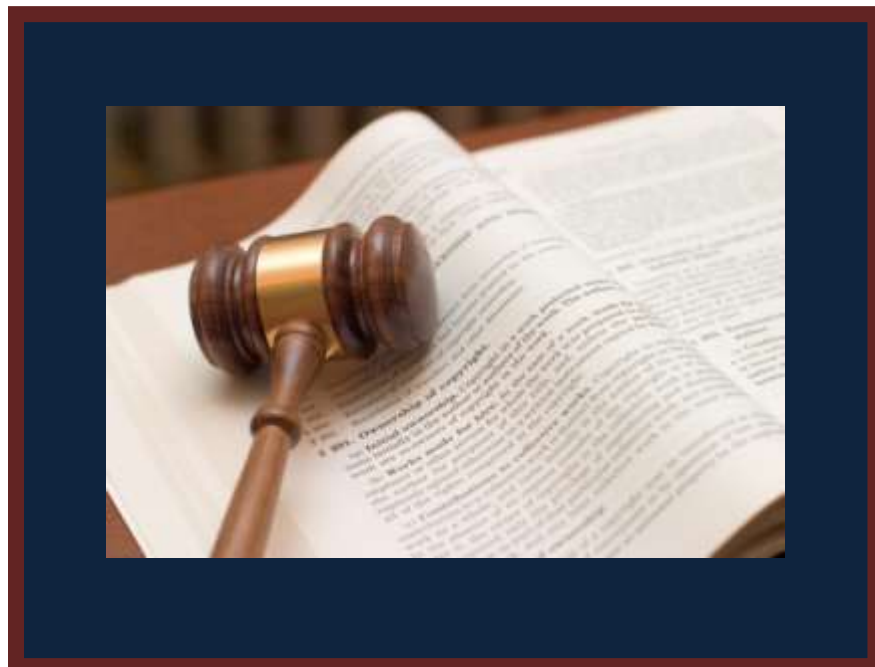


# WOMEN IN SCIENCE

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A Publication for Seattle AWIS Members • Spring 2011

## Intellectual Property





SPRING 2011

WOMEN IN SCIENCE

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## **Contents**

### **AWIS**

- 1 President's Letter
- 2 Program Summaries

### **State/Nation/World**

- 6 Product Development and Licensing News
- 7 Biotechnology and Pharmaceutical Industry News
- 8 State Government News

### **Opinion**

- 9 Op-Ed: The Need to Make Universities Deliver Global Solutions

### **Features**

- 11 Interview with Dr. Stephen Jones
- 12 From Scientist to Patent Attorney
- 13 Transferred
- 14 Protecting Intellectual Property: Can You? Or Should You? A Perspective from the University/Startup Interface
- 18 Leaving the Bench for the Board Room

**And....Fun Facts Throughout the Issue!**

# President's Letter

*By Ann Wilson*

## **WELCOME NEW AWIS MEMBERS! WE LOOK FORWARD TO MEETING YOU AT ONE OF OUR UPCOMING MONTHLY PROGRAMS.**

This issue of our quarterly newsletter focuses on intellectual property – a topic that is important as science is more quickly moving from the bench to the marketplace.

The research news and biotechnology/pharmaceutical industry news columns keep us in the know about local, state, and international product development and industry licensing.

Jessica Gigot interviewed Dr. Stephen Jones, Director of the WSU-Mount Vernon Research and Extension Center, who shares his views on public breeding programs, agricultural biotechnology, and intellectual property rights issues in plant breeding.

Three fascinating women share their career stories in the articles titled “*From Scientist to Patent Attorney*,” “*Transferred*,” and “*Leaving the Bench for the Board Room*.” Through these authors, Melissa M. Harwood, Jennifer S. McCullar, and Anna Lisa Somera, respectively, we learn about their paths from chemist to patent lawyer, from postdoc to technology manager in life sciences, and from life scientist to entrepreneur and venture capitalist.

Kjell Nelson, a research scientist turned entrepreneur, discusses the pros and cons of pursuing patent protection in the article “*Protecting Intellectual Property: Can You? Or Should You?*”

Aarthy Vallur provides an interesting opinion in “*Op-Ed: The Need to Make Universities Deliver Global Solutions*.” Should universities, as opposed to private industry, take the lead in developing and commercializing products?

In case you couldn't be there, read summaries of our winter monthly programs about the Gates Foundation and the HIV Vaccine Trials Unit, as well as our Amgen social.

*The Seattle AWIS board wants to **THANK ALL OUR MEMBERS** for their involvement. It has been great to see members bring their colleagues to our programs. We are very interested in having members join our board and provide fresh ideas in order to further our organization.*

*We are actively looking for a Vice-president and a Secretary and for Co-chairs for Programs, Newsletter, Outreach, Publicity, and GEMS committees. Please contact me through [president@seattleawis.org](mailto:president@seattleawis.org) for position details.*

**Ann Wilson**

# Program Summaries

## (February, March, and April)

February, By Dani Vinh

### The Gates Foundation: How to Help Defeat Global Health Challenges

In February, two Program Officers in the Global Health Program from the **BILL & MELINDA GATES FOUNDATION** spoke about ***how this philanthropic nonprofit helps alleviate diseases in the world***. In the first half of the presentation, Gretchen Meller discussed the Foundation's basic philosophy and approaches to grant giving. In the second half, Siobhan Malone described specific funding strategies for the HIV Prevention subprogram.

**GRETCHEN** obtained her Ph.D. in molecular and cell biology from the University of Virginia and previously worked as a research scientist at Targeted Genetics and in the Swedish Perinatal Research Group. **SIOBHAN** received a B.S. in science technology and international health from Georgetown University and an M.S. in epidemiology from the University of Washington. She received a Fulbright fellowship to do research on HIV prevention in the Ivory Coast and was also a project coordinator for the HIV Vaccine Trials Network at the Fred Hutchinson Cancer Research Center.

The Gates Foundation bases much of its grant funding approach on the belief that ***"all lives have equal value."*** They focus on issues that are of the utmost urgency and where they can make the most difference. For example, they do not fund cancer work because the NIH and other governmental agencies are already heavily involved. They encourage grantees to form new partnerships and to come up with scalable and sustainable solutions. But they also endorse risky, "crazy" ideas through the Grand Challenge with a seed grant of \$100K, followed by \$1M if successful.

***Besides infectious diseases, grants funded in the US Program focus on access to and readiness for post-secondary education.*** In the Global Development Program, the emphasis is on combating poverty by promoting agriculture, financial services, water access, and special initiatives such as aid to Haiti. In the Global Health Program, grants range from high-burden infectious diseases such as HIV and malaria to maternal/neonatal care and tobacco-related illnesses, with the main focus on prevention and immunization.

