Statement

of

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before the

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Education and Related Agencies

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Mr. Chairman and Members of the Subcommittee:

I am Q. Todd Dickinson, Acting Assistant Secretary of Commerce and Acting Commissioner of Patents and Trademarks. I want to thank you for providing me with this opportunity to discuss the patent system, more specifically the patenting of stem cells, and the licensing of technology. It is my understanding that you have recently been considering the scientific implications of research into these cells and are now interested in investigating the patent and technology transfer implications.

Background

The history of the U.S Patent System is a long and distinguished one. Grounded in Article 1, Section 8 of the Constitution, the Patent Act of 1790 was one of the first statutes passed by the First Congress sitting in Philadelphia. The first patent was granted that same year to Samuel Hopkins, also of Philadelphia, for a method of making potash, a chemical useful for fertilizer and gunpowder - critical technologies for a new, agriculturally based nation. The application was examined by the first patent examining board: Secretary of State Thomas Jefferson, Attorney General Edmund Randolph and Secretary of War Henry Knox. The patent itself was personally signed by the President of the United States, George Washington.

The system has evolved in many ways since that auspicious beginning, and continues to serve the primary function it was intended to serve by the Founding Fathers: as an incentive to technological innovation and economic growth. From the cotton gin to the computer, America has been a model for technological development throughout its history, and patents have provided protection for the fledgling enterprises that were based on that innovation. For example, Thomas Edison still holds the record as the individual inventor holding the most patents, and his efforts led to the General Electric Co., one of the most successful and aluable corporations in the United States.

The premise on which the system is based is a simple one: in exchange for a full and complete disclosure of an invention, the government grants a limited right in that invention to the inventor or his or her assignee. It is not a monopoly right to own an invention, as is sometimes suggested, but rather the right to exclude others from making using or selling it. Moreover, at the patent owner's discretion, this right may or may not be exercised.

The public benefits from this arrangement since full disclosure permits others to improve that technology by developing alternative solutions, or to find a better, unexpected species invention within the broad genus of the patent claim, thereby expanding mankind's technological base. Additional benefits include preventing wasteful duplication of research and development; a comprehensive teaching of the technology, permitting it to be used efficiently after the patent term expires; and the creation of indexed databases of technology in the form of the patent classification system which permit easier and more comprehensive searching.

Studies have consistently shown that many important industries rely on a strong and effective patent system. University of Pennsylvania economist Edwin Mansfield surveyed 100 U.S. corporations chosen randomly in six industries.(1) In each case, he asked senior management if strong intellectual property laws were a significant consideration for different kinds of investment the corporation would make in a particular country. The survey found that approximately 60% of companies investing in final product manufacturing facilities said that intellectual property rights had a "strong effect" on whether direct investment would be made. In chemical, pharmaceutical, or electrical equipment manufacturing, the percentages were even higher, between 74 and 87%. Even more telling, when executives were asked if they would invest in research and development facilities (the top end of wealth creation in an economy), 80% said that the strength or weakness of intellectual property rights in a country would have a strong effect on whether the company invests there.

Non-profit research institutions also benefit financially from strong intellectual property protection. The largest public university system in the United States is the University of California with over 7,000 faculty members among its 9 campuses. In 1997, the University had 2,943 active inventions. Revenues on those patent and technology licenses produced $74.7 million for the University in 1997. Carnegie Mellon University in Pittsburgh recently assigned a patent claiming spidering technology used to search the World Wide Web to Lycos for a reported $500,000 in cash, 20% equity in the start-up and an unspecified percentage of royalties.

In the biotechnology field, this effect is even more apparent. I recently participated in a conference hosted by members of the European Parliament who were finally successful in passing a new biotechnology patent law for Europe after more than ten years of effort. (It is reputed to be the most extended debate ever about a piece of legislation before the European Parliament.). Speaker after speaker bemoaned the fact that the absence of such legislation in Europe, and the presence of strong biotechnological patent protection in the U.S., had caused significant research and development funds, manufacturing investment, and large numbers of research scientists to relocate to the United States.

U.S Patent Law

The current patent statute, title 35 of the United States Code, dates from 1952, and specifies that to obtain a atent the applicant must meet four basic statutory requirements: that the claimed invention be statutory ubject matter (35 U.S.C. ß101); that it be novel, i.e. that it was not invented before, (35 U.S.C. ß102); that it not be obvious to a person having ordinary skill in the art to which it pertains (35 U.S.C. ß103); and that it e fully and unambiguously disclosed in the text of the patent itself, sufficient to enable the skilled practitioner to practice the claimed invention (35 U.S.C. ß112). If the patent application and its claims do not eet these requirements, it is rejected. These requirements are not easy hurdles to overcome. Section 103 non-obviousness, in particular, requires a careful review of the state of the art and often very skillful crafting of claims to avoid it. In the biotechnology field, the ß112 enablement requirement is often a major stumbling block.

