FRANKLIN PIERCE LAW CENTER
GERMESHAUSEN CENTER NEWSLETTER • *Summer/Fall 2003*

INSIDE THIS ISSUE:

Franklin Pierce Law Center Web Sites Win Recognition / **1**

Karen Hersey: A Life in the Law / **1**

IP Faculty Activities / **2**

Notable Happenings / **3**

Copyrights Uncensored: The Dirty Truth About CleanFlicks / **4**

Stent Wars: The Intellectual Property Battle Continues / **5**

Proposal for Intermediate Sanctions for Excessive, Unearned Profits from Technology Transfers / **7**

The Affirmative Defense of Prosecution Laches / **9**

Should Medical Methods Be Patented? / **11**

From the Editor / **13**

Calendar of Events / **16**

FRANKLIN PIERCE LAW CENTER WEB SITES WIN RECOGNITION

PIERCE LAW'S WEB SITES recently earned honors again. The school's main site (www.piercelaw.edu) won first place in the education category at the 5th Annual New Hampshire Internet Awards held in March. In addition, the school's IP Mall, a web site dedicated to intellectual property law, received high praise in a recent issue of Internet Law Researcher magazine. It stated, "New Hampshire's Franklin Pierce Law Center keeps improving its pioneering IP web site, www.ipmall.info. In its latest rendition, Pierce Law's IP Mall has revised the look of its web site into a navigable, content-filled site, and continued to fill the site with useful information…. The IP Mall Web Resources page is a researcher's paradise. All kinds of comprehensive Web link lists have been compiled…. There is much to explore at the IP Mall and the site should remain at the top of the IP researcher's list."

KAREN HERSEY: A LIFE IN THE LAW

BY NANCY B. DELAIN (JD '03)

PROFESSOR KAREN HERSEY teaches two courses in licensing and managing knowledge assets for non-profits at Pierce Law: Nonprofit Technology Transfer, and Managing Knowledge Assets in the University. She comes here after retiring from a 20-year career at the Massachusetts Institute of Technology (MIT) where she was Senior Counsel for Intellectual Property.

Professor Hersey's path to MIT took her from Boston University Law School to Thailand, Iran, the Southwestern United States, Saudi Arabia, North Carolina, and back to Massachusetts. Early on, she says, "I fell in love with the law."

She studied political science in college, with an eye toward a career in politics. To further that aim, she went to law school starting in the fall of the year she graduated from college. At Boston University School of Law, she was one of only seven women in her graduating class, and one of only three women on the law review editorial board. She is pleased that times have changed.

When she graduated, she went to work for a law firm; they assigned her to the Trusts and Estates Department, where she worked for a year before leaving the firm. She had good reason to leave: she had the opportunity to go to Thailand to work in a trademarks firm.

Ms. Hersey married a career military man, and followed him around the world, working in law firms and corporations wherever they went. In this capacity, she lived in Germany, Saudi Arabia (for one year; women are not allowed to work in Saudi Arabia), and Iran. While in Iran, she worked for GTE for two years.



PROFESSOR KAREN HERSEY

See HERSEY, page 10

PIERCE LAW
FRANKLIN PIERCE LAW CENTER

IP FACULTY ACTIVITIES

A group of about 100 8th grade students from the Weare, NH Middle School came to Pierce Law on September 12th to learn about patents. They were very receptive, having recently heard about the invention of the Segway. Professor **Tom Field** explained how patents make such innovation possible but that one doesn't lock up inventions unlikely to be stolen. He also answered many questions about the number of patents that have been granted, what can be patented and why it takes so long and costs so much.

Carolina Academic Press recently published Professor **Field's** fairly conventional casebook entitled *Introduction to Intellectual Property*. Besides covering IP fundamentals from an economic and historical as well as a legal perspective, the book pays particular attention to preemption and speech-related concerns. It is accompanied by a CD. Tables of contents and cases and other introductory material may be seen at: http://www.cap-press.com/bookinfo.php3?id=1301.

Professor **William Hennessey** traveled to Taiwan September 4-8, 2003 to speak with judges and government officials on current issues in international intellectual property policy, at the invitation of the U.S. Department of State. He met with faculty and students at the Law School of National Taiwan University to discuss current developments in U.S. intellectual property legislation and jurisprudence and gave lectures (in Chinese) to judges, government officials, and attorneys on enforcing laws against trademark counterfeiting and copyright piracy at the National Judicial Training Institute, The American Chamber of Commerce, and the American Institute on Taiwan in Taipei, and at Wenzao University in Kaohsiung. He also met with customs officials concerning the connection between IP enforcement and organized crime.

Professors **Susan Richey** and **Karl Jorda** gave presentations at a workshop on March 13 in New York City for the World Intellectual Property Organization (WIPO) and UNITAR, the training arm of the United Nations, on the subjects of "Basic Principles of Trademarks" and "Basic Principles of Industrial Property —Patents, Trade Secrets/Unfair Competition," respectively.



WEARE MIDDLE SCHOOL DELEGATION WITH PIERCE LAW PROFESSOR TOM FIELD AND DEAN JOHN HUTSON

On April 8 Professor **Karl Jorda** gave a presentation at Pierce Law at a seminar sponsored by Atlantic Bridge Network of Bedford, NH on "Increasing Importance of IP in the Global Economy." Professor **Jorda** was a guest speaker at the April 21 meeting of INCA (Inventors' Network of the Capital Area) in Potomac, MD on the topic of "Increasing Importance of IP." He addressed: 1) The Blackbox Dilemma in Licensing New Inventions; 2) Cultural Considerations in International Licensing; and 3) Royalty Setting in Technology Licensing. On April 17 **Jorda** spoke at the Boston firm of Greenberg Traurig on the topic "Patents and Trade Secrets: a Happy Marriage." He also participated in a Lemelson/MIT Workshop on "How Does Intellectual Property Support the Creative Processes of Invention?" held at the University Park Hotel at MIT, September 12-13. The 2-day panel discussion also included Bronwyn Hall (Berkeley), Sid Winter (Pennsylvania), David Taelin (MIT), Rochelle Dreyfuss (NY Law), Todd Dickinson (Howrey Simon Arnold & White), Tony Breitzman (CHI Research), Bob Gundlach (Xerox Research), and Lita Nelson (MIT).

GERMESHAUSEN CENTER NEWSLETTER

Published by the Kenneth J. Germeshausen Center for the Law of Innovation and Entrepreneurship

Editor:
Karl Jorda

Student Editors:
Michael Dirksen (JD '04)
Troy Watts (JD '03)

Assistant Student Editor:
Mark Jenkins (JD '05)

Administrative Editor:
Carol Ruh

Photography:
Linda Turner

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 twice a year for alumni/ae, students and friends of Pierce Law.

Our readers are encouraged to send news, photos, comments or letters to:

Carol Ruh
Franklin Pierce Law Center
2 White Street
Concord, NH 03301 USA
cruh@piercelaw.edu

Graphic Design & Typography:
Ampers&® Studio, Newmarket, NH

NOTABLE HAPPENINGS...

PIERCE LAW TAKES SECOND PLACE IN NATIONAL LEFKOWITZ TRADEMARK MOOT COURT COMPETITION

Pierce Law students won second place in the National Saul Lefkowitz Moot Court Competition held in Washington, DC this past spring. The team of Kee Kim (JD '04) and Fran Whitaker (JD '04) also won the award for "Best Brief in the Nation." Ann Yates (JD '03), President of the Moot Court Board, and Jennifer Wamsley (JD '03) served as coaches. Approximately 60 teams competed nationwide in this event, with four teams proceeding to the national competition. According to faculty adviser, Professor Susan Richey, "The students displayed an in-depth knowledge of trademark law and an ability to react quickly to the intense questioning of the judges. They distinguished themselves and Franklin Pierce Law Center." The team qualified for the national competition in February when they took first place in the Northeast Regional Saul Lefkowitz Moot Court Competition. The annual competition is sponsored by the Brand Names Education Foundation, the educational complement to the International Trademark Association, and is intended to introduce law students to the varied issues involving trademark law and unfair competition. The competition bears the name of Saul Lefkowitz who served for more than 30 years in the U.S. Patent & Trademark Office.

12TH ANNUAL ADVANCED LICENSING INSTITUTE

Pierce Law held its 12th Annual Advanced Licensing Institute (ALI) in Concord on 7/14-18/03. Designed by Karl Jorda, the David Rines Professor of Intellectual Property Law and Industrial Innovation, and taught by experts in the licensing and intellectual property world, the four-day Institute offered insights into the basic organization and subtle details of licensing and technology transfer. Topics included business arrangements involving patents, trademarks and copyrights, their negotiation and implementation. ALI is part of Pierce Law's 17th Annual Intellectual Property Summer Institute (IPSI), one of the most comprehensive summer academic programs in intellectual property law and licensing in the U.S. IPSI, which ran 5/19-7/18/03, offered 25 intensive intellectual property law courses focusing on the development of practical skills.

