

March 2014

Curriculum Vitae of Robert W. Kneller

Business-Related Work on Biomedical Technology and Startup Development

(details provided upon request)

1. Co-founder with a Japanese partner of a biomedical accelerator
2. Advisor to several Japanese biomedical startups and entrepreneurial scientists. Areas include:
 - Medical needs analysis,
 - Strategies for showing proof of concept,
 - Strategies for obtaining funding
(including linking to potential investors),
 - Intellectual property strategy,
 - Strategies for obtaining regulatory (FD/PMDA) approval,
 - Strategies for engaging development collaborators
(in universities, NGOs or private sector),
 - Negotiation of license contracts,
3. Bridge to North American translational research and phase1/2 clinical trial centers

Academic Work, Main Themes:

Please see, www.kneller.asia, for links to selected articles.

- **startups and entrepreneurship,**
- **university-industry collaboration and technology transfer,**
- **intellectual property law,**
- **regulatory issues facing biomedical startups,**
- **higher education and innovation linkage,**
- **international comparisons of the above**

My research has focused on startups, entrepreneurship, intellectual property, university-industry technology transfer, and the importance of these factors for the development of biomedical and other scientific discoveries for public benefit. Recent works include an analysis of the Japanese and American environments for

science-based entrepreneurship and the importance of science-based startups for innovation (*Bridging Islands* (Oxford 2007)), and a study of the origins of all the new drugs approved by the US FDA 1998-2007 which shows the importance of new companies for the discovery of innovative pharmaceuticals (*Nature Reviews Drug Discovery* 2010). Following a sabbatical in Stanford Medical School (2010-11) to better understand the support systems for science-based entrepreneurship in North America and how Japanese entrepreneurs can link to these systems, the focus of my work has shifted to (1) ways to foster the growth of startups based upon Japanese discoveries, particularly ways to help such startups to grow by developing international ties, and (2) ways to encourage invention in Japanese universities to meet important health needs (*invent for health*).

I am board certified in General Preventive Medicine having completed my residency and public health studies in Johns Hopkins University. My MD is from Mayo Medical School (1984). I have a JD from Harvard Law School (1980). I graduated from Swarthmore College in 1975 with a major in physics and minor in economics. From 1988 to 1997 I worked in the US National Institutes of Health, first as a cancer epidemiologist, then in science policy, and finally at the coordinator for clinical cooperative R&D agreements with industry to develop NIH cancer drugs. I have worked in China on epidemiology studies and in clinical medicine and public health.

Present Employment:

Professor, Research Center for Advanced Science and Technology (RCAST)
University of Tokyo
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Employment History:

9/1998-present: Professor, University of Tokyo, RCAST
8/2010-7/2011: Visiting Professor, Stanford Medical School, Stanford, California
9/1997-8/1998: Abe Fellow and Guest Researcher at the University of Tokyo, Research Center for Advanced Science and Technology (RCAST)
11/1995-8/1997: Technology Transfer and Development Specialist, Technology Development and Commercialization Branch, NCI, NIH, Rockville, Maryland
9/1992-11/1995: Program Officer for East Asia, Fogarty International Center, NIH, Bethesda, Maryland
6/1992-7/1992: Office of Medicine, Occupational Safety and Health Administration (OSHA), Department of Labor (Preventive Medicine Residency internship)
11/1991-5/1992: Medical Officer, Programme for the Control of Acute Respiratory Infections, World Health Organization, Geneva, Switzerland (Preventive Medicine Residency internship)
4/1991-7/1991: Medical Delegate on Red Cross Relief Missions along the Iraqi-Turkish border and in China
1988-1991: Cancer Epidemiologist, NCI, NIH, Rockville, Maryland. Main research

areas: (1) risk factors for precancerous gastric changes in an area of high stomach cancer mortality in rural China
(2) benzene exposure and cancer risks among factory workers
1987: Lecturer in Social Medicine, Chinese Academy of Preventive Medicine, Beijing, China
1986-87: Clinical Fellow, Tianjin Children's Hospital, Tianjin, China

Education:

1992: completed General Preventive Medicine Residency at Johns Hopkins University, Baltimore, Maryland
1986: M.P.H., Johns Hopkins University, Baltimore, Maryland
1985: completed Pediatric Internship, Kapiolani Women's and Children's Medical Center, University of Hawaii, Honolulu, Hawaii
1984: M.D., Mayo Medical School, Rochester, Minnesota
1980: J.D., Harvard Law School, Cambridge, Massachusetts
1975: B.A. (major Physics, minor Economics) Swarthmore College, Swarthmore, Pennsylvania
1971: graduated from Richfield High School, Richfield, Minnesota

Professional Licenses and Certifications:

Admitted to the bars of: New York (1980), Massachusetts (1981), Minnesota (1982),
Medical license: Maryland (since 1985)
Board Certified in General Preventive Medicine (1995)

Foreign Languages:

Mandarin Chinese, Japanese, French and Russian

Professional Societies:

Delta Omega Public Health Honor Society

Courses:

Spring-Summer: *Needs Inspired Invention* – Students (possibly working in teams) will research health related (or other perhaps other) needs that their expertise can address. Then they will develop solutions for these needs, choosing one that is feasible, and has high market potential to prototype and to patent.

