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Perspectives in Patent Law: Overview, Careers, and Controversies

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***Abstract*—This paper is directed to scientists and engineers who wish to learn more about careers in patent law. It presents an overview of the patent process along with a description of the various roles of individuals and institutions involved. Finally, the paper briefly discusses a few of the more controversial issues in the patent law field today.**

I. Introduction

The concept of a *patent*, or the right to exclude others from benefiting from one's invention, has been in the public domain for centuries. The sense of justice that is satisfied by the exclusionary rights provided by patent law may have roots in our fundamental human desire for individuality and self expression. Even small children complain when a peer or sibling "copies" their drawing or *magnum opus*.

Although patents are referred to as intellectual *property*, they operate as monopolies, granting to the patent holder the right to *exclude* others from making or using the invention claimed in the patent. However, U.S. courts, particularly in the early days of this country, went to great lengths to distinguish patents from monopolies because of the detested English system of allowing the monarch to grant monopolies (denoted "letters patents") to loyal subjects. These "patents" which differ significantly from modern patents because they were not based on new inventions, were primarily a mechanism for raising money for the crown by requiring established businesses to either pay royalties to the patent holder or stop doing business.

In 1624, the Statute of Monopolies (which would have been more appropriately titled the Statute *Against* Monopolies) was passed by the Parliament, abolishing the power of the monarch to grant exclusive monopolies. A significant exception was included in this statute, however, in that patents could still be conferred upon inventors allowing them exclusive rights to their new inventions for a period of fourteen years.

The abusive monopolies of England caused so much fear and loathing that founding influential thinkers in the U.S., notably Thomas Jefferson, were skeptical of expansive patent rights. [1] Nevertheless, Section 8 paragraph I was included in the U.S. Constitution granting to Congress the power "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."

U.S. patent law was born in controversy, and so it remains today.

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II. Overview of the Patent Process

A. Obtaining a patent

Patents are intended to "promote the progress" by encouraging inventors to reveal their innovation to the wider community so that others may learn from and extend these concepts. Patents have two major portions: 1) the *specification*, which describes the invention in a way that is understandable to others in the field and presents the best mode of making/using the invention; and 2) the *claims*, which provide the legal description of the invention and the basis for the inventor's exclusive rights. In exchange for the disclosure of the invention to the world, inventors receive a time limited monopoly to exclude others from making or using the invention that is presented in the patent claims.

Many corporations and universities have an incentive policy to encourage engineers and scientists to document patentable ideas. Typically, all rights to any inventions related to an employee's work are pre-assigned to the organization upon employment.

Fig. 1 provides a simplified overview of the patent process. [2] Starting with the idea, or "flash of genius," the basic concepts of the invention are usually documented in an invention disclosure that is dated and witnessed. In the U.S., currently the person who first invents has the right to obtain a patent. (This practice is in contrast with much of the rest of the world where the first to file a patent application will be able to obtain the patent. Legislation is currently making its way through the U.S. Congress which would change the U.S. system to a first-to-file system rather than a first-to-invent system.) In a first-to-invent patent system, documentation of the date of the invention is important because the documents may be needed later to determine who was the first inventor.

Even after the invention is documented in the inventor's notebook or invention disclosure, it is important for the inventor to avoid making the invention public by engaging in

other activities that could forfeit patent rights. Examples include, publishing the invention, selling or even offering to sell the invention, or simply telling someone else about the invention without a non-disclosure agreement.

