EDITOR’S MESSAGE

The Maryland Intellectual Property Student Association (MIPSA) has recently undertaken the effort of publishing the Maryland IP Law Electronic Newsletter. Professor Lawrence M. Sung advises MIPSA and through his guidance this newsletter is possible. MIPSA is excited about its new initiative and welcomes article ideas as well as subscription requests. To be placed on our electronic circulation list, please send the appropriate e-mail address information to Alex Hanna at ahann001@umaryland.edu.

FEATURE ARTICLE

WAITING FOR FISHER
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About the author: Lawrence M. Sung, Ph.D., is Law School Professor and Intellectual Property Program Director at the University of Maryland School of Law. He is also in private law practice in Washington, DC, specializing in biotechnology patent counseling.

In early 1997, the U.S. Patent and Trademark Office (PTO) uncovered a hornet’s nest when it announced the likelihood that patent claims would be granted to genomic fragments called expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs). In the heady times of The Human Genome Project, thousands of these ESTs and SNPs were being obtained with only a nominal understanding of their biological significance.

Undaunted, companies filed hundreds of patent applications seeking intellectual property rights to these genomic fragments with bare indications of what they were and even fainter disclosures of what they did. Moreover, these patent claims were of broad enough scope to capture as an infringer any user of a product derived from genomic material that included a patented sequence. Such fears rekindled the public outcry over gene patenting generally and its potential chilling effect on biotechnology and pharmaceutical research and development. But the Patent Gold Rush was on.

Still, like most gold rushes, the dreams of riches from the ownership of genomic data alone began to fade almost as quickly as they arose. The PTO established an instant moratorium on the examination of EST and SNP claims. Although faced routinely with new technologies, perhaps no other class of inventions has ever so significantly challenged the patent law dogma. To qualify for patent protection, an invention must be useful, new and nonobvious to one skilled in the pertinent technical field. Also, the invention must be described in a manner compliant with the standards of written description, enablement, best mode and definiteness. These requirements help ensure that the public receives a valuable benefit from the disclosure of an innovative technology in return for a grant of temporary exclusivity to the patentee.

In particular, a patent applicant must be able to teach the public about the invention by providing a reasonably clear answer to two fundamental questions: “What is it?” and “What does it do?” With regard to ESTs and SNPs, the response to “What is it?” was problematic enough, and the response to “What does it do?” was simply unknown. The
PTO struggled with attempts to reconcile the applicability of traditional, generic principles of patent law to this emerging technology. The PTO initially issued the 1999 Revised Interim Utility Examination Guidelines, only to withdraw them in the face of critical public comment. The reissue of the PTO prescriptions in this regard ultimately came in the form of the 2001 Utility Examination Guidelines. The operative framework for meeting the requirements of 35 U.S.C. 101 now includes the mandate for a patent applicant to articulate a specific, substantial and credible utility.

One inherent problem with making sense of the patent law is the temporal distortion that occurs between the time patent claims are filed and the time the PTO and/or federal courts pass on the patentability or invalidity of those claims. In some cases, a decade or more can separate these two events.

Of course, much, if not everything, can change in that time. What seemed impossible back then can be child’s play today. When ESTs and SNPs were discovered, their elucidation through the automated isolation and purification of vast numbers of genomic fragments to facilitate chemical formula descriptions (high throughput polynucleotide sequencing) occurred without learning anything about their origin, fit or function. Such an abstract process of invention hardly came with a complete answer to what the invention was, much less yielded any insight as to what the invention did. The question therefore sat like the Riddle of the Sphinx: Can you patent ESTs and SNPs? The U.S. Court of Appeals for the Federal Circuit will have an opportunity shortly in In re Fisher, No. 04-1465 (appeal filed July 14, 2004), to write the last chapter in a long-awaited ending to this suspenseful story.