FIFTH BASIC PATENT COOPERATION TREATY SEMINAR

WIPO and Pierce Law co-sponsored the 5th Basic Patent Cooperation Treaty (PCT) Seminar held in Concord on 4/25-26/03. Vital for patent attorneys, patent agents and patent administrators, the seminar provided participants in-depth knowledge and understanding of the PCT. The program was directed by Professor Karl Jorda and included speakers Louis Maassel, Consultant, PCT Legal Division, WIPO and David Reed, Section Head, International Patent Division, Procter & Gamble Company, Cincinnati, OH.

7TH ANNUAL LES STUDENT CHAPTER SYMPOSIUM

On April 5, 2003, the Pierce Law Licensing Executive Society (LES) Student Chapter (the first and only student chapter of LES, founded in 1995) held its 7th Annual Licensing Symposium, bringing together inventors, entrepreneurs and students. Speakers included: James G. Cullem, (JD '99), in-house IP counsel for Cell Signaling Technologies, who covered aspects of IP strategy, acquisition, and management; Dr. Robert P. Santandrea, (JD/MIP '99) patent attorney at General Electric Global Research, who addressed strategic and business development counseling, licensing, and negotiation; Dr. Avery N. Gilbert, entrepreneur and sensory psychologist, specializing in odor perception at Cranial One Corporation, who shared experiences regarding IP development, trade secret protection, and marketing trends in stimulating olfactory senses; and Scott O. Brown, the award-winning publisher for Cyberosia Publishing and freelance writer in the comic book industry, who enlightened the audience regarding copyright and trademark licensing.



PROF. JORDA, JIM CULLEM, BOB SANTANDREA, AVERY GILBERT, JEFF LODDING, JULIA BAZALDUA, DEAN HUTSON



TOKYO DELEGATION PICTURED HERE WITH PIERCE LAW PROFESSOR BILL HENNESSEY, DEAN JOHN HUTSON AND PROFESSOR KARL JORDA (BACK ROW)

TOKYO INSTITUTE OF TECHNOLOGY VISITORS

A delegation from the Tokyo Institute of Technology (TIT) paid Pierce Law a visit on March 4. The delegation consisted of Professor Tomoko Saiki, Dr. Hiroyuki Umemuro and Research Associate, Noriyuki Oikawa. The purpose of their visit was to exchange views on establishing IP education and training programs at their very prominent institution in Tokyo and a possible cooperative tie with Pierce Law as well as to initiate plans for a symposium on "IP Management

See HAPPENINGS, page 5

COPYRIGHTS UNCENSORED: THE DIRTY TRUTH ABOUT CLEANFLICKS

BY ANDREW MATISZIW (JD '05)

WHAT IS LEFT BEHIND in Steven Spielberg's World War II epics without the graphic realism of troops storming the beach at Normandy or of human suffering in Nazi concentration camps? What replaces David Mamet's poetic string of profanity in perfect iambic pentameter? What remains is not art, according to Hollywood. However, against Hollywood's wishes, objectionable material is being edited out of films by two different tribes as the demand for censored motion pictures booms throughout Colorado and Utah.

One group, "maskers," develops computer software that skips, mutes, and masks objectionable material on DVDs by playing the movie through a filter specially created for each film. The technology is progressing to the point of adding clothing onto nude bodies and modifying movement of lips during offensive speech. The second group, "content editors," creates a master copy of their edited version of a film and then copies it over a purchased studio copy, leaving the studio packaging and cassette intact. With DVDs, they purchase a copy of the retail DVD and send it destroyed or intact to their consumer along with a version of their edited VHS master recorded on a DVD.

The motion picture studios that hold the copyright on the films authorized none of the editing. In response, the Directors Guild of America (DGA) announced plans to sue a group of film editing companies, naming the directors who would be the plaintiffs in the lawsuit. One of the listed companies, CleanFlicks, was understandably concerned with being sued for copyright and trademark infringement in California's Ninth Circuit where they would be surely doomed. CleanFlicks pre-empted their unhappy sojourn to California and filed first in U.S. District Court in Colorado's Tenth Circuit. Suing sixteen of the DGA's prominent members, including Steven Spielberg, Martin Scorsese, and Robert Redford, CleanFlicks sought a declaratory judgment that they were not violating the U.S. Constitution, the Copyright Act, or the Lanham Act.

A flurry of legal filings responded CleanFlicks move. First, the DGA moved to intervene and represent the directors being sued. Second, they counterclaimed for violation of the Lanham Act—false designation of origin (15 U.S.C. § 1125(a)), trademark dilution (15 U.S.C. § 1125(c)), and unfair competition under California law (Cal. Bus. & Prof. Code § 17200 et seq.). Third, they moved to join seven other third-party film editing companies as counter defendants. Since the DGA was being sued for a declaratory judgment that CleanFlicks was not infringing the Copyright Act, the DGA compelled joinder of the motion picture studios as the copyright holders of the films.

The studios, trying to avoid the fracas for as long as possible, were drawn in against their will. For them, the lawsuit is a lose-lose situation. If the DGA wins on Lanham Act claims, the court will recognize that the directors have a greater legal right to their films than has historically been given to artists under the "work for hire" doctrine. Consequently, the studios will lose some control of their films and will ultimately have to pay more money to the DGA and its members. If the DGA loses on the Lanham Act, the studios' claims of copyright infringement may not be enough on their own to stop the unauthorized editing of their films. The studios counterclaimed against the "content editors" for violation of the Lanham Act—false designation of origin (15 U.S.C. § 1125(a)), trademark dilution (15 U.S.C. § 1125(c)), unfair competition under California law (Cal. Bus. & Prof. Code § 17200 et seq.), trademark infringement and unfair competition (15 U.S.C. §§ 1114, 1116), and copyright infringement (17 U.S.C. § 101 et seq.) citing their exclusive rights to reproduce films and create derivative works. The studios counterclaimed against the "maskers" only for copyright infringement.

In an ironic twist, the DGA and studios, facing off with moral content film editing companies, have no moral right under U.S. copyright law. The "droit moral" right that many artists in Europe appreciate is not afforded under U.S. law. Instead, the DGA and studios are using the Lanham Act to protect the artists' integrity. The DGA focuses specifically on one case in generating their theory: *Gilliam v. American Broadcasting Companies, Inc.*, 538 F.2d 14 (2d Cir. 1976). In *Gilliam*, the members of Monty Python sued ABC for editing their programs for broadcast on American television without their consent or approval. *Id.* at 17. Although under license from the BBC to air the programs, ABC was in violation of the copyrights that the members of Monty Python possessed on the programs' scripts. *Id.* at 21. The court found that cuts in the shows constituted actionable infringement and that the edited episodes were unauthorized derivatives of the copyrighted script. *Id.* at 23-24. The substantial editing of the programs was considered mutilation as material was cut out in such a way that it removed critical scenes and left the entire work disjointed and distorted. *Id.* at 25. Since no moral right exists in U.S. copyright law, the Lanham Act was applied instead. *Id.* at 24. Although it was created for trademarks, the Lanham Act was written broadly enough to allow the artists to recover for misrepresentations done to their work that may injure their business or personal reputation. *Id.* at 26.

It is unclear how far any circuit will use the Lanham Act as a substitute for droit moral. Even the Second Circuit, in the *Gilliam* decision, expressed concern with its application of the Lanham Act. The concurrence believed that copyright infringement brought Monty Python sufficient relief on its own. *Id.* at 27. Therefore, it was unnecessary to apply the Lanham Act as a moral right. *Id.* To satisfy the plaintiff's artistic integrity, the concurrence suggested placing a simple disclaimer before the edited program clarifying that the artists did not approve of the editing. *Id.*

One case that might shed light on how the Tenth Circuit will apply the Lanham Act is *Paramount Pictures Co. v. Video Broadcasting Systems, Inc.*, 724 F. Supp. 808 (D. Kan. 1989). Paramount sued Video Broadcasting Systems under the Lanham and Copyright Acts for copying unauthorized commercials onto home video cassettes before the film began. *Id.* at 812. The court followed *Gilliam*; however, they didn't find that copying commercials onto tapes before the film began to be sufficient alterations to the

See CLEANFLICKS, page 6

HAPPENINGS, from page 3

Strategies in the U.S. and Japan" to to be held at the TIT in Tokyo on December 14 with the participation of Professor Karl Jorda.

DELEGATION FROM NATIONAL MAGISTRATES INSTITUTE (NMI) VISITS PIERCE LAW

Pierce Law hosted an Algerian judicial delegation, including two judges from the Algerian Supreme Court, as visitors on April 16, 2003, sponsored by the U.S. Dept. of Commerce Commercial Law Development Program [CLDP]. The delegation visited both the NH Supreme and NH Federal District Courts and met with Judges Nadeau, Duggan, DiClerico, and Muirhead. Algeria is attempting to comply with WTO obligations in order to enter the WTO in 2004. This visit was in conjunction with Algeria's ongoing program to bring its laws and judicial system into compliance with those obligations.



