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IP AND THE GLOBAL PUBLIC INTEREST: CHALLENGES AND OPPORTUNITIES

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AND STANLEY P. KOWALSKI (JD '05)

INTELLECTUAL PROPERTY CAPACITY AND PUBLIC HEALTH AND NUTRITION IN DEVELOPING COUNTRIES

INTELLECTUAL PROPERTY (IP) CAPACITY is essential for economic development, particularly as countries transition into the higher technology sectors, for example biotechnology. For developing countries, a commitment to minimal IP rights protection will determine inclusion in the World Trade Organization (WTO), facilitate access to foreign-direct investment, and accelerate economic development. However, on a more fundamental level, capacity in IP management will affect whether a country can provide basic health and nutritional needs for its citizens. For example, sustainable food security presents a serious challenge in many developing countries; as their economies rapidly emerge, urban centers expand, arable land and fresh water decrease, and growing populations demand more protein in their diets. This is where the promise of agricultural biotechnology can make a difference. Yet, such cutting edge innovations in biotechnology invariably have IP rights attached; and depending on the level of IP education, awareness and human and institutional capacity present in a developing country, accessing such essential innovations can be straightforward, difficult or simply impossible.

Thus, inadequate awareness, protection and enforcement of IP rights inhibit international technology transfer and stymies domestic innovation. This is particularly the case with cutting edge advances in biotechnology and pharmaceuticals; ironically the very products vital for public health and nutrition. Pierce Law, via its innovative educational programs and unique curriculum, has traditionally sought to contribute to building and strengthening the human and institutional capacity required for successful IP management and technology transfer. This, then, helps developing countries to proactively manage and overcome the potentially complex tangle of IP constraints that limit access to essential health and agricultural technologies. In the longer term, such initiatives and programs are in the global public interest, as they can positively affect the lives of many of the most needy in developing countries. This illustrates and exemplifies Pierce Law's commitment to providing a solid legal and IP education, in the context of promoting social justice and serving the public interest.

In the broader perspective, challenges related to access to fundamental innovations in health and agriculture have triggered numerous efforts at the intersection of science, business, and law. For example, public private development partnerships are taking an increasingly dynamic role in addressing global concerns in public health and nutrition. However, notwithstanding the approaches and/or strategies pursued, the common cornerstone of every effort is the requirement for systematic establishment and strengthening of technology transfer and IP management capacity in developing countries.

PUBLIC HEALTH AND NUTRITION AS A GLOBAL PRIORITY: THE ROLE OF IP CAPACITY

Developing countries have prioritized technology development in food security (agriculture) and public health (pharmaceuticals and vaccines), essential technologies that are broadly termed biotechnology. As most of these biotechnologies are owned by entities residing in the industrialized nations, IP constraints restricting access present a critical problem; impeding, and even inhibiting, effective and equitable transfer of essential innovation to those who most need yet can least afford. Whereas these constraints are largely in IP, they also include contract, business, and tax law, as IP law is integrated into the larger, seamless web of the law.

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In developing countries, building and strengthening of human and institutional capacity in IP management will:

- Promote industrialized country entities to partner with developing countries in international development initiatives;
- Encourage developing countries to advance legal infrastructure congruent with their economic, urban and population growth;
- Foster domestic invention and innovation; and
- Stabilize food and health security in many regions of the world.

From a practical perspective, financial support, leadership, organization, training, and education are all essential components for successful IP management. For example, an IP management, technology transfer office cannot be staffed by amateurs, for example scientists and/or administrators who “know something” about IP and patents. To succeed, and fully capture innovative energies, trained IP professionals, practitioners and lawyers must staff the office. This solid foundation, this “*IP team*,” will then be poised to manage IP, foster innovation, and thereby promote allocation of resources for maximum progress.

INNOVATION, IP AND TECHNOLOGY: THE CRITICAL CONNECTION

In addition to fostering increased technology transfer and research and development partnership opportunities, strengthened human and institutional IP capacity in developing countries will also drive domestic innovation, generating products and processes which address the specific needs of the country and region.

The connection between IP, innovation and technological progress is fundamental. Innovation is all about developing new ideas and then putting them into practice. By providing incentives, IP is a vital component of an innovation system. The key incentive IP provides is temporary exclusivity to inventions, thereby protecting these valuable investments from misappropriation (*i.e.*, piracy). A balanced approach to IP protection will therefore foster innovation, so that the full value of IP will be captured, developed and utilized. Such protection is essential,

as innovation requires intensive investment of human, intellectual and physical capital. Hence, the innovator, by enforcing his IP rights, will protect his innovations and develop them for maximal commercial and social benefit.