The facts behind ‘Fisher’

The Fisher case arrived this past summer for the Federal Circuit’s review from a decision by the PTO Board of Patent Appeals and Interferences that affirmed in-part and reversed in-part the patent examiner’s rejection of the patent claims in a Monsanto Co. patent application to ESTs derived from a maize leaf tissue cDNA library. Ex parte Fisher, No. 2002-2046 (Bd. Pat. Apps. & Interferences March 16, 2004) (concerning U.S. patent application Serial No. 09/619,643).

The board agreed with the patent examiner that the claimed invention failed to satisfy the utility and enablement requirements, but disagreed with the written description rejection. Monsanto had asserted that the claimed ESTs were useful for producing a plant containing reduced levels of a protein; determining an association between a polymorphism and a plant trait; isolating a genetic region or nucleic acid; determining a level or pattern in a plant cell of a protein in a plant; determining a mutation in a plant whose presence is predictive of a mutation affecting a level or pattern of a protein; acting as molecular tags to isolate genetic regions, isolate genes, map genes and determine gene function; and identifying tissues. However, the board reasoned that virtually any nucleic acid could manifest these generic uses.

Among other things, Monsanto argued to the board that ESTs have real-world value as seen from the growth of a multimillion-dollar industry in the United States premised on the usefulness of ESTs. The board noted that the claims were drawn to ESTs alone, rather than EST databases, clone sets or micro arrays, or other practical applications of ESTs. In any event, the patent examiner and the board found that absent a teaching about particular plant proteins or traits, these asserted uses were not specific or substantial enough to satisfy the utility requirement of 35 U.S.C. 101. Based on the same scarcity of information of a specific or substantial utility, the patent examiner and the board concluded that the patent applicant did not satisfy the enablement requirement of 35
U.S.C. 112, which demands an adequate instruction to one skilled in the art about how to make and use the claimed invention without undue experimentation.

As for the written description requirement aspect of § 112, uncertainty has plagued the patent jurisprudence. The itinerant standard presently requires, at least for genomic inventions, that the patent applicant has taught the complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. In Fisher, the board concluded with little, if any, explanation that Monsanto’s patent claims were supported by adequate written description.

In addressing the patentability of the EST claims in Fisher, the Federal Circuit has the chance to reinforce the quid pro quo of a suitable primer on the claimed invention in exchange for the patent grant. In the words of the U.S. Supreme Court about the utility requirement: “[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.” Brenner v. Manson, 383 U.S. 519, 536 (1966).

Furthermore, because the true scope of a patent claim can be difficult to assess, especially when the patent is granted, the potential consequences of conferring the power to block off whole areas of scientific development warrants a healthy skepticism at the start. In this regard, it would seem ill advised to undermine the ability of the PTO to engage in anything less than a deliberate scrutiny of patent claims to prevent any reach beyond what is deserved by the knowledge otherwise imparted by the patent.

The Federal Circuit, therefore, may well decide to authorize the PTO to place a stricter demand on patent applicants to clarify what the invention does. In turn, a reinvigoration of the utility requirement will have the collateral effect of enhancing the public’s appreciation of what the invention is. This might help offset criticism that the public has received little, if any, educational benefit in trade for the grant of exclusivity to the patent holder.

THINKING IP

WHAT IS INTELLECTUAL PROPERTY LAW? A BRIEF SURVEY OF TRADE SECRETS, TRADEMARKS, COPYRIGHTS, & PATENTS
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The concept of property has been well established in society for thousands of years. Clear boundaries and possession rights tend to eliminate complex disputes over persons’ interests in real property, tangible objects, and chattel that results from the fruits of one’s physical labor. What about ideas, facts, works of expression, methods, and functional objects, which result from “intellectual labor?” How should property rights be recognized over the “intangible?”

Intellectual Property Law (IP) attempts to guide the allocation of such rights. It combines the important public policies of disclosure and publication, while providing incentives to innovate. Generally, it allows authors and inventors to hold limited temporal and ownership rights to their creativity in a manner somewhat similar to real property (i.e. right to exclude others). Contrary to popular belief, IP is not a new field of law. In the mid 1400s, the first patent right is claimed to have been granted for stained glass. The English monarchy realized the need to protect useful inventions and arts through state
granted monopolies. This practice continued in several forms during the colonial period and throughout the industrial revolution. Moreover, the United States Constitution specifically enumerates the right to Congress to enact laws promoting the “progress of science and useful arts.” See U.S. CONST. art. 1, § 8, cl. 8.