JUDGE LI SCHICHENG

JUDGE LI VISIT

The Law Center hosted a visit on March 10 and 11, 2003, of Judge Li Shicheng, Chief Justice of the No. 3 Civil Tribunal of the People's Higher Court of Sichuan Province, China, sponsored by the U.S. Department of State and the New Hampshire World Affairs Council. During his visit, Judge Li met with Pierce Law faculty members concerning rule of law issues and visited with members of the state's judiciary, including Justices Joseph Nadeau and James Duggan of the New

See HAPPENINGS, page 7

STENT WARS: THE INTELLECTUAL PROPERTY BATTLE CONTINUES

BY MARK JENKINS (JD '05) AND DOUG PORTNOW (JD '05)

IN 1994 the U.S. Food and Drug Administration (FDA) granted market clearance to Johnson & Johnson (J&J) for their new cardiovascular product, the Palmaz-Shatz coronary stent. Named after the two physician inventors, this tiny metallic tube (3 mm x 15 mm) is implanted into the coronary arteries of a patient's heart with a catheter. Once correctly positioned at the site of an obstructed artery, a balloon angioplasty catheter is then used to expand the stent's diameter, pressing it into the walls of the vessel. This opens up a clear channel for blood flow and provides a mechanical scaffolding to keep the artery from collapsing. The need for open-heart bypass surgery has been significantly reduced by this minimally invasive procedure, and stenting also provides superior results compared to balloon angioplasty alone. J&J dominated the market for three years until newer, competing technology hit the market in 1997. Today, approximately 800,000 patients receive stents every year with annual sales exceeding $2 billion. Manufacturers are currently relying not only on research and development (R&D) advancements but also on intellectual property rights to protect their individual market shares in the fiercely competitive and rapidly advancing world of medical devices.

The first coronary stent manufactured by Cook, Inc. was approved for use in 1993. However, general stent use did not become widely adopted by cardiologists until J&J introduced the Palmaz-Shatz one year later. The launch of the J&J stent was the result of approximately eight years of research, development, and clinical testing. The dramatic increase in stent use in cardiac catherization laboratories resulted in a backorder that took J&J eight months to clear. By late 1995, J&J's stent sales were estimated at $450 million and they dominated the market. Hoping to solidify its strong market position for the long term, J&J made a $1.6 billion hostile takeover of Cordis Corporation, a manufacturer of angioplasty balloon catheters and other stent procedure accessories. Additionally, Cordis had their own proprietary stent under development. J&J's acquisition was its first hostile takeover and surprised many people because of its wholesome, family image as a provider of baby powder and shampoo. A number of other large medical device manufacturers quickly followed suit acquiring smaller manufacturers in order to obtain their own stent technology. One such acquisition occurred in March 1996 when Medtronic, known for its pacemaker technology, acquired InStent Incorporated for $215 million. A year later, US Surgical acquired the exclusive option to purchase Progressive Angioplasty Systems Incorporated, a manufacturer of angioplasty catheters and stents.

In addition to corporate acquisitions, R&D efforts were also coming to fruition. By October 1997, Guidant, a spin-off of pharmaceutical giant Eli Lilly, began marketing its next generation ACS Multi-Link stent, which offered a more flexible and maneuverable design in comparison to its market competitors. The Arterial Vascular Engineering Incorporated (AVE) stent hit the market two months later and by August 1998, Boston Scientific Corporation's Nir stent was launched.

With the enormous influx of new stent technology in the late 1990's, many lawsuits concerning intellectual property rights were initiated. One of the earliest suits involving stent technology was between J&J and Cook over an alleged patent infringement of the Palmaz-Shatz '665 patent (U.S. Patent No. 4,733,665). The suit was settled in January 1997. With over a billion dollars in stent sales in 1997, medical device manufacturers began mitigating their risks of infringement by cross-licensing stent technology. Medtronic and Cordis followed this trend by signing a cross-license agreement in November 1997 for patents on stents and stent delivery systems, thus ending litigation and patent interference proceedings between the two rivals.

New stents continued to be developed and by late 1998, annual stent sales reached $1.5 billion. Corporate acquisitions also continued. Boston Scientific purchased the Schneider unit from Pfizer and attained FDA approval to market the Magic Wallstent. Also in order to gain fast entry into the lucrative stent market, Medtronic agreed to purchase the seven-year upstart, AVE for $3.7 billion.

See STENT WARS, page 6

CLEANFLICKS, from page 4

movie to satisfy Lanham or Copyright Act violations under *Gilliam*. *Id.* at 819.

Despite how the court may apply the Lanham Act, a simple disclaimer may satisfy all claims under the act. CleanFlicks argues that there is no confusion about the origin of the edited film. In fact, their customers purchase the CleanFlicks versions because they are edited. The customers of the content-edited films understand that the movies have been morally altered without the directors' input. What the consumers already infer may be clarified by a disclaimer that would invalidate all claims.

The content-editors' alleged copyright violations may also be dismissed under the defenses of "first sale" and "fair use" under the Copyright Act. Under the "first sale" doctrine (17 U.S.C. § 109(a)), an owner of a particular copy of a copyrighted work may sell or dispose of it as he sees fit since the copyright is exhausted as to that particular copy. The "maskers" appear to be protected under this defense since the user who has purchased the DVD of the studio's motion picture controls the masking software. The "content editors" on the other hand, have a more difficult road to travel. While they purchase a studio copy for each edited copy they sell, the "first sale" doctrine appears to be more of a loophole for a manufacturer than a legitimate legal defense. Under the doctrine, such editing would clearly be a right of the end user. However, whether the court applies the same standard to a manufacturer remains to be seen.

Under the "fair use" doctrine (17 U.S.C. § 107), the Copyright Act gives four factors for determining fair use. The first factor determines if the use is for commercial or nonprofit uses. In this case, the use is commercial, with the content-editors making a profit off of editing films. The second element weighs the nature of the work, which is an otherwise unavailable edited version of a film. The third factor examines the amount of work copied. Since almost the whole film is reproduced, the copying is substantial. The final factor involves the impact on the market for the copyrighted work. The content-editors point out that they should be thanked by the studios for opening up the films to consumers who would normally not purchase the films, thereby giving a positive impact on the market. However, the studios will surely counter with the possible impact on any official or licensed edited copies of the films.

In the end, it is a far-right value that desire films to be edited for moral content. They have found unlikely support among the far-left that sees copyrights as monopolies that hinder creative freedom. Meanwhile, the usually liberal Hollywood community is up in arms about this attack on their artistic integrity and they seek complete copyright control along with more conservative minded people. It is no wonder why the studios avoided the issue for as long as they could. The ruling will be a Pyrrhic Victory that nobody will win, no matter their views. ■

Andrew Matiszw (JD '05) holds a BA in English from Westminster College in Fulton, Missouri. Andrew is planning on practicing Entertainment law in California upon graduation.



STENT WARS, from page 5

Medtronic's acquisition of AVE was not its only strategic move. In July 1999, they filed a fourth patent infringement suit against Boston Scientific. Medtronic filed the suit in U.S. District Court in Minnesota intending to stop Boston Scientific from selling two types of stents made of nitinol, a nickel-titanium alloy. In March 2000, Boston Scientific countered by suing Medtronic for infringement of U.S. Patent No. 4,762,129 which protected "rapid exchange" catheter technology. Medtronic responded by demanding arbitration per the terms of a prior agreement between AVE and Schneider. The arbitration panel awarded Boston Scientific $84.5 million in damages and then doubled the award due to willful infringement. Medtronic appealed the panel's award. The matter was ultimately settled for $175 million and an agreement to cross-license various patents.

Boston Scientific's next move was to file suit against J&J seeking an injunction to prevent sales of J&J's new BX Velocity stent. Boston Scientific claimed the stent infringed on a patent they had licensed from their Israeli supplier, Medinol, Ltd. Meanwhile, Guidant and J&J formed a broad technology exchange agreement limiting Guidant's exposure to patent litigation and giving J&J access to Guidant's balloon catheter system. Additionally, Guidant agreed to pay between $125 and $400 million for electrical technology in an exchange for an agreement to send all patent litigation to arbitration. In August 2003, an arbitration panel upheld a ruling requiring Guidant to pay $425 million to Cordis by year's end. Guidant also negotiated an agreement with Boston Scientific to cross-license certain patents and end all pending patent litigation concerning coronary stents and balloon catheters.

In November 2000, a jury found that Medtronic infringed two of J&J's stent patents. Damages were awarded in December, and Medtronic was ordered to pay J&J $270 million in damages. In April 2002, the U.S. District Court for the District of Delaware found Medtronic did not infringe J&J's patents and overturned the $270 million damage. In August of 2003, the U.S. Court of Appeals for the Federal Circuit reversed and remanded the district court's judgment granting summary judgment on the issue of literal infringement, and the judgment granting judgment as a matter of law on the issue of infringement under the doctrine of equivalents. The validity of the two patents at issue was affirmed. During this time period, a federal jury found Boston Scientific's Nir stent infringed on J&J's broadest patent resulting in a $324 million damage award for J&J. In April 2002, the jury verdict was set aside and a new trial was set to determine damages. J&J continued to struggle to protect its intellectual property when a German court ruled that J&J infringed on a patent owned by Boston Scientific's partner, Medinol. In addition to an award for damages, the decision gave Boston Scientific the right to obtain an injunction terminating German sales of J&J's BX Velocity stent.

