**Statement of**

# Q. TODD DICKINSON

## UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY & DIRECTOR OF THE U.S. PATENT & TRADEMARK OFFICE

**before the**

## SUBCOMMITTEE ON COURTS AND INTELLECTUAL PROPERTY COMMITTEE ON THE JUDICIARY U.S. HOUSE OF REPRESENTATIVES

**July 13, 2000**

Mr. Chairman and Members of the Subcommittee:

Thank you very much for inviting me to testify today on the patenting of genes and other genomic inventions. As you know, patents in this cutting-edge area of biotechnology are a topic of considerable interest and debate in many circles. While some of this debate is unfortunately fueled by misinformation, legitimate questions have been raised about just what genomic discoveries, if any, should be patentable and whether genomic patents will inhibit researchers' access to the data, materials, and methods needed to develop new tools for the diagnosis and treatment of disease.

Given the gravity and far-reaching implications of these issues, I commend the Subcommittee for holding this hearing. I am hopeful that this morning's discussion will help clear the air of some misperceptions of just what is and isn't patentable and provide all parties with a better understanding of the essential role the patent system plays in unlocking the mysteries of the human body.

**U.S. Patent System**

In order to understand why genes are patentable, I believe it is necessary to first review the underpinnings of the U.S. patent system itself and the role of the United States Patent and Trademark Office (USPTO) in administering this system. The basis for our patent system is found in Article 1, Section 8, of the Constitution, which provides that Congress shall have the power:

> ***To promote the progress of science and useful arts by securing for limited times to . . .inventors the exclusive right to their . . . discoveries.***

In carrying out the intent of this Constitutional directive, our Founding Fathers designed an extremely flexible patent system based on principles that have proven remarkably suitable to 210

years of unceasing technological advancement. Indeed, one of the key tenets of our patent system is that it is technology-neutral; from gearshifts to genomics, it applies the same norms to all inventions in all technologies.

While some are critical of this aspect of the patent system, the uniformity and facileness of the patenting standards of novelty, obviousness, and utility -- coupled with the incentives patents provide to invent, invest in, and disclose new technology -- have allowed millions of new inventions to be developed and commercialized. This has enhanced the quality of life for all Americans and helped fuel our country's transformation from a small, struggling nation to the most powerful economy in the world. Equally as impressive, the patent system has done all this without the need for Congress to constantly retool the law -- a powerful testament to the system's effectiveness in simultaneously promoting the innovation and dissemination of new technologies.

**Patentability Criteria**

In administering the patent system, the USPTO takes its direction on what subject matter is patentable from Congress and our reviewing courts. The current Act that details the standards of patentability, the Patent Act of 1952, specifies four basic statutory requirements that must be met to obtain a patent: (1) the claimed invention must be statutory subject matter and have utility; (2) it must be novel; (3) it must not have been obvious to a person having ordinary skill in the art at the time the invention was made; and (4) it must be fully and unambiguously disclosed in the text of the patent application, so that the skilled practitioner would be able to practice the claimed invention.

Prior to granting a patent, the USPTO examines each patent application to determine whether it meets these four criteria, as set forth in Title 35 of the U.S. Code. With respect to the first statutory requirement, 35 U.S.C. § 101 states that any person who "invents or discovers any new and useful…composition of matter, or any new and useful improvement thereof, may obtain a patent…" subject to the conditions and requirements of the law.

Going back nearly a half century, the courts began to rule that isolated and purified products of nature were eligible, as compositions of matter, to be patented. For example, not long after James Watson and Francis Crick published their seminal work on the structure of deoxyribonucleic acid (DNA) in 1953, the Fourth Circuit stated in 1958 in a case involving naturally occurring vitamin $B_{12}$ compounds that "There is nothing in the language of the [1952] Act which precludes the issuance of a patent upon a 'product of nature' when it is a 'new and useful composition of matter'…. All of the tangible things … for which patent protection is granted are products of nature in the sense that nature provides the source materials." The court further noted that "[t]he fact … that a new and useful product is the result of processes of extraction, concentration and purification of natural materials does not defeat its patentability." (**Merck & Co., Inc. v. Olin Mathieson Chem. Corp**., 253 F.2d 156, 161, 163). Two decades later, the Court of Customs and Patent Appeals ruled in 1979 that a biologically pure bacterial culture was patentable since the culture did not exist in nature in its pure form and could only be produced in a laboratory under carefully controlled circumstances. (**In re Bergy**, 596 F.2d 952, 201 U.S.P.Q. 352.)