It should also be noted that the claims are the only legally operative portion of the patent itself. Readers of patents often incorrectly assume that the teaching of the detailed description or background of the invention found in the body of the patent in some way defines the metes and bounds of the protected invention, or that the "concept" of the invention taught in the claims is what is covered. This is incorrect. Furthermore, while the applicant may be his or her own lexicographer and define terms, undisclosed meanings not apparent in the text cannot be read into a claim and inferences cannot be drawn; the plain language of the claim alone defines the parameters of the invention. This means that claim interpretation is a difficult and often semantic art.

It is also important to remember that the patent grant is a limited right in time. The patent term runs for twenty years from the date that the application is filed. After it expires, anyone is free to use it. Furthermore, owners of patents do not necessarily have to enforce their rights: they can and do dedicate them to the public. Since a patent may not be granted on an invention known to the public for more than a year, inventors may also dedicate their inventions to the public through public disclosure without filing applications.

Biotechnology and Stem Cell Research

Biotechnology generally encompasses any technique that uses living organisms or their components to make or modify products, to improve plants and animals, or to use microorganisms for specific uses. Biotechnology has begun to affect our daily lives in ever-increasing ways. It is opening new pathways in the treatment of incurable diseases and is showing promising alternatives to less effective traditional treatments. In the field of nutrition, biotechnology makes ever-greater headway to improve food production and plant breeding in a manner that one could only dream about a decade ago. In the field of genetics, the use of new techniques is beginning to open substantial and wide-ranging benefits for human and animal health, the protection of the environment and the potential for productivity gains in food, agricultural and pharmaceutical industries.

A serious downside of research and development in the biotechnology area is that it is voraciously expensive and often requires substantial time periods for commercial development. Moreover, many lines of research eventually prove to have been fruitless. Yet, the successful results, once known, are often not difficult to replicate by others. Other factors, including public perception regarding anything new and different, also keep many biotechnology inventions from reaching their full market potential. Consequently, very few biotechnology companies are profitable at this time. Many continue to require substantial additional investment to maintain operations. As a consequence, the biotechnology industry has a demonstrated need for patent protection to act as an effective incentive to innovation and to serve as a tangible asset for investment.

One exciting development in biotechnology research has been the isolation and purification of particular types of undifferentiated cells that can give rise to a succession of specialized functional cells. These are known as stem cells, and are currently the

subject of intensive research. Although most non-cancerous cells can divide only a limited number of times, the division of stem cells can be unlimited and may serve as a useful tool in solving many previously intractable medical conditions. In addition some stem cells are "pluripotent" cell lines, meaning they can be made to develop into a variety of different specialized cells.

Patentability

Since stem cells are both living and found in nature, however, a question that may legitimately be raised is how they can constitute patentable subject matter under ß101 of our patent law. Although the question of the subject matter patentability of living organisms may have been answered as long ago as 1873, when Louis Pasteur was granted a United States patent on yeast, it was most firmly addressed by the Supreme Court almost twenty years ago in the famous case Diamond v. Chakrabarty(2). In that case, Chief Justice Burger, writing for the Court, found that genetically engineered bacteria useful for cleaning up oil spills by ingesting hydrocarbons were themselves patentable. As noted by the Court (citing the Congressional Report accompanying the 1952 Act(3)), "Congress intended statutory subject matter to 'include anything under the sun that is made by man". Many commentators believe that this case was a major factor in the phenomenal growth of the biotechnology industry. And it should also be noted that the PTO has long issued patents to living plants under the provisions of the Plant Patent Act of 1930.

Moreover, although stem cells do indeed occur in nature, most evidence indicates that they are always mixed with other cell types and do not occur in an isolated and purified form. Purified and isolated cell lines, as well as methods for their purification and isolation, represent important technological advances. They may also have novel or unexpected properties or uses, and may therefore result in a patent.(4) As stated by the Supreme Court, "To obtain a patent for a product made from raw material, it must possess a new or distinctive form, quality, or property."(5)

The patentability of biologically pure compositions has been the law for over twenty years. In In re Bergy (1977)(6), the Court of Customs and Patent Appeals (the predecessor court to the Court of Appeals for the Federal Circuit (CAFC), the appeals court to which PTO appeals are taken) ruled that a biologically pure bacterial culture was patentable, and not a "product of nature", since the culture did not exist in nature in its pure form and could only be produced in a laboratory under carefully controlled circumstances.(7) This has been extended since that time to "'purified and isolated' DNA sequences encoding human erythropoietin (EPO)",(8) and a preparation of Factor VIII: C, used for treating hemophilia. ("Although Factor VIII: C molecules occur in nature, a purified and concentrated preparation of Factor VIII: C as claimed in the patent constitutes a new form or combination not existing in nature, and hence is patentable under 35 U.S.C. ß101.")(9)

Accordingly, it is the present position of the Patent and Trademark Office that purified and isolated stem cell lines are patentable subject matter under 35 U.S.C. ß101.

Licensing

Concerns have also been raised regarding the licensing of technology in the biotechnology area, specifically in the context of the availability of research tools. While the Patent and Trademark Office does not normally concern itself with access issues, we do have responsibility for intellectual property policy generally, and, as such, have some experience in these matters.