*Can you guess what the number 1 killer illness is in the world? Answer: pneumonia, with 1.5 million deaths/year, mostly neonates; number 2 is diarrhea with 1.3 million deaths/year.*

The HIV Prevention program funds research and technology that contribute to vaccine development, along with advocacy work and the dissemination of tools and methods for effective prevention. The goals are to lower incidence and increase life expectancy of people with HIV infections. The HIV vaccine substrategy complements NIH-funded grants to move more products through the pipeline.

*Continued on the next page.....*

# Program Summaries

After the first vaccine trial launched in 2003 was shown to have no effect, the community decided that a global vaccine approach was needed to bring together researchers in order to consolidate and share information and efforts. Together with the NIH, the Foundation funded many grants with the condition that worldwide investigators collaborate and share data, so information can be centralized and accessed. Thereafter, consortia were formed with many grantees working together towards similar goals. At annual meetings organized in Seattle, a shift towards trusting each other more was observed among the researchers. Other evaluation tools are also used to measure progress such as individual perceptions of how collaborations have affected their work, or how many publications or patents come out of the shared groups. The result of all this was a second vaccine trial that was launched in 2010 in Thailand that shows a *60% efficacy*. Moving forward, the Foundation is working together with the US government and Novartis to launch a much expanded vaccine trial.

During a lively Q and A session post-talk, a question was directed at what the daily routine for the Program Officers looks like and how much does the science background contribute to their day-to-day work. Their daily routine involves interactions with many grantees and management of the grants. There is lots of report reading and writing. The science knowledge is required for understanding the content and strategies of the grants. **Short answer: half strategy, half project management.**

*March, By Lisette Coye*

## **Engaging the Community in HIV Research: The Seattle HIV Vaccine Trials Unit Experience.**

For our March program, **DR. JANINE MAENZA, MD**, Clinical Director at Seattle HIV Vaccine Trials Unit (HVTU) spoke about her work.

HVTU is a program of the Vaccine and Infectious Disease Division of the Fred Hutchinson Cancer Research Center and University of Washington. It is the clinical trials unit of the HIV Vaccine Trials Network (HVTN). HVTN spans the globe with numerous sites in North and South America, the Caribbean, Europe, Africa and Asia with the commitment to finding a vaccine that will work for diverse populations. *The HVTN's role is to provide the scientific, management, and statistical expertise along with laboratories while the HVTU educates the public and recruits and enrolls volunteers.*

Located at the Cabrini Medical Tower in First Hill, Seattle HVTU initiated HIV trials in 1987 with HIV-negative adults between the ages of 18 and 50. The HVTU educates and recruits volunteers through the media, Internet and grassroots advertisements. In addition HVTU has an outreach team that keeps a presence in the community and actively educates and recruits participants.

In order to incorporate the community in the ongoing trials, HVTU assembled a Community Advisory Board (CAB) that includes a diverse group of people from the community including individuals who are HIV positive, vaccine trial participants, professionals, individuals from different ethnicities, homosexuals and transgender individuals. CAB gives advice on protocols as well as ethical issues at both the local and global level by participating in monthly meetings, serving on committees and attending conferences.

*Continued on the next page.....*

# Program Summaries

In addition, HVTU is continually striving to better understand the public perception of the vaccine trials by performing surveys. From these surveys they discovered several major misconceptions that include (1) the HIV vaccine contains the HIV virus, (2) the vaccine could result in HIV infection and (3) the participant must be HIV positive. This survey aided in developing the message that the vaccine will not result in HIV infection and that participants are HIV-negative.

Since 1990 the Seattle HVTU has enrolled 1110 volunteers with most of them receiving the active experimental vaccine. From 2005 through 2007 the Seattle HVTU recruited high-risk men who have sex with men (MSM) in a phase IIb HIV vaccine study. Currently, they have enrolled 98 volunteers for a phase II HIV vaccine study. They are also performing a twin study and actively recruiting twins to volunteer in a phase Ib trial to examine the role of host genetics versus the environment in determining the immune response to vaccination.

*To learn more about HVTU or to volunteer for the clinical trial, visit their website at [www.seattlevaccines.org](http://www.seattlevaccines.org) or call (206) 667-2300.*

*April, By Melissa Lerch*

## Amgen Social

As part of the **EARTHWEEK CELEBRATIONS** at the Seattle Amgen Inc. site, Seattle-AWIS came for a social hour to celebrate. Around 30 women from the local AWIS chapter joined Amgen employees to network during the first hour of the event. The featured speaker was **SUE ROONEY**, the executive director of the Friends of Cedar River Watershed (The Friends). The Friends engage people to enhance and sustain local watersheds through restoration, education, and stewardship. They have generated community-based volunteerism supporting habitat restoration, public education, and regional investment in the ecological health and integrity of the local watersheds, primarily the Cedar and Lake Washington basins. Sue joined the organization four years ago and brought new life and goals to the program. The big message from the event was to understand how your life is intertwined with the watershed that you live in. *“Do you know your watershed address?”* This is the pitch line that inspired high school students to become stewards of the environment and leaders in their community as part of the Watershed Report. The Friends are implementing an innovative approach to engaging these students to advocate for the environment and educate younger students.

*Continued on the next page.....*

# Program Summaries

Their other popular programs include habitat restoration along rivers, outreach to the public through Cedar River Salmon Journey, and installation of rain gardens at elementary schools as part of a learning tool to teach young children about the natural cycles of water. Volunteer naturalists educate the public at the Ballard Locks and on Cedar River to share the story of salmon and their diminishing habitat. The habitat restoration program has been successful at engaging local business in team building exercises. If your company is looking for a way to contribute, contact Sue Rooney for more information.

The cornerstone of the presentation was a video produced by the student leaders trained to be environmental ambassadors about the Watershed Report. It is a really great video and the first in a series of four that are available on their YouTube channel. I highly recommend watching them and sharing the link with your friends, colleagues, and students if you are an educator.

*Here is the link to the Award-winning Watershed Report video series:*

<http://www.youtube.com/friendsofcedar>

***Make every day Earth Day by being conscious of where your water comes from and where it goes. Learn your watershed address.***



*Sue Rooney at the podium.*

*Pictures provided by Melinda Jodry*



*Networking with Amgen Employees.*

## **Fun Facts - By Denise Inman**

Humpback whales sing a repetitive, stereotyped, but evolving song to attract mates and establish social hierarchy. Australian scientists recorded songs sung by male humpback whales and then documented unidirectional transmission of those songs to genetically separate social groups eastward around the planet. They confirmed the exchange of multiple songs over an 11-year period from whales in Australia to groups found near French Polynesia. Their research appeared in recent issue of *Current Biology*.

