STATEMENT OF

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PRESIDENT-ELECT
AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION

BEFORE THE

SUBCOMMITTEE ON COURTS
AND INTELLECTUAL PROPERTY
COMMITTEE ON THE JUDICIARY
UNITED STATES HOUSE OF REPRESENTATIVES

OVERSIGHT HEARING
ON

Gene Patents and other Genomic Inventions

July 13, 2000

Mr. Chairman:

The American Intellectual Property Law Association (AIPLA) congratulates you and the Subcommittee for holding this oversight hearing on the relationship between the human genome and the United States patent system. We are particularly pleased to have the opportunity to offer our thoughts on this very timely and important subject.

The AIPLA is a national bar association whose more than 10,000 members are primarily lawyers in private and corporate practice, in government service, and in the academic community. The AIPLA represents a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property.

Introduction

AIPLA members practicing in the area of biotechnology are acutely aware of the important public policy issues that the Subcommittee is examining. AIPLA believes that these policy issues can be fully addressed by a straightforward application of existing principles of basic patent law.

The U.S. Constitution gives Congress the power to enact laws to protect the rights of inventors. These rights are granted and exist under the Constitution "to promote the progress of science and the useful arts." The foresight of the drafters of the Constitution in setting out a "patent clause" not only led in 1790 to the establishment of the U.S. patent system, but the action of the first of our 106 Congresses stands even today as a model throughout the world for promoting innovation. Over the years the U.S. patent system has been improved by the passage of more effective patent laws, such as the American Inventors Protection Act, which passed earlier in this Congress. The patent system has also been invigorated by the faithful manner in which these laws have been implemented by the courts, notably the Court of Appeals for the Federal Circuit – a new appellate court created in 1983. For the most part, the US patent system in its present form works
effectively as an incentive to innovators. AIPLA believes that it will continue to work well even as technology changes and becomes more complex. Finally, we believe that where changes in the patent laws are needed, Congress will make them as it has many times over the past two decades. The Patent Law Amendments Act of 1984, the Drug Price Competition and Patent Term Restoration Act of 1984, the Patent Process Amendments Act of 1988, the Uruguay Round Agreements Act, and the American Inventors Protection Act of 1999 are all examples of innovative and responsive changes that have worked to improve the operation and effectiveness of the U.S. patent system.

Discussion

The issues surrounding patent protection relating to newly discovered genes and the often novel proteins that are products of the expression of these genes raises public policy and substantive law issues of patent law that are in many respects even more complex than the issue addressed by the Supreme Court in 1980 in *Diamond v. Chakrabarty*. In that case, the Supreme Court decided whether the fact that an invention was living should exclude the invention from the definition of patentable subject matter. The Supreme Court answered that question in the negative, by a five-to-four margin, and stated in effect that patent protection should be made available to anything "under the sun that is made by man". Those words and that court decision were instrumental in launching the modern biotechnology industry – and establishing the preeminent role of the United States as a leader in that industry.

The biotechnology patents that issued in the years that followed that important decision and the rapidly evolving technology brought us to the issue you are examining today. AIPLA believes that *Chakrabarty* was correctly decided by the Supreme Court. The Court's decision was firmly grounded in the legislative history of the 1952 Patent Act. The Congressional intent that "everything under the sun made by man" should be patentable was long applied to chemical substances. It is, therefore, inconceivable the Congress would permit the patenting of a genetically modified microbe that makes a life-saving drug, such as insulin, but not allow the person discovering the insulin gene to obtain a patent claiming the gene itself. Merely because there are clear and compelling policy justification for allowing patents related to genes to be patented does not, however, answer the most difficult questions: how broad should the protection afforded by such patents be, what work must be completed to make a gene-related invention ready for patenting, and how should patents of this type impact on research directed to understanding the gene and the full complexity of its biological role and functioning?

