FRANKLIN PIERCE LAW CENTER
GERMESHAUSEN CENTER NEWSLETTER • *Winter/Spring 2006*

INSIDE THIS ISSUE:

EIGHTH IP SYSTEM MAJOR ISSUES CONFERENCE

ON APRIL 1, 2006 Franklin Pierce Law Center, in cooperation with Germeshausen Center for the Law of Innovation & Entrepreneurship, held its 8th IP System Major Issues Conference. The 8th Conference continues a tradition of scholarship and discussion begun in 1987 by former Pierce Law David Rines Professor of Law and Germeshausen Center Director, Homer O. Blair.

As in previous years, the '06 Conference was designed to bring together a significant number of invited scholars, industry representatives, practicing attorneys and government

See CONFERENCE, page 9

PORTRAIT: FOUNDING FATHER OF TAIWANESE PIERCE LAW ALUMNI ASSOCIATION

BY ASHLEY J. WALKER (JD '07)

THOMAS Q. T. TSAI, (MIP '89/JD '91) is now one of the few IP practitioners focusing on patent drafting and prosecution in Taiwan. He is a Managing Partner of Tsai, Lee, & Chen in Taipei, one of the top ten IP firms in Taiwan. Since graduating from Pierce Law, Mr. Tsai has distinguished himself in all aspects of his IP career, fulfilling his own ideal goal which he believes all lawyers in civil law countries like Taiwan and China should achieve: building up a law firm organization

See TSAI, page 12

THOMAS Q. TSAI

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GERMESHAUSEN CENTER NEWSLETTER

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Created in 1985 through the generosity of Kenneth J. and Pauline Germeshausen, the Germeshausen Center is the umbrella organization for Pierce Law 's specialization and policy studies in the legal protection, management and transfer of intellectual property, especially relating to the commercialization of technology. The Germeshausen Center Newsletter is published two times a year for alumni/ae, students and friends of Pierce Law.

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IP FACULTY ACTIVITIES

BY CAROL RUH

Professor Tom Field was commissioned to write the lead article in an illustrated publication recently released by the US Department of State, Bureau of International Information Programs. The publication, available online at **http://usinfo.state.gov/products/pubs/intelprp/index.htm**, is entitled *Focus on Intellectual Property Rights*, and Field's article is entitled "What is Intellectual Property." In mid-March **Field** also moderated an online chat hosted by the State Department.

* *

Professor Bill Hennessey on February 1 spoke on "The Emergence of China's Intellectual Property System" at a 2-day conference in New York City on "Protecting IP Value in China," sponsored by the World Resources Group (**www.wrgroup.com**). **Professor Hennessey** presented a lecture entitled "Enacting International Laws and Implementing Public Policies to Protect the Rights of Indigenous Peoples to Knowledge and Biodiversity: Challenges and Opportunities" at the Global Summit on HIV/AIDS, Traditional Medicine and Indigenous Knowledge in Ghana, March 14-18. (**www.africa-first.com/gsaidstmik2006/default.aspx**)

* *

Professor Karen Hersey presented a series of lectures based on the theme "Faculty Member as Innovator, Inventor and Entrepreneur" on November 8-9 at the University of Illinois at Urbana-Champaign. **Professor Hersey** also presented "How Copyright Works" on November 17 and "Patent Licensing in the University" on December 8 at Brandeis University. On February 1, **Hersey** conducted a workshop, entitled "Establishing a Technology Transfer Function," for the Swedish organization, VINNOVA, in Stockholm.

On March 4 **Professor Hersey** participated in a panel at the AUTM Annual Meeting, Orlando, FL to discuss "Licensing Law Developments: How Recent Decisions Affect University Technology Transfer."

* *

Professor Karl Jorda spoke on "International Considerations in Licensing" at a Practicing Law Institute (PLI) Seminar on "Understanding the Intellectual Property License" in New York on November 18. On November 24 and 25 he lectured at an LES Philippines Seminar on "Technology Licensing Today" in Manila covering Patent Licensing, Hybrid Patent/Trade Secret Licensing, Trademark Licensing/Franchising and Cultural Aspects in International Licensing in terms of highlights of his Technology Licensing course. On February 28 **Professor Jorda** participated in a panel discussion on "Intellectual Property Rights for Sustainable Agricultural Systems in Developing Countries" at the World Bank in Washington, DC. On March 21, **Professor Jorda** lectured on the "Basic Principles of Patents" at the WIPO-UNITAR Workshop on IP for UN Diplomats held in the WIPO Coordination Office in New York City.

* *

Professor Bill Murphy gave a presentation on "Use of Intellectual Property for Financing and Risk Transfer" at the Annual Conference of the Irish Association of Law Teachers (IALT) in Cork, Ireland on April 8.

* *

Congratulations to **Professor Susan Richey**, who has been recently appointed to the position of Associate Dean of Graduate Programs at Pierce Law. **Professor Susan Richey** gave a presentation on December 12 on the "Legal Implications of the Appropriation Art Movement" at Endicott College in Beverly, MA. She also gave the same presentation at Montserat School of Art in Beverly, MA on February 7. **Professor Richey** is currently Chair of the INTA Panel of Neutrals this years as well as Chair of the INTA Neutrals Standards and Measurement Subcommittee.

NOTABLE HAPPENINGS...

BY CAROL RUH

GERMESHAUSEN CENTER 20TH ANNIVERSARY RECOGNITION DINNER

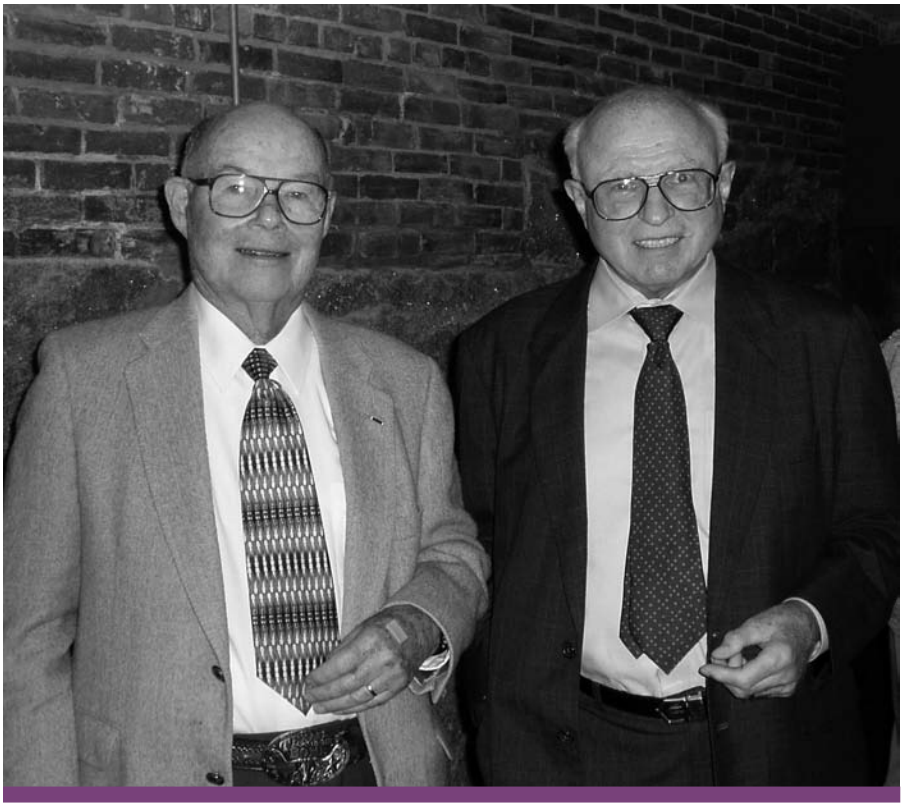
On November 4, following the Advisory Council on IP (ACIP) meeting, a dinner took place at the Centennial Inn marking the 20th Anniversary of the Germeshausen Center (1985-2005). Attendees included ACIP members, Pierce Law faculty and Board of Trustees members. **Dean Hutson** recognized **Homer Blair**, **Karl Jorda** and **Carol Ruh** for their contributions in establishing and maintaining the Germeshausen Center over two decades.