(doi:10.1016/j.cub.2011.03.019)

# Product Development and Licensing News

By Ashley Atwood

➤ **K2M, INC.**, a spinal device company, announced that their **EVEREST™ DEGENERATIVE SPINAL SYSTEM HAS RECEIVED 510(K) CLEARANCE FROM THE US FOOD AND DRUG ADMINISTRATION (FDA)**. A 510(k) cleared device is not “approved” by the FDA, but the clearance allows the device to be marketed and sold in the United States. The EVEREST device is a pedicle screw spinal fixation system used to help individuals with degenerative disc disease (or other spinal pathology) regain functionality.

➤ *K2M, April 27, 2011*

➤ **AID GROUP DOCTORS WITHOUT BORDERS** publicly criticized pharmaceutical company **JOHNSON & JOHNSON** recently for refusing to license three HIV drug patents to a program that makes HIV medications more cheaply available in developing countries. **ROCHE** and **GILEAD SCIENCES, INC.** have agreed to participate in the Medicines Patent Pool, but Johnson & Johnson stated that they prefer to provide access to their compounds via generic drug manufacturers.

➤ *Newark Star-Ledger, April 27, 2011*

➤ **VERTEX PHARMACEUTICALS'** stock price jumped 10 percent after an FDA review stating that **TELAPREVIR**, Vertex's experimental hepatitis C drug, combined with standard drug treatments, showed better clinical activity than the standard drugs alone. **VERTEX** and **MERCK & CO.**, among others, are each trying to be the first to offer hepatitis C drugs that are more efficacious and have fewer side effects than current drug regimens. Merck's drug, **BOCEPREVIR**, also showed improved activity compared to standard treatments. Both drugs are protease inhibitors that block a viral replication enzyme, but no clinical studies so far have compared the two drugs directly. Both drugs are likely to gain FDA approval and may reach the market this summer, with a combined projected 3-year revenue of over \$6 billion.

➤ *News-medical.net, April 26, 2011*

➤ **R**esearchers at the **LOS ALAMOS NATIONAL LABORATORY** have filed a patent application for a low-cost non-precious-metal catalyst that can replace expensive platinum in hydrogen fuel cells. In a project funded partially by the US Department of Energy (DOE)'s Office of Energy Efficiency and Renewable Energy, the team developed a carbon-iron-cobalt catalyst yielding high power output, efficiency, and longevity. Further research is planned to better understand the mechanism behind the catalyst.

➤ *DOE/Los Alamos National Laboratory, April 25, 2011*

➤ **U**nder a licensing agreement with **NOVARTIS, MYLAN PHARMACEUTICALS** has launched **LETROZOLE** Tablets USP, 2.5 mg. Mylan was the first company to file a substantially complete ANDA (Abbreviated New Drug Application) containing a certification for Letrozole Tablets and will enjoy a period of exclusivity in marketing the product. Letrozole is the generic formulation of **NOVARTIS' FEMARA®** tablets, a treatment for hormone receptor-positive breast cancer. Mylan currently has 46 first-to-file pending ANDA applications representing almost \$26 billion in annual brand sales.

➤ *Mylan, Inc., April 25, 2011*



By Cathy Manner

**A** Phase II, randomized, double-blind clinical trial of **NEUROSIGMA, INC.'S** external trigeminal nerve stimulation (*eTNS™*) therapy demonstrated significant seizure reduction and improved mood in people with drug-resistant epilepsy, according to data presented at the Antiepileptic Drug Trials XI Conference in Miami. The TNS technology was invented at the University of California, Los Angeles. NeuroSigma, which is also developing an implantable seizure therapy known as *sTNS™*, holds an exclusive worldwide license for the TNS intellectual property.

➤ *BioSpace, April 29, 2011*

**H**ORIZON PHARMA, INC. has received US FDA approval of **DUEXIS®** for the relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis. DUEXIS is a novel formulation of ibuprofen, a pain reliever, and famotidine, which decreases the amount of acid made in the stomach. In two pivotal clinical trials of over 1,500 patients with mild-to-moderate pain or arthritis, individuals taking DUEXIS developed significantly fewer upper gastrointestinal ulcers than those receiving ibuprofen alone. This is the company's first US regulatory approval.

➤ *BioSpace, April 25, 2011*

**N**OVARTIS AG is discontinuing the development of *Tasigna* as an initial treatment for patients with gastrointestinal stromal tumors (GISTs) because the drug is unlikely to be more effective than another Novartis drug, *Gleevec*, that is the current standard of care. Interim analysis of a late-stage trial revealed that GIST patients taking *Tasigna* were not likely to live longer than those taking *Gleevec*. Novartis had hoped that *Tasigna* would be able to fully replace *Gleevec*, the company's second-best selling drug, when the latter loses patent protection in a few years.

➤ *Wall Street Journal, April 12, 2011*

**G**ILEAD SCIENCES, INC. has signed a licensing deal with **MICRODOSE THERAPEUTX, INC.**, to co-develop *MDT-637* for the treatment of respiratory syncytial virus (RSV). RSV, the most common cause of lower respiratory tract infections in infants and young children, also infects about 8.5 million adults annually. Gilead will provide an upfront payment and research funding to support development through Phase IIa clinical trials, and then take over development thereafter. MicroDose may also receive milestone payments, development fees, and royalties on future potential sales.

➤ *Bloomberg Businessweek, April 20, 2011*

**L**aquinimod, **TEVA PHARMACEUTICALS'** new oral medication for multiple sclerosis (MS), was found to slow disease progression, reduce brain atrophy, and decrease the relapse rate compared to placebo in a Phase III trial. The drug was safe and well tolerated in the study, which involved over 1,100 MS patients in 24 countries. Although these data are encouraging, the study has not yet been published in a peer-reviewed journal, and the drug still needs to be compared head-to-head with other MS treatments. Should laquinimod eventually be approved for use, it would be only the second oral MS drug on the market; all other approved treatments must be injected.

➤ *Bloomberg Businessweek, April 11, 2011*

By Denise Inman

**S**tate Senator **LISA BROWN** (3rd Legislative District, representing downtown Spokane) introduced a bill (Senate Bill 5449) this legislative session to strengthen intellectual property laws in Washington state. The bill passed the Senate on *March 3, 2011* and now waits second reading in the House. According to Senator Brown's office, intellectual property related to software piracy threatens the state's \$14 billion information technology sector.<sup>1</sup> Nearly 200,000 Washington residents employed by 1,500 companies in the state work in information technology. Although software piracy rates hover at 20 percent in the United States,<sup>2</sup> ***a major threat to intellectual property is abroad.*** Senator Brown notes that the rate of intellectual property theft in China can be as high as 90 percent. Christopher Bodeen of the Associated Press reports that Chinese courts have heard 40 percent more intellectual property cases in 2010 than in 2009, covering property valued at \$1.2 billion.<sup>3</sup> However, the increase included few cases related to foreign firms' intellectual property. ***Senator Brown hopes that strengthening laws in Washington will encourage the federal government to pursue the issue.*** The United States has complained to the World Trade Organization (WTO) that China's unwillingness to prosecute intellectual property theft amounted to violation of trade agreements. In 2009, the WTO agreed. In response, Chinese courts have increased copyright disputes hearings, which comprise more than 50 percent of cases filed.

