IN THE *GLOBAL* INTEREST

By Dr. Stanley Kowalski JD '05, Visiting Scholar



Pierce Law's Intellectual Property Research Tools team conducted a patent research project on HIV-1 for the Public-sector Intellectual Property Resource for Agriculture (PIPRA). Pictured (l.-rt.) are Yu-Hui (Lisa) Sung '09, Weonmee Park MIP '08, Bum Rae Cho '09, Michelle Windom '09 and Arshdeep Sidhu MIP '08.

Human Immunodeficiency Virus-1 (HIV-1) has been responsible for more than 25 million deaths worldwide since its emergence in 1981. Of the approximately 11,000 new cases identified each day an estimated 60% are diagnosed in the developing countries of Sub-Saharan Africa. The immense morbidity and mortality rates, and the public health expense to governments caused by HIV-1, places an enormous social and economic toll on countries. Despite significant global investment in research and development, a preventative vaccine against HIV-1 remains elusive due to HIV-1's ability to evade the immune system.

Pierce Law is now working with the Public-sector Intellectual Property Resource for Agriculture (PIPRA), an organization that seeks to facilitate access to intellectual property in order to foster international development, to build a publicly available, user-friendly online HIV-1 vaccine patent database.

The database will be composed of both issued patents and published applications that are pertinent to the global patent landscape for HIV vaccine-related technologies. Technologies covered will be any that might impact the worldwide research, development, commercialization or deployment of a vaccine. Due to the nefarious nature of the HIV virus (its capacity to evade the body's defenses, attack the immune system, invade human DNA and rapidly evolve), an effective vaccine presents a complex technological challenge; therefore the scope of required methodologies and inputs will likely be extensive and hence difficult to predict. For example, it will be necessary to consider various vaccine types (DNA, peptide, inactivated virus, etc.), vaccination strategies (booster regimens, immune enhancers, etc.) and vaccination delivery procedures (injection, gene gun, patches, oral administration, etc.). Many of these technologies are proprietary and are either patented or subject matter in patent applications.

By providing information that will help minimize the risk of global intellectual property constraints, yet maximize sustainable global impact, this database will assist scientists and policy-makers in making informed decisions regarding the research, development, commercialization and global deployment of efficacious HIV-1 vaccines. This work, conducted as part of an upper level Intellectual Property Research Tools course taught by Professor Jon Cavicchi JD '84/LLM '99, resulted in a patent literature educational resource produced by the students that serves as both a graded report and a document delivered to PIPRA. The document contains the raw material for building the database.

The Pierce Law Intellectual Property Research Tools team included Bum Rae Cho '09, Weonmee Park MIP '08 *(read her profile on page 38)*, Arshdeep Sidhu MIP '08, Yu-Hui (Lisa) Sung '09 and Michelle Windom '09. The team conducted a preliminary assessment of the patent landscape database, identifying patents related to DNA vaccines and the prime boost vaccination strategy. Initial searches of the United States Patent and Trademark Office, Delphion and GenomeQuest patent database searching for patents related to HIV-1 DNA vaccines identified 2284 potential patent documents. This was further distilled into a subset of 307 patent documents, of which additional scrutiny identified 174 relevant documents. Interestingly, the Pierce Law team discovered that the public sector, represented by the United States Department of Health and Human Services, appears to own the largest percentage of patents and patent applications associated with DNA vaccines and HIV-1. Chiron Corporation, and Merck own the second and third largest portion of patents. Further analysis is needed to determine if there are any potential patent thickets.

This project is yet another example of how Pierce Law, via its tradition of practice-based scholarship, continues to transform challenges into opportunities, and in this manner creates solutions to the intellectual property, technology transfer and legal impediments restricting access to innovative products urgently needed for improving public health. This, in turn, advances social justice by facilitating equitable access to essential innovations in health and agricultural, and promotes the global public interest by improving basic health, especially among the poor of developing countries, disproportionately represented by women and children.

Through its innovative programs, Pierce Law continues to simultaneously promote the international rule of law, social justice and the greater global public interest. The development of an efficacious HIV vaccine, particularly one that could be widely and efficiently administered in Sub-Saharan Africa, would, arguably, advance social justice and serve the greater global public interest.

In addition to these activities, Dr. Jaya Murthy Josyula MIP '07 continues to provide pro-bono services to PIPRA. This summer she is directing a patent portfolio analysis of PIPRA's collective intellectual property, containing key technologies in agriculture. This analysis will uncover the public sector's strengths and provide the basis for how the comprehensive public sector portfolio of technologies can be better managed and used to support global agricultural development. (*Read her profile on page 37.*)