LES

On November 17 the Pierce Law Student LES (Licensing Executives Society) Chapter held a Symposium on "Cross-border Licensing on IP." The speakers were: **John M. Garvey** (JD '93), Partner, Foley & Lardner, Boston; **Karl Jorda**, Pierce Law Professor of Law and **Louis C. Schmidt Ruiz Del Moral** (MIP '90), Partner, Olivares & Cia., Mexico. Go to: **www.students.piercelaw.edu/les/speakers.htm** for bios and Powerpoint presentations of the speakers. Representatives from ipCapital Group, Williston, VT (**Mike Bielski**, Head IP Counsel, **Sandy Lewis**, Director of Human Resources, **Rachael Schwartz**, Senior Management) gave a presentation at Pierce Law March 15 on "Intellectual Asset Management."

SIPLA

On November 9 the Pierce Law Student IP Law Association (SIPLA) presented **Robert Rines** (Pierce Law founder) who discussed his involvement in the watershed Figueroa v. United States litigation. On February 23 **John Whealan**, Solicitor and Deputy General Counsel for IP Law of the USPTO, spoke at Pierce Law discussing current IP law issues before the Supreme Court. On March 10 SIPLA presented **Stephen Whiteside**, In-house Counsel to Invitrogen Corporation, Frederick, MD who compared working as an associate for a firm vs. in-house counsel for a corporation and real-life situations IP attorneys deal with.



HOMER BLAIR (FORMER GERMESHAUSEN CENTER DIRECTOR, 1985–1989) AND KARL JORDA (CURRENT GERMESHAUSEN CENTER DIRECTOR, 1989–PRESENT) AT 20TH ANNIVERSARY EVENT

MOOT COURT COMPETITIONS

Congratulations are in order for the many students that have been involved in various Moot Court competitions over the past several months including the Giles Sutherland Rich Moot Court Competition, BMI Cardozo Entertainment Law Moot Court Competition, Jessup International Law Moot Court Competition, 35th Annual Spring Constitutional Law National Moot Court Competition, Saul Lefkowitz Moot Court Competition in Trademark Law and Willem C. Vis International Commercial Arbitration Moot. Their successful performances reflect the huge amount of effort and talent that went into all their presentations. Great job!!

PIERCE LAW STUDENT INTERNSHIPS IN ASIA

Gemma Hoffman (JD '06) completed a month-long internship at the Hong Kong Intellectual Property Department (IPD) this past December. During her internship Gemma learned about IP in Hong Kong by studying the substantive patent, trademark and copyright laws and attending informational briefing sessions prepared by attorneys and Examiners. To see the law in practice, she attended several opposition and TM registration hearings. At the end of her internship Gemma gave a presentation on technology transfer, demonstrating how Hong Kong can consider the Bayh-Dole Act and other U.S. statutory provisions to implement its proposed "Digital 21 Strategy."

Gemma's internship was an invaluable experience and indeed the perfect introductory "crash course" on IP law and practice in Hong Kong and the greater Asian Pacific Delta region. For more information on the Hong Kong IPD, see **www.ipd.gov.hk**. (*See page 11 Guest Editorial*)

DETERRING TRADEMARK INFRINGEMENT IN COUNTERFEIT GOODS—SCMGA

BY KUMIKO IDE (JD'06)

COUNTERFEITING brings various harms to both industries and consumers. In the last decade, the spread of Internet usage has made it particularly easy for counterfeiters to distribute their goods. While the Internet has increased the ease with which criminals enter the counterfeiting market, it has also made it more difficult for companies that produce authentic goods to police those counterfeiting activities. Over the course of the past twenty years, there has been a dramatic increase in the levels of counterfeiting and piracy both domestically and internationally. IACC, *White Paper, The Negative Consequences of International Intellectual Property Theft: Economic Harm, Threats to the Public and Safety, and Links to Organized Crime Terrorist Organizations 1*, **http://www.iacc.org/WhitesPaper.pdf** (Jan. 2005).

International Anti Counterfeiting Coalition, Inc. (IACC) noted that "worldwide production of counterfeit goods, everything from DVDs to pharmaceuticals, has jumped 1700% since 1993." *Id.* (referencing Kate Betts, *The Purse-Party Blues*, Time (Aug. 2, 2004)). Counterfeiting has been experienced in industries such as auto parts, electrical appliances, medicines, tools, toys, office equipment, and clothing. *Stop Counterfeiting in Manufactured Goods Act*, Sen. 1699, 109th Cong. § 1 (November 10, 2005).

There are numerous reasons why counterfeiting activities need to be deterred. The most obvious reason is that industries and legitimate IP owners experience the loss of profit and the loss of goodwill through sales of counterfeit goods which are inferior to the legitimate goods. The sales of counterfeit goods reduces the profit to the manufacturer of authentic goods. Further, when a person innocently buys counterfeit goods, its poor craftsmanship or quality of goods could result in the loss of consumer trust and goodwill of legitimate intellectual property owners. Moreover, the production of counterfeit goods may transform a strong and distinctive trademark into a generic term over time through dilution.

More importantly, however, the increasing size of the counterfeit market affects the U.S. economy by reducing tax revenue as well as jobs within the country. Sen. 1699, 109th Cong. at § 1(b)(1). The Bureau of Customs and Border Protection estimates that counterfeiting costs the U.S. $200 billion annually. *Id.* at § 1(b)(2).

In addition, IACC reports a connection between terrorist organizations and the manufacture and sale of counterfeit and pirate products. *Id.* at § 1(b)(5). Congress reports that these organizations raise and launder money through sales of counterfeit goods. *Id.* IACC writes the "low risk of prosecution and enormous profit potential have made criminal counterfeiting an attractive enterprise for organized crime groups," and these organized crime groups "exert significant influence and control over the manufacturing, distribution and sale of counterfeit and pirate goods." IACC, *White Paper, The Negative Consequences of International Intellectual Property Theft: Economic Harm, Threats to the Public and Safety, and Links to Organized Crime Terrorist Organizations I*, **http://www.iacc.org/WhitesPaper.pdf** (Jan. 2005). Thus, counterfeiting activity is posing a threat to the safety of the country.

Finally, sales of counterfeit goods pose a threat to public health and safety. Sen. 1699, 109th Cong. at § 1(b)(7). For example, in recent news, U.S. Customs intercepted more than 50 shipments of counterfeit Tamiflu, the antiviral drug being stockpiled in anticipation of a bird flu epidemic. Brian Skoloff, *Customs Agents Seize Counterfeit Tamiflu* **http://abcnews.go.com/Health/wireStory?id=1419494** (Dec. 18, 2005). Tests on these counterfeit drugs confirmed that they did not contain any of the active ingredients contained in the authentic Tamiflu. *Id.* David Elder, director of the Food and Drug Administration Office of Enforcement, encouraged the public to always gain a diagnosis from a health care professional and ensure they obtain Tamiflu from a reliable source, as they "may never be able to track down the manufacturers." *Id.*

Consequently, IP theft not only affects the industries whose IP rights are being illegitimately utilized; consumers and even the country as a whole could be in danger if IP theft is not rigorously prosecuted. Because of these negative effects on the various industries, on the economy of the country, as well as on the safety of consumers, finding a solution to better deter the criminals from entering the counterfeiting market is of utmost importance.

Congress has been active in finding effective deterrents against counterfeiting activities. On January 4, 2005, Stop Counterfeiting in Manufactured Goods Act (SCMGA) was introduced to amend Title 18 of the U.S. Code. 18 U.S.C. § 2320 makes it a crime to intentionally traffic goods or services bearing a counterfeit trademark. While this criminal code served as a deterrent against trafficking in counterfeit trademarks even prior to the amendment, counterfeiters had discovered a loophole which allowed them to escape criminal sanctions. The loophole allowed counterfeiters to legally ship labels bearing counterfeit trademarks and attach those labels to separately shipped unlabeled goods for distribution of counterfeit products. *See U.S. v. Giles*, 213 F.3d 1247, 1251 (10th Cir. 2000).

For example, in *U.S. v. Giles*, the Tenth Circuit Court of Appeals found that the defendant who trafficked "patch sets" bearing the logo of Dooney & Bourke free of any 18 U.S.C. § 2320 liability, where a set included a leather patch and a gold medallion bearing the Dooney & Bourke logo which could be applied to generic purses to make them appear as though made by Dooney & Bourke. *Id.* at 1253. To find a defendant guilty of violating § 2320, the government had to prove that the defendant: 1) trafficked or attempted to traffic in goods or services; 2) did so intentionally; 3) used a counterfeit mark on or in connection with such goods and services; and 4) knew the mark was counterfeit. *Id.* at 1249. In *Giles*, the court found the "goods" at issue in the case are

See COUNTERFEITING, page 5

COUNTERFEITING, from page 4

the purses and handbags; the court did not consider patch sets to be "goods". *Id.* at 1251. Absent language in the statute which specifically prohibits trafficking in counterfeit labels, the court determined that § 2320 did not forbid the mere act of trafficking in counterfeit labels such as the one engaged by the defendant. *Id.* at 1251.