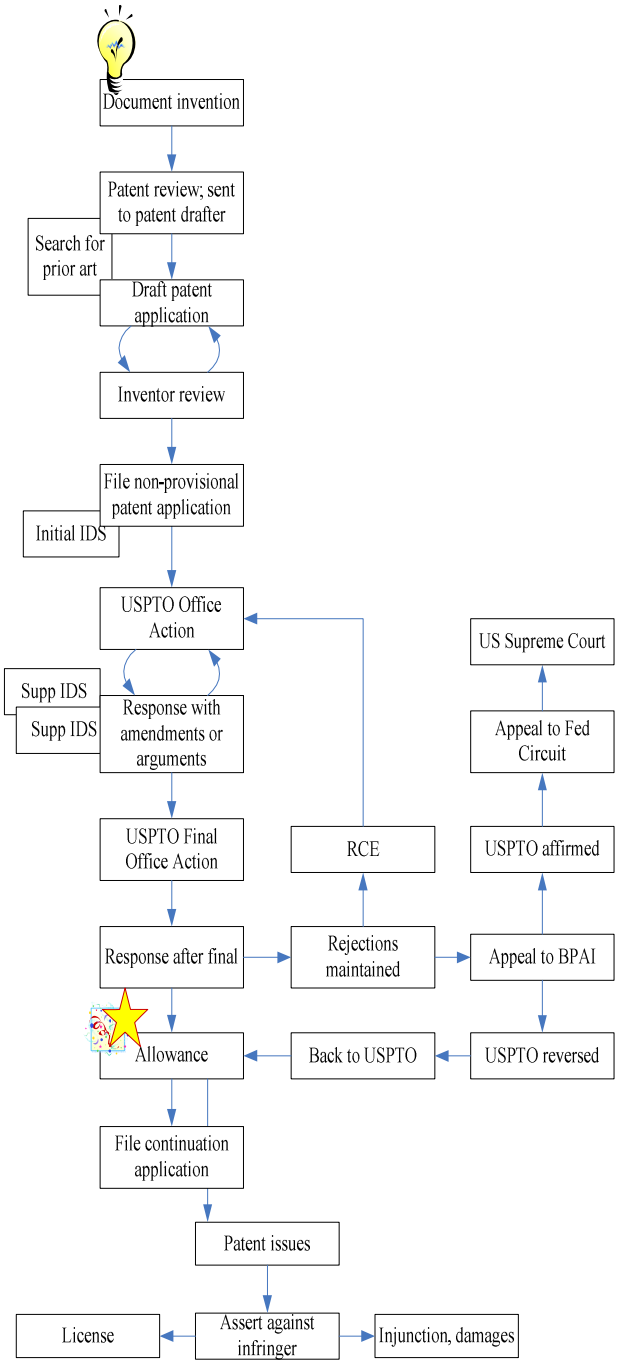

Fig. 1 Overview of the patent process

Currently in the U.S., an inventor may obtain a patent for the invention if a patent application is filed within a one year grace period after public disclosure of the invention. The patent systems of other nations are not so forgiving. An inventor would not be able to receive a patent in Europe, for example, if public disclosure of the invention occurred before a patent application is filed. Therefore, if the inventor wishes to receive patent coverage for the invention outside the U.S., no public disclosure of the patent can be made prior to filing the U.S. patent application.

Many organizations have some kind of invention review process, where the invention disclosure is evaluated to determine both the likelihood of obtaining a patent on the invention and the business value of the patent. During this stage, a search may be performed to identify earlier publications or patents that would make the invention unpatentable.

After the invention disclosure passes through the review process, it may be transferred to a patent prosecutor (patent attorney or patent agent) to prepare a patent application. The patent prosecutor works with the inventor to draft the specification and claims.

At times, if additional assistance is required to draft and/or prosecute the patent application, the patent prosecutor may work with a technical specialist (sometimes referred to as a patent engineer) who is an expert in the field of the patent application. For example, working with a technical specialist may be beneficial if the subject matter of the patent is particularly complex or if there are a large number of prior art references that need to be analyzed. After approval by the inventor, the patent application is filed with the United States Patent Trademark Office (USPTO) which is the administrative agency of the U.S. government that has the authority to grant U.S. patents.

