotiations within fifteen (15) days of the end of the 15-day negotiation period referred to above, at a time and place mutually acceptable to both Senior Executives. If the Dispute has not been resolved within thirty (30) days after the end of the 15-day negotiation period referred to above (which period may be extended by mutual agreement), the other Party can immediately bring an action relating to the Dispute before a court of competent jurisdiction.



Japanese-Style Provisions-2

- eMembrane will not provide to KJK any confidential information of third parties, or technology or Patent Rights licensed under any third party licenses, for which it does not have the authority to use on behalf of or disclose to KJK, that would cause KJK to be subject to any suit for infringement, or other such actions or proceedings



Conclusion

- Creative strategies can be used to bridge cultural gaps
- Don't focus solely on traditional modes of thinking
- Don't force issues that are culturally uncomfortable
- Final deal must let the parties "coexist" (i.e., be a win-win deal) for both parties