An estimated one million Americans will undergo angioplasty this year and 80% of those patients will receive a stent. The stent market is expected to expand to $5 billion during the next few years with the release of next-generation devices that allow more patients to be treated. The latest technology

See STENT WARS, page 9

HAPPENINGS, from page 5

Hampshire Supreme Court, and Magistrate Judge James Muirhead of the U.S. Federal District Court for the District of New Hampshire. Judge Li, who is chief adviser to the judiciary in his province, was particularly interested in discussing American methods for management of cases and for the administration of justice.

PIERCE LAW PARTNERS WITH PENN STATE'S EBERLY COLLEGE OF SCIENCE

Pierce Law and Penn State's Eberly College of Science have finalized an agreement establishing an accelerated program in science and intellectual property law. Participants in the program will receive a BS degree from Penn State and a JD degree from Pierce Law when they complete the six-year program. "This initiative in intellectual property law with the Franklin Pierce Law Center closes the circle of accelerated science-medicine, science-business, and science-law programs offered by the Eberly College of Science," said Norman Freed, Associate Dean of the Eberly College of Science at Penn State. "Intellectual property law, a rapidly growing field, builds upon a solid foundation in the sciences and we are particularly delighted to have developed this initiative with the top-ranked intellectual property law school in the nation."

Similar joint cooperative and early admissions programs have been in place for many years with Clarkson University, Potsdam, NY and Worcester Polytechnic Institute, Worcester, MA.

Pierce Law has now also entered into a new arrangement with the University of New Mexico Law School in Albuquerque, NM which essentially provides student exchanges. Their students can come here for a semester to study IP law and our students can go there for a semester to take advantage of their programs in Clinical Law, Native American Law and Natural Resources Law.

PROPOSAL FOR INTERMEDIATE SANCTIONS FOR EXCESSIVE, UNEARNED PROFITS FROM TECHNOLOGY TRANSFERS

BY NANCY W. CHILDRESS (JD '03)

IN JANUARY 2002, the IRS imposed new regulations to protect donors and charities from insider dealing and excessive compensation for executives. Nonprofits must document how and why they compensate those with influence over the organization. If an executive or person with influence (disqualified person) is overcompensated, and does not repay the difference, a stiff penalty of 200% of the excess amount could be imposed. In addition, there is a 25% tax on the excess for the individual and the organization itself may lose its tax-exempt status. A manager's penalty tax is capped at $10,000 per occurrence.

Compensation is usually in the form of salary, but may extend to equity taken in a company, licensing fees on technology transfers, or other consideration in a transaction. To determine an insider status, the regulations cite the opinion of the Seventh Circuit that prohibited inurement under IRS Code Section 501(c)(3), which stated that the transaction cannot result from a contractual relationship negotiated at arm's length with a party having no prior relationship with the organization, regardless of relative bargaining strength of the parties or resultant control over the tax exempt organization created by the terms of the contract. This *initial contract exception* benefits nonprofits because a contract entered into, will not be considered excess benefit transaction so they do not have to report it although it could be a private benefit that would be a basis for denying tax exempt status. So even though the person is protected, the organization may not be protected.

Since a nonprofit with a board of directors has no shareholders to report to, it also does not have to follow the same requirements for disclosure as publicly traded corporations do. When a nonprofit converts to a for-profit status, it allows officers/directors to be privately enriched without any consequences. Along the same line, assets are sometimes diverted to insiders. For example, health care assets are sometimes purchased at an undervalued price and later sold for their current value, which could be 50-125 times the amount actually paid.

State response has become increasingly vigilant. As of November 1997, twelve states and D.C. had passed legislation to ensure greater control over these sales. In California, legislators passed the California Not-For-Profit Public Benefit Corporation Act in 1996, which made it illegal for a nonprofit health care facility to dispose/transfer assets to a for-profit corporation without notifying the attorney general and receiving his/her consent.

The attorney general may hire experts to investigate the proposed sale or transfer at the nonprofit's expense and must hold one public meeting in the county where the health care facility is located. Factors considered in the decision are whether an individual benefits, the value of the assets depreciated, and whether there was a breach of trust.

States, in general, lack the police force to enforce the control over these transactions. Since these are very complicated and sophisticated transactions, the state attorneys may lack the skill in this area of law to pursue any intervention. Often it is the smaller transactions that do not catch the eye of the media that cause the most damage as they proceed without notice.

Therefore, there is a need for the federal government to step in and regulate. In addition, there are federal interests that need to be protected. By providing nonprofits with their tax exempt status, deductions for donors, and lower rate bonds, the government has helped them accumulate assets which need to be put aside for charitable purposes and not to be procured by private individuals.

IRS penalties have not been successful for a number of reasons. First, revocation of a tax-exempt status for a hospital outweighs the excessive benefit for the individual. Secondly, it

See SANCTIONS, page 8

SANCTIONS, from page 7

did not discourage further procurements because it had no direct effect on the individual. Lastly, it places the fine on the organization, which curtailed their financial ability to serve the community, resulting in cutbacks in services. Thus the Intermediate Sanctions were born. They differ from private foundation provisions against self-dealing. These provisions prohibit certain types of transactions between private foundations and insiders. In contrast, the intermediate sanction kicks in only if the insider receives a benefit that exceeds the benefit received by the nonprofit. In a sale, the consideration received must not exceed its fair market value. However, sales *from* insiders to private foundations are not allowed even if the price is right.

Examples of excessive benefits would be excess salary, sales at a depreciated value (including technology transfer licenses), or any transaction, which directly or indirectly benefits the individual (disqualified person), manager, director, employee, family member, or other officer in the position to influence the decision of the transaction.

Distinguishing the policing of the self-dealing provisions with the Intermediate Sanctions, the self-dealing provisions are easily caught with an audit. However, the transactions involving many assets would be difficult to catch with an audit because the value of these assets is commingled. Likewise, with the self-dealing, the individuals are easily targeted whereas with the disqualified person, it must be one in the position to exercise influence over the transaction. This is more difficult to sort out. Therefore, there is little incentive for the directors/officers to comply with these sanctions if they feel they can escape their wrath. IRS has cut back on employees, which further emphasizes the need for different policing of Intermediate Sanctions.

One of the areas in need of policing is that of patent pooling. Looking at the background of patent pooling, it has been a process of linking similar patents together in a cross-licensing agreement thereby allowing companies to avoid separate licenses, encouraging more licensing and sharing of know-how, and of course the sharing of profits. Many times it is the profit sharing in a patent pool that is held to be questionable. Recipients of profits often may not have participated in the patent but their name appeared on the patent application. It is hard to track the money flow back to the rightful inventors. In genome companies, patent owners may not have similar goals within the company or nonprofit institution. This industry involves many institutions in a pool, which increases the chances of one of the institutions holding back on joining the pool. If a large amount of patents were lumped together in a pool in order to represent all the institutions, there would be antitrust claims.

In 1995, the Justice Department and the FTC issued the *Antitrust Guidelines for the Licensing of Intellectual Property* ("*IP Guidelines*"), which sets forth their enforcement policies in this area. The *IP Guidelines* specifically address patent pooling arrangements. The guidelines that prohibit participants from obtaining market power or colluding on prices seem to be a huge disincentive for executives or board members receiving overcompensation through the patent pooling process. If not an answer to our problem of "reporting," it certainly would serve as a model for checking on income derived from the simple licensing transfers and could easily be applied to these transactions.

With all these checks on overcompensation, there is a loophole through which the organization can jump. If they can establish a rebuttable presumption that the compensation is reasonable by showing that the decision maker in the organization exercised care and prudence in the process relating to the transaction, the burden shifts to the IRS to prove unreasonableness. To establish reasonableness, the amount of compensation is compared with the value of services performed, taking in all facts and circumstances. Differences in opinion will arise when the employee feels he/she should share in the company's profits and yet the IRS Code defines an employee's reasonableness for the deductibility of compensation as different from the owner's "reasonableness" of salary.

Important factors found by the courts to be particularly relevant to a reasonable compensation determination are the employee's qualifications, the nature, extent and scope of the employee's work, the size and complexity of the business, a comparison of salaries paid with sales and net income, general economic conditions, a comparison of salaries to distributions to shareholders and retained earnings, the employer's salary policy, the employer's financial condition, compensation paid in prior years, whether the employee and employer dealt at arm's length and whether the employee guaranteed the employer's debt.

The IRS does not look at the company's history when examining reasonableness, but rather focuses on the specific time in question. As mentioned earlier, they take into account many factors, no single factor is controlling. However, to rebut an IRS finding, the organization can present their entire financial history, economic indicators within the general business climate, and other organizations using the same executive salaries. Proxy statements of similar businesses can identify subparts of compensation and serve as comparisons. In doing a compensation analysis to determine reasonableness and competitiveness, the organization should include a performance analysis (relationship between performance and pay) and a foregone pay analysis to see if the executive was first under-compensated in prior years and in subsequent years overcompensated to balance out his/her salary.