Creativity, invention, and innovation represent a linked, systematic process. IP, *firstly*, protects innovative endeavors, *secondly*, provides a shelter for development, and *thirdly*, fosters a platform for commercialization and market entry. However, such extraordinary value will only be fully developed and realized when functional and professional IP management institutions are established. A serious investment in both human and physical resources is essential, crucial and urgent. If ignored, the innovative assets of developing countries will remain disorganized, haphazardly managed and chronically underutilized.

EXAMPLES OF TECHNOLOGY APPLICABLE TO THE NEEDS OF DEVELOPING COUNTRIES

Examples of agricultural and pharmaceutical technologies having direct applicability to the needs of developing countries, but which will likely be proprietary and hence require IP management expertise in order to access, include Golden Rice, ascariasis vaccines, phytoremediation of dioxin, and the “Red Detect” mine detection system. Each of these is briefly discussed, *solely to illustrate* the types of possible benefits that might accrue from strengthening human and institutional IP capacity in developing countries, which will foster increased technology transfer, innovation, development, and utilization of advanced biotechnologies, essential for advancing public health and nutrition.

GOLDEN RICE

Vitamin A deficiency is a global crisis. In the developing world, an estimated 140 million preschool-age children and over seven million pregnant women are afflicted. The long-term effects of vitamin A deficiency are devastating: anemia, growth retardation, increased infectious morbidity and death. It is not surprising that the greatest toll is among those from the developing world. Recent advances in plant biotechnology are producing a new

generation of wonder crops that accumulate vital nutrients, *e.g.*, vitamin E, iron, and beta-carotene...the precursor of vitamin A. “Golden Rice” is genetically engineered to accumulate beta-carotene (pro-vitamin A) in the grain and thereby provide a cost-effective means for production and delivery of vitamin A to those suffering from deficiency. However, this is a very complex biotechnological invention, embodying numerous patented technologies. This complicates transfer and restricts access, particularly to those who most need its benefits. Hence, to overcome such challenges and obstacles, building expertise in IP management and technology transfer in developing countries is essential.

PARASITIC ROUNDWORMS (ASCARIS)

Ascaris is a parasitic roundworm that lives in the small intestine of humans. The worms can become quite large, up to one foot (30 centimeters) in length, and have an appearance similar, in size and dimensions, to the common earthworm (*i.e.*, “night crawler”). *Ascaris* is spread via fecal contamination; eggs are ingested, hatch in the stomach, and immature worms migrate to the lungs and then up into the throat, where they are either swallowed or coughed out. In the intestines, a large, slimy bolus of worms can present an obstruction, leading to serious complications, *i.e.*, increased morbidity and mortality. This is especially critical in children. *Ascaris* infections, known as ascariasis, are common throughout tropical regions of the world, especially where sanitation and hygiene are poor. Ascariasis is endemic in many developing countries: the number of infections is estimated at over one billion. As with so many other “neglected diseases,” the greatest burden of suffering due to ascariasis falls onto the poorest people in developing countries. Vaccines have been developed that immunize against nematode parasitic infections (*e.g.*, *Ascaris*). However, these are proprietary...protected by patents.

PHYTOREMEDIATION OF DIOXIN

From 1961 until 1971 the U.S. military conducted a series of defoliation sprayings in Vietnam, and to a lesser extent in Cambodia

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and Laos. Codenamed “Operation Ranch Hand”, the objective was to deprive hostile forces of cover and crops: to achieve this 13 million gallons were sprayed over 6500 square miles. The dominant herbicide used was Agent Orange, which is contaminated with highly toxic dioxin. In Vietnam, residual dioxin contamination in the soil has been linked to elevated risks of cancer and birth defects. Phytoremediation is the use of plants to remove pollutants (e.g., heavy metals, pesticides, explosives, toxic organics) from the soil, rather like a biological vacuum cleaner. Genetically engineered plants will likely be able to not only extract but also detoxify dioxin from contaminated soils. This would be a biotechnological innovation directly applicable to the needs of Vietnam, Cambodia and Laos. Thus, the legacy of war could be ameliorated with a green “vacuum cleaner”. Such advanced biotechnologies are currently being developed (and, perhaps not surprisingly, patented).