**SENATE BILL 5449** was written to address the unfair competition from the theft or misappropriation of information technology used to manufacture products sold within the state.<sup>4</sup> The bill also describes the penalties for violating this law. The law does not apply when the end product is copyrightable or is a product to which a copyright owner has granted license. Nor does the law supersede existing federal law in the enforcement of copyright. Alleged violators of the new proposed law must be notified in writing of their alleged violation by the owner or exclusive licensee of the information technology and are given 90 days to respond or comply. The law empowers the state Attorney General to prosecute violators. Damages are awarded to the owners of the information technology according to the egregiousness of the violation.

*Sources:*

- 1) [http://www.sdc.wa.gov/senators/brown/enews/e-news\\_3-6-11.pdf](http://www.sdc.wa.gov/senators/brown/enews/e-news_3-6-11.pdf)
- 2) [http://www.nationmaster.com/graph/cr\\_i\\_sof\\_pir\\_rat-crime-software-piracy-rate](http://www.nationmaster.com/graph/cr_i_sof_pir_rat-crime-software-piracy-rate)
- 3) <http://www.theolympian.com/2011/04/19/1621818/china-court-hears-more-intellectual.html>
- 4) <http://apps.leg.wa.gov/billinfo/summary.aspx?bill=5449&year=2011>

# Op-Ed: The Need to Make Universities Deliver Global Solutions

By Aarthy Vallur

**R**esearch in universities, especially in the biomedical sciences, relies heavily on the US government's funding agencies, including the National Institutes of Health (NIH) and the National Science Foundation (NSF). Further, even private sources of funding largely channel public donations, meaning that almost 99% of research support comes from taxpayers. Redeeming features of public research include open publication, sharing of resources, and the non-profit nature of the endeavor. *But in times of increasing emphasis on "developing solutions," whether technology or products, can public-domain research solutions compete with private industry's large capacity and marketing skills?* From the Bayh-Dole Act, created in 1980 to even out patent rules for non-profits and public universities, universities have come a long way, especially driven by the technology boom of the 1990s and the human genome sequencing experience. Certain prickly considerations still remain, given the pressures created by the collaborative and broad nature of research in the public domain and the complexities of identifying what indeed is patentable. But I want to draw your attention to why public-domain research is really necessary today, despite the real concerns over commercialization that scientists have.

*When it comes to living organisms, what is patentable has still not been resolved. What separates "discovered" from "invented" in this context?* These gray areas emerged in the 1980 decision by the US Supreme Court in *Diamond v. Chakrabarty*. Ananda Mohan Chakrabarty, a microbiologist working for GE, genetically modified a bacterium to confer oil-feeding capabilities. He was refused a patent because "natural living things" were not patentable by law. In a landmark 5-4 decision, the Supreme Court upheld the patent because a "genetically" modified organism is not natural, with no guidelines to define "modification." What is controversial is not the concept of patenting anything "modified," but the sheer lack of clarity when dealing with living organisms and their complexity. Throw in the complexities of globalization, and you get the big picture. Take the case of RiceSelect of Texas, which has introduced various hybrid varieties of rice into US supermarkets, beginning with the controversial Texmati® to the more recent Jasmati®. Cloning genes from widely available and native rice forms from countries that do not allow aggressive patenting of native foods, RiceSelect created and trademarked these varieties based on the fact that "they are engineered." Is this effectively cheating the millennia-old natural rice species of the East and the generations of growers there, who do not benefit from these trademarks but have been inadvertently blindsided by technology?

Moving to a more serious issue of global reach, giant conglomerates like Monsanto have been allowed access to international markets under trade treaties, with little regulation of what they are selling as "natural" and "improved." In India, this controversy ignited hundreds of bankruptcy-propelled suicides over cotton seeds sold by Monsanto to farmers.

By Aarthy Vallur

And coming to the really serious issue of global pharmaceuticals, can we trust profit-oriented drug companies to lead equitable drug distribution? Or do legal loopholes allow them to aggressively acquire improper patents and choke the development of affordable generics, thus denying life-saving medicine to the most needy populations in the developing world? This is the question that has really propelled demands that the public sector -- which requires stringent peer review, open publication, and resource sharing - and not the pharmaceutical industry take the lead in developing and commercializing technology and products. ***For this to happen, well-defined intellectual property sharing and patenting rules are essential.*** Such rules will enable ethical commercialization of inventions, defray the costs associated with scaling up a laboratory invention, and provide ways for open research to compete. Towards this end, existing intellectual property rights, between the researcher and the university as well as the researcher and the funding agency, need to be made more transparent and equitable. More important is to even out rights among the members of a research group, since life sciences research is so broad-based and collaborative. A new demand for "humanitarian licensing" to modify current laws to reflect compassionate licensing and commercializing of a lifesaving procedure or product has also developed across university campuses. If these movements succeed, it would not only put an end to the wide gap in communication between academia and lay people regarding taxpayer-funded research, it would also reinvigorate our cash-strapped national funding agencies that have borne most of the global costs of leading scientific research.

#### References:

1. T. A. Caulfield. 2003. *From human genes to stem cells: new challenges for patent law? Trends in Biotechnology 21: 101-103.*
2. B.N. Sampat. 2010. *Innovating for development: research locally, diffuse globally? American universities, patents and global public health. Journal of International Affairs 64:69-82.*

*Aarthy Vallur is a Senior Fellow at the University of Washington*

#### **Fun Facts - By Denise Inman**

Fog harvesting may provide water to drought-stricken areas and the poor. By borrowing a concept used by the desert beetle *Stenocara gracilipes*, Shreerang Chhatre, an engineer at the Massachusetts Institute of Technology, wants to capture water in morning fog for use by people who live in arid climates, especially the poor. The fog harvesting device is a mesh panel that attracts, but also can release, water droplets. Field tests of the mesh with this unique combination of properties yielded 1 liter of water for every square meter of mesh each day. (Massachusetts Institute of Technology. "Development in fog harvesting process may make water available to the world's poor." *ScienceDaily*, April 21, 2011. Web, April 22, 2011.)

