TESTIMONY
OF THE
BIOTECHNOLOGY INDUSTRY ORGANIZATION
ON
COMPETITION AND INTELLECTUAL PROPERTY LAW AND POLICY IN THE KNOWLEDGE E-BASED ECONOMY

BEFORE THE
FEDERAL TRADE COMMISSION
AND THE
DEPARTMENT OF JUSTICE

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SUMMARY

The biotechnology industry is the most research and development intensive and capital-focused industry in the world. As such, it is very dependent on a robust intellectual property system as well as a strong set of competition laws. [1/] Recent experience suggests that intellectual property law and administration in the United States offers both sufficient incentives to innovate and appropriate competitive safeguards, and that the current system is superior to alternative schemes in place in other nations or in the proposals of some commentators. [2/] The Federal Trade Commission and the Department of Justice are performing an important service by focusing attention on the emerging intellectual property and competition policy issues that affect American innovators. Scrutiny by these agencies can help further improve an already well-functioning legal regime.

BACKGROUND

BIO and the Biotechnology Industry

The Biotechnology Industry Organization (BIO) is a trade association of more than 1,000 companies, universities, research institutions worldwide and state and affiliated organizations engaged in biotechnology research on medicines, diagnostics, agriculture, pollution control and industrial applications. BIO represents an industry that has already provided more than 250 million people with benefits from more than 117 commercially approved drugs, biologics and vaccines. [3/] More than 75 percent of these medicines have been approved in the past 6 years. There are more than 350 biotech drug products and vaccines in late stage clinical trials to treat more than 200 diseases, including various cancers, AIDS, Alzheimer's disease, heart disease, diabetes, multiple sclerosis and arthritis. In addition, biotechnology companies and researchers are responsible for the development of hundreds of medical diagnostic tests, many biotechnology derived foods, environmental products and other industrial products. [4/]

There are over 1,200 biotechnology companies in the United States of which about 30 percent are publicly traded. [5/] The revenue of these companies was about $22.3 billion in 2000 and the market capitalization of the industry equaled

over $350 billion in 2000, although it is somewhat lower today. The biotechnology industry is very research intensive. The industry spent $10.7 billion on R&D in 2000, with the top five companies) spending an average of $89,400 per employee on R&D. This intensity in R&D spending is more than double the average of the pharmaceutical industry (both on a per employee basis and as a percentage of sales), and the pharmaceutical industry is several times more R&D intensive than any other industry.

The biotechnology industry is also a dynamic one. The industry doubled in size between 1993 and 1999. Currently the industry helps to create 437,000 U. S. jobs, including 150,800 direct jobs. The industry has direct revenues of about $20 billion, and additional revenues for companies supplying inputs or selling goods to the industry of $27 billion. The biotechnology industry, as a whole, is not yet profitable, yet those companies that are in a tax-paying situation make tax payments of $10 billion per year (with 2/3 going to the federal government). [6/]

Role of Intellectual Property in the Biotechnology Industry

The biotechnology industry is very dependent upon strong intellectual property protection. Biotech companies rely heavily on private investments for financing, and patents are among the most important benchmarks of progress in developing a new company's product line.

Empirical evidence suggests that patents are an important means for protecting the value of biotechnology firms. Economist Joshua Lerner has found that not only do patents help biotechnology companies attract venture financing, but also that the valuation of a start-up biotechnology firm is directly proportional to the breadth and scope of the firm's patents.[7/] In another recent economic analysis, specific values were attributed to biotechnology patents as calculated from a function depending on the patents' content.[8/] Individual patents in the core areas of biotechnology development were shown in this study to be valued between $13 and $21 million on average. [9/] This same analysis also revealed that a biotechnology patent yields significant economic value to rival firms of the patent holder due to the public knowledge spillover from the patent's disclosure. [10/]

Biotechnology firms recognize the value of patents in their industry and survey evidence has tended to show that the biotechnology industry places a greater emphasis on seeking patent protection than do many other industries. In a 1989 study, firms in over 100 industrial disciplines ranked patents as the least important of several available strategies for competing in new-product markets. [11/] These firms placed more emphasis on the effectiveness of trade secrecy, early entry, and customer service when engaging emerging product sectors. The same study revealed, however, that firms in the chemical and pharmaceutical disciplines (into which most biotechnology firms were categorized at the time) ranked patents as one

of the most effective means for effecting competition. [12] In a similar study undertaken in 1986, empirical data suggested that not only did the chemical and pharmaceutical industries place more emphasis on patents, but a relatively large portion of the innovations in those industries would never have succeeded to market without patent protection (as compared to innovations in ten other industries). [13] The 1986 study also showed that in those industries (including chemical and pharmaceutical) where patents were regarded as a relatively important means for competition, patents were more likely to be sought for patentable inventions than in those industries that did not regard patents as relatively important. [14]

The results of these mid-1980s studies were re-examined in a 1999 survey, which delineated biotechnology firms from the chemical and pharmaceutical industries. [15] This more recent survey suggested that in industries other than biotechnology, chemical, and pharmaceutical, to which patents remain very important, the emphasis on secrecy and non-disclosure has generally increased since 1987. The importance of patents to the biotechnology industry, however, remains high. This can be seen because companies have continued to file more and more patent applications even though the cost of filing and presenting biotechnology patents is higher and it takes longer than inventions in some other fields because long administrative delays in the Patent and Trademark Office are common for biotechnology patents.[16]

Patents and Competition Policy in Biotechnology

The primary purpose of patents is to offer a limited period of exclusivity [17] and an appropriately circumscribed scope of protection against commercial use of an invention by a third party, thereby protecting against the "free riding" that would sap the incentive to innovate. [18] The patent system also assures that inventions will eventually be publicly disseminated. Patents are granted for a limited period of time (20 years from filing), and once the patent expires, the subject matter of the patent enters the public domain. Once an invention is in the public domain it may be freely used by anyone. In addition, the patent system promotes scientific progress by offering valuable additions to the existing art in the field. This is especially true now that patent applications must be published within 18 months after filing. The existence of patents actually can foster competition [19] by pointing potential competitors a way to invent around a patent or invent improvements to the patent subject matter. [20]

As the President's Council of Economic Advisors put it in its recently issued Economic Report of the President:[21]

> "[I]n many cases, firms or individuals might not embark on developing an innovation because, although the social

> benefit from it may be large enough to justify its development costs, the firm or individual could not expect to reap enough of that benefit to justify those costs. The consequences of this problem were recognized in the U.S. Constitution, which empowered Congress to develop a body of intellectual property laws, including those establishing patents. A patent for an invention confers on an individual or firm (the patent holder) limited rights to exclude others from making, selling, or using the invention without the patent holder's consent. Patents generally are granted for 20 years, and as the rights they provide imply, the patent holder can license to other individuals or firms the right to use its innovation. Patents give a firm the legal power to keep others from using its innovation to create competing products without bearing the cost of the innovation. Licensing provides a means whereby the innovator can receive compensation, in the form of licensing fees, from others that find a beneficial use for the innovation. Thus policy has long recognized that, to encourage innovation, firms must expect that successful innovations will yield a market position that allows them to earn profits adequate to compensate for the risk and cost of their efforts."