Patent law has traditionally treated all biological materials – even genes – as chemicals, or "compositions of matter" – a traditional category of patent-eligible "invention." Patents, however, do not extent to products of nature, as such. Thus, naturally occurring biological substances have traditionally been patented once they have been isolated and identified as useful for a specific purpose or a specific function. At that point, a naturally occurring biological material, such as a gene, a hormone, an enzyme or the like can only be patented in the isolated or purified form that does not exist in nature. According to the Supreme Court ruling in *Chakrabarty* and established patent law, any product of nature is patentable if it is transformed in some way by man and it is also new, useful, and non-obvious.

The isolated or purified biological product cannot be validly patented unless the patent application contains a claim to the product provides an adequate written description of the invention. Further, the disclosure in the patent application must enable persons skilled in biotechnology to make and use the claimed product. Some real-world utility for the claimed product must also be set out in the patent application – in some presently available form. Thus, for several decades, the patent law issue has not been whether an isolated or purified product obtained from nature, such as a gene-based invention, is eligible for patenting or is adequately disclosed in a patent application, but, rather, what is the proper form and scope of the application and claims for the patent to be granted?

A great deal has been written recently both in the popular press and in respected scientific journals on the topic of granting patents to inventions that relate to human genes and – most particularly – gene fragments. Some accounts in the popular press reflect a confusion concerning basic patent law principles and have generated much misinformation on this issue. Even worse, some accounts of the workings of the patent system have been erroneous and regrettably inflammatory.

In order to understand the patent issues raised, most recently by the publicity surrounding the human genome project and related subject matter, it is important to understand the basic science that leads to the inventions for which patent protection is being sought. One key to understanding biotechnology is in understanding the terms and definitions.

Any complex living being is made up of trillions of cells and inside every cell is a nucleus which contains a set of chromosomes. The information contained in all of the chromosomes in a cell is the genome of that being. The genome is the complete set of information for building and maintaining life of every organism. The genome contains the master blueprint for creating all cellular structure and activities for the living organism. The chromosomes which contain the
Interspersed with the genes which carry the essential protein coding information are intron sequences which have no apparent coding function and are sometimes referred to as "Junk DNA". Genes make up only a small percentage of the genome. It is this small percent of the genome that is the focus of so much attention and generally raises the questions about granting patents. The genome is a map of the entire area, but what is most interesting to scientists and the patent attorneys who work with them is not the genome, but the genes, portion of genes, and the sequences of nucleotides that a gene is made up of, including SNPs (single nucleotide polymorphisms) which are variations which occur in the DNA sequence of the gene and ESTs (expression sequence tags). Scientists believe that these tools will help them to identify the multiple genes associated with complex diseases and to design better and more specific drugs and treatments for these diseases.

Much of the discussion about the use of genes and related inventions is still speculation. Genes and the other related gene technology may or may not turn out to be good targets for drug design. It may be possible to design drugs from the genetic information, but that will take years to determine. Not only must scientists determine what each gene does, but also precisely which proteins each gene produces. In order to design a drug, they will also need to know the structure and the function of the proteins which is expressed (produced) by the gene. This has been determined for some proteins, but in addition to knowing the protein structure, the actual folding of the protein also appears to be important in designing drugs to cure specific diseases. Determining the way a protein folds is apparently a difficult job. Steven Holyman of Millennium Pharmaceuticals focused the discussion on the right place when he recently said "the race is in assigning to genes and to variations in genes a role in disease initiation and progress and drug response".

Nobel Prize winner, David Baltimore apparently agrees. In a recent article in the New York Times he recognized that "the sequencing of the genome is a landmark of progress in specifying information, decoding it into its many coded meanings, and learning how it goes wrong in disease. While it is a moment worthy of the attention of every human, we should not mistake progress for a solution. There is yet much hard work to be done".