The limitation of § 2320 was also demonstrated by a case in the Federal District Court of Massachusetts. In November, 2005, four Massachusetts residents were charged with trafficking counterfeit luxury handbags of Louis Vuitton, Kate Spade, Prada, Gucci, Fendi, Burberry, and Coach. "Four Massachusetts Residents Charged with Scheme to Sell More than 30,000 Counterfeit Luxury Goods" **http://www.usdoj.gov/criminal/cybercrime/luongIndict.html** (November 3, 2005). The raid revealed approximately 12,231 counterfeit handbags; 7,651 counterfeit wallets; more than 17,000 generic handbags and wallets; and enough counterfeit labels and medallions to turn more than 50,000 generic handbags and wallets into counterfeits. *Id.* (quotes omitted). While charges against trafficking and attempting to traffic counterfeit handbags could be pursued, § 2320 limited any charges regarding the 50,000 counterfeit labels and medallions that were found during the raid. Sen. 1699, 109th Cong. at § 3.

To prevent such individuals who traffic items bearing counterfeit trademarks from walking free, the SCMGA amendment expanded § 2320 by adding the language "labels, patches, stickers" and any other items in which trademarks are applied, so that individuals trafficking in those items would be held criminally liable as those that traffic in counterfeit goods. *Id.* at § 2.

In addition, the SCMGA heightened penalties to individuals trafficking counterfeit labels. Specifically, the amendment modified § 2320 by imposing mandatory destruction and seizure of counterfeit goods and labels, as well as forfeiture of any properties used to produce those items. *Id.* at § 2.

See COUNTERFEITING, page 9

THE NEWLY BROADENED PATENT INFRINGEMENT EXEMPTION

BY SANDRA SZELA CONGDON (JD '06)

ACCORDING TO 35 U.S.C. § 271(a), it is generally an act of patent infringement if "…whoever without authority makes, uses, offers to sell, or sells any patented invention…during the term of the patent…" 35 U.S.C. § 271 (2003). Despite the existence of a common law experimental use exception to patent infringement, this common law exception exists mostly in name only. However, in 1984, Congress enacted a narrow exemption to infringement through 35 U.S.C § 271(e)(1) where "it shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention…solely for uses reasonably related to the development and submission of information under [the Federal Food, Drug and Cosmetic Act]." *Id.* This exemption was introduced to title 35 as part of the Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 Act), also known as the Hatch-Waxman Act or Safe Harbor Provision to patent infringement. Pub. L. No. 98-417, 98 Stat. 1585 (1984). The Act allows for an abbreviated approval process for generic drugs and "ensure[s] that a patentee's rights do not extend past the expiration of the patent term because a generic competitor also could not enter the market without regulatory approval. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 865 (Fed. Cir. 2003).

In practice, the Act permits experiments on patented drugs "in advance of the patent expiration as long as those activities were reasonably related to securing regulatory approval." *Id.* at 865.

In *Integra Lifesciences I, Ltd. v. Merck KGaA*, the Court of Appeals for the Federal Circuit narrowed the construction of 35 USC § 271(e)(1). *Id.* at 865-867. The critical question the Court of Appeals answered was "whether the § 271(e)(1) safe harbor reaches back down the chain of experimentation to embrace development and identification of new drugs that will, in turn, be subject to FDA approval." *Id.* at 865-866. The Court of Appeals looked in part to the legislative history of the 1984 Act in formulating its narrow construction stating, "the express objective of the 1984 Act was to facilitate the immediate entry of safe, effective generic drugs into the marketplace upon expiration of a pioneer drug patent." *Id.* at 866-867. In this context, § 271(e)(1) "does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process." *Id.* at 867. Therefore, Merck's research which involved testing of new pharmaceutical compounds was not considered an experimental use exemption under § 271(e)(1) by the Court of Appeals because neither the drug candidate nor the testing was ultimately submitted to the FDA during the approval process. *Id.* at 866. Further, the Court of Appeals called Merck's research "general biomedical research" that was "not clinical testing to supply information to the FDA" and thus did not fall under the statutory exemption. *Id.* at 866.

The U.S. Supreme Court granted certiorari to review the Court of Appeals' construction of § 271(e)(1). *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 823 (2005). The very focused issue decided here was "whether uses of patented inventions in preclinical research, the results of which are not ultimately included in a submission to the FDA are exempted from infringement under § 271(e)(1)." *Id.* at 2376. The Court decided that using "patented compounds in preclinical studies is protected under § 271(e)(1) as long as there is a reasonable basis for believing that the experiments will produce the types of information that are relevant to [submissions to the FDA]", regardless of whether the submissions are ever made. *Id.* at 2383-84. This decision broadened the exemption beyond the scope of the Court of Appeals' decision.

The consequences of this decision will no doubt affect the way pharmaceutical and biotechnology companies do their research, and more specifically, their preclinical research. According to the FDA, preclinical drug development involves evaluation of the

See EXEMPTION, page 6

OUTSOURCING'S AFFECT ON INTELLECTUAL PROPERTY AND THE ECONOMY

BY SUMON DASGUPTA (JD '07)

IP IS A MULTI-BILLION DOLLAR BUSINESS IN THE U.S. For many companies, IP is their most valuable asset. F. John Reh, *Non-Disclosure Agreements (NDAs) To Protect Your Intellectual Property*, **http://management.about.com/cs/ipandpatents/a/NDA062199.htm** (2005). According to *Rembrandts in the Attic*, a book on the patenting business, Texas Instruments and National Semiconductor were both saved from bankruptcy though their aggressive use of patents. Kevin G. Rivette & David Kline, *Rembrandts in the Attic*, 125-126 (Harvard Business School Press, 2000). Other companies have followed suite, causing a jump in patent applications from 90,982 in 1963, to 382,139 in 2004. United States Patent and Trademark Office, *U.S. Patent Statistics Chart Calendar Years 1963 – 2004*, **http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm**, (last updated 09/06/2005). In an effort to spur IP growth and minimize costs using cheap labor, many companies have begun to move major research operations into third world countries. CIO Magazine, *Comments on Inside Outsourcing in India: Dell Outsourcing*, **http://comment.cio.com/comments/19119.html** (June 1, 2003). The recent phenomena to move work overseas is known as offsite outsourcing. Outsourced jobs range from technical fields such as computer science to legal work including patent drafting. Donna Ghelfi, *The 'Outsourcing Offshore' Conundrum: An Intellectual Property Perspective*, **http://www.wipo.int/sme/en/documents/outsourcing.htm** (accessed August 29, 2005).

Outsourcing can be felt everyday in American society. Microsoft has outsourced $33 million of work a year to China and plans on increasing that amount to $55 million a year. This equates to over 1,000 jobs outsourced to China alone. Brier Dudley, *Microsoft Plans to Outsource More, Ways Ex-Worker*, **http://seattletimes.nwsource.com/html/businesstechnology/2002468560_msftgoogle03.html** (September 3, 2005). In 2002 the Forrester Researcher, a consultancy, estimated that 3.3 million American service-industry jobs will have gone overseas by 2015. The Economist, *The Great Hollowing-out Myth*, **http://www.economist.com/agenda/displayStory.cfm?story_id=2454530** (February 19, 2004). Only one year later, scientists at the University of California-Berkeley predicted an increase in that number, and estimated that as many as 14 million jobs could be at risk by the year 2015. Daniel McGinn, *Help Not Wanted*, **http://msnbc.msn.com/id/4340784/** (accessed August 29, 2005).

Outsourcing has necessarily included the sharing of proprietary information and trade secrets. Each country has its own distinct national law for different types of IP, which adds further complexity to protection. Donna Ghelfi, *The 'Outsourcing Offshore' Conundrum: An Intellectual Property Perspective*, **http://www.wipo.int/sme/en/documents/outsourcing.htm**. For example, in Russia many practices that would qualify as trade secret appropriation are not prohibited. Steven J. Frank, *Source Out, Risk In*, **http://www.spectrum.ieee.org/careers/careerstemplate.jsp?ArticleId=i040405** (October 18, 2005). An estimated

See OUTSOURCING, page 10

■ **EXEMPTION, from page 5**

drug's toxic and pharmacologic effects through *in vitro* and *in vivo* laboratory animal testing. U.S. Food and Drug Administration, *Center for Drug Evaluation and Research Handbook*, **http://www.fda.gov/cder/handbook/preclin.htm** (accessed 10/17/2005). The most direct effect of this decision is that it may ease restrictions placed on some pharmaceutical companies to perform pre-clinical research. This broadened exemption allows these pharmaceutical companies to perform pre-clinical research on patented compounds, regardless of whether the compound is considered a generic drug or a new drug. It also eliminates the need for these companies to obtain licenses to use and test these compounds. This may have a significant impact on the value of some patents and will decrease the return that patent holders may obtain on those patented inventions. Patent holders may lose much of the control over who uses their patented compound and their power as licensors will be eliminated.