# Interview with Dr. Stephen Jones,

*Professor of Crop and Soil Science at Washington State University (WSU) and  
Director of the WSU-Mount Vernon Research and Extension Center*

*By Jessica Gigot*

**THE PLANT BREEDING PROGRAM** at WSU-Mount Vernon (<http://plantbreeding.wsu.edu/>) concentrates on crops that fit into diverse annual and perennial rotations on small and mid-sized farms. Farmer participatory approaches and other innovative methods are utilized to improve crops such as small grains. Research is prioritized to favor producer groups and crops that are not being served by conventional research programs and approaches.

**DR. JONES** received his Ph.D. in genetics from the University of California, Davis, in 1981. At WSU-Pullman, he has been a wheat breeder and has released several new winter wheat varieties throughout his career. He named the wheat variety "**Xerpha**" after Xerpha Mae Gaines (1891-1970), a WSU alumna, botanist, taxonomist, and weed scientist, in honor and recognition of her vast and lasting contributions to agriculture and science at WSU and in the Pacific Northwest. Now director of WSU-Mount Vernon, the goal of his research is to breed improved wheat varieties (and other crops) for traditional and organic systems that incorporate diverse rotations and systems. His research has been mentioned in *Audubon*, *Newsweek*, *The Wall Street Journal*, National Public Radio, Bill Nye the Science Guy's PBS show "*The Eyes of Nye*," CBS News, the documentary film "*Not For Sale*," and other national and international news journals.

*Currently he has several Ph.D. students with research programs focused on wheat breeding, perennial wheat, nitrogen-use efficiency, and organic grain production. His program will be hosting the Kneading Conference West this fall to discuss more issues with local grain quality and use: <http://kneadingconferencewest.com>.*

## **IN A SHORT INTERVIEW WITH DR. JONES, HE DISCUSSES THE FUTURE OF PUBLIC BREEDING AND INTELLECTUAL PROPERTY RIGHTS ISSUES.**

*How long have you been a public plant breeder? Describe the crops you have worked with.*

- I have been involved in wheat breeding programs since 1981. I've worked for the US Department of Agriculture (USDA), a private breeding company, and two university programs.

*How many public plant breeders have active breeding programs in the US?*

- The best answer is fewer than there were. I know it is not much of an answer, but there is less support from the states and federal government for breeders who release varieties to the public. The trend is to commercialize what is produced to bring money back into research programs.

*What is the main intellectual property rights issue facing plant breeders?*

- To me it is ownership of what we produce. I feel that whatever a public program produces should stay in the public realm. Private researchers can lock up whatever they want, that is fine, but if the public pays for research to occur, it should be freely available.

*What is the future of biotechnology in agriculture? How could this impact western Washington?*

- It will be here from now on, the question is what will it look like? If it did not have the ownership issues tied to it in terms of restricted access of knowledge and materials, the impacts could be positive. As it is, to predict the impacts is difficult. What I feel quite strongly, though, is that we can do just fine without it. If you look at what 30 years and billions of dollars of R&D have yielded, it is surprisingly little. Practical plant breeding is still a powerful tool for crop improvement.

*Jessica Gigot is adjunct faculty at WSU-Mount Vernon (Northwestern Washington Research and Extension Center) and a faculty member at Northwest Indian College-Swinomish. She owns a small farm in Bow, WA called Harmony Fields that grows mixed herbs and vegetables and is interested in future research projects related to soil quality and food production systems.*

# From Scientist to Patent Attorney

By Melissa M. Harwood, Ph.D., J.D.

*After devoting 11 years of my life to the study of chemistry, I made what many would consider a dramatic change and decided to become a patent attorney.* It is difficult to recall the particular moment or reason that I decided to become a patent attorney, although I remember being intrigued as a child by the fact that my dad was an inventor and patent holder. Ultimately, however, I think I decided to become a patent attorney when I realized that the things I enjoyed most about science involved scientific analysis and writing. I correctly assumed that a patent attorney would spend a considerable amount of time doing both analysis and writing.

Before making the transition to patent law, I spent significant time researching the field to be sure it was right for me. I talked to several patent attorneys and law professors, I read about patent law and the Patent Bar Exam, and I took a few intellectual property courses through the University of Washington. Being satisfied with everything I had heard, I made the decision to become a patent attorney and have never regretted it since.

While a scientist or engineer can work as a patent agent by passing the United States Patent and Trademark Office's (USPTO's) Patent Bar Exam, most people in this field will opt to attend law school and become patent attorneys. To become a patent attorney, a number of steps are required, including: taking the Law School Admissions Test (LSAT), completing law school, passing the state bar exam, and passing the Patent Bar Exam. Because the Patent Bar Exam can be taken prior to the completion of law school, I opted to take the Patent Bar Exam during law school. This provided me additional opportunities to work at a law firm during law school as a patent agent. Of all the things I learned during law school, I have always considered my work experience as a patent agent during that time to be the most valuable.

*People often ask me why I decided to change from a career in science to a career in law.* They wonder why I would bother getting a Ph.D. in chemistry and then transition into law. The great thing about working as a patent attorney, however, is that *I get to wear the hats of both a scientist and a lawyer.* I spend much of my time talking to scientists, reading about science, researching science, analyzing science, and writing about science. Because of the wide breadth of technologies that I have been fortunate enough to work with, *I believe being a patent attorney has made me a better scientist.* In this sense, I have never felt that I have left my science career behind.

In addition to working closely with innovators and their new technologies, I am fortunate to work in an exciting and fluid area of the law. There are few areas of law that have the profound impact that patent law has in our economy. A patent system that is either too strong or too weak significantly diminishes the incentives for innovation; and it is exciting to see how these two extremes are balanced in Congress and the courts. For instance, the Myriad Genetics case now being appealed before the Federal Circuit is an example of an important case that will have a significant impact in the biotechnology space. The Myriad Genetics case deals with the patent eligibility of isolated DNA sequences and weighs the balance between creating incentives for innovators and providing free access to DNA. *The Myriad Genetics case is just one example of the groundbreaking impact that patent law can have in our country, and in particular, the personalized medicine industry.*

In addition to my roles as an attorney and technologist, I am often fortunate to serve as a business advisor to my clients. For most of my clients, patents are their most significant business assets. The success and ultimate value of my clients' companies depend strongly on having strategic patent protection. When it comes down to it, the greatest part of my job *is having the opportunity to assist my clients in developing strategic patent portfolios that add value to their companies and watching them succeed as a result of those efforts.*

# Transferred

By Jennifer S. McCullar, Ph.D.