The United States biotechnology industry was provided with the "fuel of interest" [22/] for the inventive genius of American scientists when the Supreme Court decided the case of *Diamond v. Chakrabarty* in 1980. [23/] In that case the Court upheld the notion that biotechnology-related inventions are patentable. Since the Chakrabarty decision the biotechnology industry has been able to attract venture capital and sustain the innovation through massive investments in research and development. The industry, and the customers it serves, has further benefited from a series of administrative, Congressional, and judicial determinations, which have fashioned a stable, strong, and relatively clear set of patent rules for biotechnology.

The biotechnology industry also has benefited from the pro-competitive effects of vigilance exercised by the competition enforcement agencies, especially the Federal Trade Commission and the United States Department of Justice. These agencies have, over the life of the industry, modernized the rules on intellectual property licensing and moved to a more economically rational rule of reason approach in appropriate cases. The continued use of tools that permit fact sensitive evaluations of competition issues can help sustain the continued viability of the biotechnology industry, while assuring an open marketplace that will benefit consumers through further innovation and competitively-priced products.

SUMMARY OF THE ISSUES ADDRESSED IN THIS TESTIMONY

This testimony addresses the following issues:

- **Patent scope and quality**. Do developments in patent law and practice pose any important competition questions?

- **Patent term and competition.** Have changes in patent term been pro-competitive?

- **Patents for "research tools" and the development of "patent thickets."** Is there sufficient evidence from the real world to suggest the need for changes in law or agency guidelines?

- **Merger enforcement and "innovation markets."** How should the enforcement agencies, in conducting merger reviews, take into account the intellectual property assets and R&D efforts of the merging parties?

- **Unilateral refusals to deal.** What considerations should the enforcement agencies take into account when evaluating unilateral refusals to license intellectual property?

- **Treatment of biotechnology inventions under international law.** Should the United States continue to advocate strong global patent protection for biotechnology inventions?

These questions are addressed in this testimony by first offering a summary conclusion followed by a brief discussion and rationale for that conclusion. The views expressed in this testimony are those of the trade association and should not be imputed to any individual member(s) of the association.

PATENT SCOPE AND QUALITY

The scope and quality of patents have improved in recent years due to increased management attention to these issues within the U.S. Patent and Trademark Office (PTO), and multiple legislative actions by the U. S. Congress. The Patent and Trademark Office, under a series of Commissioners (starting with Mossinghoff and including Manbeck, Quigg, Lehman and Dickinson), have taken actions to improve the processing of biotechnology related inventions. These

changes include new utility. [24] *and written description guidelines,* [25] *creation of a separate art unit for biotechnology,* [26] *increased training for biotechnology oriented examiners, dramatic increases in the number of biotechnology examiners, frequent reviews of biotechnology related patent policy questions, ,* [27] *and support for an open and thorough dialogue on these issues with all affected parties.*

The most important changes in patent law relating to biotechnology include the issuance of new gene patent utility guidelines (Jan. 2001), [28] *new instructions on "business method" patents (March 2000),* [29] *and the enactment of the American Inventors Protection Act (AIPA) by the Congress (creating an 18-month publication requirement along with some partial revisions to the re-examination process).* [30] *These changes -- taken together -- will substantively address issues of patent quality as well as increase the transparency and accountability of the American patent system. More could be done, particularly by providing that the PTO should retain all of the user fees that it generates.* [31] *In general terms, however, the United States patent system has been remarkably responsive in addressing legitimate criticisms.*

An effective patent system requires that the patents that are issued are valid, and confer an appropriate scope of protection on their owners. The agency charged with ensuring that patent grants meet the requirements of patentability, and are of an appropriate scope is the Patent and Trademark Office. The PTO must discharge this obligation through adoption and use of rules, practices and procedures that are designed to yield accurate determinations of patentability, and issuance of patent claims reflecting those accurate determinations.

The PTO has, without question, faced numerous challenges in the 22 years following the landmark *Chakrabarty* decision authorizing the granting of patents on living organisms. The PTO, and the industry, have had to respond to these challenges through adoption of new and refined examination standards and practices. In the experience of BIO and its members, the PTO has adapted its examination practices and procedures successfully to meet these challenges as they have arisen.

For example, in the late 1980's, the PTO faced a significant challenge in the form of a remarkable increase in filings of applications directed to "biotechnology" inventions. The increased rate of filings led to the accumulation of a significant backlog of unexamined applications, and an significant increase in the pendency of biotechnology applications. The PTO responded to this challenge by developing and implementing a 12 point plan. Parts of the plan included formation of a special biotechnology examination group, adjustment of examiner salaries to attract and retain highly qualified examiners and development of rules to govern issues unique to the industry (e.g., governing deposits of samples of living

organisms and submission of sequence listings). The PTO also commenced an aggressive effort to procure specialized information technology systems to assist search and examination efforts.

The PTO was able to successfully manage the increased workload and ultimately to eliminate the backlog of unexamined applications. These steps have also paid significant dividends in the form of increased quality. The biotechnology examination group boasts a level of education and experience shared by virtually no other examination authority in the world (e.g., more than 60% of the examiners hold Ph.D. degrees). The PTO's information technology infrastructure is extremely sophisticated, and its capacity to search and analyze sequence information is matched by few commercial or academic institutions in the world.

The implementation of the 12-point plan is only one example where the PTO has adapted to challenges in the biotechnology field. In the mid-1990's, the PTO promulgated examination guidelines concerning the utility requirement to address concerns in the patent user community. The examination guidelines were produced in transparent and participatory process, where the PTO actively sought input from the patent user community and the public on appropriate standards and practices the Office should adopt.

Over the last 25 years there have been certain criticisms of the U.S. patent system. In the 1980s the criticism centered around such issues as the lack of sound statutory underpinnings (e.g., lack of adequate process patent protection), judicial incoherence caused by differing approaches to patent law questions between regional circuit courts of appeals, and a need for improvement in the operation of the Patent and Trademark Office. Over the last two decades, Congress and the PTO have gradually addressed virtually all of these criticisms.