In concluding, the checks and balances applied to corporations to detect over-compensation can be applied to the nonprofit university. Through their technology transfers, they can either have Intermediate Sanctions imposed on the executive, "disqualified person," or organization because they failed to have the transfer approved in advance by those not in conflict with the transaction, lacked comparability data, and failed to document the basis for the determination of the benefit, or they can avoid sanctions by a showing a rebuttable presumption of reasonableness. If the transfer takes place within a patent pool, the organization can follow the *IP Guidelines* prohibiting participants from obtaining market power or colluding on prices, and therefore avoid antitrust issues. Providing the IRS with a well-prepared financial history, comparability data, and compensation analysis will help the organization defend an IRS finding of unreasonableness.

Nancy Childress (JD '03) received her BS in Elementary Education from Plymouth State College. Nancy plans to practice nonprofit law upon graduation with her consulting firm, Nonprofit Consulting Services.



STENT WARS, from page 6

includes using stents as delivery systems for radiation or drugs in the coronary arteries in an effort to reduce restenosis (a renarrowing or blockage of an artery at the same site where treatment, such as an angioplasty or a stent procedure, has already taken place). Two promising drugs include Paclitaxel (an active ingredient in the cancer drug Taxol) and Rapamycin (an immune system suppressant used in organ transplantation originally derived from a soil sample obtained on Easter Island). The FDA approved J&J's Rapamycin coated stent this year and is the result of evaluations of hundreds of drugs and an $800 million development program. Boston Scientific's Paclitaxel stent program is about six months behind J&J and should be approved in early 2004. Guidant attempted to acquire drug coating technology from Cook in a proposed $3 billion acquisition, however this deal failed when early clinical results proved unsatisfactory and litigation with Boston Scientific prevented Cook from licensing the use of the drug Paclitaxel.

With the stent market expected to expand to over $5 billion annually, medical device manufacturers are striving to develop new technology that reduces the restenosis rate after stent implantation. Manufacturers also continue to rely on their respective intellectual property portfolios to protect their products from competition. A new round of litigation occurred in January of this year when Cordis filed suit against Boston Scientific alleging patent infringement based on Boston Scientific's Express 2 stent. This is certain to be one of many patent infringement suits in the coming years. In the short history of stents, there have been over thirty domestic patent infringement suits with damages amounting to millions of dollars. Stent wars are sure to continue in this high stakes sector.

Mark Jenkins (JD '05) received his BS in Chemistry from the University of Tennessee and his MS in Biophysical Chemistry from Vanderbilt University. Mark plans on practicing IP law upon graduation.



Doug Portnow (JD '05) received his BS in Mechanical Engineering from MIT, a MS in Bioengineering from the University of Michigan and an MBA in Finance from Santa Clara University. Doug plans on practicing IP law in the Silicon Valley area.



THE AFFIRMATIVE DEFENSE OF PROSECUTION LACHES

BY CHRISTIAN BAUER (JD '03)

IN JANUARY OF 2002, the U.S. Court of Appeals for the Federal Circuit held in *Symbol Technologies v. Lemelson Medical*, 277 F.3d 1361 (Fed. Cir. 2002) that a potential patent infringer could assert the affirmative defense of prosecution history laches.

Symbol Technologies brought a declaratory action in the U.S. District Court for the District of Nevada against Lemelson Medical seeking to have Lemelson's patents held invalid, unenforceable, and not infringed. The gravamen of *Symbol Technologies* was prosecution laches. Lemelson Medical moved for dismissal arguing that the assertion of prosecution laches fails to state a claim upon which relief could be granted. The district court dismissed the laches claims. The issue on appeal was whether the equitable doctrine of laches may be a basis for the defense asserting that patent claims issued after an unreasonable and unexplained delay in the prosecution, even though the patentee complied with the applicable statutes and U.S. Patent & Trademark Office rules. The Federal Circuit reversed and remanded for a decision on the facts. (base file opened June 15, 2001 docket no. cv-S-01-0701-PMP-RJJ; consolidated with cv-N-99-0397, cv-S-01-0702 and cv-S-01-0703).

In evaluating the defense of prosecution laches, the Federal Circuit reviewed the historical treatment of prosecution laches beginning with *Woodbridge v. United States*, 263 U.S. 50 (1923) (holding that where the actions behind patentee's delay are found to be a deliberate and unlawful purpose to postpone the beginning of the term of his patent and thus put off the free public enjoyment, the patentee is barred by laches) and *Webster Electric, Co. v. Splitdorf Electrical Co.*, 264 U.S. 463 (1924) (holding that a finding of unreasonable delay and neglect on the part of the applicant invalidates a patent due to prosecution laches). Upon reviewing these precedent opinions, the Federal Circuit concluded that the equitable doctrine of prosecution laches was a viable defense, especially when there was evidence of intervening public rights. *Symbol Technologies*, 277 F.3d at 1365.

Lemelson also relied on the history of prosecution laches in forming his argument. Lemelson argued that laches is not available as a defense because: (1) the defense of prosecution laches in *Webster* only applied to claims in interference proceedings; (2) the legislative history of the 1952 Patent Act foreclosed the defense of prosecution laches; and (3) the Federal Circuit is bound by two non-precedential opinions that rejected the theory of prosecution laches.

The Federal Circuit rebutted Lemelson's first argument stating that nothing in *Webster* limited laches to interference practice. *Id.* at 1361. The court rebutted Lemelson's second argument because the court could find no intent by the drafters of the 1952 Patent Act abrogating the defense of prosecution laches by allowing for continuation practices. *Id.*

Before the 1952 Patent Act, the continuation practice was governed by common law. The court concluded that because the continuation practice existed in common law at the time of the decisions in *Woodbridge* and *Webster*, the defense of prosecution laches and the continuation practice coexisted. The court further stated the drafters of the 1952 Patent Act codified the common law when drafting Section 120 of 35 U.S.C. Section 120 provides that if "an application for a patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States…by the same inventor shall have the same effect, as to such invention, as though filed on the date of the prior application." 35 U.S.C. §120 (1994). The court thus concluded, "There is nothing in the legislative history to suggest that Congress did not intend to carry forward the defense of prosecution laches as well. To the contrary, a careful reading of the history and commentary on the 1952 Act shows an intent to maintain the defense." *Id.* at 1361.

The court rebuked Lemelson's third argument by declining to consider the non-precedential opinions. The court followed the decision of the Judicial Conference Committee giving the courts discretion to publish only those opinions that are of general and precedential

See LACHES, page 10

HERSEY, from page1

She and her husband and children left Iran in the mid-1970s because of the political situation.

Back in the U.S., she and her family lived in the Southwest, where she worked for one of the early cable television companies. Her job was to develop cable television leases.

After many years of globe-trotting, the family moved back to Massachusetts, where Ms. Hersey was licensed to practice law and began to plant roots for the children. There, Ms. Hersey answered an advertisement from the MIT Patent and Copyright Office; they wanted a technology transfer officer to license software out of the Institute. She says she was "very lucky" to land the job, which opened up an unexpected career opportunity in academia. This happened in 1980—the same year that saw the passage of the Bayh-Dole Act. The 1976 Copyright Act went into effect only three years before, so this was a very active period in intellectual property legislation, resulting in new opportunities for universities to commercialize their intellectual property.

However, in 1985, MIT eliminated all of its lawyers in its out-licensing program during a restructuring in which the Patent Office became the Technology Licensing Office. Ms. Hersey transferred to the Office of Sponsored Programs where she negotiated research contracts with research funding organizations. This experience provided a new skill in negotiating contracts with both the federal government and private industry.

In 1987, Ms. Hersey left MIT to move to North Carolina State University in Raleigh. They had a fledgling technology transfer office, and she had the opportunity to spend the next three years designing policy, making deals with private industry, licensing startups spinning off of research done at NC State, and getting a high-tech incubator up and running.

MIT called again in 1990, inviting her back as IP Counsel. She returned because by 1990 technology was changing. MIT's legal needs were now heavily focused on computer law. Copyright issues arose with software development; the Institute was licensing a lot of software, both into and out of its academic departments, and all that software had to transfer under contracts. While at MIT this time, Ms. Hersey developed the IP Counsel's office from one lawyer to four associated IP lawyers and one paralegal. The office expanded its practice to advising and participating in virtually all intellectual property-related areas of activity within MIT, including policy-making.

For a large part of her career, Ms. Hersey was active with AUTM, the Association of University Technology Managers, serving

See HERSEY, page 11

LACHES, from page 9

value. *Judicial Conference of the United States, Report of the Proceedings of the Judicial Conference of the United States*, 11 (1964). (Non-precedential opinions merely permit a judgment about whether a case contributes significantly to the body of law). The Federal Circuit concluded that once a court issues a precedential opinion on a principle of law, it is up to the courts to apply that principle to cases that follow. Courts should, in non-precedential opinions, only explain the principle of law as it applies to the individual parties' facts and not flood the law by issuing repetitive opinions on principles already established. *Symbol Technologies*, 277 F.3d at 1369.