A traditional way to exploit one's patent is to license it to others, under a wide variety of possible terms: exclusive or non-exclusive; royalty-free or royalty bearing. Patent owners may also choose not to license, for a variety of reasons, such as a desire to preserve exclusivity or maintain competitive advantage. This right is fundamental to the patent grant.

While some speculate that patent owners who refuse to license or exclusively license others may adversely affect access to biotechnological research tools, it has been my experience that market realities and/or good will almost always resolve this problem. One famous example may prove illustrative.

Almost two decades ago, Stanford University was granted a patent on a method covering basic recombinant DNA technology, the so-called Cohen-Boyer patent, U.S Patent Number 4,237,224. Because of the fundamental nature of the technology, great public concern was raised that biotechnology research would be blocked, or that Stanford would charge such exorbitant royalty rates that research would be priced out of reach. In reality, nothing of the sort occurred. Stanford quickly developed a reasonable and widely available licensing program and alternative technologies were developed to compete with it. Because the licenses were offered at reasonable rates to all who sought them, technology was not stymied. Improvements to the technology also arose resulting in a moderating cross-licensing program.

Another question which has been raised concerns specific additional grants or limitations contained in certain licensing agreements. These include such provisions as a requirement that any improvements in the licensed technology be licensed back to the patent holder, commonly known as grant-backs. Provisions such as this are fairly common in commercial technology licenses, although they are also often the subjects of significant negotiation.

It is also important to note that many of these aspects of intellectual property licenses may be subject to antitrust scrutiny. See, for example, the Antitrust Guidelines for the Licensing of Intellectual Property, recently promulgated by the Antitrust Division of the Justice Department and the Federal Trade Commission.

In the context of these licensing considerations, it is also important to define specifically what "research tools" are being implicated in these concerns. Many of the instruments, chemicals and equipment used daily in research have patented technologies associated with them. A license to practice under those patents, and the related royalties, are often captured in the purchase price.

Lastly, and significantly, it should be noted that restrictions on licensing or subject matter patentability must also comply with United States international obligations. Through protracted negotiations, the U.S. has convinced many of our trading partners of the great value of intellectual property protection and has been able to reach agreement with them to provide strong intellectual property protection. In fact, we were able to incorporate our position on intellectual property protection into the Uruguay Round Trade Agreements of GATT. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires the United States and all other members of the World Trade Organization to provide similar patent protection for all patentable subject matter.

We have encouraged strong pharmaceutical patent protection by our trading partners and must continue to provide strong patent protection for biotechnological inventions, such as cell lines. That protection should not be diminished by inappropriate incursions into the rights of the patent owner. In fact, U.S. patent policy toward our trading partners strongly discourages compulsory licenses or any other such limitations on a patent holder's rights

While we certainly share concerns about access to technology, and would highly recommend that oversight of potential abuses be maintained, the balance of interests in this area is currently a carefully calibrated one, and should not be upset absent strongly reasoned analysis and demonstration of actual harm.

Summary

The United States leads the world in biotechnology research and development. We also lead the world in intellectual property protection. It is imperative to the former that we maintain the latter. As stated long ago by President Abraham Lincoln, a patent holder himself: the patent system has "added the fuel of interest to the fire of genius." Our continued success as the most technologically advanced nation in the history of the world demands that we honor that system and the benefits it brings.

Thank you.

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1 E. Mansfield; "Intellectual Property Protection, Foreign Direct Investment and Technology Transfer"; International Finance Corporation, Discussion Paper Number 19, The World Bank, 1994.

2 447 U.S. 303, 65 L.Ed.2d 144, 100 S.Ct. 2207, 206 U.S.P.Q. 193 (1980)

3 S.Rep. No. 1979, 82nd Cong., 2d Sess., 5(1952); H.R.Rep. No. 1923, 82nd Cong., 2d Sess., 6 (1952).

4 See generally Bozicevic, "Distinguishing 'Products of Nature' from Products Derived from Nature," 69 Journal of the Patent and Trademark Office Society 415 (1987).

5 American Fruit Growers, Inc. v. Brodex Co., 283 U.S. 1, 11, 8 U.S.P.Q. 131, 133 (1931)

6 568 F.2d 1031, 195 U.S.P.Q. 344 (ccpa 1977)

7 The Supreme Court granted certiorari, but summarily remanded to the CCPA in light of another related case. The CCPA later affirmed its earlier opinion.

8 Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 13 USPQ2d 1737, aff'd in part, rev'd in part, vacated in part, 927 F.2d1200, 18 USPQ2d 1016 (Fed Cir. 1991), cert.denied, 112 S. Ct. 169 (1991).

9 Scripps Clinic & Research Foundation v. Genentech Inc., 666 F.Supp. 1379, 1389 n.6, 3 USPQ2d 1481, 1487 n6. (N.D. Calif. 1897), aff'd.in part, rev'd in part, vacated in part & remanded,927 F.2d 1565, 18 USPQ2d 1001.