In 1982, Congress addressed the problem of disparate results in patent-related court decisions -- especially as a result of divergent opinions on questions of national applicability between various federal appellate courts -- by creating the Court of Appeals for the Federal Circuit. [32/] While not every decision by that court has been uniformly praised, [33/] the Federal Circuit Court of Appeals has brought a beneficial degree of uniformity to patent law in the United States.[34/] Moreover, Congress has gradually addressed defects in the patent law through a series of patent law changes, including biotechnology process patent protection [35/] and patent term restoration. [36/] In addition, the federal courts have applied the law to new technologies through new court decisions [37/] addressing issues of technological change. The Congress and the PTO have taken action to expand patent rights [38/,] improve examination procedures, and better define appropriate patent scope. Finally, in response to criticism of the status of, and funding levels for, the PTO, [39/] Congress enacted a series of incremental improvements that have elevated the status of the office [40/] and increased its resources. [41/]

More recently, there has been a new strain of criticism concerning the scope and quality of certain types of patents, particularly gene patents and business method patents. [42] Whatever the validity of that criticism concerning practices in the late 1990s, the current situation is far different and the quality of patent examination and the scope of claims on issued patents has improved. The issuance of business method patent guidelines has improved patent examination in that field and should lead to higher quality patents. With respect to gene patents, the PTO's new utility guidelines go a long way toward fully addressing critics' concerns regarding the legal requirements that applicants must meet before obtaining a so-called "gene patent".

PATENT TERM AND COMPETITION

Duration of patent term has been adjusted in recent years to achieve international harmonization (e.g., the World Trade Organization's "20-year from filing" rule adopted in 1994), [43] and recent Congressional actions have compensated for delays caused by the PTO by partially permitting patent restoration. [44] Additional action should be taken to fully extend patent terms to compensate for delays attributable to the approval processes of the Food and Drug Administration. [45] Specifically, federal law should offer full patent term extensions to account for the total period during which drugs are undergoing clinical trials. [46]

In addition to criticism of patent scope and quality, there has been criticism evident in the patent community in recent years pertaining to whether patent terms are fair and adequate or, alternatively, if they have been artificially extended. Before addressing those issues in detail, it is important to note the history of patent term in the United States.

Throughout most of American history, the period of patent term was 17 years and it ran from the date of patent issuance. [47] This system was workable for many years for two reasons. First, there was less substantive examination of patents, so there was little delay between filing a patent application and its eventual issuance. Also, under a 17-year term that began at issuance there was less risk of patent term erosion. Second, until the last several decades there were very few products that were subject to extensive federal government review before they could be marketed. In the 1960's and 1970's the federal government began to impose new public health and safety requirements that must be met before some patented products could be marketed. [48] This requirement of pre-market approval had the net effect of eroding patent term for these products and creating, in some cases, very substantial differences in patent term for products based upon whether and how they were regulated.

In response to the unfairness of eroding patent term due to the imposition of pre-market approval processes, Congress enacted the patent extension provisions of the Hatch-Waxman Act, which attempted to partially restore the effective patent term of products subject to this type of regulatory delay.[49] When these provisions were enacted, Congress assumed that there would be an increase in patent term for pharmaceutical- and biotechnology-related products. Congress, in the same act, created additional drug competition by creating a new, expansive generic drug approval process.

One authoritative study suggests that inventors in these fields did not receive the kind or length of patent term restoration that was expected to result from the Hatch-Waxman provisions.[50] This study found that the Hatch-Waxman provisions offered an average of about 3 years of patent restoration for drug products approved between 1993 and 1995, but that those same products still lost about one-third of their full patent term due to the patent term restoration rules set by Congress. The competition component of Hatch Waxman has been a success. The number and percentage of generic drug prescriptions has grown dramatically.

In the 1990's, Congress once again altered patent term in order to move toward an internationally agreed-upon norm of 20 years from filing.[51] The net effect of this change was to risk the loss of patent term due to regulatory delays in the PTO. When these changes were enacted, the average review period for a biotechnology patent within the PTO was substantial.[52] As a result, between the date of enactment of the 20-year term and more recent Congressional action, there has been practical erosion of biotechnology patent term. In 1999, Congress acted to provide for partial compensation for this form of regulatory delay.[53] Congress created a system to add back patent terms for applicants that the PTO does not act on within three years.

In sum, over the last 20 years Congress has consistently recognized that patent term should be calculated in a manner that takes into account the practical difficulties that some inventions, and some industries, face as a result of regulatory delay beyond their control. Congress has, as a result, passed a series of measures permitting the adjustment of patent term to restore time lost due to regulatory requirements.

BIO believes that Congress should continue this work by providing for full patent term restoration for ***all*** the patent term lost as a result of requirements imposed by federal agencies such as the FDA. Specifically, BIO believes that inventors should receive full patent term restoration for each day that products covered by applicable patent are undergoing human clinical trials.[54]

CONCERNS ABOUT PATENT THICKETS / RESEARCH TOOLS

International law generally bars discrimination in patent law against certain technologies. [55/] *Domestically this concept of non-discrimination between categories of inventions has been seen to contribute to the progress of science and the useful arts.* [56/] *Policy makers should reject suggestions that biotechnology patents have "special" patent rules.*

There is insufficient evidence to suggest that significant problems exist within the PTO [57/] *or in the licensing processes used for patents in commerce (including alleged patent thickets, or patent stacking)* [58/] *with respect to "research tools,"* [59/] *or in decisions by either the lower courts or the Federal Circuit Court of Appeals* [60/] *to suggest the need for governmental intervention by creating a statutory research exception,* [61/] *any mandatory patent pooling* [62/] *or other interventions.*

Before turning to some of the policy questions raised by the FTC and Department of Justice about "patent thickets," it would be useful to describe the kinds of patent practices that are common in the industry. At least for the health-oriented part of the biotechnology industry, the most desirable kind of intellectual property protection is a product patent, especially one that can protect against unfair "free riding" after a new drug or biological product has been approved by the Food and Drug Administration. Thus, companies and their investors see the existence of these strong product patents as the most stable form of intellectual property. Not surprisingly during the last 20 years of exploding gains in our knowledge of biology there has been a dramatic increase in the issuance of relevant product patents.[63/]

There are instances in which disputes have arisen about the validity and scope of basic biotechnology patents. Those cases have been fully, fairly and extensively litigated in the Federal courts. Virtually no one in the industry or the university community -- winners or losers in these cases -- has sought major legislative relief or reform of the judicial system for adjudicating patent disputes. This suggests a general level of satisfaction with the processes used to judicially resolve these disputes.

Over the past 20 years there has been a dramatic increase in the amount and quality of university research in biotechnology. [64/] This research explosion has been stimulated by a series of changes in federal law as well as increased interest by universities in transferring technology into the private sector. This paradigm shift also occurred in parallel to similar changes, including expanded technology transfer, from the federal research establishment to the private sector. Thus, the picture of technology transfer is a remarkably vibrant two way street between the university and government communities and the for profit biotechnology community.

