



**Dr. Stanley Kowalski JD '05:** *Director ITTI*

## Pierce Law's Contribution to Combating the Global AIDS Crisis: Developing a Patent Landscape of HIV Vaccine Technologies

“Building intellectual property capacity in developing countries will accelerate equitable access to essential innovations in pharmaceuticals, vaccines and agricultural technologies. This will advance social justice and promote the global public interest by improving basic health and nutrition, especially among the poor ... disproportionately represented by women and children. Stable societies will only be built, sustained, grow and prosper, when such fundamental needs are adequately provided.” – *Dr. Stanley Kowalski JD '05, Director, International Technology Transfer Institute (ITTI) and Assistant Clinical Professor of Law*

**Q: What projects are you currently working on in Pierce Law's new International Technology Transfer Institute (ITTI)?**

**SK:** Within ITTI, we have two programs, one that focuses on patent landscape analysis and the other on intellectual property (IP), innovation management and technology transfer capacity building in developing countries. We view our work in ITTI as an integrated approach that links IP to international development via education, scholarship and outreach. The combined vision and expertise of the ITTI faculty, which includes Professors Jon Cavicchi JD '84/LLM '99, John Orcutt and Karen Hersey, creates the synergy that drives our global mission.

The patent landscape analysis program, which Jon Cavicchi and I cofounded in the fall of 2006, focuses on technologies that are critical to the needs of developing countries. For example, we recently worked on agricultural innovations, such as genetically-engineered insect-resistant sweet potato cultivars, critical to the needs of resource-poor farmers in Africa.

Right now we are working on a larger project in collaboration with our colleagues at the Public Intellectual Property Resource for Agriculture (PIPRA) at the University of California-Davis, on a significant patent landscape involving technologies that are relevant to the research and development of a vaccine for HIV, also for eventual deployment in Sub-Saharan Africa.

Our work involves layers of analysis, as there are many technologies and steps involved in developing vaccines, from viral purification to delivery. We examine these technology-by-technology, step-by-step, and have worked on DNA, protein and viral vector platforms, prime boost methodologies, and now we are working on adjuvants.



**Q: Once you have thoroughly researched a patent landscape, does this then allow for the development and distribution of a vaccine? Would you explain how the process works?**

**SK:** Well, let's take it step by step. In the ITTI Patent Landscape Clinic, our students first analyze the technology. For example, we will look at all the parts of a vaccine. We look at the final product (the vaccine itself). We then look at its components and the processes used to develop the vaccine. This all requires a somewhat sophisticated understanding of the science and technology, which the students are expected to acquire from assigned readings. Then we ask, what are the patent documents potentially relevant to each of these? We search patent databases to identify the potentially relevant documents. A vaccine might have a patent applicable to each component and method that goes into making it. Therefore, we attempt to assemble and analyze a solid representative set of patent documents that are related to a specific vaccine technology. We begin to ask questions as to what components are covered. Who owns the patents? Are they dominated by corporate or by public sector organizations? Who dominates this technology sector? Then, we discuss potential strategies for managing these types of 'patent barriers' or 'thickets.'



Students worked during the spring semester in the International Technology Transfer Institute (ITTI) as members of the clinic's HIV Patent Landscape Team. They researched protein/peptide vaccines for HIV. Pictured (l.-rt.) are: first row, Chika Teranishi '10, Kristal Wicks '10 and Pravin Conda '10, second row, Swetha Maladkar MIP '09 and Ramani Marakani '11, third row, Michelle Windom JD '09 (project leader) and Alex Ferre '10 (team leader).

Of course, the ultimate objective of our work is to contribute to the global effort to accelerate the development and delivery of an efficacious HIV vaccine to those who most desperately need it. Possible strategies could involve partnerships between public and private sectors to assemble their technologies (and IP) in order to more rapidly develop a vaccine and accelerate its deployment. But it is important to remember that ITTI is in the education business; we are here to build global capacities that will then support sustainable and equitable development.

The patent landscape research work also relates to the other major component of ITTI, which is to build IP capacity in developing countries. If a future HIV vaccine is going to be distributed to countries of Sub-Saharan Africa, such as Ghana, Uganda, Tanzania, and Nigeria, we need to identify the potential IP issues associated with it, and determine who in these countries could be our counterparts ... responsible for accessing and managing this technology. The critical question is whether these countries have adequate human and institutional capacity needed to manage IP and innovations in health in order to facilitate access and deployment.

**Q: Would you provide an example of a technology transfer office in the United States?**

**SK:** Good examples include the National Institutes of Health and the University of California system, Cornell University and MIT. Developing countries need either national or regional technology transfer offices that could serve as hubs for fostering and advancing technological and innovation development. This would facilitate both the development and the moving of innovations to the people who live both in the country and in the region, for example Vietnam and the greater Indochina region.

**Q: Have you set up a technology transfer office in a developing country?**

**SK:** As a matter of fact, one of our outstanding students, Natalia Pence JD '09, led a team comprised of myself and Professor Peter Gregory (Cornell University) to Bogotá, Colombia in November 2008, to visit The Universidad Militar Nueva Granada (UMNG) and engage in discussions about setting up a technology transfer office there. This office would facilitate innovation development within the university, and possibly the country, and work to implement a system for bio-prospecting and developing Colombia's vast treasure of genetic resources and biodiversity, which has scarcely been tapped.

**Q: Please tell us about the publications that you plan to submit articles to regarding these projects?**

**SK:** We would like to publish an article about the Colombia project, as a case study about how this type of technology transfer office is set up and established in a country such as Colombia — a country that is truly innovative but now needs enhanced institutional infrastructure in order to move ahead in development towards a knowledge-based economy. It's all there (the human capital); all that is needed now is education, organization and implementation.

We also are preparing an article on our HIV vaccine patent landscape work, which will be published in *Nature Biotechnology*. This will focus on the complexity of the technology as well as the complexity of the patent landscape, which, in turn, creates challenges for research, global access and deployment. We also have several manuscripts in preparation which address IP and technology transfer capacity building in Africa, where we will not only examine the current challenges but also suggest strategic options for overcoming these.

*Kowalski holds a PhD in plant breeding from Cornell University. As a research scientist he worked in the fields of crop science, genetics, biochemistry and cell biology. Long interested in international development, due both to his exposure to the international programs at Cornell and the influence of Professor Norman Borlaug, a 1970 Nobel Peace Prize Laureate, he has transitioned his career towards building intellectual property capacity and innovation systems in developing countries. At the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), Kowalski conducted the preliminary freedom-to-operate analysis of Golden Rice. After ISAAA, he earned a JD with an emphasis in intellectual property at Pierce Law.*