Intellectual property touches our everyday lives in ways we seldom can imagine. Consider the next time you consume a can of Coca-Cola. The goodness that is Coke has been protected over the years by rights granted through IP law. For instance, the drink’s recipe is protected as a trade secret. Trademark law protects the product’s names Coke and Coca-Cola, while copyright law protects the expression inherent in the Coke can itself. Four substantive types of protection - Trade Secrets, Trademarks, Copyrights, and Patents - some of which provide overlapping protection, are jointly referred to as IP Law.

**Trade Secrets.** Trade Secrets are a matter of state law. The law protects information that has economic value because it is not generally known, and is the subject of reasonable efforts to maintain its secrecy. Trade secrets may include a formula, pattern, compilation, program, device, method, technique, or process. In addition to the Coke recipe, common examples include methods of mixing paint, business customer lists, and accounting methods, etc. Having a trade secret means that one has a legal cause of action if another party steals, copies, or uses the trade secret without permission. However, the burden is on the trade secret holder to prove that his/her steps in ensuring secrecy were “reasonable” under the circumstances. Limiting access to information thought to be a trade secret and demanding confidentiality agreements from those with access, are examples of the types of protective steps that may qualify as “reasonable.” Trade secrets may not be registered and its laws are outlined by the Uniformed Trade Secrets Act (UTSA), the federal Economic Espionage Act (18 U.S.C. § 1832), and common law tort theories. Trade secrets protection can be perpetual so long as secrecy is maintained, however, if secrecy is lost, then a trade secret is gone forever and is considered part of the public domain.

**Trademarks.** Trademarks identify the source of a product and distinguish them from those manufactured or sold by others. The mark can be a word, symbol, design or a combination of these elements. In many countries, a trademark could also be a sound, color, or even a texture. For instance, the distinctive chirp sounds of many walkie-talkie cell phones and the pink color of a famous insulation product have trademark protection. A principal goal of trademark law is to protect consumers by providing an indication of the quality of goods. The trademark owner enjoys the goodwill derived from such indication and favorable identification of its products. A trademark can also last forever so long as it is associated with a product or service.

The most important requirement for obtaining a trademark is association with a product. One must apply for a trademark with the United States Patent and Trademark Office (USPTO). Trademarks may be protected by the Federal Lanham Act (15 U.S.C. § 1051 et seq.) and state unfair competition statutory, and/or common law. The similarity of the marks, nature of the goods or businesses, geographic location of the parties, and the time point when the mark became associated with a product are important considerations for a court presiding over a trademark infringement dispute under both federal and state laws.

**Copyrights.** A copyright comes into existence when an original work of authorship is fixed in a tangible medium of expression. Copyright protects literary, dramatic, musical, and artistic works such as poetry, novels, movies, songs, computer software, and architecture. Copyright does not protect names, facts, recipes, ideas, systems, or methods of operation, although the expression of such things may be protected. For instance, if someone writes a factual statement about the weather outside, copyright law does not
protect the author’s right to the facts, rather, protection is granted to the author’s writing of the fact (i.e. his expression, the words, and the layout). Similarly, the layouts of many famous Internet search engines, as they appear on a computer screen, are copyrightable even though the underlying search methods are not. The work is considered fixed in a “tangible” medium even if its perception requires the aid of a machine or device (e.g. a computer screen that displays a poem, which was typed and saved on a computer). A copyright exists at the moment of fixation whether the work is registered at the Library of Congress or bears the copyright symbol, ©.

Copyright law, as codified in 17 U.S.C. § 101 et seq., prevents persons other than the rightful copyright holder to publicly perform, distribute, reproduce, and create derivative works of the original work of authorship. Certain exceptions to these exclusive rights exist (e.g. fair use and nominal use), however, in assessing the propriety of unauthorized use, courts turn on the nature of the copyrighted work, character and purpose of use (whether commercial in nature), substantiality of the use, and effect on the market and value of the copyrighted work. Depending on the type of work, copyrights can last for decades past the original author’s life.