**Like many of you, I have been trained in academics.** My research experiences started as an undergraduate and continued through bachelor's and master's degrees, a doctorate and one and a half postdocs. Now I find myself at the University of Washington (UW) Center for Commercialization (C4C), evaluating commercial opportunity in innovation and helping academics venture into the commercial world. *How did I get here?*

There will always be moments in our lives that we look back on and recognize as decision points. With experience, we learn to identify those times when they occur and can make choices that will precipitate change in a new or needed direction. For me, it was a combination of factors that led me onto a new career path that I never knew I loved.

My first postdoc ended for funding reasons after a short 13 months. Having just relocated to a new city and gotten established, my priority at that time was to find another local postdoc that would broaden my expertise. During my second postdoc I gained experience working in animal models; it was much closer to clinical research than I had been before. I learned a lot, did my research, wrote grants... all the typical events one expects in a postdoctoral experience. The funding ran out again, but it had been a reasonable three years, it was at a fairly timely point in my research, and I had about a year to prepare.

**The next steps led me to the amazing job I have now.** And while the endpoint might not be the same for every person (not everyone wants to be in tech transfer), I feel like the road I took could be helpful to others preparing for a transition to a new field.

1. Join a professional organization – Joining AWIS was my first step in integrating myself into networking opportunities. It provided me with contacts who were well versed in helping people make connections. After attending for a few months, I joined the board, both to try new things and to add some value back to the organization I felt was propelling me along my path.
2. Reflect on how "spare" time is spent – This was probably the most direction changing. When I talked to other postdocs, I realized they were filling their time with side research collaborations and I was filling mine with new journal clubs, science organizations and outreach events. It became clear to me then that I should be looking for facilitative roles in science.
3. Gather information – I participated in informational interviews, individual/group mentoring, and short courses in fields I thought I would like to explore. I set out in all these tasks with the idea of learning more about a potential new field and meeting people in that field to get firsthand information about their jobs.
4. Try it out – The best decision I made was to volunteer in the field in which I had the most interest. I cannot recommend this highly enough. It validated and reinforced my interests, and it provided networking opportunities and great experience. In my case, my internship at the UW C4C, combined with my excitement for the job, led to an opportunity to work for the department as a temp and eventually to a permanent hire.

I still pinch myself to see if it is real, a job I love every day that keeps me involved in the most cutting edge science coming out of the university. I certainly realize that luck was a factor in being at the right place, at the right time, with the right attitude... but in the two years from first notice regarding the imminent end of research funding to the last day as a temp, the steps I had taken along the way contributed enormously to being in that right place. If you are interested in volunteering for UW C4C, we interview for interns year-round. The information can be found at <http://depts.washington.edu/uwc4c/about-c4c/jobs-at-c4c/#intern>.

*Jennifer S. McCullar, Ph.D. is a Technology Manager in Life Sciences at the University of Washington Center for Commercialization. She also co-organizes Science on Tap (Ravenna) and is on the Seattle AWIS board.*

# Protecting Intellectual Property:

## Can You? Or Should You?

### A Perspective from the University/Start-up Interface

*By Kjell Nelson, Ph.D.*

*It's been said that necessity is the mother of invention. That's often true, but in my experience, it isn't always. Sometimes in the course of scientific investigation an invention is made; only then the question is asked: is it necessary?*

I believe that what drives invention in an academic environment is often very different from the forces at play in the private sector. Academic research is nothing if not cutting edge. Cutting-edge research often leads to innovation, but not all innovations ought to be patented. In my view, the principal consideration as to whether to seek patent protection for novel intellectual property (IP) is this: ***Does a compelling market opportunity for the technology exist?***

Today I am an entrepreneur. Two years ago I was a research scientist. My journey away from academia and into the private sector was principally motivated because I helped to invent and patent a novel solution to a problem for which (I believe) there is a substantial unmet need in the marketplace. Further, I felt that this new technology holds sufficient promise to justify the difficult challenge of fully commercializing it. So I left academia and formed my own company (*Assay Dynamics*) to license the technology to build a business around it. Since then, as the business model is refined and prototype development continues, I (alone and in partnership with others inside and outside my organization) continue to develop new IP and seek patent protection for it. Thus, I have had the opportunity to consider the pros and cons of pursuing patent protection for my own and others' inventions from a number of different and complementary perspectives: as an inventor, as a licensee, and now as the leader of a small start-up company seeking investment capital.

*I've been asked to share some of my experiences and perspectives for the benefit / amusement of those who may also have conceived something novel, non-obvious, and useful (all requirements for a patentable invention) and are considering whether to apply for patent protection for their invention.*

**Some background:** I am an inventor on three issued US patents and am listed on a patent application currently under review<sup>1</sup>. Because these inventions were developed while I was a graduate student or staff at the University of Washington (UW), I was obliged to assign all my rights to any inventions to that institution. I am currently working out the terms to license some of that technology from UW through the Center for Commercialization. And since leaving the University, I contributed to the development of additional IP in partnership with a team of researchers engaged with another private entity; together we and our counsels are drafting a patent application for this invention and are negotiating how to share the rights to it. *As a result, I have taken "inventive steps" and filed patent applications both as a researcher working for a large institution and also as an entrepreneur.*

<sup>1</sup> *Most of this work is centered on devices and methods for microfluidic immunoassays, although one patent is a "composition of matter" (an engineered protein), and another is an electrochemical signal amplification technology. Due to space constraints, I won't discuss other forms of intellectual property such as trademarks, copyrights, or trade secrets here, and unless noted otherwise I will focus mainly on pursuing patent protection in the US.*

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It's worth noting that I'm no expert and space is limited; fitting my experiences and perspectives into the larger context of the vast smorgasbord of information on protecting IP that is readily available on the web is quite a challenge<sup>2</sup>. What I feel I can best offer is how my perspective on protecting IP has changed as my relationship to that IP has evolved. It is my hope that by sharing these perspectives I might help guide the thinking of others who are considering seeking patent protection for their intellectual property from whatever relationship they may have with it, either as an academic researcher or as an entrepreneur (especially one on a tight budget!). I think the primary difference between the two can be put like this:

#### *Can you or should you pursue patent protection for your idea?*

As a researcher employed by the University, the question was: "Can I report an innovation?" It is common for institutions with a strong R&D focus (such as universities and biotech start-ups) to require the disclosure of all inventions (and all rights thereto) that the employee conceives while at work for the employer. It is the employee's responsibility to recognize whenever they have made an inventive step and, if so, to disclose the invention; the responsibility to choose whether to pursue patent protection belongs to the employer. In most instances the IP manager at the institution will seek the inventor's help to fully describe both the technology and its potential applications in order to make the decision as to whether or not to file a patent application. In many cases, the decision will strongly depend on whether the technology manager has confidence that some entrepreneur or company will try to commercialize the IP. Otherwise, the patent will simply cost money to languish until it expires or is abandoned.