The U.S. District Court for the Northern District of New York followed this precedent. On December 5, 2000, Ford Oxaal ("Oxaal") filed a complaint alleging patent infringement by Internet Pictures Corp. ("iPIX"). iPIX motioned and was granted an order requesting leave to file and serve an amended answer and counterclaim after the deadline for amended pleadings had passed. *Ford Oxaal v. Internet Pictures Corp.*, CV-1863-(LEK/DRH) 2002 U.S. Dist. LEXIS 5178, (March 27, 2002 N.D.N.Y.). A pretrial schedule established a deadline of August 31, 2001 for amendment of pleadings and May 1, 2002 for completion of discovery. Defendant iPIX filed a motion on February 1, 2002, seeking leave to file and serve an amended answer and counterclaim asserting the additional defense of prosecution laches based upon the decision in *Symbol Technologies*. Plaintiff Oxaal objected and argued that because the iPIX motion was filed after the August 31, 2001 deadline for amended pleadings, iPIX must demonstrate "good cause" to extend that deadline. The *Oxaal* court held that the *Symbol Technologies* decision provided a new legal basis for iPIX to assert the defense of prosecution laches and was a sufficient reason to allow iPIX to amend.

Four months after *Oxaal*, Intuitive Surgical, Inc. and International Business Machines Corporation ("IBM") filed an action against defendant Computer Motion, Inc. ("Computer Motion") alleging infringement of certain claims of U.S. Patent No. 6,201,984 ("the '984 patent"). Defendent filed counterclaims seeking a declaratory judgment of noninfringement, invalidity and unenforceability. The court denied defendant's motions. *Intuitive Surgical, Inc. v. Computer Motion, Inc.*, 214 F. Supp. 2d 433 (July 30, 2002 D. Del.).

IBM argued that the '984 patent should be declared unenforceable due to the equitable doctrine of prosecution laches. Computer Motion cited *Symbol Technologies* for the proposition that prosecution laches bars enforcement of a patent that issued after an "unreasonable and unexplained delay" in prosecution, even though the applicant complied with pertinent statutes and rules. *Id.* at 441. The *Intuitive* court denied defendant's summary judgment motion

See LACHES, page 12

HERSEY, from page 10

on its board for several years, and as President in 1999. Her experience led to a board seat on the Council for Governmental Relations, a research-university based organization that monitors federal legislation and regulations as they affect universities. Her focus on IP policy at MIT and work with COGR gave her a long-desired chance to have an influence on federal policy and legislation, bringing her career almost full circle back to her early interest in politics.

Karen Hersey teaches because she firmly believes there are far too few lawyers working in a university setting who are trained in intellectual property law. The people who currently work in technology transfer at the universities generally do not have a lawyer's training, which she sees as being essential to manage IP. Licenses drafted by university technology transfer offices are often written by non-lawyers, putting the universities at a negotiating disadvantage and risking future litigation in the high-stakes game of academic technology transfer.

Ms. Hersey encourages her students to fill the legal gap and enter the field as academic technology transfer officers and IP managers.

Karen Hersey says of teaching at Pierce Law, "After a 20-year career as an IP lawyer in academia, the opportunity to help train new lawyers is hugely rewarding."

Nancy Delain (JD '03) is from New York. She has an AB in Biological Sciences from Smith College and an MS in Technical Writing from Rensselaer Polytechnic Institute and plans to practice IP law upon graduation.



SHOULD MEDICAL METHODS BE PATENTED?

BY KALYAN C. KANKANALA (LLM '03)

THE PATENT SYSTEM has played a critical role in promoting the progress of science and technology since its inception by providing incentives to invent, to disclose, to design around and to invest. These incentives encourage the progress of science and technology and in turn contribute to the economic development and prosperity of mankind. Though the patent system has played a critical role in the progress of science generally, its benefits have not been extended to medical methods. (The term "medical methods" used hereinafter shall mean surgical, therapeutic and diagnostic methods of treatment except methods of administering drugs.)

Most countries in the world have excluded methods of medical treatment from the scope of their patent systems. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) under Paragraph 3 of Article 27 allows members to exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animals from the scope of patentable subject matter. Similarly, U.S. patent law allows methods of medical treatment to be patented but denies a remedy for its infringement, thus nullifying the right insofar as there is no enforceability. The nullification provision was hurriedly enacted in 1996 after wide dissatisfaction was provoked in the medical community by *Pallin's* case. The European Patent Convention under Article 52 Clause 4 excludes from the scope of patentable subject matter methods of treatment of the human or animal body by surgery and therapy and diagnostic methods practiced on humans. The issue has been litigated to a considerable extent in the European courts. Instead of excluding medical methods completely, the judges have found *In vitro* diagnostic methods and cosmetic surgeries or therapies to be patentable.

The patent law of Japan also excludes methods of medical treatment from the scope of patentable subject matter. Part II of the Examination Guidelines for Patent and Utility Models provides extensive guidelines for patenting methods of medical treatment similar to European law. The Examination Guidelines permit patenting of *In vitro* diagnostic methods and cosmetic methods. China and India also explicitly exclude methods of medical treatment from patentability. Contrary to the world trend, Australian patent law does not exclude methods of medical treatment from patentability. In *Bristol-Myers Squibb Co v. F H Faulding & Co Ltd*, the Federal Court of Australia in a case involving the validity of petty patents that claimed a method of administering the anti-cancer drug Taxol opined in dictum that a method of medical treatment is patentable. This court has validated the statute by positively allowing methods of medical treatment to be patentable. With the exception of Australia and perhaps a few other countries, most nations of the world exclude methods of medical treatment from the scope of patentable subject matter and in doing so they have taken away the incentives offered by the patent system. Such a policy has been adopted in light of the ethics inherent in the practice of medicine.

The American Medical Association (AMA) Council on Ethical and Judicial Affairs is very concerned about the effects of patenting a medical method with regard to ethics inherent in the practice of medicine. ("Ethical Issues in the Patenting of Medical Procedures," *Food and Drug Law Journal* 341 (1998)). The AMA is worried that the duty of a doctor to disclose information about a medical method which has been laid down under Principal V of the Principles of Medical Ethics of the AMA, will be restricted by the patent system. It is also afraid that the health care of the patient, which should be the basic concern of the doctor, will be driven by an economic motive if medical methods are patented. Furthermore, fears of patenting a medical method will restrict clinical and academic access to that method. Additionally, the AMA is concerned that patenting a medical method will increase the financial burden on the patient if royalties must be paid, in addition to the doctor's fee, for undergoing the patented method. Moreover, it is concerned that patient confidentiality and privacy may be hampered if the enforcement of the patent right involves identifying

See MEDICAL, page 12

MEDICAL, from page 11

the patient who has undergone the patented method. Finally, it is apprehensive that physician autonomy may be compromised if the doctor is motivated to maximize his profit as a patentee or a licensee.

These concerns of the AMA indicate a conflict between the incentives offered by the patent system and ethics inherent in the practice of medicine. Best results can be achieved by neutralizing this conflict. All the concerns enunciated by the AMA have alternatives that can be employed to balance the conflict. The issue of a doctor being guided by an economic motive while treating a patient can be partially neutralized by fixing royalty rates on licenses based on the importance of the medical method employed. For example, a method of treating cancer can have a lower royalty when compared to a method of performing a plastic surgery. Furthermore, a compulsory licensing scheme can be enforced to ensure broad practice of the method. The duty of a doctor to disclose information will not be affected because the patent system mandates disclosure of information in order to obtain a patent. The AMA's concern that patenting a medical method impedes clinical and educational access is not true because the patent system does not restrict access; it makes it conditional on obtaining a license. This condition is also only temporary, as the method will fall into the public domain after the patent term expires at which time access is available to all. Academic access is not affected because exemptions have already been provided in the patent laws of most nations for academic use and research. The disadvantage to the patient who may have to pay a high fee to get access to the patented medical method can be neutralized by government action. The government may subsidize payments to patients who cannot afford the treatment. Further, this concern of the AMA is not completely true because invention of a new method reduces the overall cost of treatment. Dr. Pallin's self-healing incision saved $17 per stitch. (Point made by Senator Hatch of the U.S. Senate while opposing the medical procedures reform legislation). Patient confidentiality can be protected by conducting in camera proceedings when privacy issues are involved.

Finally, the concern of physician autonomy can be balanced by mandating payment to the patent holder in the form of a running royalty, i.e. making royalties payable after the patented method is practiced on the patient. The doctor who practices a method for his selfish financial interests can be controlled by severe disciplinary or other legal sanctions for violating ethical norms.

See MEDICAL, page 13

LACHES, from page 10

based upon prosecution laches because the factual record was incomplete. *Id.* at 442.

Prosecution laches also arose in *In re Bogese*, a decision of the Board of Patent Appeals and Interferences, which the Court of Appeals for the Federal Circuit affirmed. *In re Bogese*, 303 F.3d 1362 (Sept. 23, 2002).