Autumn-Winter: *University Entrepreneurship* – how to start a company, driven by market needs, and based upon engineering, scientific or medical discoveries.

Publications related to the fields listed at the top of this CV. (* indicates major individual work or major contribution to a joint work):

* Robert Kneller, Marcel Mongeon, Jeff Cope, Cathy Garner, Philip Ternouth. 2014. Industry-university collaborations in Canada, Japan, the UK and USA – with emphasis on publication freedom and managing the intellectual property lock-up problem. PLOS ONE 9 (3) (e90302).

Kneller, Robert. 2013. Commercializing promising but dormant Japanese industry-university joint discoveries via independent, venture capital funded spin-offs. In Hishida, K (Ed.). *Fulfilling the Promise of Technology Transfer: Fostering Innovation for the Benefit of Society*. Springer. Pp 23-33.

Kneller, Robert. 2013. Umemura, *The Japanese Pharmaceutical Industry: Its Evolution and Current Challenges* (Review). Journal of Japanese Studies 39 (no. 1, winter 2013) 235-240.

ロバート・ケネラー 2011 イノベーションにおけるベンチャー企業の役割—アントレプレナーシップの環境改善に向けて—。渡部俊也「編」。イノベーションシステムとしての大学と人材 (東京大学知的資産経営総括寄付講座シリーズ、第3巻、第3章)。白桃書房 173-200。[Translated from the English original by Shudo, Sachiko. English citation: Kneller, Robert. 2011. The importance of new companies for innovation, and ways to improve Japan's environment for science based entrepreneurship. Chapter 3 in Watanabe, Toshiya [ed]. University and Human Resource Development in Innovation Systems. Tokyo: Hakuto-Shobo Publishing Co. 173-200]

Kneller RW 2011. 'Invention Management in Japanese Universities and its Implications for Innovation: Insights from the University of Tokyo' Chapter 3 in Wong PK (ed). *Academic Entrepreneurship in Asia: The Role and Impact of Universities in National Innovation Systems*. Cheltenham UK: Elgar 69-85.

*Kneller, Robert. 2010. Importance of new companies for drug discovery: origins of a decade of new drugs. Nature Reviews Drug Discovery 9 (November) 867-882.

*Kneller RW 2010, 'The changing governance of Japanese public science', In R. Whitley, J. Gläser & L. Engwall (eds), *Reconfiguring Knowledge Production: Changing Authority Relations in the Sciences and Their Consequences for Intellectual Innovation*, Oxford: Oxford U. Press. Pp 110-145.

Kneller RW 2010, 'Ruth Taplin's Intellectual Property and the New Global Japanese Economy' (book review), *Pacific Affairs* 83 (no. 4) 786-787.

Van Eeke, Patrick; Kelly, Jeane; Bolger, Peter; Truyens, Maarten. 2009. *Monitoring and Analysis of Technology Transfer and Intellectual Property Regimes and Their Use: Results of a Study Carried out on Behalf of the European Commission (DG Research)*. Gent, Belgium: STORY Publishers. (R. Kneller is the main author of the portions of this

study relating to Japan.)

Ternouth P, Garner C, Mongeon M, Cope J, Kneller RW 2009, What Industry Wants from Universities University-Business Interaction: a comparative study of Mechanisms and Incentives in Four Countries. Issued by Council for Industry and Higher Education (UK) as a Kauffman Seminar White Paper. Presented at seminar of the same title, sponsored by the Kauffman Foundation and the University of California San Diego in San Diego 12-14 March, 2009. Follow on analysis under publication review.

ロバート・ケネラー、首藤 佐智子 2008 大学共同研究における企業のプリエンプションの健全性を問うベンチャーを育む研究環境こそが真の科学を生み出す。日本知財学会誌。第5巻第2号。Kneller, R. & Shudo S. 2008. Large companies' preemption of university inventions by joint research is strangling Japanese entrepreneurship and contributing to the degradation of university science. *Journal of the Intellectual Property Association of Japan* 5 (no. 2) 36-50. (Japanese and English)

Kneller, RW. 2008. Invention Management in a Major Japanese University and its Implications for Innovation (Chapter 10). AUTM Technology Transfer Practice Manual 3rd Ed. Vol. 3, Part 2.

Etzkowitz H, Ranga M, Benner M, Guarany L, Maculan AM, Kneller R. 2008. Pathways to the entrepreneurial university: towards a global convergence. *Science and Public Policy* 35 (no 9, November) 681-695.

*Kneller, RW. 2007. *Bridging Islands: Venture Companies and the Future of Japanese and American Industry*. Oxford U. Press.