Another effect of the Supreme Court's decision is the lack of direction it gave in the area of patented "research tools." The National Institute of Health defines research tool "in its broadest sense to embrace the full range of resources that scientists use in the laboratory…, includ[ing] cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools (such as PCR), methods, laboratory equipment and machines, databases and computer software. *Report of the National Institutes of Health (NIH) Working Group on Research Tools*, **http://www.nih.gov/news/researchtools/#exec** (accessed 10/17/05). In essence, the Supreme Court focused its decision on patented drug compounds rather than the patented inventions that facilitate the discovery of drug compounds even though the language of § 271(e)(1) refers to patented inventions, and not just patented compounds. 35 U.S.C. § 271.

Quite the reverse of the Supreme Court, the Court of Appeals did address the issue of research tools, and suggested that a limited construction of § 271(e)(1) is necessary to avoid depriving research tools of the complete value of their patents. *Integra*, 331 F.3d at 867. However, the U.S. Supreme Court, in a footnote, explicitly stated that the U.S. Supreme Court "need not—and do[es] not—express a view

See EXEMPTION, page 7

EXEMPTION, from page 6

about whether, or to what extent, § 271(e)(1) exempts from infringement the use of "research tools" in the development of information for the regulatory process." *Merck*, 125 S. Ct. at 2382.

Licensing patented research tools can be a significant source of revenue to research tool makers. Because many patented research tools are used at the preclinical stage of testing that is reasonably related to an FDA submission and therefore would fall under the patent infringement exemption, does the Supreme Court decision that broadens the § 271(e)(1) exemption to patent infringement take away the value of these patents? Since the Supreme Court chose specifically not to express a view regarding how this new interpretation of § 271(e)(1) effects the use of research tools this leaves this question free and clear for interpretation.

Including patented research tools in the § 271(e)(1) exemption would give no incentive to the research tool makers to create new and better tools, and force other research tool makers out of the business. In contrast, excluding research tools from the exemption might increase the cost of drugs to consumers because of the increase in licensing fees, and also cause some confusion among scientists of when they need to obtain a license to perform research using these tools. Since the language of § 271(e)(1) does not make a distinction between patented compounds and patented research tools, this may suggest that use of patented research tools is protected from patent infringement by this provision.

Scientists can be happy for now about the latitude that this broadening of the patent infringement exemption has given them in performing their research, but the unclear position of patented research tools will make the next chapter of this story all the more interesting. Only new lawsuits will tell. ■

Sandra Szela Congdon (JD '06) has a BS and MS in Chemical Engineering from Tufts University. She plans to practice IP in Cambridge, MA.

ORDER #37 OF THE PEOPLE'S REPUBLIC OF CHINA

BY RICHARD A. CASTELLANO (JD/MIP'06)

CHINA'S ORDER # 37, implementing the "Declaration on the TRIPS Agreement and Public Health" of the World Trade Organization Ministerial Conference in Doha (2001) and the "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" (2003) (providing for export and import of drugs made under domestic compulsory license; such import and export previously barred by TRIPS Article 31(f) which limited compulsory licensing to domestic use), is the most recent in a series of actions by the People's Republic of China (PRC) that demonstrate a continuing commitment to the rule of law. See SIPO Order #37: Measures to Implement Public Health-Related Compulsory Licensing (Nov. 1 2005, effective January 1, 2006) (available at **www.sipo.gov.cn/ sipo/ggtz/jzl/t2 0051129_ 61455.htm**). The PRC's State IP Office issued the administrative order, which is indicative of the PRC's willingness to assist developing and least-developed countries who are unable to supply domestic markets with pharmaceuticals during times of need.

Skepticism towards the PRC's 2001 accession to the World Trade Organization (WTO) has been pervasive. While the PRC Patent Law (PLPRC) is strong in letter, enforcement is still a concern among foreign investors. The PRC is clearly aware, however, of the importance of IP rights (IPRs) in achieving technology absorption and a healthy innovative domestic industry; and in very short time, they have achieved a great deal by meeting TRIPS minimum standards for IP protection. Their IP regime has given way to a vibrant domestic biotechnology and pharmaceutical industry that is apparently capable of lending a hand to certain members of the WTO community who lack the capacity to help them in the face of aggressive infectious diseases.

DOMESTIC PHARMACEUTICAL INDUSTRY STRONGER THAN EVER FOLLOWING ACCESSION TO THE WTO

The PRC acceded to the WTO on December 11, 2001 and joined the Agreement on TRIPS, which requires Members to establish in their national law a minimum standard of IP protection. In 2001 they accordingly adopted new IP and pharmaceutical legislation designed to centralize government oversight on the drug industry, encourage competition, and battle piracy. Accession was followed by phenomenal economic growth and the country with the world's largest population has become an attractive market indeed. They now have one of the world's largest pharmaceutical industries with over 5,000 companies.

China's burgeoning pharmaceutical industry is a strong contender. Beijing Genomics Institute represented China as the only developing country to participate in the Human Genome Project. Shenzhen-based SiBiono GeneTech Co., Ltd. developed in 2003 the world's first gene therapy medication. China's biopharmaceutical market is growing at an estimated 13% annually. *See* Mathew Chervenak, *An Emerging Biotech Giant?: Opportunities for Well-Informed Foreign Investors Abound in China's Growing Pharmaceutical Sector*, The China Business Review, 48, 49 (May-June 2005). Changes in the patent law, pursuant to TRIPS requirements, have provided more than mere empty legislation, but also an effective forum in which enforce IPRs.

VIAGRA CASE DEMONSTRATIVE OF INCREASING EFFICACY OF PATENT ENFORCEMENT

Patents are particularly important to biotechnology and pharmaceutical firms that invest substantial resources in research and development and rely on patents to protect resulting technology that is amenable to reverse engineering. Accordingly, the PRC has amended the PLPRC to provide, for example, pendente lite equitable relief, *see* Judge Jiang Zhipei, Justice of the Supreme Court of the PRC, *Regarding Preliminary Injunction in Patent Suit of [sic] China*, (2002) available at **www.chinaiprlaw.com/english/forum/forum17htm**)

See PRC, page 8

PRC, from page 7

(providing clarification on the authority and application of preliminary injunctive relief pursuant to Article 61 of the PLPRC via the Civil Procedure Law Articles 93-96). Still another important provision of PLPRC allows for judicial review of patent reexamination by SIPO.

Where SIPO reexamines and invalidates an issued patent pursuant to PLPRC Article 48, the patentee may seek judicial review in accordance with Article 49. The PRC courts have power only to affirm or reverse an administrative decision by SIPO. Currently, Pfizer, Inc. is taking advantage of this provision in an effort to persuade the Beijing People's No. 1 Intermediate Court to reverse SIPO's decision to invalidate Pfizer's patent on a method of using a PDE inhibiting compound to treat MED, which is marketed as VIAGRA. The patent issued in 2001, only to be challenged shortly thereafter by domestic pharmaceutical firms. CN Pat. No. 94,192,386 (Sept. 19, 2001).

When China invalidated the VIAGRA patent in July, 2004, a spokesman for the U.S. Trade Representative's Office said: "It's hard not to view this case within a pattern of IP infringement in China…. [The U.S.] remains deeply concerned about IP problems in China." Duan Hongqing, Zhu Xiaochao, Fu Li'ao, *China Revokes Viagra Patent*, Caijing English Newsltr., ¶ 7, **http://caijing.com.cn/English/2004/040720/040720 viagra.htm** (accessed Nov. 25, 2004). Despite criticism of China's IP regime by the U.S., Pfizer's second use patent is under director-ordered reexamination by the USPTO. *See* U.S. Pat. No. 6,469,012 (Oct. 22, 2002). Pfizer filed patent infringement lawsuits against Eli Lilly ICOS and Bayer after both firms sought market approval of their PDE inhibiting MED drugs, CIALIS and LEVITRA respectively. Pfizer, in an attempt to maintain their hold on the MED market, filed complaints seeking equitable relief. Compl. at ¶ 20, *Pfizer Inc. v. Lilly ICOS L.L.C.*, No. 02-1561 (D. Del. Oct. 22, 2002). Pfizer's case is stayed pending the director-ordered reexamination.