An initial Information Disclosure Statement (IDS) is usually filed along with the patent application. The IDS is a document that lists or provides a copy of each reference or publication that may be relevant to the patentability of the invention. Supplemental IDSs may be filed at other times during the patent application process as additional publications or information comes to the attention of the inventor, patent prosecutor, or others involved with the patent application. Submitting to the USPTO every reference known to the inventor or patent prosecutor which may be relevant to patentability is critically important. Intentionally withholding information from the USPTO (or in some cases even if the withholding is unintentional) may result in all claims of the patent being deemed unenforceable due to inequitable conduct. Inventors, patent prosecutors, and others involved in the patent application process have a specific duty to disclose all relevant information to the USPTO.

At the USPTO, the patent application is reviewed by a patent examiner who evaluates the patent specification and claims. The patent examiner reviews the application to determine if all legal requirements have been met, including 1) enablement (does the specification provide an adequate description of the claimed invention?); 2) novelty (is the claimed invention novel in view of previous knowledge?); and 3) non-obviousness (even though the invention is novel,

would it have been obvious in view of previous knowledge?). If, in the patent examiner's view, any of these requirements are not met, the patent application is initially rejected. The patent examiner presents the objections and/or rejections to the patent prosecutor in a written Office Action.

After reviewing the Office Action, the patent prosecutor responds to the Office Action by amending the claims and/or the specification to overcome the objections/rejections. However, no additional concepts may be added to specification and any amendments to the claims must be fully described in the specification.

After one or several Office Actions by the USPTO and Office Action responses by the patent prosecutor, the patent application is either allowed, or is finally rejected. If the patent application is allowed, it issues as a patent. If the patent application specification includes other patentable concepts that the inventor wishes to patent, a continuation application can be filed prior to the patent issuance.

If the patent application is finally rejected, the inventor may choose to file a Request for Continued Examination (RCE) which allows further arguments to be made and/or further claim amendments to be presented to the patent examiner. However, if the inventor is convinced that the invention is patentable and the patent examiner's rejections are in error, the inventor may appeal to the Board of Patent Appeals and Interferences (BPAI), to the Court of Appeals for the Federal Circuit (CAFC), and to the U.S. Supreme Court.

B. Enforcing a patent

After a patent issues, it can be asserted against an infringer. If the inventor believes that a competitor's product infringes the patent, the inventor may retain an attorney litigator to sue the alleged infringer in federal court. The lawsuit may ask for an injunction to stop the competitor from making or selling the product and may ask for money damages to compensate the patent holder for the loss of profits that resulted from the infringing product. The alleged infringer may attempt to prove that the product does not infringe the patent, that the patent is not valid because the invention is not patentable, that the patent is unenforceable, and/or may present other defenses during the litigation.

In some cases, the infringer may resolve the lawsuit by agreeing to license the patent. If so, the infringer agrees to pay the patent holder in exchange for being able to continue to make and sell the infringing product. In this scenario, an attorney prepares the license, which is similar to a contract, setting forth the obligations of the parties to the license.

III. PATENT LAW CAREERS

A. People involved in the patent process

The overview described in Section II introduces the roles of some of the primary people involved in the patent process. The career field includes positions for patent prosecutors, litigators, transactional attorneys, paralegals, patent engineers, and patent examiners and others.

1) Patent prosecutors draft patent applications and interact with patent examiners by filing responses to USPTO Office Actions to obtain patents for their clients. Patent prosecutors may be patent agents or patent attorneys. Patent agents and patent attorneys are licensed to practice before the USPTO which is an administrative agency that falls under the U.S. government's executive branch. Although representation of clients in courts of law is limited exclusively to attorneys, specially qualified non-attorneys may represent clients before some administrative agencies, such as the USPTO.