*Kneller, RW. 2007. Prospective and retrospective evaluation systems in context: insights from Japan. In Whitley, Richard & Glaser, Jochen (eds.), *Changing Governance of the Sciences: the Advent of Research Evaluation Systems*. Springer: Dordrecht, Netherlands 51-73.

*Kneller, RW. 2007. The beginning of university entrepreneurship in Japan: TLOs and bioventures lead the way. *Journal of Technology Transfer* 32 (no. 4, August) 435-456.

*Kneller, RW. 2006. Japan's new technology transfer system and the preemption of university discoveries by sponsored research and co-inventorship. *Journal of the Association of University Technology Managers* 18 (no. 1, summer) 15-35.

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*Kneller, RW. 2005. Correspondence: The national origins of new drugs. *Nature Biotechnology* 23(6) (June), pp. 655-656.

*Kneller, RW. 2005. Correspondence: The origin of new drugs. *Nature Biotechnology* 23(5) (May), pp. 529-530.

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Kneller, RW. 2004. Developing countries' access to patented pharmaceuticals and the international IP system In S.K. Verma and Raman Mittal (eds.) *Intellectual Property Rights – a Global Vision*. New Dehli: Indian Law Institute, pp. 141-147.

Kneller, RW. 2004. University-industry cooperation and technology transfer in Japan compared with the US: another reason for Japan's economic malaise? *Global Outsourcing Review* Vol.6(1) (spring) pp 18-26 (bilingual condensed version of 2003 article in *U of Pennsylvania J of International Economic Law*).

Kneller, RW. 2004. Japan's corporate and innovation landscape. In *Papers Presented at the NISTEP Research Seminar, "R&D Strategy and Science and Technology Policy."* Research Report No. 104 (February). Tokyo: National Institute for Science and Technology Policy (NISTEP) of the Ministry of Education, Culture, Sports, Science and Technology (MEXT). 文部科学省 科学技術政策研究所 第一研究グループ。研究開発戦略と科学技術政策」研究セミナー。報告論文集。

*Kneller, RW. 2003. Autarkic drug discovery in Japanese pharmaceutical companies: insights into national differences in industrial innovation. *Research Policy* 32: 1805-1827.

ロバート・ケネラー 2003 医薬品開発にみる日本の製薬企業の自前主義。医薬産業政策研究所の政策研ニュース No. 11 (7月)。 (Japanese translation of above)

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ロバート・ケネラー 2003 知的財産制度とイノベーション。後藤 晃・長岡 貞男 (編)。産学連携制度の日米比較(第2章)。 (Japanese version of above)

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ロバート・ケネラー、首藤佐智子 2001 産学間の技術移転における知的財産権の役割。研究開発マネジメント (6月)。 Kneller, R and Shudo S. 2001. The role of intellectual property in university-industry technology transfer. *R&D Management* (June) 30-45 (Japanese only).

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Kneller RW: University-Industry Technology Transfer in the United States. Tokugikon.
[a publication of the Japan Patent Office] 198:15-46 (March, 1998) (in Japanese and English).

Publications prior to Employment at University of Tokyo related to Science and Technology in Japan:

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**Protein Engineering in Japan: Report of a U.S. Protein Engineering Study Team on its Visit to Japan, November, 1992* (edited by Cassman M and Kneller R).

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You WC, Blot WJ, Zhang L, Kneller RW, Li JY, Jin ML, Chang YS, Zeng XR, Zhao L, Fraumeni JF Jr, Xu GW, Samloff MI. Serum pepsinogens in relation to precancerous gastric lesions in a population at high for gastric cancer. *Cancer Epidemiology, Biomarkers and Prevention* 1993; 2:113-7.

*You WC, Blot WJ, Li JY, Jin ML, Chang YS, Kneller RW, Zhang L, Han ZX, Zeng XR, Liu WD, Zhao L, Correa P, Fraumeni JF Jr, Xu GW. Precancerous gastric lesions in a population at high risk for stomach cancer. *Cancer Res* 1993; 53:1317-21.

*Kneller RW, You WC, Chang YS, Liu WD, Zhang L, Zhao L, Xu GW, Fraumeni JF Jr, Blot WJ. Cigarette smoking and other risk factors for the progression of precancerous stomach lesions. *J Natl Cancer Inst* 1992; 84:1261-6.

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You WC, Chang YS, Yang ZT, Xu GW, Blot WJ, Kneller RW, Keefer L, Fraumeni JF Jr. Etiologic research on stomach cancer and its precursor lesions in Shandong, China. In O'Neill IK, Chen JS, Lu SH, Bartsch H (eds.). *Relevance to Human Cancer of N-Nitroso Compounds, Tobacco Smoke and Mycotoxins*. Lyon, International Agency for Research on Cancer, 1991; 33-38.

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Publication based on Medical School Research:

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Publication on International Development Institutions based on Research during Law School:

Kneller RW: Human rights, politics and the multilateral development banks. *Yale Studies in World Public Order* [subsequently renamed the *Yale Journal of International Law*] 6:361-428, 1980.