Inevitably a few of the inventions created in the private sector have produced patents which have the potential to impinge on the operations of non-commercial entities, including universities. Before turning in detail to the merits of a proposed "research exemption", it is important to keep in mind that the number and frequency of disputes in this area is very, very small. Universities, and other non-profit enter do not seek to "make or sell" products that are covered by product patents. On occasion, these non-commercial entities may want to "use" a patented product or process to conduct an experiment or test. In the vast majority of even these cases, the patent owner and the researcher reach an informal understanding about when and under what circumstances such experimentation is permissible. So, it is misleading to assume that isolated cases reported in the trade press, or in academic journals, about friction between the university community and the biotechnology industry are the norm. Rather the norm is a cooperative and collaborative relationship in which the industry seeks out universities as partners and collaborators, and frequently where the industry is licensing intellectual property from the university or government.

Discrimination Based on Patentable Subject Matter Is Not Justified

On occasion, some advocates have urged Congress to create special rules for patents pertaining to pharmaceutical products or biotechnology inventions. For example, in the 1980's some members of Congress suggested the institution of a moratorium on the issuance of patents on transgenic animals (which are genetically modified animals, generally needed in research on drug production. Fortunately, those suggestions were rejected and the use of transgenic animals is currently viewed as one of the most positive steps in the drug development process in recent years, especially with respect to AIDS-related drugs. The expanded use of transgenic animals in research would not have been possible had Congress barred the use of patents in conjunction with this kind of research. In more recent years, some members have suggested that drug-related patents should be treated differently and opened up to automatic compulsory government licensing. This approach has also, wisely, been rejected.

Congress has recognized that there is substantial merit to applying the general rules of patent law to all technologies. This approach has prevented the "Balkanization" of intellectual property protection based on the classification of an invention.

Concern over Research Tools and the Alleged "Patent Thicket"

In recent years, criticism has been leveled regarding the existence of certain patents with overly broad scope, and complaints have been voiced that patents in certain fields have the net effect of blocking new research. [65/] In some instances it has been suggested that Congress consider enacting a statutory

"*research exception*." Some, in the academic community, have argued that virtually all non-profit work should be "non-infringing." [66] In general, these criticisms have been misplaced, and the proposed solutions would be either worse than the alleged problem or inconsistent with federal and/or international law. For some of the complaints about multiple patents there are solutions already available under existing federal law.

The emergence of biotechnology-related inventions and patents in the genomics field, and the issuance of patents for genes, have caused some commentators to articulate the view that there is a "real risk" that the existence of multiple patents will create an "anticommons" [67] or that multiple patents will create a "patent thicket". [68]

Our experience, however, echoes the conclusions of a recent study supported by the National Academy of Science [69] which concludes that:

> "…There has been an increase in patents on the inputs to drug discover [sic]("research tools")… we find drug discovery has not been substantially impeded by these changes." [70]

This study reflects the experience within the industry. According to this study, there are numerous means of addressing circumstances involving multiple patents, including: (1) taking licenses, (2) inventing around patents; (3) using an informal *non-statutory* practice of judicious non-enforcement by patent holders; (4) creating public domain oriented databases; and (5) challenging patents in court. While there is no doubt that the current licensing situation in the biotechnology field is more complex -- and the resolution of licensing problems more time consuming, and sometimes more expensive -- than 20 years ago, it is still manageable. More importantly, considering the many patients who benefit from the products of biotechnology, there is insufficient evidence to suggest that valuable research have been abandoned as a result of intellectual property issues.

Patent Pools [71]

One of the important potential solutions to concerns regarding overlapping patents is the creation of *voluntary* patent pools. As the PTO noted in its white paper on *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents* (January 2001), these arrangements can offer very positive pro-competitive benefits. [72] Indeed, the benefits that can result from cross licensing were recognized in the intellectual property guidelines issued by the Federal Trade Commission and the Department of Justice in 1995. [73]

As noted by the Patent and Trademark Office, the benefits of voluntary patent pooling can result in the reduction of transaction costs, clearance of blocking patent positions, integration of complementary technologies, avoidance of costly infringement litigation, and promotion of the dissemination of technology. [74]/

There are, no doubt, countervailing anti-competitive risks [75]/ and appropriate safeguards need to be put in place, [76]/ but it is vitally important that the federal competition agencies maintain the current guidelines and avoid any hint of a return to the mechanistic rules of earlier eras of multiple and unjustified *per se* rules. [77]/

This resistance to compulsory licensing and government-imposed solutions is especially important to uphold in the United States because of the potentially adverse international consequences of ambiguity in this area. As noted above, under the provisions of the TRIPS agreement [78]/, countries that have agreed to the terms of World Trade Organization membership are required to patent technology on a non-discriminatory basis. [79]/ In addition, there are severe limitations on the use of compulsory licenses where patents are concerned. [80]/ To the extent that the United States permits the imposition of compulsory licenses more easily than in the past, other countries, especially in the developing world, will be tempted to stretch even further the definitions of when compulsory licenses are permitted. [81]/

MERGER ENFORCEMENT AND "INNOVATION MARKETS"

In some cases involving the merger of biotechnology or pharmaceutical companies, the federal antitrust agencies have required the divestiture or licensure of intellectual property assets, even in cases in which it was unclear whether, if at all, these assets would be used in the production of a product that would actually be marketed. In considering whether the intellectual property assets of merging firms raise competitive concerns, it is essential that these agencies exercise caution in light of the uncertainties involved in predicting the future importance of such assets, the lack of a clear understanding between industry concentration, R&D efforts and innovation, and the potential that mergers can have to increase innovation by combining complementary efforts and eliminating redundancies. The agencies should conduct a retrospective review of past mandatory licensing and/or divestiture requirements to determine whether such steps were necessary to maintain competition.

During the last decade, both the DOJ and the FTC increasingly raised concerns regarding the impact of mergers and acquisitions on innovation. For example, a recent survey found that the agencies had alleged innovation effects in 47 challenges to mergers and acquisitions during the 5-year period ending

September 30, 1999, or in 17.5 percent of the cases that they brought. [82/] One of the first cases to raise innovation concerns involved the 1990 acquisition by Roche Holdings of a controlling interest in Genentech, a biotechnology firm. [83/] Transactions involving the biotechnology and pharmaceutical sectors continue to be closely scrutinized, and sometimes challenged, due to concerns about the impact on innovation. [84/]

This increased scrutiny with respect to effects on innovation has coincided with the announcement, in the *IP Guidelines,* that in addition to the traditional market for goods, the agencies will also scrutinize possible competitive effects in markets for technology (consisting of intellectual property that is licensed and its close substitutes) and markets for research and development or "innovation markets." The latter consists of the "research and development directed to particular new or improved goods or processes, and the close substitutes for that research and development." [85/]

The concept and utility of "innovation markets" have been hotly debated. [86/] No one doubts the importance or benefits of innovation in our economy. But to the extent that one or both of two merging firms have R&D efforts that are likely to result in the offering of products that compete with each other, the transaction can be scrutinized under traditional antitrust analysis as involving either "actual" or "perceived" potential entry. [87/] To use "innovation markets" to attack transactions that do not involve potential competition (for example, because neither party has an actual product in the market) raises the concern that antitrust enforcement will venture into areas where the likely effects are extremely speculative and where more harm than good may result.