SIPO's decision to invalidate Pfizer's patent was soundly based on Article 26, PLPRC. SIPO, "*Ten Thousand Mugworts May" The Patent Announce Invalid*, **http://216.239.37.104/translate_c?hl=en&sl=zh-CN&u=http:/www.sipo.gov.cn/sipo/zscqb/yaowen/t20040713_31275.htm**. Article 26 requires a clear, complete, and enabling description to support the technical solution. SIPO ruled for petitioners, finding the disclosure inadequate to support the claimed technical solution of using sildenafil citrate to treat MED. Investors appeared shaken by the decision—GSK waived patent protection for its diabetic drug Avandia about one month following the VIAGRA decision. Kalley Chen, *Li Kui v. Li Gui, China's Path to Development: Enforcement and Challenges*, Corporate Counsel A4, A5 (Oct. 2004). The VIAGRA case should be viewed as a positive indication of the efficacy of the enforcement mechanisms afforded by PRC Patent Law and SIPO, and the domestic industry's willingness to adhere thereto. *See also, In re Bayer A.G.* [2005] SIPO (unpublished) (Board deciding in favor of Bayer, licensor of a fipronil patent, in invalidation action initiated by the Anhu Huaxing Chemical Co.).

COMPULSORY LICENSING AND THE IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION

In November of 2005, Taiwan became the first jurisdiction to issue a domestic compulsory license for the production of oseltamivir phosphate, an oral antiviral drug marketed as Tamiflu by Roche Holding, AG, who is an exclusive licensee of patent owner Gilead Sciences, Inc. In the shadow of an impending avian flu pandemic, Tiawan's decision followed a series of failed negotiations between the Economic Ministry's Intellectual Property Office and Roche. Roche has allowed only one sub-license for Tamiflu to Indonesia, where neither Roche nor Gilead hold exclusive rights to the drug. Most countries can compel patentees to accept reasonable royalties in return for licensure for the use of patented pharmaceuticals. In the U.S., for example, under eminent domain power, pursuant to 28 U.S.C. § 1498 or other specific compulsory licensing provisions, a patentee may be forced to license in return for a reasonable royalty. Indeed, China's PLPRC includes in Articles 51-58 provisions for domestic compulsory licensing, which conforms to TRIPS Article 31(f) and is therefore restricted to licensing for domestic purposes.

Order #37, however, ensures that China will be able to both import and export pharmaceuticals that are produced under a domestic compulsory license in accordance with provisions of the Order that mirror paragraph 6 requirements of the WTO Ministerial Declaration on Public Health, which suspends the Article 31(f) domestic use limitation for those countries who opt to take advantage of the paragraph 6 decision. China's Order #37 is hardly offensive to the rights of pharmaceutical patentees or IP rights-holders. Indeed, the implementation provisions are limited to certain enumerated infectious diseases. *See* SIPO Order #37 Article 5.

CONCLUSION

Order #37, effective as of January 2006, allows China to help others in need, and should be viewed as a welcome development in light of a recent Asian-centered avian flu scare. Now that China's developing IP regime has fostered a bustling domestic biotechnology and pharmaceutical industry, there is another strong player in the fight against infectious diseases. China has demonstrated adherence to obligations as a Member of the WTO community and is a developing country that may be a TRIPS success story.

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COUNTERFEITING, from page 5

The Senate unanimously passed the SCMGA on February 15, 2006. President Bush then signed it into law on March 16, 2006. The amendment closed the loophole and now provides a much stricter punishment to deter counterfeit activities.

Because of the low entry cost to the counterfeit market, a complete elimination of all counterfeiters would prove to be a difficult task. Yet, by creating harsher punishments through legislative actions, hopefully, individuals will think twice about entering the market. In addition to the legislative actions, consumers can help reduce the market size by choosing not to buy counterfeit goods or services. There is a large counterfeit market because there is such a high consumer demand. In some cases, consumers know they are buying counterfeits. Consumers need to be aware that with every purchase of counterfeit goods, they are not only reducing the profit to the legitimate trademark owners, but are also putting their safety at risk.

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CONFERENCE, from page 1

officials for a roundtable discussion. The conference was designed to encourage in-depth discussion and exchanges among the attendees, without formal, prepared presentations other than the prefatory comments offered by Pierce Law Professor Craig Jepson and Professor Tom Field to introduce the topics: "Reform of Continuation Practice," "Reform of Prior Art Definition," and "Reform of Patent Remedies."

The proceedings will be published in *IDEA*, Vol. 47, No. 1 2006. Copies upon request at: **mlavache@piercelaw.edu.**

PRODUCT PATENTS IN INDIA: CAUSE TO CELEBRATE?

BY MRINALINI KOCHUPILLAI (LLM '06)

YOU MIGHT THINK THAT INDIA'S INTRODUCTION of product patents for pharmaceuticals and chemicals effective from January 1, 2005 would give the international pharmaceutical industry cause to celebrate. But does it? We know that in trying to keep its obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), India passed the Patents (Amendment) Act, 2005 (the "amendments") deleting the controversial § 5 of India's Patents Act, 1970. *The Patents (Amendment) Act, 2005* **http://patentoffice.nic.in/ipr/patent/patent_ 2005.pdf** (accessed October 17, 2005) (India's Patents Act, 1970 as amended by the Patents [Amendment] Act 2005 shall be referred to hereinafter as the "Indian Patents Act"). Under § 5, substances intended for use as food, medicine or drugs, as well as substances prepared by chemical processes, merely enjoyed eligibility for method or process patents. § 5 of the Patents Act, 1970 deleted by the Patents (Amendment) Act 2005. With its deletion of § 5, India, no doubt, expects to meet the TRIPS mandate to developing countries like India to introduce product patents for pharmaceuticals and chemicals by 2005. *Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)* Article 65 (January 1, 1995), **http://www.wto.org/english/docs_e/legal_e/27-trips.doc** (accessed October 16, 2005). Nevertheless, questions remain.

To give some background, Indian pharmaceutical companies, supported by India's "pro-generics" patent regime, provided generic versions of patented drugs at rock bottom prices in the international market. As might be expected, this practice created competition that forced international pharmaceutical companies to reduce their prices and to forego profit margins considered by them as necessary to recompense R&D expenditures. The introduction of product patents in India, therefore, seems to answer the international pharmaceutical companies' long held desire to see Indian generic companies' reverse engineering practices come to an end. Along with the stated deletion of § 5, however, India added a number of new provisions—purportedly to cushion the impact that India anticipates its new product patent regime will exact on drug prices in India. Arguably, many of these new provisions are in violation of TRIPS and may be viewed by some as continuing impediments to free and fair international trade.

COMPULSORY LICENSES FOR PATENTS FROM THE "MAIL BOX"

As required by Article 70(8) of TRIPS, India introduced "mail box applications" for pharmaceutical inventions in 1999. *§ 5(2) and Chapter IVA of the Patents Act, 1970* omitted by the Patents (Amendment) Act 2005. Reviews for these applications were to commence on 31 December 2004. *Id.* Patent rights, if granted, would then accrue retrospectively from the date of the mail box application. *Id. and § 53 of the Indian Patents Act*. However, the new amendments considerably dilute the rights of mail box applicants by providing that an automatic compulsory license shall be given to those generic companies that, prior to 2005, 'made significant investment' and were 'producing and marketing' any drug granted a patent pursuant to a mailbox application. *Proviso to § 11A(7)* of the Indian Patents Act, 1970. While the proviso states that these compulsory licenses shall be granted subject to the payment of a 'reasonable royalty', it may nevertheless fall foul of TRIPS mandates that permit grants of compulsory licenses only in very limited circumstances. Further, the Indian Patents Act grants retrospective damages to patentees from the date of publication of patent applications in case of infringements pending grant of patent. *§ 11A(7) of the Indian Patents Act*. Nevertheless, in relation to mail box applications, another newly added Proviso states that damages shall be recoverable only from the date of grant of patents. *Proviso to § 11A(7) of the Indian Patents Act*. These two provisions appear to be aimed at ensuring continued availability of affordable drugs in India, but

See INDIA, page 10

■ OUTSOURCING, from page 6

70% of business software was pirated in 2002 by India. China was even higher at a 92% rate. If China had paid for its software, U.S. companies would have received an additional $1.6 billion in revenue and lowered China's trade deficit with the US. Robert Atkinson, *Meeting the Offshore Challenge*, **http://www.ppionline.org/documents/offshoring2_0704.pdf** (July, 2004). As a result, Intellectual Property theft is estimated to cost U.S.-based companies about $250 billion in sales annually, contributing to the loss of 750,000 jobs, according to the Commerce Department. Mark LePudus, *U.S. talks tough on IP enforcement*, **http://www.eetimes.com/news/semi/showArticle.jhtml?articleID=171000854** (accessed August 29, 2005).