RED DETECT

Landmine contamination, a persistently lethal problem, is another legacy of war. In 2004 there were 6000 worldwide casualties from landmine encounters, with the overwhelmingly majority occurring in developing countries. Among the most landmine-polluted countries is Cambodia; decades of war and social upheaval have left wounds still felt to this day. For example 2.4% of Cambodia’s territory, approximately 2000 square miles, has been laid with landmines. In 2004, Cambodia suffered 900 casualties from landmine encounters, a disproportionate number of whom are women and children. Common wounds include traumatic amputations and blindness. However, there is now a biotechnological innovation that can help to rid the countryside of this hidden terror. A Danish company, in collaboration with the Danish army, has invented (and patented) the remarkable “Red Detect” landmine bio-detection system. In Red Detect, plants are genetically engineered to turn from green to red when grown in the vicinity of high explosives (TNT)

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leaching out of landmines. In a field sown with these plants, the green expanse would be dotted with red patches, like red checkers on a green pool table, indicating where civilians may not venture but where explosives teams are to clear the deadly devices.

THE ROLE AND ACTIVITIES OF PIERCE LAW IN PROMOTING IP CAPACITY

Pierce Law, which has been rated among the “top 10” U.S. law schools for its IP rights specialization every year for over a decade, established the first international, interdisciplinary program in IP rights education in the U.S. in 1986, with specific focus on educating IP rights professionals from developing nations on how IP rights systems work. The IP curriculum at Pierce Law is both deep and broad, incorporating intensive instruction in U.S. law, as well as recognizing emerging global realities by teaching IP law and management from an international perspective. Over the past two decades, government officials, tech-transfer professionals, research institute administrators, and lawyers from over 95 countries have attended these programs, supported by many public and private institutions, including the World Intellectual Property Organization (WIPO), U.S. Agency for International Development (AID), and the Fulbright Program.

In addition to, and consistent with, its traditional role in educating IP professionals from developing countries, Pierce Law has also recently participated in projects organized by:

- The Public-sector Intellectual Property Resource for Agriculture (PIPRA), www.pipra.org, an organization that seeks to facilitate access to IP in order to foster the development and distribution of improved crops, for use in developing countries, and
- The Centre for the Management of Intellectual Property in Health Research and Development (MIHR), www.mihr.org, which seeks to promote access to health technologies in order to improve the well-being of poor people across the globe, via improved management of innovation and IP in research and development.

With PIPRA, Pierce Law has provided assistance in evaluation of patent landscapes associated with agricultural biotechnological applications having specific potential for distribution and use in developing countries. These studies have been conducted as part of an upper level IP Research Tools course taught by Professor Jon Cavicchi, with a patent literature survey produced by the students serving as both a graded report and also an informational document delivered to PIPRA. In a second phase of this project, led by Shelly Temple (a New Hampshire patent attorney and Pierce Law graduate), students assembled the results of the patent survey, analyzed these in detail, and then explored freedom to operate considerations. In addition to these PIPRA projects, outstanding student papers from Professor Karen Hersey’s Non-profit Technology Transfer course have been posted on the PIPRA website as important and valuable resources for all to access and read.

In 2006, several members of the greater Pierce Law community participated in an important meeting organized by MIHR: “Intellectual Property Management Strategies to Facilitate Early Access and Global Health Benefits: Case Studies in Pandemic Influenza and Malaria.” The objective was to explore and discuss IP and licensing issues which impact the distribution of vaccines to developing countries, a topic of heightened worldwide importance given the looming threat of a global influenza pandemic. In an intensive one-day session, the diverse panel of world experts worked together to formulate a list of realistic, creative and dynamic options for managing and resolving IP constraints on vaccines and related biotechnologies, so as to accelerate access by the poor of the developing world. A detailed report has subsequently been published.

CONCLUSIONS

When properly managed by cadres of trained professionals, IP can advance social justice by facilitating equitable access to essential innovations in pharmaceuticals, vaccines, and agricultural biotechnologies. This will then promote the global public interest by improving basic health and nutrition, especially among the poor of developing countries, disproportionately

represented by women and children. Stable societies will only be built and sustained, grow and prosper, when such fundamental needs are adequately provided. Otherwise, disease, hunger and poverty will continue to drive the engines of despair, instability and war.

A solid foundation of integrity, leadership and vision has made Pierce Law unique among law schools. In a spirit of innovation and entrepreneurship, Pierce Law, via practical application and scholarship, transforms challenges into opportunities; and, in so doing, empowers colleagues from around the world to proactively work towards finding creative solutions to the IP, technology transfer and legal impediments restricting access to products needed for improving public health and nutrition. Pierce Law thereby simultaneously promotes the international rule of law, social justice, and the greater global public interest. The Pierce Law community, an assembled abundance of diversity, talent, perspective and experience, continues to forge dynamic synergisms, promoting and cultivating legal infrastructure around the world. ■

Jon Cavicchi (JD '84, LLM (IP) '99) has been Research Professor and IP Librarian at Pierce Law for 15 years. He administers the IP Library as well as the award winning IP Mall Website. He teaches classes on IP legal research and patent searching. He is the author of articles on IP research tools and strategies.



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