There are several reasons why the agencies should exercise caution when considering a challenge based on the intellectual property assets of one or both merging parties – regardless of whether the challenge is based on a "potential competition" or "innovation market" theory. These include the following:

- **The value of intellectual property assets is often very uncertain**. For example, in the biotechnology and pharmaceutical industries, a patent represents only a modest beginning step in a very long, and extremely expensive, process of creating a marketable product. The best available research on this topic suggests that with respect to pharmaceutical products, only one out of five thousand inventions survives to the point of screening in clinical trials; that only one out of five products in clinical trials receive FDA approval; and that out of every ten products approved for the commercial market, only three make money. The vast majority of money spent on development is spent after a patent application has been filed (*e.g.*, after human clinical trials have begun. In addition to the uncertainty associated with whether any particular R&D effort will ultimately prove successful, in highly innovative fields

such as biotechnology one must also factor in the uncertainty associated with whether others will achieve better results with alternative technologies, rendering one's product obsolete even before it comes to market.

- **The likely anticompetitive effects resulting from combining the R&D efforts of merging firms are very difficult to predict.** In traditional antitrust analysis, where the focus is on firms that are currently selling a particular good or service, it is as least possible to obtain an understanding of the number and relative strengths of the competitors in the market. There are also well-accepted economic theories that can be applied in determining whether a particular transaction is likely to result in anticompetitive unilateral or coordinated effects. This is not the case where the concerns involve the possible impact on innovation in a market where neither party is currently producing a good. Unlike an existing goods market in which concentration levels can be measured in terms of sales or capacity, in this case the agencies must measure the competitive significance of the R&D efforts of the merging parties and others that are engaged in similar efforts. But a mere counting of R&D dollars or personnel is unlikely to be a useful measure of the value of an R&D effort. Thus, it is very difficult for the agencies to confidently assess how "concentrated" the field may be with respect to specific R&D efforts. Moreover, there is little consensus on the general relationship between concentration, R&D effort and innovation; consequently, it is unclear how the agencies can confidently predict whether the removal of one entity engaged in R&D could likely have any real competitive significance.

- **Overzealous enforcement can result in lost efficiencies and less innovation.** Finally, it is crucial to remember that significant benefits may be lost as the result of an unnecessary challenge to an R&D merger or acquisition. Collaboration on research can result in the sharing of economic risks, increased economies of scale, the pooling of complementary skills and intellectual property, and the elimination of redundancies. Indeed, Congress has recognized the potential benefits of joint research ventures by according them special antitrust treatment. [88/]

In light of these considerations, we urge the agencies to exercise caution in assessing the potential competitive effects associated with the R&D efforts or intellectual property of firms involved in a merger or acquisition. Moreover, we believe that it would be useful to engage in a retrospective review of agency enforcement actions in which a divestiture or mandatory licensing of intellectual property was required as a condition for agency clearance. This review could help inform the agencies of the benefits and costs of such imposing such

conditions, and could shed light on the wisdom in using them as a tool to preserve competition.

UNILATERAL REFUSALS TO LICENSE INTELLECTUAL PROPERTY

At present, the law is unclear as to the circumstances in which a patent holder may be held liable under the antitrust laws for unilaterally refusing to license its intellectual property. The Federal Circuit Court of Appeals took a narrow view of the scope of potential liability, holding that "[i]n the absence of any indication of illegal tying, fraud in the Patent and Trademark Office, or sham litigation, the patent holder may enforce the statutory right to exclude others from making, using, or selling the claimed invention free from liability under the antitrust laws," and that inquiry into a patent holder's motive in refusing to deal is inappropriate "so long as [the] anticompetitive effect [of refusing to sell or license a patented invention] is not illegally extended beyond the statutory patent grant." [89]/

The Ninth Circuit Court of Appeals has taken a somewhat broader view. In *Image Technical Services, Inc.* v. *Eastman Kodak Co.*[90], that court ruled while there is a rebuttable presumption that exercising the statutory right to exclude constitutes a legitimate business justification immunizing a refusal to license from liability under section 2 of the Sherman Act, that presumption may be rebutted by evidence that the proffered business justification is merely pretextual.

BIO offers the following comments to assist the Commission and the Division in evaluating refusals to license. *First*, the patent law is expressly premised on the notion that during the statutory term of a patent, the patent holder has the right to exclude others from making, selling or using the patented invention.[91]/ Refusing to license a patented work is thus ordinarily a necessary incident of the Congressional determination that, in order to encourage invention, patent holders must be afforded the exclusive right to determine how their inventions are used during the statutory patent term. For that reason, refusals to license a patented invention should be afforded a presumption of legality under the antitrust laws, and liability for refusal to license should be found only in highly unusual circumstances.

Second, there are a broad variety of legitimate business justifications for refusing to license a patented work. First among these is the right to obtain the full value of the invention during the patented term. The inventor of a new drug, for example, does not violate the antitrust laws by failing to license another manufacturer to make and sell that drug during the statutory term.

And *third*, because of the high cost of antitrust litigation, BIO supports the establishment of guidelines that establish clear rules for determining when

unilateral refusals to license violate the antitrust laws, and providing for safe harbors for refusals that do not violate those laws. Those guidelines should, to the greatest extent possible, rely on objective, rather than subjective, factors for determining the legality of a patent holder's conduct.

INTELLECTUAL PROPERTY: AN INTERNATIONAL DIMENSION FOR BIOTECHNOLOGY

Special care should be taken in reviewing the international intellectual property regime. [92/] *Strong patent protection in developing countries can serve to stimulate domestic industrial growth and increased domestic research and development,* [93/] *and widespread exemptions (or compulsory licenses) do not serve the public interest. Moreover, without sufficient protections against "free riding," the incentive necessary to create new products for markets outside the developed world, especially in the health care arena, will be undermined. The United States should continue its leadership role in advocating for patent protection for biotechnology related inventions within the World Trade Organization and the World Intellectual Property Organization and other international fora.*

The market for biotechnology-derived inventions extends well beyond the United States. There is an urgent need for the United States government to maintain its advocacy on behalf of the science of the biotechnology industry as well as to push for strong intellectual property regimes in other countries.

Biotechnology products, including medicines, devices, diagnostics and agricultural items, are increasingly sold on a worldwide basis. In 1996, U.S. biotechnology exports totaled nearly $1.2 billion. [94/]

A key to assuring the continued viability of the United States biotechnology industry is continued vigilance concerning the methods used by governments to regulate the approval and marketing of biotechnology products. It is vital that the executive branch continue to focus attention on the need for other nations to implement regulatory regimes that are exclusively based on sound science, and not motivated by fear or concern about fair competition with domestically created products. The imposition of unfair or arbitrary moratoria on the approval of products for commercial marketing based on unproven safety claims or on the alleged economic impact of new technology on older industries, should be rejected. If other nations are able to freeze out biotechnology derived products based on irrational regulatory schemes, they will have undermined innovation and thwarted the marketing of patented products. An aggressive stance on this issue by the Administration is of vital importance to the biotechnology enterprise.