Since China joined the World Trade Organization (WTO) in 2001 however, its laws on IP theft have become more strict. Stan Gibson, *Caution Marks Outsourcing In China*, **http://www.eweek.com/article2/0,1895,1853643,00.asp** (accessed August 29, 2005). The WTO is known as a multilateral trading system where agreements are negotiated and signed by a large majority of world's trading nations and must be adhered to. *WTO, What is the World Trade Organization*, **http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact1_e.htm** (accessed August 29, 2005). The United States is also a member of the WTO. *Id.* China has passed laws since joining this organization to conform with WTO standards. Stan Gibson, *Caution Marks Outsourcing In China*, **http://www.eweek.com/article2/0,1895,1853643,00.asp** (accessed August 29, 2005).

Although China has established several organizations, such as the State IP Office and State Copyright Bureau for protection of IP, enforcement of IP laws is still lacking. *Id.* In many instances it is left up to the independent Chinese contractor who deals with US businesses to take their own precautions against theft. *Id.* To avoid legal issues, companies have taken precautions such as having several geographically separate development centers and welcoming on site liaison mangers. *Id.* As an added precaution, employees are not allowed to take in with them to work USB drives or printers. *Id.*

In addition to IP theft by employees, companies should be equally worried about state intrusions. *Id.* In state controlled China, public security and government employees have the right to examine employee communications. Id. This capability raises the question as to whether the government could be seizing information to create its own data repository. *Id.* Although this has not occurred in any instances to date, the danger still exists and is similar to that of industrial espionage. *Id.*

The bottom line is that IP in foreign countries is always in danger. Companies are taking this risk very seriously. Steven J. Frank, *Source Out, Risk In*, **http://www.spectrum.ieee.org/careers/careerstemplate.jsp?ArticleId=i040405** (October 18, 2005). An estimated 38% of executives rank IP theft as their top concern involving outsourcing. Prevention, rather than cure, is seen as the best instrument against theft. *Id.* Most companies are following this philosophy and just do not trust their most valuable information to be sent overseas. Instead, they choose to keep their most important research and development out of third world countries and in locations with more robust security. *Economist Intelligence Unit, Scattering The Seeds Of Invention: The Globalization Of Research And Development*, **http://graphics.eiu.com/files/ad_pdfs/RnD_GLOBILISATION_WHITEPAPER.pdf** (2004). However, as more countries develop institutions to enforce IP laws, there is no telling how long this attitude will prevail and what will be outsourced tomorrow. ■

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■ INDIA, from page 9

they may fall foul of the non-discrimination mandate under Article 27(1) of TRIPS. They may also lead to considerable losses for Multinational Companies (MNCs) that have invested in the India.

NEW USE EXCLUSION

The Patents (Amendment) Act, 2005 also introduces a detailed 'new use exclusion' that provides that a 'new use of a know invention' will not be considered an invention under the Patents Act. *§ 3(d) of the Indian Patents Act*. The legislative debates indicate that its proponents introduced this provision with the intention of preventing what is referred to as 'evergreening' of patents. Shamnad Basheer and Mrinalini Kochupillai, *The Patents (Amendment) Act 2005: Its Implications In And Outside India*, 62 IIP 43 (Summer 2005) [hereinafter *Patents (Amendment) Act: Implications*]. The provision excludes the patenting of 'the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance." *§ 3(d) of the Indian Patents Act*. The explanation attached to the section further states that salts, esters, esthers, polymorphs, metabolites, etc. shall be considered to be the same substance unless they 'differ significantly in properties with regard to efficacy'. Id. This explanation raises an important question: what is the expected standard of 'efficacy'? Should the Indian patent office continue to have strong anti-patent undercurrents, the required standard of 'efficacy' may be very high. Shamnad Basheer, *'Policy Style' Reasoning at the Indian Patent Office* Intellectual Property Quarterly Issue 3 (2005) pp 309-323. Potentially, an entire range of 'new

See INDIA, page 11

INDIA, from page 10

uses' may be denied patent protection in India pursuant to this exclusion.

PARALLEL IMPORTATION

Prior to the amendments, the Patents Act, 1970 permitted "importation of patented products by any person from a person authorized by the patentee to sell or distribute the product." *§107A(b) of the Patents Act, 1970* (prior to its amendment by the Patents (Amendment) Act 2005). Amended, this section now allows "importation of patented products by any person from a person authorized under the law to produce and sell or distribute the product." *§ 107A(b) of the Indian Patents Act*. Now, should an Indian generics company shift its base of operation to Bangladesh, 107A(b) will permit the importation of that company's drugs from Bangladesh into India since these products are legally manufactured and sold in Bangladesh where product patents are not required be granted to pharmaceuticals until 2016. *Declaration on the TRIPS Agreement and Public Health (Doha Declaration)* ¶ 7 (November 14, 2001) WT/ MIN(01)/DEC/2, **http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm** (accessed December 1, 2005). While TRIPs is silent on exhaustion of rights, the amended § 107A(b) arguably goes beyond the principle of exhaustion and considerably emasculates the exclusive importation rights of patentees in India.

OTHER KEY PROVISIONS

The amendments introduce numerous other significant modifications: In relation to compulsory licenses, in keeping with paragraph 6 of the Doha Declaration, a new § 92A permits the grant of compulsory licenses for export of pharmaceutical products to countries having no manufacturing capacity of their own. *§ 92A of the Indian Patents Act*. § 92A allows an Indian exporter to obtain a compulsory license when the importing country has either granted a compulsory license or 'has, by notification or

See INDIA, page 12

From the Editor

GUEST EDITORIAL: IP LAW AND POLICY IN HONG KONG

BY GEMMA E. HOFFMAN (JD '06)

AT A TIME WHEN WE ARE CONSTANTLY BARRAGED with news reports on IP violations in China, it is refreshing to know that at least one of China's administrative regions is actually facing its tough IP challenges head-on. Over the winter break, I traveled to Hong Kong where I had the chance to witness this first-hand as an intern at the Hong Kong IP Department (IPD) (an administrative governmental office like the U.S. Patent & Trademark Office). As I studied Hong Kong's IP laws, attended briefings and hearings, I could see and feel the enthusiasm, excitement and unending dedication to IP protection in this small, South-east Asian region. Thanks to my generous colleagues at the IPD, I learned not only about Hong Kong's IP laws, but also about Hong Kong's rich history and culture. This article will serve as a brief tutorial on IP law and policy in Hong Kong.

Once ruled by the British, Hong Kong was handed over to the People's Republic of China (PRC) in 1997. Today, Hong Kong is often referred to as one country, two systems, signifying its curious position between the English and Chinese legal systems. IP owners must therefore be careful not to confuse IP rights (IPRs) granted in Mainland China and surrounding countries, like Macau, with those granted in Hong Kong. Steven Selby, Director of the IPD noted that, "many non-Governmental trading entities in the Mainland had been under a misapprehension that their Mainland-registered patents, trademarks, and design patents would be recognized and protected in Hong Kong following the reversion of Chinese sovereignty... To some extent, it has been a disappointment to enterprises in China to learn that this was not to be so."

Like the U.S., Hong Kong's IP laws are based on constitutional or Basic Law provisions. Article 139 of the Basic Law states that the *Government shall formulate policies on science and technology and protect achievements in scientific research* and Article 140 extends Article 139 to protect the *rights of authors in their literary and artistic creations*. Together with the Basic Law articles, international treaties, and a strong governmental focus on IPRs protection, Hong Kong offers protection for trademarks, copyrights, patents, and designs.

TRADEMARKS

Hong Kong's Trademarks Ordinance dates back to 1873 with Nestle's trademark for Eaglebrand milk assuming the first place on the Trademark Register. Revisions to the Ordinance occurred in 1955, and most recently in 1996 bringing Hong Kong into compliance with its TRIPs obligations. Like the U.S., a sign capable of graphic representation and of distinguishing goods/services of one undertaking from another is eligible for trademark registration in Hong Kong. Ordinary trademarks, certification marks, defensive marks, and collective marks are available for registration. Trademark registration may be denied based on absolute and/or relative grounds of refusal. An absolute grounds refusal may occur if a mark has no distinctive character or if the mark designates the kind, quality/quantity or geographic origin of the goods and services for which registration is sought. A relative grounds refusal occurs when the mark applied for is similar or identical to an earlier registered mark. Once accepted for registration, a mark is published and assumes a three-month opposition period.