Both patent agents and patent attorneys qualify to practice before the USPTO by 1) having a bachelor's degree in science or engineering; 2) passing a qualifying exam, known as the "patent bar"; and 3) being of good moral character and reputation. Currently, less than about 50,000 patent attorneys and agents practice before the USPTO. Compare this relatively small number of practitioners with estimated U.S. employment statistics for attorneys in general (760,000), physicians (630,000), and engineers (1,500,000). [3]

In addition to preparing and prosecuting patent applications, patent prosecutors counsel clients to help them better understand the patent process and assist clients in developing and optimizing the value of their patent portfolio. Patent attorneys may perform clearance evaluations and/or assist their clients in developing work around designs to ensure that a client's products do not infringe a competitor's patents.

Although the roles of patent attorneys and patent agents often overlap, patent agents avoid giving legal advice beyond their practice before the USPTO. Issues involving patent infringement and/or licensing, which are legal issues that fall under the jurisprudence of the courts, are only addressed by patent attorneys.

2) Patent litigators are trial lawyers who represent plaintiffs or defendants in court, thus their role as an attorney is probably more familiar to the general public than the role of the patent prosecutor. Patent litigators are not necessarily patent attorneys (that title is reserved only for attorneys licensed to practice before the USPTO) and don't necessarily have a technical background. During the course of a patent lawsuit, litigators may team up with patent attorneys, agents, and/or technical specialists who provide technical expertise. Some attorneys develop practices that include both patent prosecution and litigation.

3) Technical specialists are engineers or scientists who provide technical support for patent prosecutors and/or litigators. Technical specialists typically have advanced degrees in their subject of interest along with significant experience in academia and/or industry. Often technical specialists who continue in patent law for a period of time eventually take the patent bar so that they can practice before the USPTO.

4) Patent examiners are employees of the U.S. government

working for the USPTO which is located in Alexandria, Virginia. Patent examiners perform the role of advocate for the public interest to ensure that patents are not issued for substandard inventions that are non-novel or obvious, or that fail to sufficiently describe how to make and use the invention to provide the *quid pro quo* of disclosure in exchange for the exclusive monopoly of a patent.

B. Nature of the work in institutions involved in the patent process

1) Law firms – most patent attorneys, patent agents, technical specialists, paralegals and litigators are employed by law firms. The law firms range from large general practice firms (hundreds of attorneys) to very small "boutique" law firms (solo or a few attorneys) that limit their practice solely or primarily to patent law. In either type of firm, patent attorneys may work exclusively as patent prosecutors, may work exclusively as patent litigators, or may have a blended practice of patent prosecution and litigation.

Patent prosecutors and litigators often bill their clients by the hour, although fixed fees for some patent prosecution services are becoming increasingly widespread. Because of the number of personnel required to support litigation and the money at stake (hundreds of millions of dollars may be awarded as damages in an infringement lawsuit), litigators often work in larger law firms, have fewer budget constraints, and charge higher hourly fees than patent prosecutors. A patent litigator's work load can have a roller coaster aspect with periods of long work hours during some demanding phases of a lawsuit interspersed with periods of relative calm during less demanding phases. Litigators almost always work in teams of other attorneys and paralegals during the course of a patent lawsuit.

In contrast to litigators, the work of a patent prosecutor typically involves an individual effort to prepare and prosecute patent applications. For this reason, the patent prosecutor career path is often appealing to people who prefer to spend a significant portion of their time working individually rather than in groups. Patent prosecutors usually have an hourly rate, although fees for patent prosecution services are generally fixed fees or are budget capped at a dollar amount. Patent prosecutors have to become proficient at their job to comply with these budget constraints. In a typical scenario, if the patent preparation or prosecution exceeds the budgeted amount (hours x attorney billing rate/hour), the attorney or agent is expected to absorb the loss rather than the law firm. Therefore, particularly early in their career, patent prosecutors often end up working additional hours to meet their billing goal as they gain the requisite level of proficiency.

Law firms typically establish an attorney's billing rate and billing goal, which is the number of hours of work that the attorney is expected to bill and collect from clients during a year. Billing rates may range widely from about $180/hr to more than $500/hr depending on the type of work and level of experience. Geographic region is also a significant factor in attorney billing rates, with east and west coast attorneys generally charging higher rates than attorneys in the Midwest, for example. Attorney billing goals can range from about 1500 hours per year to 1900 hours per year.