Because academic researchers are strongly motivated to publish important new findings or technology, and because public disclosure limits or forfeits outright the right to patent<sup>3</sup>, *a provisional or full patent application must be filed with the patent office before presenting your exciting new results at a conference or submitting a manuscript for peer review*. The pressure to publish as soon as possible, and yet still protect potentially valuable IP, often leads to filing a "provisional" patent application for a general concept that hasn't yet been fully developed. This gives the inventor 12 months to further develop the technology and come up with a more carefully drafted set of claims for the full application. (This provisional patent application might then be useful later if you needed to argue you were the first to invent in case a competitor claims priority and has filed a full application before you did).

<sup>2</sup>A cursory initial toe-dipping can begin here:

<http://www.uspto.gov>

<http://www.mcw.edu/OTD/router.asp?docid=10538>

[http://www.patenthawk.com/blog/2005/06/when\\_is\\_an\\_invention\\_patentabl.html](http://www.patenthawk.com/blog/2005/06/when_is_an_invention_patentabl.html)

<http://inventivestep.net/2010/07/13/conception-and-reduction-to-practice/>

<http://inventivestep.net/2009/11/05/should-you-file-a-patent-application-now-or-can-you-wait/>

<sup>3</sup>In the US, inventors have up to one calendar year from the date of the first public disclosure to protect their rights to that IP by filing a completed patent application.

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This approach has risks and, some would argue, questionable benefit. For instance, patent applications are made public after 12 months, and, once available, the text of the application can teach potential competitors a great deal about the basis for your technology. If the claims are not carefully drafted, or are not broad enough, it may be relatively easy for them to “invent around” your IP, and potentially avoid the early R&D that you did to develop the technology from the ground up. Therefore, the “file early and often” approach can undermine efforts to develop and protect a competitive advantage if the technology isn’t well developed before the patent application is filed. On the other hand, taking the time to carefully develop the technology before a public disclosure risks the chance that your competitor (who can afford a team of postdocs) will publish first!

What often happens in this case is that the researcher quickly drafts an application and then “throws it over the fence” to their IP manager at the institution’s technology transfer office. Because the IP manager usually needs additional input from the researcher to evaluate the commercial potential of the invention, it is important for the researcher to try to stay realistic about the prospects for turning the new technology into a successful product. It’s not uncommon for inventors to think that their new idea is the greatest thing since oxygen, which, unfortunately, rarely plays out in the marketplace, but can lead to their convincing the IP manager, resulting in the consumption of much time and energy scrambling to prepare a patent application for something with little actual market potential. *This leads to “empty calories” in patent portfolios, which cost a lot of money to build and sustain but have relatively little value.*

Looking at it from the standpoint of actually commercializing new technology, it’s worth making plain that raising private investment to commercialize any potentially valuable technology is basically impossible if there is no sustainable competitive advantage, which is often obtained through key patent protection. So, in this sense, even patent applications themselves can be an important arrow in a start-up’s quiver, provided, of course, that there is a solid business that can be built around the technology. The lead time gained by doing the initial development of novel technology within an academic institution (particularly large ones), with their research facilities and IP budgets, can provide significant lead time on the painful early stages of commercialization, especially those undertaken by start-ups, leading to issued patents that are particularly attractive to investors.

This leads to a summary of some of the primary factors that a start-up may consider in deciding whether or not to pursue patent protection for their novel IP: *what are the general outlines of a business model that might successfully “monetize” the invention?*

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Though it takes a great deal of effort to develop a solid business plan around a given market opportunity, the absence of even an outline makes it extremely difficult to answer the questions that are associated with seeking to protect and license intellectual property, such as:

- 1 **Who are your competitors?** (Who holds IP in this space?) How does your invention differ from theirs? Do you have “freedom to practice” your invention in view of existing IP?
- 2 **How big is the market?** Can you build a successful business around a small market? Do you need patents to do so?
- 3 **What are the broadest possible claims for your invention?** Do these claims represent a key “gating” technology, or are there relatively simple ways to “invent around” them?
- 4 **How fast is the market changing?** Can you wait for IP protection, or should you simply keep it a trade secret and stay ahead of your competitors by the sheer velocity of your innovations?
- 5 **What is your market entry strategy?** Do you wish to pursue global or just US patent protection?
- 6 **Can you build out your IP portfolio around your core technology?** Is this an opportunity to license your invention out, build a single product, or a whole company around the core IP?
- 7 **What are the general terms for licensing IP from the assignee?** Maintenance fees and other costs of IP can be onerous, and it is difficult to know what to negotiate for unless your business plan is thoroughly worked out.
- 8 **Will this help secure investment?** Can you convince your investors that you have a strong competitive advantage and favorable license terms (e.g., do you have exclusive, perpetual, global rights in all fields of use)?

Of course this isn't an exhaustive list, but if your answers to these key questions are not clear, it may be a better use of time and resources to clarify the market opportunity, and whether your invention fits within it, before deciding whether or not to seek patent protection for it.

*In summary, in my view the best patents to pursue are those that cover key enabling technology that permits one to solve a difficult problem for which a large market clearly exists, and for which the general concept of a viable business plan has already been worked out.*

If at all possible, research should be conducted in close collaboration with entrepreneurs who (ideally) have the resources and experience necessary to execute on a commercialization plan, whether the inventor works in academia or not.

*Questions or comments?* Feel free to contact me at [kjell@assaydynamics.com](mailto:kjell@assaydynamics.com).

# Leaving the Bench for the Board Room

By Anna Lisa Somera, M.S., MBA, MPH

**ASKING CHILDREN WHAT THEY WANT TO BE WHEN THEY GROW UP IS A TIMELESS QUESTION.** For a long time I thought I wanted to be a doctor because, for the most part, the career is straightforward, easily recognizable, and highly regarded. I never once thought I would be an entrepreneur, a career often filled with a significant amount of risk, uncertainty, and turbulence. *Seven years ago I took the leap. I left my career path in science and jumped into the “fiery pit” of entrepreneurship and have not once regretted my decision.*

Life science is my comfort zone, and I planned my life around it. I thought that after getting my graduate degree in cell biology and anatomy, I would get a great postdoc position, work at a prestigious institution as an academic, and publish in top-ranking journals. As graduation neared, something about that career plan did not seem right for me. I certainly enjoyed research, but my curiosity extended beyond the lab. I wanted to understand the entire process of research, not just the science part. I wanted to know how something discovered by a scientist becomes a blockbuster drug or device. The business behind science was a hazy, yet fascinating cloud to me at the time. *So I decided the day before graduation that I wanted to go to business school and traded in my lab coat for a business suit.*

I enrolled in a dual master’s degree program in business and public health a few months after I graduated with my first master’s degree. In addition to my full-time course load and involvement in student leadership groups, I also worked 20 hours a week at the university’s licensing office, where I was first introduced to the field of technology commercialization. My job involved evaluating the technical merit and patentability of potential drugs, devices, and diagnostics coming out of the Colleges of Medicine, Pharmacy, Public Health, and Engineering.