Applying basic patent law to these concepts means that in spite of the fact that patents are being applied for and granted now, there is still much more to be discovered and those discoveries should not only be patentable, but valuable. One of the touchstones of patentability is whether or not the invention is the solution to a problem and if so, how difficult was the problem to solve. Paraphrasing Dr. Baltimore, the genome is not the solution; years of work remain to be done by researchers to apply genomic and gene related inventions to curing diseases and designing drugs which also in themselves should be patentable.

The patent issues surrounding biotechnology and specifically genes and gene-related technology are less than 20 years old and it will take time to sort out the application of the patent laws to this technology. As the United States Patent and Trademark Office ("the USPTO") works its way through the new applications and the Courts deal with challenges to already issued patents, more clarity will be found. Time will help – there is no immediate need to solve all of these issues. The patent law like the technology will evolve and grow to address the new issues. The Court of Appeals for the Federal Circuit is addressing and will continue to address the questions of which genes, SNPs, ESTs and other genetic material are patentable. The Courts and the USPTO need time to work through these issues and they have the basic tools that they need to do this.

AIIPLA approves of the USPTO’s efforts to clarify and provide for consistency in the training of its examiners as to the manner in which the written description requirement and the utility requirement for a patent application is to be applied to the examination of patent applications. An adequate written description is fundamental to the proper functioning of the patent system. The full benefits of a patent cannot be realized if it does not contain a written description which discloses the "manner and process of making and using an invention in such full, clear, concise, and exact terms as to enable any person skilled in the art" to make and use the invention. This is particularly critical in the area of patents and patent applications involving genes, gene sequences, and related biotechnological inventions.

We believe the Revised Written Description Guidelines and the Utility Guidelines as published by the Office have taken great steps forward in the complex area of the written description requirements for a biotechnology patent. The AIIPLA urges that patent examiners should be instructed in the Revised Written Description Guidelines to exercise vigilance and to make rejections of patent claims on written description grounds whenever there is a clear and reasonable basis for doing so. If the USPTO fails to exercise vigilance in the identification and rejection of written description defects, patents with invalid, overly broad claims could be issued, spawning expensive and time consuming litigation that could have been
AIPLA strongly urges the USPTO to follow the decisional law of the past decade that in certain respects has elevated the importance of the written description and utility requirements and use this guidance to reject claims in applications or invalidate claims in patents. AIPLA believes that it would be preferable for the law on the written description and utility requirements to be developed at an early stage through ex parte appeals from the USPTO rather than through later, more expensive post-issue litigation in the Federal Courts. This belief necessarily translates into a desire to see the USPTO rigorously apply the statutory written description and utility requirements as applied by the Federal Circuit. Moreover, AIPLA would urge the USPTO to identify appeals on these issues and expedite their disposition within the USPTO, to the extent consistent with law and regulation.

In addition, AIPLA believes that additional changes to the current patent law could also help to address some of the questions raised by the granting of patents in the area of genes and related new subject matter. AIPLA recognizes and commends the efforts of this Subcommittee for striving to achieve some of the changes which would be beneficial in this regard. H.R. 400, as reported by this Subcommittee last year, contained what promised to be a very helpful expansion of the existing reexamination system. It would have allowed members of the public limited participation in the reexamination process before the USPTO, including the ability to appeal and to participate in appeals in the Office and before the Court of Appeals for the Federal Circuit. This would have provided a very cost effective means of challenging problematic patents granted in this area. Unfortunately, the inter partes reexamination procedures were drastically curtailed during the subsequent legislative deliberations that led to the AIPA. Another limitation that was adopted that we would like to address at a future time involves the exception to 18-month publication in the AIPA. Full publication of all pending applications would provide researchers and companies in the biotechnology field greater certainty regarding their freedom to pursue costly and expensive research in this field.

Questions

Questions have been raised regarding whether there are any unintended impacts of the existing patent laws on basic scientific research and on the freedom of doctors to use new gene related inventions in the treatment of patients. This latter concern was the subject of legislation some four years ago when Congress excluded from the definition of infringement surgical and medical procedures that a doctor might perform on a patient. While AIPLA opposed that amendment on the basis that it was based on only a single example of dubious real-world significance and was inconsistent with the obligations of TRIPs, it is nonetheless the law and should remove this concern from the list of allegedly harmful consequences of granting patents in the area of gene and related inventions.