**Patents.** Patents are rights granted under the auspices of the Constitution for inventions that meet the thresholds of being new, useful, and non-obvious. Since the early 1980s, even living organisms have become patentable subject matter. Patents are also granted for designs, plants, and business methods. A patent can only be obtained through application with the USPTO, which is the federal agency charged with ensuring that applications satisfy the criteria for patentability. If granted, utility patents give the holder the right to exclude others for a period of 20 years from the application’s filing date (design patents exclude others for a period of 14 years). In return, the USPTO asks for full disclosure of the invention to allow others to design around the patent and to encourage further innovations. Deception in disclosure may render a patent invalid even after its issuance.

Federal courts have exclusive jurisdiction over patent infringement and invalidity cases. In infringement cases, the courts evaluate whether a competitor has created something that infringes on the patentee’s invention, either literally or equivalently. In patent invalidity cases, courts consider whether a patent was issued erroneously due to improper prior art search or inequitable conduct of the patentee, including improper restrictions on the use of the patented item in downstream commerce. Patent laws are enumerated in 35 U.S.C. § 101 et seq.

Today, IP laws have become important business tools in many sectors of the economy. Small and large companies alike find securing their IP rights to be vital to their business plan. Inventors and creators work closely with attorneys to determine how best to exploit the entitlements of the IP doctrines to maximize return on their labor. An invention or creation may be protected under several IP rights at the same time. The decision to choose one form of IP protection over another is usually a calculated one based on the invention, market opportunities, and desires of the inventor. With advancement in technology, IP may become an even more complex area of the law. However, the policy goal for which intellectual property laws have been created – to encourage inventions, innovations, and creativity – remain simple, and the few words in our Constitution have ensured that essence is not lost in the complexity.

ALUMNUS SPOTLIGHT

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The electronics and computer industry is growing at an exponential rate, and with it comes the need for quality intellectual property counsel. At the forefront of this revolution is an alumnus of the University of Maryland School of Law, Robert Sterne. Mr. Sterne is a founding member, principal and director of one of the largest intellectual property “boutique” firms in the Washington, D.C. area.

At a time when few legal visionaries endorsed the practice of intellectual property law, Mr. Sterne chose the road less traveled and started his own law firm at the age of 26. Creating his own path has led him to over twenty years of experience maintaining a lucrative practice in the field of intellectual property. Mr. Sterne specializes in the areas of electronics, computers, telecommunications, Internet, e-commerce and business method technology. His legal experience extends to all aspects of IP including strategic planning, protection, licensing and litigation.

An example of Mr. Sterne's visionary impact is his work as the lead attorney of the groundbreaking case In re Beauregard, 53 F.3d 1583 (Fed. Cir. 1995). Beauregard was brought before the Court of Appeals for the Federal Circuit by IBM to establish if a computer program on a disk was patentable subject matter. In response to the court’s monumental decision, the United States Patent & Trademark Office (USPTO) rewrote their software patent guidelines to expand the scope of patent protection for software and enable inventors to patent computer-implemented inventions, which the USPTO had previously considered unpatentable.

Mr. Sterne graduated from the University of Maryland School of Law, with honors, in 1977. Prior to matriculation at Maryland, Mr. Sterne studied Electrical Engineering at Tufts University, where he graduated with a Bachelor of Science in 1973 and a Master of Science in 1975.

You can learn more about Mr. Sterne and Sterne, Kessler, Goldstein & Fox at http://www.skgf.com/.