Patent prosecutors and litigators are usually compensated based on a percentage of the fees they bill and collect from a client annually. For example, an attorney employed by a law firm may receive from about 25 to about 50 percent of the fees they collect annually from clients, with the remainder going to cover the overhead costs of the law firm or to the law firm owners. [4]

2) Corporations and universities may maintain a staff of in-house patent attorneys, agents, technical specialists and/or litigators. The number of people employed in these positions is generally related to the size of the organization and the patent portfolio that is being developed or maintained by the corporation. Corporate attorneys working on patent matters usually direct the litigation, patent preparation/prosecution and/or patent transactional work performed with assistance from outside law firms. In their role of director for a spectrum of legal services provided by outside law firms, in house attorneys often have the opportunity to have a more generalized practice than the focused practices of patent prosecutors and litigators working for law firms.

Corporate/university attorneys working in patent law traditionally receive slightly lower compensation than attorneys in private practice. They are usually paid a salary based on their specific responsibilities, their years of experience or seniority with the organization rather than a salary based on hours billed and billing rate. Corporate attorneys can often maintain more consistent working hours than attorneys in private practice with paid time off for vacations and sick leave, rather than having a billing goal as in private law firms.

3) U.S. Patent Trademark Office employs over 5000 patent examiners to evaluate patent applications submitted to the USPTO. Patent examiners need not be attorneys or patent agents, but must have a bachelor's degree in a field of science or engineering. [5]

Patent examiners review references identified in the IDS submitted by the patent prosecutor and perform independent prior art searches to discover additional publications and/or previously filed patent applications that are relevant to the patent application under examination. They formulate arguments as to why a patent application may not be patentable, for example, due to lack of enablement, obviousness, and/or lack of novelty. Patent examiners correspond with their counterpart patent prosecutors by written Office Actions and during telephonic or in-person interviews.

In contrast to opposing counsel in our adversarial judicial system, the patent prosecutor's and patent examiner's roles are not intended to be adversarial. Whereas patent

prosecutors advocate on behalf of their client's interest, patent examiner's serve the public interest by critically reviewing patent applications to ensure that patent monopolies are not granted for patent applications describing obvious or non-novel inventions. Ideally, the interaction between the patent examiner and the patent prosecutor involves working together in a cooperative way that eventually identifies patent claims having the broadest scope allowable in view of the prior art.

Beginning patent examiners are hired in as GS 5/7/9 U.S. government employees with a starting salary of about $41,000 to $78,000, depending on their technical degree and prior experience. Experienced patent examiners can make a base salary of up to about $158,000 with additional compensation for overproduction. [6] Patent examiners must work at the USPTO facility in Alexandria, Virginia until they reach level GS-12 which usually takes about 3 years from their start date. After achieving GS-12, patent examiners can work at home and are only required to come in to the USPTO facility 1 hour per week. If a patent examiner wishes to continue their education in law school, they can receive tuition reimbursement.

Patent examiners' jobs are not immune to the political cycle in Washington with Democratic administrations being generally more sympathetic to positions taken by their union (Patent Office Professional Association (POPA)) than Republican administrations.

IV. Current Controversies in Patent Law

A. The strength and number of patents

Over the past number of years, all three branches of the U.S. government have rendered decisions, promulgated rules or introduced legislation intended to weaken the effect of patents. Many of these changes created much controversy among people working in the field of patent law and not all of the proposed changes were implemented. In part, some of the changes proposed or implemented may be attributed to the anti-plaintiff sentiment which took hold in Washington during the previous administration. More significantly, at least some of the changes were introduced in large part due to lobbying efforts by the tech industry (computer and software companies) and were probably pulled back in part due to the competing lobbying efforts of the pharmaceutical/biotech industry.