The most significant ruling on the patentability of biological products occurred a year later, in the Supreme Court's landmark decision in **Diamond v. Chakrabarty**, 447 U.S. 303, 309, 206 U.S.P.Q.

193, 197 (1980). In that decision, which found that genetically engineered bacteria were patentable, Chief Justice Burger cited the Congressional Report accompanying the 1952 Patent Act in noting that "Congress intended statutory subject matter to 'include anything under the sun that is made by man'." When considering the scope of subject matter eligible for patent protection, the U.S. Supreme Court stated:

> ***[Chakrabarty's] microorganism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity "having a distinctive name, character [and] use." (*****Hartranft v. Wiegmann*****, 121 US 609, 615 (1887))… [T]he patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under §101.***

Many commentators believe the **Chakrabarty** decision was a major factor in the phenomenal growth of the biotechnology industry. Indeed, the Supreme Court's ruling altered somewhat the philosophy of the USPTO, from one of skepticism of patentability to more openness, and paved the way for a variety of patents involving living materials. In the wake of **Chakrabarty**, for example, we issued the first transgenic animal patent to the now-famous Harvard "onco mouse," a mouse genetically engineered to be more susceptible to tumor growth. Patents have since issued on other genetically engineered plants and animals.

Over the past twenty years, many patent applications have been filed that are drawn to subject matter relating to genes. The filing rate of applications relating to genes has dramatically increased in the past few years. Currently, over 20,000 applications relating to genes are pending before the USPTO. Since the first gene related applications were filed, approximately 6,000 patents have issued which are drawn to full-length genes from human, animal, plant, bacterial and viral sources. Of these 6,000 patents, over 1,000 are specifically drawn to human genes and human gene variations that distinguish individuals.

To digress for a moment, the complexity of some of these applications is almost unimaginable. For example, we received a DNA sequence listing as part of a patent application that, had it been submitted on paper, would have totaled more than 400,000 pages. The challenges of searching and examining applications of this complexity are great, and we are working with our customers and industry to generate creative solutions to examining applications in these technologies. This is yet another reason why it is vital that the USPTO have sufficient funding, and I want to thank you, Mr. Chairman, for your outstanding leadership on that issue.

Consistent with the findings in **Chakrabarty,** the courts have consistently ruled that genomic products and their mutations fall within the statutory categories of compositions of matter and manufactures. (See, e.g., **In re O'Farrell**, 853 F.2d 894, 7 U.S.P.Q.2d 1673 (Fed. Cir. 1988) and **Amgen, Inc. v. Chugai Pharm. Co., Ltd.**, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991)). However, in order to be patentable, they must not be in their naturally occurring state, and their invention must be the result of human intervention. In other words, the gene must be isolated and

purified from its natural environment. The patent statutes also provide that a new use for an old and known compound (e.g. a gene or gene fragment) would also be eligible for patent protection.

Provided that these conditions are met, a key issue for determining whether a genomic invention is patentable is the question of utility. As with any other invention, a nucleic acid must be useful in order to be patentable. Raw DNA sequenced data, such as that recently generated by the Human Genome Project and various corporate endeavors, is not patentable.