STUDENT PERSPECTIVE

USPTO IMPLEMENTS COMPUTER-BASED PATENT BAR EXAM
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When I took the United States Patent and Trademark Office’s (USPTO) Patent Bar Exam in April of 2001, I had to worry about several logistical issues. First, I had to borrow a dolly to wheel my crate, filled with books, through security at the George H. Fallon Federal Building and into the testing room. Second, I had to arrive early enough to commandeering an extra desk to move next to mine. It
was the only way to have quick access to all of the books I had wheeled in. Finally, I will never forget the odd exam proctor who talked continuously to no one in particular. From prior test takers, I found out that she was a distracting, yet entertaining fixture, who regularly proctored the twice-a-year Patent Bar at the Baltimore testing center. Unfortunately, my only other option was Washington, D.C., where the testing center was a noisy hotel ballroom with diffuse chandelier lighting that left many test takers with a migraine headache.

Fortunately, computer-based changes implemented by the USPTO on July 26, 2004 have done away with these logistical problems. Now, future patent attorneys and agents, who pass the USPTO’s General Requirements (unaltered since computer-based implementation, see http://www.uspto.gov/web/offices/dcom/gcounsel/oed.htm), are free from the constraints of taking the exam either in April or October. After an applicant is notified that they are qualified to sit for the exam, they can schedule any weekday date as long as it is within 90-days of the mailing date of that notification. Moreover, there is no longer a need for transporting stacks of books on wheels. The USPTO computer-based exam does not allow any patent law related books or other materials in the test center classroom. Instead, the exam remains “open book” through on-line access to the patent rules, statutes and the Manual Patent Examining Procedure (MPEP). Finally, the options for Patent Bar test centers in the Baltimore area have greatly increased. The USPTO’s out-sourced exam contractor, Thomson Prometric (http://www.prometric.com/), has eight test center locations in the Baltimore region alone.

The Patent Bar continues to test one’s knowledge of patent laws, rules and procedures, as documented in the MPEP. The exam still tests one’s ability to analyze fact patterns and properly apply patent laws, rules and procedures to give valuable assistance to clients in the preparation and prosecution of patent applications. Additionally, standards of ethical and professional conduct remain within the scope of the exam. The basic format of the exam also remains unchanged. The Patent Bar still consists of 100, 5-answer multiple-choice, questions in two sessions. Fifty questions are asked in each of two three-hour morning and afternoon sessions. In order to pass, applicants must receive a grade of 70% or higher. Since the computer-based exam was implemented, no pass-fail statistics are available, but the pass rate for the 2000-2003 exams range from 37% to 72%, with an average of 52.1%. Unlike my six-week wait to find out that I had passed, immediate notification of scores is planned for future computer-based exam applicants.

The most common question faced by many law students is whether they should take the Patent Bar during law school or defer it until after graduation. Among the many factors to consider is the amount of time required for adequate preparation. The rule of thumb is that it takes an applicant 150-200 hours of studying, in 3-4 hour sessions, divided over a period of 2-3 months. Along with a law student’s time constraints, the financial costs of the exam must also be considered. Fees include a $40 Office of Enrollment and Discipline application fee, a $200 USPTO examination fee and a $150 Thomson Prometric exam administration fee. Finally, given that the computer-based exam is relatively new, one may wish to wait until “all of the bugs are worked out.” For example, prior to August 24, 2004, test takers were faced with the problem of apparent freezing of the MPEP computer search functionality. The testing software has since been updated and, hopefully, that will be the last software problem nervous examinees will have to face.
Intellectual Property (IP) law is a very unique field in terms of career opportunities. For example, in order to prosecute patents, an attorney is required to have taken and passed the patent bar exam. But not so fast! To qualify for taking the exam, one needs a technical or engineering degree. As a result, patent prosecution is a “niche” field of practice with a relatively small number of attorneys. While it is not necessary to have passed the patent bar exam in order to practice patent litigation, it is rare to find such a practitioner; the field is just too competitive and tends to be technical in nature, thus, it warrants what has now become a de facto requirement. Recall, however, that IP law also consists of trademarks, trade secrets, and copyrights. These fields do not require a technical or engineering education and do not require a special exam like the patent bar. Thus, in contrast to popular belief, it is possible to practice IP without having a technical background!