1) U.S. Supreme Court and Federal Circuit decisions: The U.S. Supreme Court has tilted significantly toward weaker patent rights which favor the tech industry. Within the past three years, the U.S. Supreme Court has considered and rendered decisions in an unusually large number of patent law cases. Most of these decisions have weakened the strength of patents: *eBay Inc. v. MercExchange LLC*, 547 U.S. 388 (2006) (limited injunctive relief); *KSR v. Teleflex*, 550 U.S. 398 (2007) (changed the standard of obviousness making it easier to invalidate patents); *MedImmune v. Genentech*, 549 U.S. 118 (2007) (made it easier for licensees to invalidate licensed patents); *Microsoft v. AT&T*, 550 U.S. 437 (2007); (made it harder for U.S. patent holders to prevent infringing methods performed overseas).

In addition, the Federal Circuit has also rendered recent decisions that weaken the rights of patent holders: *In re Seagate Technology,* 497 F.3d 1360 (Fed. Cir. 2007) (reduced damage awards); *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008) (limited patentable subject matter); *McKesson Information Solutions v. Bridge Medical* (Fed. Cir. 2007) (expanded the standard for determining inequitable conduct making it easier to find patents unenforceable).

2) Legislative patent law reform: Significant modifications to patent law are currently being considered by House and Senate committees. Among other changes, this proposed legislation would place limitations on damages awards, convert the U.S. patent system to a first-to-file system rather than a first-to-invent system, and place limitations on venue for patent litigation. [7]

3) Drop in patent application allowance rate: Since 2002, the patent allowance rates reported by the USPTO have plummeted. [8]

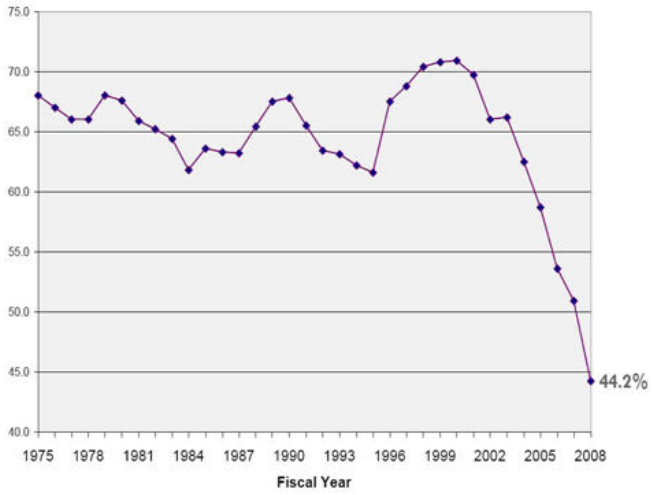

Fig. 2 Percentage of allowed patent applications

According to the USPTO, the drop in allowance rate is due to changes in their internal procedures to focus on patent quality. However, the drop in allowance rates is so dramatic that it is increasing the time and cost of patent prosecution and having an impact on some industries. In addition, the decrease in allowance rates is also decreasing issue and patent maintenance fees paid to the USPTO. It is unclear at this point whether patent quality has increased.

4) Rule changes proposed by the USPTO: Over the past several years, the USPTO attempted to implement changes in the patent prosecution rules which would significantly alter the substantive rights of patent holders. The proposed changes are an attempt to 1) limit the number of claims an inventor could present in a patent application; 2) limit the

number of continuation applications that could be filed from a parent application; 3) shift the burden for identifying relevant prior and analyzing the prior art in a way adverse to the patent application from the patent examiners to the patent prosecutors (IDS rules); and 4) introduce additional complexity into the procedure for appealing a rejection of a patent application by the USPTO to the BPAI (appeals rules).