Equally important is a renewed effort on implementation of adequate and effective intellectual property systems. The global intellectual property

standards reflected in the WTO TRIPS Agreement came about as a result of significant effort by the United States, particularly the United States Trade Representative (USTR), the Patent and Trademark Office (PTO) and the Department of State. A more significant problem lies in the lack of implementation of adequate and effective national intellectual property systems based on the TRIPS agreement, particularly by major developing countries. Many countries have not made any attempt at implementation, while others have omitted key protections relevant to the biotechnology industry. The lack of implementation, now more than two years past the due date for developing nations, is a significant problem that companies face outside the United States.

The failure of many countries to provide adequate and effective protection through their national systems is foreclosing growth of the biotechnology industry in these markets. When countries have enacted new patent laws it has led to increased research and development and economic growth within the innovative industries in those countries. Specifically, there has been rapid growth in the pharmaceutical and biotechnology sectors in those countries that honor intellectual property protection, especially patents.

BIO and its Members believe it is important for the Federal Trade Commission and the Department of Justice to acknowledge and promote the critical importance of the exclusive rights that must be conferred by the grant of a patent. This is true not only in the United States, but also in any country where patents are to function properly. This right to exclude is substantially more important and valuable than the right to collect royalties from persons who use your inventions. Indeed, the international community has agreed that intellectual property --- in this case a patent --- must be given the status of property rights. As with real property, a property owner must retain the right to exclude others from using the property if this right is to have any real meaning. Real property owners --- except in rare circumstances --- can not be forced to permit strangers to come onto their property in exchange for only rent payments. In the same way, the international community has made it clear that, absent extraordinary circumstances countries will not restrict these exclusive rights, either by revoking patent grants or by issuing compulsory licenses. This approach to intellectual property protection is the central ingredient that the United States government must strive to protect in various international institutions and domestically. [95/]

One of the important features of the TRIPS agreement is the broad rule requiring that all technologies be eligible for patents (with exceptions that are not applicable to commercial biotechnology patents). This non-discrimination rule in the patent provisions of TRIPS is an important safeguard against the creation of different patent or intellectual property rules based on unfounded scientific claims or fear of downstream economic consequences of new technologies. Moreover, this

approach to patent eligibility is a positive development in contrast to the Paris Convention.

As the United States government evaluates the pending issues within the WTO on the application of the TRIPS agreement to public health issues, several points are important to note. First, the TRIPS agreement is not intended to solve the public health problems of developing countries. Rather, the Agreement is separate and apart from the pre-existing problems of those countries with respect to their need for increased public health spending and infrastructure. TRIPS becomes relevant once a country seeks access to products which are not available in their own country. In these cases it is permissible for a member of the WTO to use a compulsory license to obtain access to a patented product. That kind of compulsory license, however, under the terms of the TRIPS agreement, requires compensation and a limitation on such a license to in-country production.

CONCLUSION

The Federal Trade Commission and the Department of Justice are to be congratulated for undertaking this careful and thorough examination of the interface between competition policy and intellectual property protection. BIO appreciates the opportunity to appear before you to describe the nature of the industry and its contributions to the improvement of the human condition, and to assess the issues presented by these two federal agencies.

In the main, we are strong supporters of maintaining the *status quo* with respect to both competition policy and patent policy. With limited exceptions, we believe that the combination of Congressional action, agency actions and judicial interpretations have addressed many issues concerning both patent scope and quality. We also believe that current competition policy is a sound balance of interests and that there is no compelling need to revise either the *IP Guidelines* merger guidelines used by the competition policy agencies of the federal government.

ENDNOTES

1/ The importance of patents to the pharmaceutical industry was established more than a decade ago by Professors Scherer of the Massachusetts Institute of Technology and Mansfield of the University of Pennsylvania. Scherer, F.M. *et al.* Patents and the Corporation: A Report on Industrial Technology Under Changing Public Policy, 2nd ed. Boston: n.p., 1959; Mansfield, Edwin. "Patents and Innovation: An Empirical Study." *Management Science* Feb. 1986: 173-181) (Mansfield notes that patents are substantially more important for the pharmaceutical industry than any other industry); *see also* Levin, Richard C. *et al.*, "Appropriating the Returns from Industrial Research and Development." *Brookings Papers on Economic Activity* 3 (1987): 783-820 (stressing the variability in the importance of patents between different industries, and how important they are to pharmaceuticals and biotechnology firms); Branscomb, Lewis M. and James H. Keller. "Toward a Research and Innovation Policy" in *Investing in Innovation: Creating a Research and Innovation Policy that Works*. Eds. Lewis Branscomb & James Keller. Cambridge: MIT P, 1998 (noting the need for strong patent protection for pharmaceutical and biotechnology firms). *See also* Cohen, Wesley M., Richard R. Nelson & John P. Walsh. "Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Marketing Firms Patent (Or Not)." Working paper w7552, National Bureau of Economic Research (NBER) Feb. 2000 <http://papers.nber.org/papers/W7552>.

2/ For several thoughtful reform-oriented articles urging reform of patent law with respect to biotechnology, the work of Robert P. Merges and Rebecca S. Eisenberg is illustrative. *See generally* Merges, Robert P. and Richard R. Nelson, "On the Complex Economics of Patent Scope," 90 *Colum. L. Rev.* 839 (1990); Lerner, Josh and Robert P. Merges, "The Control of Technology Alliances: An Empirical Analysis of the Biotechnology Industry," 46 *J. Ind. Econ.* 125-156 (1998); *and* Eisenberg, Rebecca S, "Reexamining the Role of Patents in Appropriating the Value of DNA Sequences," 49 *Emory L. J.* 783 (2000). For a general discussion of patent issues in the biotechnology industry *see* J. Golden, John, "Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System," 50 *Emory L. J.* 101 (2001).

In contrast to the United States, the patent situation in Europe remains less than satisfactory. While innovators can obtain patent protection under applicable Conventions such as the European Patent Convention (*see* Convention on the Grant of European Patents, October 5, 1973, *available at* <http://www.european-patent-office.org/legal/epc/e/ma1.html>, it is still the case that there is no unified patent process in Europe. This defect has been addressed repeatedly in reforms recommended by the European Commission; notwithstanding the potential economic and competitive advantages to a single EU-wide patent registration system, the European Union's member states have so far failed to agree on a European Community Patent scheme. *See Results of the Internal Market Council Brussels, 20th December 2001-Community Patent.* MEMO/01/451, *available at* <http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=MEMO/01/451|0|RAPID&lg=EN&display=>.