Bogese filed a patent application on June 14, 1978. During prosecution, Bogese filed at least eleven file wrapper continuation applications, two of which he appealed the decision of the Examiner to the Board of Patent Appeals and Interferences. A file wrapper continuation is a process to continue prosecution of an application. For a fee, the patentee files a file wrapper continuation, which is a continuation of a prior patent application. The continuation uses the same specification, drawings and oath or declaration from the prior patent application, which is to be abandoned. *See* 37 C.F.R. § 1.62.

Bogese would receive a final rejection from the Examiner, abandon that application, and then file for a continuation without responding to the Examiner's previous final rejection. The Examiner would then issue a first final rejection on the continuation application. Bogese would respond exactly one day before the 6-month statutory period to the first final rejection on the continuation application by abandoning this application and filing for another file wrapper continuation.

On March 16, 1995, the Examiner rejected all of Bogese's pending claims for three reasons. Of significance was the Examiner's third reason for rejecting Bogese's claims. The Examiner's third reason in rejecting Bogese's claims was prosecution estoppel —the forfeiture of the right to a patent. *In re Bogese*, 303 F.3d at 1365.

Bogese appealed. On appeal, the Federal Circuit addressed the issues of whether: (1) the PTO is authorized to reject a patent application where the applicant fails to advance prosecution for an unreasonably long period; and (2) the PTO acted arbitrarily in rejecting the applicant's patent application.

The Federal Circuit held the decision in *Symbol Technologies* was binding precedent. As for the application of the *Symbol Technologies* decision in PTO proceedings, the court stated that "[Regardless of] the correctness of our decision in *Symbol Technologie*s, we are nonetheless bound by it, and we see no basis for denying the power to the PTO itself that we have recognized exists in the district courts in infringement actions. It necessarily follows that the PTO has the authority to reject patent applications for patents that would be unenforceable under our holding in *Symbol Technologies*." *Id.* at 1367.

Judge Newman dissented. First Judge Newman noted that there are no PTO rules limiting the number of file wrapper continuations an applicant may file. Because the examination process is a creature of statute and operates on the premise that the inventor is entitled to a patent if the statutory requirements are met the court should not impose its own non-statutory limitations, she argued. *Id.* at 1370.

Second, Judge Newman argued that the Examiner made a determination that is generally reserved for the courts. A court

See LACHES, page 15

MEDICAL, from page 12

Thus, all concerns cited by the AMA, except the first, can be neutralized. The patent system has to be adopted despite the first concern of the AMA because it provides marked advantages to society. The desirability of patenting medical methods outweighs concerns over the ethical issues surrounding a doctor's financial motivation.

Surrogate embryo transfer, retinal implants and other new medical methods that integrate technology with medical treatment can be developed only under a patent regime. New medical methods that integrate technology require a huge investment in research, which is possible only through protection afforded by the patent system. The pace of invention of medical methods, which has been very slow, compared to the invention of drugs and medical implements, which are patentable, can be increased only by allowing them to be patented. Inventing new methods of treating a disease is as important as inventing new drugs and implements. Therefore, allowing drugs and implements to be patentable and not allowing medical methods is not sensible. Furthermore, incentives to promote the development of alternative healing methods such as acupuncture, ayurveda, homeopathy, magneto therapy, etc. whose development has been stunted due to lack of adequate economic incentives can be promoted by allowing them to be patented.

The patent system provides great impetus to the development of new and efficient methods of treatment and all ethical issues can be neutralized. Therefore, the policy makers of various nations should consider allowing medical methods to be patentable. ■

Kalyan Kankanala (LLM '03) received his LLB from P.R.R. Law College in Hyderabad, India. Kalyan plans to practice patent law in Hyderabad, India upon graduation and may also go into teaching.



From the Editor

This editor's column was authored by Gary Blaszkiewicz (LLM '03) as guest editor. It deals with a topical and controversial issue, in the tradition of many prior editor's columns. By the way, the latest on patent donations to universities is a provision in a must-pass trade bill in Congress that would substantially reduce deductions for donated patents—donors could deduct only their tax basis instead of fair market value. Interestingly, a similar imbroglio is afoot about the practice of setting up IP holding companies in states without taxation, e.g. Delaware. And Massachusetts has passed, and other states are considering passing, legislation that targets such holding companies by disallowing the asserted tax consequences as a sham. ■ *Karl F. Jorda, Editor*

PATENT DONATIONS: A WIN-WIN DEAL OR A TAX DODGE

BY GARY BLASZKIEWICZ (LLM '03)

IN THE PAST SEVERAL YEARS, corporations have increasingly approached universities and other nonprofit organizations with offers to donate patented technologies potentially worth millions of dollars. Several hundred million dollars are said to have been so donated in the last few years. Skepticism and suspicion seem to be the hallmark response to these inquiries. In the words of Gregory Aharonian, commentator for the *Internet Patent News Service*, IP donations are nothing more than large companies "donating bogus patents to universities and claiming tax deductions on their federal taxes." As regards one donation between SBC Communications and the University of Texas, valued at $7,300,000. Mr. Aharonian commented that, "The patent stinks like a dead cow in the Houston shipping channel on a hot summer day." (Gregory Aharonian, "Patent Donations Next Tax Accounting Scandal," Internet Patent News Service, March 2003.) In certain situations this may be a well-founded response. But, handled in the right way and for the right reasons, intellectual property donations can create a win-win proposition for all parties involved.

Section 170 of the Internal Revenue Code of 1954 authorizes a deduction for a charitable contribution. And subsection 170(c) provides, in pertinent part, that the term "charitable contribution" includes contributions or gifts to nonprofit organizations operated exclusively for scientific or educational purposes. The Internal Revenue Service (IRS) has advised, in Revenue Ruling 58-260, that:

The fair market value of an undivided present interest in a patent, which is contributed by the owner of the patent to an organization described in section 170(c) constitutes an allowable deduction as a charitable contribution, to the extent provided in section 170.

The donation of a patent or other intellectual property is simply treated as a noncash charitable contribution under §170 of the Internal Revenue Code.

Why do corporations donate patents? The answer to this query depends on the party asked. A nonprofit organization may answer that it is solely for the tax benefits. And the typical corporation response may, off the record, be the same.

The most practical reason for discarding a certain technology is that it simply does not fit into the corporation's business strategy. It may be important technology, but in a large corporation pursuing many initiatives, it may be difficult to compete internally for research and development dollars. The market for the technology may be viable, but initial studies may fail to meet the financial criteria set by the company.

Because of mergers, acquisitions, spin-offs, and increased research and development efforts, a corporation may be facing the dilemma of being overloaded with technology. Swollen patent portfolios and exorbitant maintenance costs, or even worse, antitrust concerns may dictate that certain technologies must be discarded or research initiatives be abandoned. Initiating a patent donation program may simply be the most cost-effective solution.

See DONATIONS, page 14

DONATIONS, from page 13

Patent donation, however, can present a number of risks for a corporation. Despite the pronouncement in Revenue Ruling 2003-28, that placing limitations on a donee's use of a patent may be permissible, a patent donation is an outright gift. Keeping an interest in a donated patent is fatal to the deduction, but putting limitations on the donee's use of a patent is permitted, as for instance, preventing the charity from transferring or licensing the patent for several years. Not only are all interests and rights in the patent relinquished, but also so are the potential future licensing revenues and opportunities for development. There are also a number of expenses associated with the gift.

In order to qualify for a tax deduction, a fair market appraisal of the value of the technology must be conducted. There is also the cost of due diligence, in the form of time, money, resources, and personnel. And ultimately, the risk that the Internal Revenue Service may disagree with a valuation and impose back taxes and penalties, which according to Tax Publication 561, could be as much as 40% of the value claimed.

The simplest reason for a nonprofit to accept a patent donation is that it can provide access to valuable intellectual property to complement or supplement existing research and technology transfer efforts. The donation may even mature into a lucrative licensing property. A successful donation can create goodwill in the community, among faculty, among students, and in alumni relations. It may also attract other valuable donations or research grants.

In some situations, however, the risks of accepting a donation may outnumber the benefits. The most obvious problem is that a donation of intellectual property, despite being labeled with a monetary value, is not a donation of money. A donation of patents can actually become a cost center for a nonprofit. The expenses of funding developmental research and paying maintenance fees can be quite exorbitant.

The donation of a potentially lucrative licensing property today could also be a donation of litigation for tomorrow. A donation is a gift of all interests and rights of ownership and all responsibilities as well; no warranties apply. The subject patents could be found to be invalid or infringing. There may be dominant patents that need to be licensed or a forgotten licensee with contractual rights in the intellectual property.

But a more common and significant issue for a nonprofit organization, is that the patent donation process can become a distraction from the mission of the technology transfer office; creating animosity both inside and outside the institution. The personnel, time, budget, and other resources of a technology transfer office are often finite commodities that are rarely sufficient to address the needs of the technology being developed inside the institution, let alone being allocated to technology that is brought in from outside the institution.

Relationships with faculty, students, alumni, other donors, and other research partners may all be strained by a patent donation. Budgets may be cut, funding reallocated, or projects temporarily suspended. Conflicts of interest with obligations owed to other research partners may be lurking in the background. And, in some instances, the publicity surrounding a large patent donation labeled with a high dollar value can cause a chilling effect for other donations.