**Utility Requirements for Genetic Materials**

The issue of the utility of an invention is one that the USPTO takes very seriously. That is why we continue to take steps to ensure that genomic patent applications are meticulously scrutinized for an adequate written description, sufficiency of the disclosure, and enabled utilities, in accordance with the standards set forth by our reviewing courts. In fact, in order to ensure the highest standards of utility, the USPTO published "Revised Interim Utility Examination Guidelines" in the ***Federal Register*** on December 21, 1999 (Volume 64, Number 244). A companion training document was also published on our website (www.ustpo.gov) on March 1, 2000. We are currently finalizing these guidelines, based upon public comments, and we expect to publish them by early this fall. We do not anticipate any substantive changes to the interim guidelines.

In order to meet the utility requirement of 35 U.S.C. § 101, our new utility guidelines require patent applicants to explicitly identify, unless already well-established, a specific, substantial and credible utility for all inventions. In effect, we have raised the bar to ensure that patent applicants demonstrate a "real world" utility. One simply cannot patent a gene itself without also clearly disclosing a use to which that gene can be put. As a result, we believe that hundreds of genomic patent applications may be rejected by the USPTO, particularly those that only disclose theoretical utilities. Let me briefly explain the new utility definitions:

- An asserted utility is **credible** unless the logic underlying the assertion is seriously flawed, or the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. For example, at least some nucleic acids might be used as probes, chromosome markers, or diagnostic markers. Therefore, the *per se* credibility of assertions regarding the use of nucleic acids is not usually questioned. However, even if credible, at least one asserted utility must also be both **specific** and **substantial**.

- A utility is **specific** when it is particular to the subject matter claimed. For example, a polynucleotide said to be useful simply as a "gene probe" or "chromosome marker" does not have specific utility in the absence of a disclosure of a particular gene or chromosome target. Similarly, a general statement of diagnostic utility would ordinarily be insufficient to meet the requirement for a specific utility in the absence of an identification of what condition can be diagnosed.

- A **substantial** utility is one that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, basic research that uses a claimed nucleic acid simply for studying the properties of the nucleic acid itself does not constitute a substantial utility.

In general, if a partial nucleic acid sequence is useful for diagnosis of a particular disease, then the sequence would likely meet the utility requirement and patent protection commensurate in scope with the disclosure would be granted assuming the other statutory requirements for patentability are met. As increased amounts of information are provided both in the nature of the nucleic acid and its uses, broader coverage would be granted.

I am very pleased with the positive feedback the USPTO has received on these new guidelines. The general consensus from the major parties involved indicates that we have set the utility standard at an appropriate level to ensure incentives for both research and the efficient dissemination of valuable data. For example, the former Director of the National Institutes of Health (NIH), Dr. Harold Varmus, stated earlier this year that he was "very pleased with the way [the USPTO] has come closer to [the NIH's] position about the need to define specific utility." Dr. Francis Collins, Director of the National Human Genome Research Institute, has said that the new utility guidelines are "quite reassuring in terms of making sure that we end up with an outcome where the patent system is used to provide an incentive for research and not a disincentive." In addition, Dr. Craig Venter, the President and Chief Scientific Officer of Celera Genomics Corporation, recently stated that he was "pleased to see [the USPTO] is raising the bar" on gene patents.

**Responding to Concerns**

Despite these favorable comments, the patenting of genomic inventions remains controversial. However, I believe much of this criticism stems from a lack of understanding of the legal issues at hand and of the functions of the patent system.

For example, some of the criticism we hear confuses issues of patentability with issues of access. Whether something is patentable subject matter is a related but entirely different issue from whether it will be licensed to ensure appropriate access by researchers. As I have described, the USPTO's chief duty is to determine whether an invention claimed in a given patent application meets the legal criteria for patentability.

With that said, the USPTO does take notice of the legitimate concerns regarding access to genomic inventions. Clearly, inventors and owners of genomic patents need to be acutely aware of the heavy responsibility inherent in that ownership; their licensing and other technology transfer practices need to strongly account for the powerful public desire to ensure that the use of these inventions for the greater good of all humankind is not unduly burdened. Moreover, the Administration is pleased to see that, in keeping with the President's recommendations, several private entities have agreed to make their raw human genome sequenced data publicly available.