Okay, so you’ve heard about other practices in IP, you’re not really interested and you have a technical degree. You’re in luck, but now the tough part. How do you secure that all-important first job? A great way is to register for the Loyola University Patent Law Interview Program held annually in Chicago, Illinois. Why should you go to Chicago? Because if you do, you will start interviewing for the next year’s summer associate positions in early August. This is almost a month and a half prior to on-campus interviewing, a time when there are many more positions ready to be filled. In addition, the program is attended by some of the most prestigious law firms in the United States. According to Loyola University, it is the largest single-practice job-fair in the nation.

The application process is simple and consists of the following steps: (1) beginning in mid-January students fill-out a registration form and submit it to their own Career Development Office, (2) in mid-March students are sent an information packet from Loyola to their respective Career Development Office for pick-up, (3) students then choose the employers they are interested in and indicate their preferences by mid-April, (4) finally, in early June students receive information regarding the employers that have chosen them for interviews and can then go ahead with making travel arrangements. The most time consuming and tedious portion of the process involves choosing the employers and following Loyola’s overly intricate instructions for submitting resumes. However, the program has been very successful, therefore, Loyola must require this process for good reason.

This past summer, the program was held at the Chicago Marriott Suites O’Hare from August 5th to the 7th. Each morning, between 7:30 and 8:30 AM, the interviewees registered at the “program hotel” to verify their presence and to determine whether any of the waiting list times could be granted to other interviewees assigned to employers’ waiting lists. Subsequently, the interviewing day commenced and continued until 5:00 PM. Throughout the day, interviewees relaxed in a suite, sponsored by a popular legal on-line research service, in order to research their interviewers and network with other law students from around the country. At night, students and their new friends took the train into downtown Chicago for some sightseeing, shopping, or dinner. Overall, the program was enjoyable and a great way for law students pursuing patent law to secure that all-important summer associate position.

For more information on this program, visit Loyola University Chicago School of Law at: http://www.luc.edu/law/academics/special/center/intellectual/patent_law.shtml
IP EVENTS @ MARYLAND LAW

RECENT EVENTS

MIPSA’s fall 2004 events were very successful. Three events were held: a visit by Robert Sterne of Sterne, Kessler, Goldstein & Fox, an IP Practitioners Panel, and the annual portfolio sale fundraiser.

In cooperation with the Career Development Office and the Alumni office, MIPSA was privileged to have Mr. Robert Sterne share his educational, legal, and professional experiences with faculty and students. On October 19th, Mr. Sterne visited Maryland Law, spoke to students interested in pursuing IP law and addressed all of their inquiries. MIPSA would like to thank Mr. Sterne for taking time from his busy schedule to share his knowledge, as well as Sterne, Kessler, Goldstein & Fox for graciously sponsoring the food and refreshments served at the event. Thank you!

Recently, MIPSA invited four IP practitioners, three of whom graduated from Maryland Law, to our IP Practitioners Panel event. We were excited that all four practitioners accepted our invitation and participated in our panel event on November 17th. The distinguished panelists were: W. Todd Baker, Esq., Senior Associate, Oblon, Spivak, McClelland, Maier & Neustadt, PC; Gene Garner, Esq., Member, Staas & Halsey, LLP; Allan M. Kiang, Esq., Senior Intellectual Property Counsel, Becton Dickinson Diagnostic Systems; Cynthia Sanders, Esq., Associate, Astrachan, Gunst & Thomas, PC.

The panelists shared their experiences as to how they were able to reach their current positions. In addition, they advised students on such things as coursework, the patent bar exam, and what it is like to practice IP law at their differing companies and firms. The event was taped and is on archive at the Thurgood Marshall Law Library.

UPCOMING EVENTS

In the spring of 2005 MIPSA is planning on hosting a conference in cooperation with the Maryland Student Health Law Organization (SHLO) to explore the constitutional, health care, and intellectual property implications of compulsory licensing in the delivery of life-saving medicines. In addition, we are planning our annual trip to the United States Court of Appeals for the Federal Circuit and a visit to a law firm with a well-established IP practice. We’ll keep you posted!

To contact MIPSA’s officers or learn about our recent events, please visit our website at http://www.law.umaryland.edu/mipsa/.

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