For evidence of the concerns of the European Union regarding the relative gap between the United States and Europe on biotechnology *see generally* Commission of the European Communities, *Communication from the Commission: Towards a Strategic Vision of Life Sciences and Biotechnology: Consultation Document.* April 9, 2001. COM(2001) 454 final, *available at* <http://europa.eu.int/comm/biotechnology/pdf/doc_en.pdf>. Moreover, the European Patent Office (EPO) has recently decided to stop examining biotechnology related patent inventions under the Patent Cooperation Treaty. *See* U.S. Patent & Trademark Office. *Notice Concerning EPO Competence to Act as a PCT Authority.* Jan. 1, 2002, *available at* <http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/epodoc.htm>.

3/ Facts about the biotechnology industry are derived from data compiled by (BIO) *at* <www.bio.org/er/statistics.asp>.

4/ Kenneth I. Shine, President, Institute of Medicine, "Welcome," *in* National Research Council, *Serving Science and Society in the New Millennium*. Washington, D.C.: Nat'l Academy Press, 1998. (proclaiming that, whereas "the 20th century will be known as the century of physics and astronomy … [b]ut the 21st century will be the century of the life sciences in all their ramifications.").

5/ In 1994, approximately 70% of U.S. biotech companies were less than 15 years old. *See* National Science Board, "Science and Engineering Indicators – 1996" at 6-28.

6/ For additional details about the industry and its economic contributions to the United States, *see* Ernst and Young Economics Consulting & Quantitative Analysis, *The Economic Contributions of the Biotechnology Industry to the U.S. Economy*, (May 2000), *available at* <www.bio.org/news/ernstyoung.pdf>. Most biotechnology companies are small; more than two thirds of them employ fewer than 135 workers. BIO, "The United States Is The World's Leader in Biotechnology," available at <www.bio.org.laws.legis2.html>.

7/ *See* Joshua Lerner, "The Importance of Patent Scope: An Empirical Analysis," 25 *Rand J. Econ.* 319, 324-27 (Summer 1994). Lerner examined a sample of 535 venture financing rounds at 173 privately held biotechnology start-ups between January 1978 and September 1992 and concluded that "firm value rises with the number of patents and the breadth of intellectual property protection . . . [and] at the mean of the independent variables, a one standard deviation increase in average patent scope leads to a 21% increase in the firm's valuation." Lerner's patent scope variable was defined as a function of the number of Patent Office technological classifications under which the patent issued.

8/ *See* Austin, David H. "Patents, Spillovers, and Competition in Biotechnology," Resources for the Future, Discussion paper #00-53 (Nov. 2000), *available at* <http://www.rff.org/disc_papers/PDF_files/0053.pdf> (further concluding that "market values of firms rise significantly when patenting occurs in contested research areas").

9/ *See id.* at 2.

10/ "Knowledge spillovers must flow most readily between firms doing similar research…[and] these individual patents may be a direct pathway, generating economic values of roughly $3 to $6 million per rival firm." *Id.*

11/ *See* Cohen, Wesley M. and Richard C. Levin. "Empirical Studies of Innovation and Market Structure." 2 *Handbook of Industrial Organization* Eds. Richard Schmalensee & Robert D. Willig. Amsterdam: North Holland, 1989: 1059.

12/ *See id.*

13/ *See* Mansfield, Edwin. "Patents and Innovation: An Empirical Study," 32 *Management Science* 173, 175 (1986). Mansfield concluded that 65% of innovations in the pharmaceutical industry and 30% of innovations in the chemicals industry would not have been commercially introduced if

patent protection could not have been obtained. No other industry showed more than 18% of commercial introduction dependent on patents.

14/ *See id.* at 177.

15/ Johnson, Matthew, Wesley Cohen and Brian Junker. "Measuring Appropriability in Research and Development with Item Response Models." Technical Report No. 690, Feb. 1999. Dept. of Statistics, Carnegie Mellon University. *Available at* <http://lib.stat.cmu.edu/www/cmu-stats/tr/tr690/tr690.pdf>.

16/ Biotechnology-related patent applications have a higher rate of reissue filings and a longer average term of pendency in the Patent Office compared to applications related to other technologies. This may be evidence that biotechnology firms expend more effort to push more of their applications through the Patent Office than do firms in other technologies. See John R. Allison and Mark A. Lemley, "Who's Patenting What? An Empirical Exploration of Patent Prosecution," 536 *Vand. L. R.* 2099, 2125-27 (2000).

17/ Economic Report of the President, February 2002, p. 133, *available at* <http://w3.access.gpo.gov/usbudget/fy2003/pdf/2002_erp.pdf>.

As one commentator put it, "[i]nvention is an uncertain business," and "[t]o spur investment in it, inventors must be reasonably assured that they will be able to recoup their costs and earn a profit." Rochelle Cooper Dreyfuss, "Dethroning Lear: Licensee Estoppel and the Incentive to Innovate," 72 *Va. L. Rev.* 677, 679 (May 1986).

18/ Among other things: (1) intellectual property is easier to misappropriate than other forms of property; (2) a patent grants the owner a power of exclusion that, in some respects, exceeds the powers that attach to tangible property; (3) the fixed costs are typically higher and the marginal costs lower than other forms of property; (4) to commercialize a product and earn a return, a larger number of complementary inputs with some degree of market power often must be brought together; and (5) the boundaries of intellectual property defy accurate survey to a much greater extent than do those of tangible property. Richard J. Gilbert and William K. Tom, "Is Innovation King at the Antitrust Agencies?: The Intellectual Property Guidelines Five Years Later, "69 *Antitrust L. J.* 43 n.8 (2001).

Without the reward of a patent and the right of exclusive use that it confers, "firms have weak incentives to absorb the costly expenditures needed to develop intellectual property." Abbott, Alden F. "Developing a Framework for Intellectual Property Protection to Advance Innovation." *Intellectual Property Rights in Science, Technology and Economic Performance: International* Comparisons Eds., Francis W. Rushing & Carole G. Brown. Boulder: Westview Press, 1990. 317. Firms "run the risk that . . . their innovations w[ill] earn insufficient profits to offset the losses stemming from failed research efforts," and that "capital markets w[ill] be far less willing to provide funds for independent research efforts." *Id.* at 321.

One scholar offers an interesting rationale for the Intellectual Property Clause by asserting that it offered a "perfect solution to encouraging the progress of science and useful arts with the least expense." Edward Walterscheid, "To Promote the Progress of Science and the Useful Arts: The Background and Origin of the Intellectual Property Clause of the United States Constitution," 2 *J. Intell. Prop. L.* 1, 34 (1994). The alternative of direct government support for promoting science was not possible for a small and "impecunious national government." *Id. at 34-35. Bauer & Cie v.*

O'Donnell, 229 U.S. 1, 10 (1913)(the patent system is based on rewarding and protecting invention). *See generally*, Robert P. Merges, "Commercial Success and Patent Standards: Economic Perspectives on Innovation," *76 Cal. L. Rev.* 803 (July 1988).