As to the general assertion that patents inherently impede access, history provides little evidence that this is the case. For example, consider the broad patents issued to inventors Cohen and Boyer that have been at the center of molecular biology research since they were issued. U.S. Patents 4,237,224 and 4,468,464, issued in 1980 and 1984, respectively, cover a significant amount of the subject matter currently being used in biological research, including recombinant DNA materials and methods of making and using such materials. These patents, which are owned by Stanford University and widely licensed for nominal fees, are considered to be some of the most profitable patents ever to issue in biotechnology. This profitability is largely due to their widespread use in the

advancement of biological research. Indeed, the dominance of these patents did not stifle research, but served instead to spur innovation by providing the incentives of patent protection.

Secondly, there is a tendency among the patent system's critics to assert that genetic material cannot be patented because it is found naturally in our bodies. However, genes are basically chemicals -- complex chemicals to be sure, but chemicals nonetheless -- and chemicals and pharmaceuticals that have been isolated and purified from naturally-occurring sources have long been held patentable.

When Dr. Fleming discovered that mold in his petri dish had killed bacteria nearby, and then isolated penicillin from that mold, that drug was patented, and the world was a safer place. The USPTO has also issued hundreds of patents to products extracted from the human body for pharmaceutical or diagnostic use, including clot-busting proteins to treat stroke, cancer antigens for detection of cancer, and antibodies to treat infection. Human Growth Hormone was originally isolated from human pituitary glands, as were some vitamins.

It was the cloning and subsequent patenting of the human insulin gene that allowed researchers to synthesize genuine human insulin in the laboratory using recombinant DNA technology. This approach results in more reliable insulin protein and reduces complications than can occur from a reaction to animal insulin. Indeed, there are so many chemicals in the human body that, if we ruled them all off limits to patenting, we would rule out an extraordinary number of valuable and important inventions.

Many of the arguments of our critics also resemble those voiced in the past about emerging technologies. For example, thirty to forty years ago when polymer chemistry was an emerging technology, some argued that the industry would be devastated if broad generic claims were granted on the building blocks of basic polymers. Clearly, that didn't happen. The U.S. polymer industry is very much alive and well. More recently, people argued that patents on software would impede the development of the software industry. Most would agree that this has not happened either. In reality, patents have been integral to the United States' biotech industry's growth into the powerhouse it is today.

Indeed, while the patent system provides protection to inventors for their innovations, it also provides for dissemination of information and technology that might otherwise be maintained as trade secrets. The biotechnology and pharmaceutical industries are some of the most research intensive industries in existence. Given that the majority of research in these areas is privately funded, it should come as no surprise that in supporting that research, the private sector often looks for financial returns. These financial returns are very often packaged as – or linked to -- patents and other intellectual property rights.

Without the funding and incentives that are provided by the patent system, research into the basis of genetic diseases and the development of tools for the diagnosis and treatment of such diseases would be significantly curtailed. Moreover, genomic patents enable companies, especially smaller enterprises, to raise the capital needed to bring beneficial products to the marketplace or fund further research.

**Conclusion**

Mr. Chairman, the USPTO is committed to ensuring that our practices and policies promote the innovation and dissemination of new technologies. I am proud to say that we have a proven track record in that regard. Indeed, thanks in large part to invention and collaboration fostered by broad patent eligibility, we stand today in the midst of an Information Revolution that rivals the great renaissances of centuries past.

While we must remain vigilant to ensure the use of genomic inventions for the greater good is not unduly burdened, the patenting of genomic inventions is consistent with our law and with our practice. Just as the patent system has nurtured the development of telephony, aeronautics, computers, and a host of other industries, the balance it strikes between generating intellectual property and distributing those ideas will ensure that new discoveries in genomics lead to healthier, longer lives for all of humankind. The USPTO and the Administration look forward to continuing to work together with you and the members of the Subcommittee toward that end.

Thank you, Mr. Chairman.