Thorough due diligence may be the single most important task for increasing the probability of a win-win patent donation. Both the donor and the donee need to exercise due diligence at every stage of the donation process.

A successful donation starts with the careful selection of suitable intellectual property assets. Almost every patent donation will represent technology in an embryonic stage, but it must still be strong, innovative technology with a high commercial value.

Due diligence in respect to the strength of the patents, is essential to describing and understanding the technology. The remaining life of the patents needs to be determined, and a schedule of estimated maintenance fees should be prepared. Related patents and trademarks need to be identified. Prior art should be searched for dependent and blocking patents. The extent and degree of trade secrets and "know how" coupled to the patents must be evaluated.

A business audit must also be prepared to assess the commercial value and competitive use of the intellectual property. The strength of the patents in terms of a business proposition needs to be evaluated. Competing technologies must be identified and the benefits and weaknesses of the competition should be assessed. Decisions about further development have to be made, specifically addressing questions such as:

- What are the remaining technical challenges?
- What are the remaining developmental milestones and how do they relate to the remaining life of the patents?
- What resources are needed and what is the cost of further development?
- What is the probability of the success of the technology?

In essence, a donor must identify and approach patents for donation as if they were going to develop and utilize the technology for their own corporate business strategy. Only strong innovative and commercially viable technology is suitable as a candidate for a patent donation.

The donee must have a reputation for expertise in the particular technology field or at least a scientist with a strong reputation for excellence in the field. The institution must be willing to commit money and resources to development of the technology and have an established record for realizing academic and financial value from intellectual property. The nonprofit's technology transfer office must have the capability and experience to commercialize the technology and perhaps, experience with the patent donation process.

The donee cannot simply sit back and wait to take possession of the patent portfolio. The donee must conduct its own stringent due diligence process.

A non-confidential summary of the technology should be evaluated by the institution's tech transfer personnel and the scientists who will further develop the technology. It must be determined whether the donation is in line with the nonprofit's research efforts, what stage of development the technology is in, and whether the principal investigators are committed to the project. The technology transfer office will be particularly interested in determining what additional development must be done to make the technology an attractive licensing package.

An estimate and a budget for the cost, in money, resources, and time for developing the technology should be prepared. The crucial milestones for development must be identified. A meeting with the donor's

See DONATIONS, page 15

LACHES, from page 12

may, on occasion, depart from statute in order to reach a just result or in order to remedy an injustice flowing from strict statutory adherence to the law. *Id.* Judge Newman argued that an Examiner's invocation of prosecution laches is quite atypical. The Examiner has invoked, in effect, an equitable remedy in order to create a desirable outcome when no one has violated the law. "The equitable power is intended to remedy harsh application of law, not to impose new penalties on those who abide by the law." *Id.*

Judge Newman concluded that in order for the PTO to create new rules by invoking the doctrine of prosecution laches, the PTO must follow administrative agency legislative procedures regarding the institution of new rules and comments. Allowing an examiner to arbitrarily decide how many continuations create prosecution laches defies accepted administrative processes. If a change in the statutory rules of prosecution is deemed appropriate, it should be processed legislatively, she argued. *Id.*

The Federal Circuit held that prosecution laches is a viable defense to infringement when the patentee has unreasonably delayed the procuring of his patent rights. The Federal Circuit was not called upon to decide which facts invoke the doctrine of prosecution laches. Now the Nevada District Court will guide patent attorneys as to which facts satisfy the unreasonable delay of prosecution history laches.

Christian Bauer (JD '03) received his BS in Biochemistry and Molecular Biology from Gettysburg College and his Masters in Forensic Science from Marshall University. Christian plans on practicing patent prosecution and litigation with Ratner Prestia in Valley Forge, Pennsylvania.



DONATIONS, from page 14

inventors should be arranged and a confidential disclosure agreement should be prepared.

A patent incapable of adequate valuation is unsuitable for donation. And a patent that may produce a highly speculative valuation will increase the business risk and may be equally unsuitable for donation. A patent donation program, under no circumstances, should be viewed as a dumping mechanism or a last resort to abandonment. A patent donation must represent a viable and valuable technology.

Section 1.170A -1(c) of the Income Tax Regulations provides that if a contribution is made in property other than money, the amount of the deduction is determined by the fair market value of the property at the time of the contribution. The IRS has argued successfully, in *Smith v. Commissioner*, 41 T.C.M. (CCH) 1427, (1981), that patent validity, technological feasibility, and difficulty of enforcement must be included in the fair market value analysis of a patent. The valuation should be prepared no sooner than one month before the donation is to be executed. The donor must engage an outside firm to determine the valuation of the patents. The goal to be attained is the right value, not the most value.

The donor has a vested interest in assuring that the patent donation is a success, both in process and long-term development by the donee. A failed donation could generate negative public relations and heavy tax penalties and fines, not to mention wasted time, money, and resources.

In order to guarantee a successful patent donation, the donor should pledge an ancillary financial gift. The value of the gift should cover patent maintenance fees for a certain time period and a percentage of the estimated research costs.

Both parties should consider setting a schedule to accomplish the various stages of the donation process. Guidelines for how publicity and public relations will be conducted need to be established. And issues regarding confidentiality must be addressed.

A significant part of a patent donation is the potential public relations and goodwill that can be generated for both the donor and the donee. The donor will certainly seek recognition for the corporation and the inventors, but may also seek to highlight the cooperative relationship with the donee, the nonprofit sector, local governments, and the benefits for the community.

The donee has similar needs. Recognition of the institution and principal investigators is certainly important, but it may also be an opportunity to advertise to, and attract potential licensees. The merits of philanthropy can be reinforced, in the hopes of attracting other patent donations and benefactors.

Both parties, however, should contemplate the risks of negative publicity. A corporation in the midst of restructuring or a major cost cutting initiative, may not want to publicize a significant gift. And a nonprofit engaged in a major fundraising campaign may wish to down play a patent donation labeled with a large dollar value; such an announcement may have a chilling effect on other donations.

The transfer of the donated patents requires more than just the handing over of a file folder full of legal forms. The transfer process may take several months or more, and will demand that each party continue to exercise the same degree of care and diligence that has been applied to every other stage of the donation process.

The donor should arrange for equipment and materials to be delivered and installed, as well as arrange for the availability of inventors and technical personnel to teach the technology to the new investigators. The donee has to coordinate scientists and researchers and retain patent counsel.

Both parties have a number of administrative tasks that must be attended to. The donor must file Tax Form 8283 to report the donation to the IRS, and the donee must file Tax Form 8282 as acknowledgement of receipt. Patent counsel, for each party, must prepare and file the appropriate patent assignment documents.

A patent donation cannot be judged a success simply because a transfer has been made. Post donation technical and commercial support may be required. Additional

See DONATIONS, page 16

DONATIONS, from page 15

technology may need to be transferred. And on-going technical consulting and patent consulting should be made available.

In conclusion, a patent donation can represent a win-win proposition for both the nonprofit donee and the corporation donor. Both parties, however, must work together to make it a winning proposition. At the center of a successful donation, there must be a commercially valuable technology. The technology must be compatible with the interests of the nonprofit donee. A thorough due diligence in respect to the strength of, and the market for the technology must be conducted. Complete cooperation, by both the donor and the donee, is essential to the seamless transfer of the donation. And there must be a willingness to provide, and to accept, post donation support to nurture the development of the donated technology.

Gary Blaszkiewicz (LLM '03) is a sole practitioner, with a general law practice in Detroit, Michigan. His aspirations are to specialize in technology transfer in the international market, particularly China.



FRANKLIN PIERCE LAW CENTER
GERMESHAUSEN CENTER • *Calendar of Events*

April 16-17, 2004	**BASIC PATENT COOPERATION TREATY (PCT) SEMINAR FOR PATENT ATTORNEYS, PATENT AGENTS AND PATENT ADMINISTRATORS** Sheraton Wayfarer, Bedford, NH www.piercelaw.edu/TreatySem/treatsem.htm
May 17-21, 2004	**MEDIATION SKILLS FOR IP & COMMERCIAL DISPUTES** Pierce Law, Concord, NH www.piercelaw.edu/ipb/ipsi00broch.htm
May 24-July 9, 2004	**INTELLECTUAL PROPERTY SUMMER INSTITUTE** Pierce Law, Concord, NH www.piercelaw.edu/ipb/ipsi00broch.htm
June 21-July 23, 2004	**INTELLECTUAL PROPERTY SUMMER INSTITUTE AT TSINGHUA UNIVERSITY SCHOOL OF LAW** Beijing, China www.piercelaw.edu/ipb/CHIPSI/ChipsiIndex.htm
July 12-16, 2004	**THIRTEENTH ANNUAL ADVANCED LICENSING INSTITUTE** Pierce Law, Concord, NH www.piercelaw.edu/ali/ali.htm

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

PIERCE LAW
FRANKLIN PIERCE LAW CENTER
TWO WHITE STREET CONCORD, NH 03301

NON-PROFIT ORG.
US POSTAGE
PAID
PERMIT NO 749
CONCORD, NH 03301