COPYRIGHT

The Hong Kong Copyright Ordinance, which took effect in June 1997, grants authors the exclusive right to copy, make available, perform, display, broadcast, and make adaptations

See EDITORIAL, page 14

INDIA, from page 10

otherwise, allowed importation of the patented pharmaceutical products from India.' *Id.* The era of international price related competition in pharmaceuticals and resulting reduced prices may therefore still be alive. Further, the Bolar exemption under § 107A of the Patents Act has been expanded to exclude from infringement, the act of importing a patented invention for the purpose of obtaining information to be submitted to a regulatory authority. *§ 107A of the Indian Patents Act*. Earlier, § 107A only excluded the acts of making, using or selling a patented invention for such purpose. *§ 107A of the Patents Act, 1970* (prior to its amendment by the Patents (Amendment) Act 2005). Clearly, this provision would also complement the parallel importation provision discussed above.

The amendments also establish a post-grant opposition period of one year from the date of publication of grant of patent. *§ 25(2) of the Indian Patents Act*. This post-grant opposition procedure is in addition to the existing pre-grant opposition as an additional measure to weed out non-meritorious patents. *Patents (Amendment) Act: Implications, supra*. Further, the amendments insert new definitions aimed at tightening the patentability criteria: the definition of 'New Invention', appears to institute an absolute novelty standard (*§ 2(1)(l)*); the amended definition of 'inventive step' while appearing to institute a tighter non-obviousness requirement seems only to reiterate the pre-existing standard (*§ 2(1)(ja)*). Shamnad Basheer, *India's Tryst with TRIPS: The Patent Amendment Act 2005* forthcoming article in IJLT (2005). The unusual wording of these definitions will probably be subject to "nuanced interpretative battles" in the course of litigation expected in the near future. *Id.* Finally, the amendment process itself, seems far from over as the Indian Parliament has yet to decide two key issues: (a) whether to limit the grant of patents for pharmaceutical substance to new chemical entities or to new medical entities involving one or more inventive steps, and (b) whether to exclude microorganisms from patenting. These issues are currently being considered by an expert committee.

WHY THERE STILL IS CAUSE TO CELEBRATE

Despite the apparently diluted 'cause for celebration', the international pharmaceutical industry should focus on the up-side of the amendments—namely, the introduction of product patents for pharmaceuticals and chemicals. Given the flexibilities and multitude of possible interpretations inherent in the language of TRIPS, astute changes in business policies and relationships may be a better means of making the new patent regime in India a cause to celebrate rather than a reason for disappointment. The US pharmaceutical industry, for example, may consider joining hands with generics companies in India who are themselves looking at changing their business models to conform to the new changes in the law. A recent study revealed that the Indian generics giants now invest more in R&D and want to partner with MNCs. Cheri Grace, *The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China* (June 2004) **http://www.who.int/3by5/amds/Grace2China.pdf** (accessed October 12, 2005). The results of these efforts are positive: one third of all abbreviated new drug applications (ANDA) filed in the FDA in 2003, came from India. *Id.* at 21. In fact, partnering with Indian generic companies may be indispensable for entering the heavily regulated but by no means insubstantial Indian market. In truth, India continues to produce a plethora of highly skilled researchers and still offers lower labor costs and lower land costs. These facts, alone, make India an ideal place to establish new business ties. Indeed, they add to the reasons that make the 2005 amendments a cause to celebrate.

Mrinalini Kochupillai (LLM '06) plans on practicing IP law upon graduation.

TSAI, from page 1

and management that mirrors the American standard of professional ethics.

Mr. Tsai has been interested in IP ever since he served as a patent examiner at the Taiwan IP Office in the early 70s. After consulting many foreign associates, including former Germeshausen Center Director and Professor of Law Homer Blair, he chose Pierce Law over Queen Mary College of the University London. He benefited greatly from his exposure to U.S. litigants while he was at Pierce Law, because it introduced him to the aggressive litigating style that he was faced with later when he returned to Taiwan and the piracy lawsuits that his country members often faced.

While at Pierce Law, Mr. Tsai was exposed to classmates from countries like Japan, Korea and China, with whom he actively discussed issues such as the equivalent of each country's infringement standard. As a reflection of his interest in comparative cross-cultural practice and study of law, Mr. Tsai believes that an effective IP attorney should know at least one foreign language so as to not limit one's career to domestic practice.

Now, in his daily work at Tsai, Lee, & Chen, he handles patent infringement, invalidation, appeals, and administration litigation, in addition to conducting comparative studies of patent issues in China, Taiwan, and the U.S. He also serves as the President of the Taiwan Group of the Asian Patent Attorneys Association (APAA), dealing with the Taiwan IP Office regarding policy matters such as law amendments, regulations, and examination standards.

In addition to working with the APAA, Mr. Tsai also founded the

See TSAI, page 14

PIERCE LAW PARTICIPATES IN PANDEMIC INFLUENZA VACCINE IP MANAGEMENT MEETING

BY STANLEY KOWALSKI (JD '05)

ON APRIL 18, 2006 several members of the greater PierceLaw community participated in an important meeting held at the World Intellectual Property Organization (WIPO) in Geneva, Switzerland. Organized by The Centre for the Management of Intellectual Property in Health Research and Development (MIHR <**www.mihr.org**>), the meeting "Intellectual Property Management Strategies to Facilitate Early Access and Global Health Benefits: Case Studies in Pandemic Influenza and Malaria" had the objective of exploring and discussing IP issues which impact the distribution of vaccines to developing countries, a topic of heightened worldwide importance given the potential 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 IP management options for providing the poor of the developing world with access to critically essential vaccines.

PICTURED (LEFT TO RIGHT): DR. KONRAD BECKER OF SWITZERLAND; STANLEY KOWALSKI '05; RICHARD WILDER '84 OF WASHINGTON, DC; PROFESSOR KARL JORDA; DR. ANATOLE KRATTIGER, DIRECTOR AT THE CENTER FOR THE MANAGEMENT OF INTELLECTUAL PROPERTY AND HEALTH RESEARCH AND DEVELOPMENT (MIHR); AND ROBET EISS, CEO OF MIHR.

The participation of the PierceLaw community in this meeting is consonant with the mission of the Germeshausen Center (GC) as the umbrella organization for IP policy analysis, both in principle and in practice; that is, it underscores the GC's enduring commitment to tackling challenging issues in international IP. By examining the broader international context, and also engaging in discussions relating to innovative IP management strategies for technology transfer to and utilization in developing countries, the GC seeks to make comprehensive and substantive contributions to such ongoing collaborative endeavors, from policy to strategy to implementation.

PierceLaw participation is also consistent with the establishment of the International Development Intellectual Property Clinical Program (ID/IP Clinic). Linkages forged between the ID/IP Clinic and international initiatives such as MIHR will synergistically advance IP awareness and capacity building in developing countries, for the express purpose of improving public health and nutrition. Facilitating the availability of a pandemic influenza vaccine is just one (very important) example of how formulating innovative IP management strategies (and licensing options) can serve the greater global public interest. ■

Stanley Kowalski (JD '05) BS in Biology, University of Pittsburgh, Ph.D. in Plant Breeding, Cornell University will be supervisor of the Pierce Law ID/IP Clinic.

TSAI, from page 12

Taiwan Association of Information Technology and Intellectual Property (TAITIP), which has successfully received delegations for the past two years from the provisional EIPOs of Shanghai, Jangsu, and Zhejiang. TAITIP's goal is to assist the government, academic community, and industries in advancing the protection and development of e-commerce, internet information, intellectual property rights, and related technology laws.

Mr. Tsai's list of achievements goes on: not only is he currently writing a book, *Corporate IP Management*, but he is also a founder of the Taiwanese Pierce Law Alumni Association. He decided to start the association after meeting many alumni at different events in Taiwan's IP community; realizing that by informally discussing issues they could present uniform suggestions and comments on newly-proposed IP bills, regulations, and exam standards to professional associations. In fact, the Alumni Association is planning on having a first reunion in conjunction with the APAA 14th General Assembly in Kaohsuing, Taiwan on November 4-8, 2006. Interested participants should contact the current Taiwanese Pierce Law Alumni Association President, Benjamin Wang, at **bywang@itri.org.tw**, or Mr. Tsai himself at ttsai@tsailee.com.tw.