My second year of graduate school solidified my decision to pursue a career in technology commercialization when I started a medical device company called **ORTHOACCEL TECHNOLOGIES** with 4 other MBA students. I served as the Director of Scientific and Regulatory Affairs, and our business revolved around a proprietary device in the dental field that expedites the treatment time for people wearing braces. The business was a win-win situation for orthodontists and patients. Faster treatment times meant that orthodontists could enroll more patients and patients could get their braces off a lot sooner than expected.

What began as a class project where we worked with faculty on campus in order to develop a business, quickly evolved into something greater than we ever thought possible. While we were still students, employed in other jobs and had family commitments, my team and I pitched our company to investors and competed in a number of business plan competitions all over the country. Although we never won a competition, we walked away with much more than accolades and short-lived press could ever give. OrthoAccel was acquired in 2007 by a Houston-based firm, and the product, *Acceleident*, is being sold in many parts of the world. Additionally, the Company recently submitted a regulatory application to the FDA to gain clearance for sale in the USA.

# Leaving the Bench for the Board Room

By Anna Lisa Somera, M.S., MBA, MPH

The excitement of the start-up environment wasn't something that I was ready to let go of after selling OrthoAccel. Pitching to investors spurred my interest in the field of venture capital. I wanted to know what it was like to sit on the other side of the table. I wanted to learn everything about the due diligence process, the management of deal flow and portfolio companies, and the financing behind companies that were "home runs." Shortly after leaving OrthoAccel, I joined the life science practice of **ILLINOIS VENTURES**, an early stage venture capital firm. Breaking into venture capital ("VC") was no easy task. Jobs in VC are almost never up on career websites. I did a lot of networking at life science events to get my foot in the VC door. Once you're in, however, the opportunities are abundant. At IllinoisVentures, I played a pivotal role in the evaluation, formation, and investment of several medical device and pharmaceutical companies. Additionally, I acted as interim management to many of these ventures and played an active role in the research and development, intellectual property, regulatory, reimbursement, business development, and marketing activities.

*After four years of working in venture capital, I decided to branch off on my own for a number of reasons.* Managing a life science portfolio and deal flow simultaneously is not an easy task. I felt I needed to give more attention to companies that my firm actually put money in rather than ones that we were still evaluating. Focusing on 3-4 companies rather than 8-10 made more sense to me, so I left a stable job to work as an independent consultant to a few companies that I helped start.

*I have been working for myself for 9 months now and love being an entrepreneur again.*

## Fun Facts - By Denise Inman

There is a new classification scheme for humans— enterotype! Researchers at the European Molecular Biology Laboratory in Heidelberg, Germany, screened gut bacteria from more than 400 people and determined that each person fell into one of three categories. A person's "enterotype" is the collection of gut bacteria they harbor. The scientists sequenced the fecal biomes of volunteers and learned that certain species predominated. The three clusters include people whose intestines are dominated by a different bacterial genus: 1) *Bacteroides*, 2) *Prevotella* or 3) *Ruminococcus*. There is no overall correlation between bacteria that a person hosts and his gender, race, age, or culture, although some bacterial genes turn up, for example, in aged populations while other bacterial functional groups were found preferentially in people with certain body mass indices. These data suggest that people have settled into "well-balanced host—microbial symbiotic states" that may indicate future targeted approaches to medical treatment depending on a patient's enterotype.

(<http://www.nature.com/nature/journal/vaop/ncurrent/full/nature09944.html>)

# Leaving the Bench for the Board Room

By Anna Lisa Somera, M.S., MBA, MPH

Many people have the misconception that I lie in bed and watch television all day since I work for myself. This could not be further from the truth. My work day starts at 7AM and often lasts until the late evening news. My computer monitor has about 15 post-it notes on it and my cell phone is always hot from talking on the phone all day. Working with game-changing technology and successful domain qualified, repeat CEOs that I constantly learn from makes the long days and risks of uncertainty all worth it.

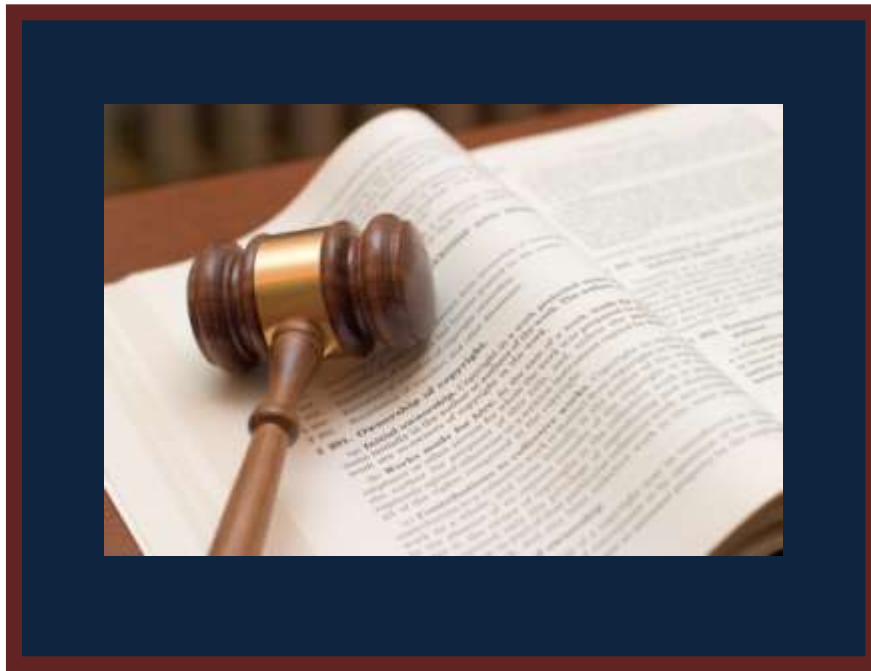
I often get asked whether working independently is something that I want to do for the remainder of my professional life, and the answer is that I do not know and I am fine with that. This is part of the thrill of being an entrepreneur. **IN THIS CAREER, NOTHING IS EVER ROUTINE, AND EACH DAY BRINGS A NEW CHALLENGE WITH A DASH OF EXCITEMENT.** *Despite the uncertainty, there is a great amount of comfort in knowing that a strong foundation in science can lead to seemingly endless opportunities.*



*Photo provided courtesy of the author*

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*Anna Lisa is also an active runner and triathlete, having competed in over 100 races including several marathons and half-ironman triathlons.*



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