Regarding the allegation that the patent laws may have unintended adverse impacts on basic scientific research, certainly the explosion of investment in the biotech field would not support such a conclusion. To start with, patents never "lock up" information or prevent the use of gene sequence information in any context. The patent system is designed to assure that information gets disclosed to the public rapidly. The information concerning an invention – what it is, how it can be made, what it is useful for – go immediately into the public domain, free for all to use. Thus, the patent system has led to the publication of massive quantities of information concerning genes and their function. Everyone has free and unfettered access to that information. While inventions can be patented, information cannot.

Second, the Supreme Court has long recognized that not all "uses" of a patented invention represent an infringement of the patent owners rights. Although very limited, an "experimental use" exemption does exist. It has been developed by the courts to assure that a patented invention can be used to understand the basic function of the invention and develop...
alternatives to it. If only as a logical matter, the patent system can never promote progress in the useful arts if the grant of a patent locks out others from gaining a basic understanding of what is patented, how to design around it, and how to improve upon it. Absent an experimental use exception, patents could theoretically freeze, not promote progress in the useful arts and frustrate the development of improvement inventions that Congress has specifically authorized to be patented. Many commentators believe that this so-called "experimental use" or "research exemption" under current case law is sufficient to assure that all basic research activities can peacefully co-exist with the broad, exclusionary rights of the patent owner to stop unauthorized uses of a patented invention.

In this regard, gene research and gene patents interplay no differently compared to research and patents in other technological fields. Similar concerns have been raised in many technological areas. To date, we have not seen emerging technology fields blocked, locked down or frozen in place by a "pioneer" patent. One very likely reason that this has not occurred in other fields is the reality of pioneer innovators. Their seminal inventions often take years to bring to full fruition through wide adoption in the marketplace. This requires that the technology be developed quickly since, once a patent issue, the patent term winds down over the course of only a few years. For many seminal inventions, such Stanford's Cohen-Boyer patents, this has meant providing licenses to the entire industry – hoping to spur develop of implementing technology.

If an invention does, however, fall within the scope of an earlier valid dominating patent or was discovered as a result of using an earlier patented invention, the later inventor/patentee may need to obtain a license, if one is available, and to pay a royalty to the owner of the earlier patent – but this is no different than in any other technology field – including the other explosively growing fields, telecommunications, Internet, software, and semiconductor-based devices. The patent system has worked in the past and, given time and the reality of the marketplace, it should work in this field as well. In brief, one should be rather chary about designing solutions in search of a problem for our time-tested and venerable patent system. Should such a problem materialize in the future, it can be appropriately dealt with at that time.

**Conclusion**

The U.S. patent system is providing unprecedented hope for the nation's sick and infirm while serving the biotechnology community. The USPTO has demonstrated that it is aware of the needs of everyone impacted by the patent system. It is seeking to improve its processing of gene and related patent applications. As indicated, however, the Office has a desperate need for all of the fee revenue it receives to keep pace with its ballooning workload in this complex field and improving the quality of its work. We are confident that with your assistance, the issue of consistent and adequate PTO funding will be successfully addressed. We believe that the Office is targeting test cases to clarify the utility and written description questions that are outstanding, and that the experience and competence of the Court of Appeals for the Federal Circuit will aide immeasurably in providing any needed guidance. We will certainly be monitoring the developments in this very important and rapidly moving field and look forward to working with this Subcommittee to resolve real issues as they arise.

In summary, we urge the Congress to stay the current course in terms of the patent laws themselves. The patent system is working in this area as it has worked effectively elsewhere– to make information on new inventions promptly available to spur further innovation, to provide incentives for investments that will produce new businesses and new products, and – ultimately – to secure the blessing of accelerating innovation for ourselves and our posterity.