Mr. Tsai's studies at Pierce Law have exposed him to cross-cultural IP issues and contacts, which he plans to continue pursuing by eventually earning a SJD (Doctor of Juridical Sciences) in the U.S. focusing on Sino-American IP issues. He has enjoyed a distinguished IP career for more than thirty years, and if the past is any indication, he will continue to do so for many more years to come. ■

Ashley J. Walker (JD '07) received her BA in English from St. Mary's College of Maryland. Upon graduation, Ashley plans on practicing sports law, with a focus on representing disabled athletes.

EDITORIAL, from page 11

to their original work. No formalities are required for copyright to vest in an author, nor for that author to enforce her rights pursuant to the primary or secondary infringement of another. An action for primary or direct infringement may be brought against anyone who copies a copyrighted work without the author's permission. Secondary or indirect/vicarious infringement provides a remedy against those who authorize others to engage in piracy of copyrighted material. The fair dealing defense is an exception to an author's copyright and is available to those who can show that the unauthorized copyright did not unreasonably prejudice the legitimate interests of the copyright owner. The fair dealing defense in Hong Kong is a deeply contentious issue. As one of the world's most narrow and restrictive copyright provisions in the world, Hong Kong's fair dealing defense (similar to the U.S. fair-use defense) allows would-be infringers to use a copyrighted work only for research, private study, criticism, review or news reporting. These narrow exceptions to infringement are particularly limiting (and frustrating) for those using or desiring to use copyrighted works for educational purposes, e.g. teaching and classroom use.

From a comparative perspective, it is interesting that Hong Kong is now considering exchanging its exhaustive approach for a more flexible, non-exhaustive approach, like the one used in the U.S, Australia and Singapore. The non-exhaustive approach relies on a multi-factor test and weighs such factors as the (1) purpose and character of use, (2) nature of the copyright work, (3) amount and substance of portion used in relation to the work as a whole and (4) effect of the use on the market for the work. Those weary of the non-exhaustive approach worry that it may cause legal uncertainty because Hong Kong lacks case law in this area. As each case would be reviewed on its own merits, Hong Kong would need to look to the U.S. for case law, whose use is dubious, as U.S. law has no binding effect in Hong Kong. Opponents also expressed concern that this model may not comply with TRIPs provisions mandating that exceptions to copyright be limited to certain special cases. Conversely, those in favor of the non-exhaustive approach, including schoolteachers and administrators, argue it would provide needed flexibility to accommodate new circumstances and uses. Although the debate over fair dealing remains a contentious issue, the Hong Kong Government appears to have taken a position. On March 16, 2006, it announced a legislative bill proposal including, among other things, a more expansive and less restrictive fair use-type defense.

PATENTS

The Hong Kong Patents Ordinance took effect in June 1997 and provides standard and short-term patents for inventions. Patents will issue only for those inventions, which are new, capable of industrial application and involve an inventive step. Unlike other jurisdictions, Hong Kong does not conduct substantive patent examination. Registration for standard patents depends on prior registration in the UK Patent Office, European Patent Office or the State IP Office (SIPO) in the PRC. Only after a patent is granted in one of these offices may an applicant apply for registration in Hong Kong. In Hong Kong, the patent undergoes a formalities examination and will be granted a 20-year term of exclusivity if its meets all statutory requirements. Short-term patents, known as petty patents in Australia and other jurisdictions, may be filed in Hong Kong directly and do not require prior registration. If all formalities are satisfied, a patent applicant will enjoy an 8-year term of exclusivity.

IP in Hong Kong is a dynamic area of law that is sure to see wide reforms and changes within the years to come. The role of technology transfer will become increasingly more important as Hong Kong implements programs like the Digital 21 Strategy, which aims to transfer ownership of government-funded information technology projects to the private sector. Also, before too long Hong Kong might even see a revamping of its ailing patent system. However, as a trip to the well-

See EDITORIAL, page 16

STUDENT PROFILE: BETTY KIPLAGAT (LLM '06) HELPING KENYAN SCIENTISTS PROTECT IP

BY DARA KURLANCHEEK (JD '08)

THROUGH THE SPONSORSHIP of the Kenya Agricultural Research Insitute (KARI), Betty Kiplagat came to Franklin Pierce Law Center to earn her LLM degree ('06). KARI is an organization that brings together research programs in the areas of food, horticultural and industrial crops as well as livestock, range, land and water management. The organization also researches socioeconomic issues. Ms. Kiplagat is pursuing an LLM degree so that she can help educate Kenyan scientists about the importance of the IP rights of their inventions. Upon her return to Kenya, Ms. Kiplagat will be working for KARI and holding seminars on IP.

BETTY KIPLAGAT (LLM '06)

Ms. Kiplagat was originally hired by KARI to set up their legal office. She is a graduate of the University of Wolverhampton, UK and has passed the bars of England, Wales and Kenya. As Ms. Kiplagat set up the KARI legal office, she and KARI realized that the scientists that she was working with were unaware of the value of the IP that they were developing, or how to protect it. Ms. Kiplagat attended seminars on IP to better her understanding of the subject so that she could help the KARI scientists understand the significance of releasing discoveries and signing Material Transfer Agreements. Since she had taken an interest in the area, and KARI realized the importance of having an IP council on staff, KARI decided to sponsor Ms. Kiplagat in obtaining her LLM.

Ms. Kiplagat decided on Pierce Law's LLM program after a recommendation from her friend and Pierce Law Alumna, Rose Ndegwa (MIP '98). Ms. Ndegwa is the IP Officer for the International Livestock Research Institute's Nairobi, Kenya location. Although Ms. Kiplagat wishes she could take more classes in her one-year program, she acknowledges the invaluable contacts she has made at Pierce Law and finds IP to be a growing and dynamic field.

In the future, Ms. Kiplagat hopes to help shape international IP policy through working with either the World Trade Organization, where she is a national council member, or the World Intellectual Property Organization. She is particularly interested in working with how IP rights affect human rights. She specifically wants to look at the issues of whether IP protection unfairly increases the price of food and the affordability of patented drugs.

Ms. Kiplagat is confident that the knowledge that she is gaining at Pierce Law will help her in her future goals. Once she finishes her degree, she will be returning to KARI to continue working with scientists to secure IP rights for their inventions. Ms. Kiplagat looks forward to helping the scientists receive recognition for their discoveries and helping create jobs for startups. Her attainment of an LLM degree will help with these goals and will assist in providing guidance to the KARI scientists as to how to protect their progress and continue profiting from their discoveries. ■

Dara Kurlancheek (JD '08) received a BS from Penn State University in Electrical Engineering. Upon graduation she plans to practice IP with a focus on patent litigation.

EDITORIAL, from page 11

known shopping district of Mong Kok in Kowloon will tell (where even I had trouble resisting the latest Louis Vuitton handbag for sale at the bargain price of $10 U.S.!), it goes without saying that Hong Kong has a long way to go in eradicating piracy and other types of IPR infringement. Therefore, above all, the future is likely to bring a surge of promotion and education activities carefully tailored to convey to the public the urgency of respecting and protecting the IP rights of others.

If you are interested in learning more about IP in Hong Kong, visit ***www.ipd.gov.hk***.

Gemma Hoffman (JD '06) received a BS in Political Science from Northern Arizona University. She plans on practicing IP law upon graduation.

FRANKLIN PIERCE LAW CENTER
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June 5- July 14, 2006	**20TH ANNUAL INTELLECTUAL PROPERTY SUMMER INSTITUTE (IPSI)** Franklin Pierce Law Center, Concord,NH ***www.piercelaw.edu/ipsi/***
June 12-July 14, 2006	**4TH ANNUAL INTELLECTUAL PROPERTY SUMMER INSTITUTE (CHIPSI)** Tsinghua University School of Law, Beijing, China ***www.piercelaw.edu/chipsi/***
July 17-21, 2006	**15TH ANNUAL ADVANCED LICENSING INSTITUTE (ALI)** Franklin Pierce Law Center, Concord, NH ***www.piercelaw.edu/ali/ali.htm***
July 17-August 11, 2006	**2ND ANNUAL eLAW SUMMER INSTITUTE (eLSI)** University College Cork, Cork, Ireland ***www.piercelaw.edu/elsi/***

The Germeshausen Newsletter can now be accessed at:
www.piercelaw.edu/news/pubs/Germindex.htm

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