None of these proposed rules have gone into effect. The proposed rules limiting the number of claims and the number of continuation applications were proposed by the USPTO in order to limit the number of patent applications filed for the purpose of reducing the USPTO's patent examination backlog. [9] These proposed rules represented a deep chasm between the views of USPTO management and most patent holders and the patent bar. [10] However, after several patent applicants sued the USPTO, an injunction was issued by the United States District Court for the Eastern District of Virginia preventing the rules from going into effect. The district court reasoned that the USPTO lacked the authority to substantively change patent rights through administrative changes to the patent rules. The Federal Circuit issued a decision in March 2009 affirming in part the District Court's decision.

Implementation of the IDS rules, which are arguably even more objectionable to patent holders and the patent bar than the continuation/claim number rules [11], has been postponed by the USPTO. There is no indication of a future implementation date for the IDS rules and the continuation/claim number rules remain enjoined. It is not clear whether the appointees of the Obama administration to management positions within the USPTO will continue to pursue these unpopular changes to the patent rules.

B. Pharmaceuticals and the world's poor

Development of new pharmaceuticals and therapies is expensive and time consuming, but the final manufacturing processes can be easy and relatively inexpensive to implement. As a result, the pharmaceutical industry has generally reserved its products for use in countries that offer patent protection and markets free of price controls.

The pharma industry argues that compulsory licensing or price controls discourages the research efforts necessary to develop new drugs. However, the people and the governments of third world nations cannot pay for drugs at prices paid by wealthy nations. Thus, people in developing areas die of conditions such as HIV that could be alleviated using patented drugs, and children are not given even basic vaccinations.

Furthermore, pharmaceutical companies argue that without patent protection it is not feasible to establish research-based industries in developing countries. Thus, drugs are developed for the less serious conditions of wealthy nations rather than for life threatening diseases of developing countries. Although the market will support development of discretionary drugs used in wealthy nations, there is no development of drugs to help the diseases that inflict people of third world countries.

C. Patenting the human genome

Over the past number of years, patenting of genes and genetic sequences has been controversial. Some people feel strongly that patenting human gene sequences should be forbidden. They argue that a gene is not a new composition of matter because it exists in nature, and that an inventor who isolates a gene does not actually invent or discover a patentable composition.

However, the USPTO has taken the position [12] that "an inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.." A DNA molecule that has been isolated and purified and which has the same sequence as a naturally occurring gene is eligible for a patent because (1) an excised gene is eligible for a patent as a composition of matter or as an article of manufacture because that DNA molecule does not occur in that isolated form in nature, or (2) synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound.

There is also concern that patenting the human genome will suppress innovation in this emerging technical area because scientists will either be prevented from using a patented gene or gene sequence in their research, or will be forced to pay high licensing fees. Additionally, some people argue that many gene patents lack a well established and specific utility. [13]

These and other controversies at the intersection between patent law and bioethics are very likely to be discussed by people involved in the patent law field for many years to come.

REFERENCES

[1] *see*, e.g., Thomas Jefferson's letter to Isaac McPherson Monticello, dated August 13, 1813.

[2] For more information about patent law and procedures for the U.S. patent application process, see 35 United States Code, 37 Code of Federal Regulations, and the *Manual for Patent Examining Procedure*

[3] Employment data available from the U.S. Bureau of Labor Statistics, www.bls.gov

[4] AIPLA Report of the Economic Survey, 2007

[5] http://usptocareers.gov/

[6] id.

[7] Bartz, Diane, "U.S. battle over patent reform headed for compromise?" www.reuters.com, March 10, 2009

[8] Information provided by the USPTO and available on their website www.uspto.gov

[9] Federal Register: January 3, 2006 (Volume 71, Number 1)

[10] Federal Register: August 21, 2007 (Volume 72, Number 161)

[11] "Impact of Patent Law Changes on Biomedical Investment and Innovation," California Health Care Institute, www.chi.org

[12] Federal Register: January 5, 2001 (Volume 66, Number 4)

[13] "Bioethics and patent law: the case of Myriad," World Intellectual Property Law Organization, WIPOMagazine, Issue 4/2006