19/ The patent system fosters innovation and investment in research and development through what the U.S. Supreme Court has described as "a carefully crafted bargain." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-151 (1989). In exchange for "disclosure and the consequent benefit to the community," the law gives inventors exclusive rights to practice their inventions for a limited period of time. *Id.*

20/ *See, e.g., Yarway Corp. v. Ever-Control USA, Inc.,* 775 F.2d 268 (Fed. Cir. 1985) (discussing the laudable goal of designing around patents and that such is evidence of good faith in instances where an infringer is charged with bad faith copying). *See also State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1236 (Fed. Cir. 1985) ("One of the benefits of a patent system is its so-called "negative incentive" to "design around" a competitor's products, even when they are patented, thus bringing a steady flow of innovations to the marketplace."); *WMS Gaming Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1355 (Fed. Cir. 1999), *and cases cited therein*.

21/ Economic Report of the President, February 2002, *available at* <http://w3.access.gpo.gov/usbudget/fy2003/pdf/2002_erp.pdf>.

22/ "The [U.S.] patent system … added the fuel of interest to the fire of genius in the discovery and production of new and useful things." Lincoln, Abraham, Lecture on "Discoveries, Inventions and Improvements," February 22, 1860, in 5 *Complete Works of Abraham Lincoln*. Eds., John G. Nicolay & John Hay. New York: Francis D. Tandy Co., 1894, p. 113.

23/ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

24/ Utility Examination Guidelines, 66 Fed. Reg. 1092-02 (January 5, 2001) superseding Revised Interim Utility Examination Guidelines, published at 64 Fed. Reg. 71440, Dec. 21, 1999; 1231 O.G. 136 (2000); and corrected at 65 FR 3425, Jan. 21, 2000; 1231 O.G. 67 (2000).

25/ Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, Paragraph 1 'Written Description' Requirement, 66 Fed. Reg. 1099 (January 5, 2001). Since 1995, the PTO has provided aids for patent applicants in complying with the computer readable form submissions and the 37 C.F.R. §§ 1.821-1.825 Requirements for Patent Applications Containing Nucleotide Sequences and/or Amino Acid Sequence Disclosures. *See* 1172 Off.Gaz.Pat.Office 33 (March 13, 1995). The PTO has also increased applicants' abilities to file applications with sequence listings via the Internet. See "Bioscience Internet Filing," Off.Gaz.Pat.Office Notice (Nov. 4, 1999).

26/ Technology groups 1200, 1800, and 2900 were consolidated in February 1998 into new Technology Centers 1600 and 2900 to handle Biotechnology, Organic Chemistry, and Designs. *See* 1204 Off.Gaz.Pat.Office ___ (Nov. 11, 1997).

27/ The Office of Patent Quality Review (OPQR) randomly selects a sample of allowed patent applications for review. The policy objective of the OPQR is to provide "a mechanism to educate the Patent Examining Corps regarding recurring examination errors so as to improve public confidence in the consistency and accuracy of the examination process and the validity of issued patents." *See* "Office of Patent Quality Review," *available at* <www.uspto.gov/web/offices/com/oqm/opqr.htm>.

28/ The new rules for gene patents were published on January 5, 2001. Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001). These rules establish a three-pronged set of requirements for establishing "utility" by requiring that claims be: (1) specific, (2) substantial and (3) credible. The vast majority of examples given in the Guidelines and in the examiner training materials relate to biotechnology inventions, even though the Guidelines are of general applicability.

29/ The new PTO rules for "business method" patents are found in the new rules for "Automated Financial or Management Data Processing Methods (Business Methods)" (Mar. 29, 2000) *available at* <http://www.uspto.gov/web/menu/busmethp/index.html>.

30/ The American Inventors Protection Act of 1999 (AIPA), Pub. L. No. 106-113, 113 Stat. 1501 (1999), requires inventors to publish their patent applications within 18 months after filing a patent application. This major change in patent law in United States law will make it more likely that the quality of patents will improve. This is so because other parties, especially competitors, will have access to the patent application and can provide the PTO with "prior art" to help defeat or narrow the patent claims being sought. In addition, this form of publication arguably will offer an earlier opportunity for other inventors to invent around the proposed patent. Both of these steps should materially improve the patent system.

Administrative review procedures can be useful for certain instances where this significant commercial risk is not present. Under existing law, it is possible to use an administrative proceeding known as reexamination to review the validity of a patent. The current authority, however, is extremely limited. Efforts to improve the reexamination procedure in 1999, yielded a new "inter partes" procedure that unfortunately has been hobbled by onerous penalties on third parties that use the procedure and unrealistic limitations, such as a prohibition of third-party appeals of PTO determinations. Efforts are underway to improve the inter partes procedure in the present Congress, and if successful, will provide a useful new means of ensuring patent quality.

AIPA also adds an inter partes reexamination scheme for third party participation in the reexamination process. For a critique of certain aspects of this particular reform, *see* "Statement of the Biotechnology Industry Organization on Patents: Improving Quality and Curing Defects," *available at* <www.bio.org/laws/state051001.html>.

31/ President Bush has proposed in his FY 2003 budget an increase of more than 21% in the PTO budget, which is most welcome. *See* "President's 2003 Budget Raises USPTO Spending and Fees By 20 Percent," *IPO News*, available at <www.ipo.org>. Unfortunately, the proposed budget for the PTO continues a practice of the last several administrations of using user fees collected by the PTO to pay for general governmental services. In this budget the practice involves the imposition of a "surcharge" on the existing user fees, only a portion of which will be used by the PTO. The PTO still requires additional resources to improve its information technology operations and to continue in the process of upgrading pay and training for staff. The PTO does a good job with its existing resources, but it could do better with more resources. The Administration and Congress have reached a bipartisan consensus over the last seven years to double the funding for research at the National Institutes of Health and to stimulate private sector research and development with tax credits, but the PTO, which must evaluate and process the inventions that stem from that research, has not experienced a similar increase in its available resources.

32/ *See* Pub. L. No. 97-164, 96 Stat. 49 (1982).

33/ *See Amicus Curiae* Brief of the Biotechnology Industry Organization in Support of Plaintiff-Cross Appellant's Petition for Rehearing or Rehearing *En Banc*, *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2001) (disagreeing with the Court of Appeals for the Federal Circuit on the issue of "double patenting").

34/ BIO expresses no view about the appropriateness of decisions of the Court of Appeals for the Federal Circuit with respect to its exercise of antitrust jurisdiction.

35/ Biotechnology Process Patent Amendments of 1995, Public Law 104-41 (eff. Nov. 1, 1995). *See generally* David Beier and Robert H. Benson, "Biotechnology Patent Protection Act," *68 Den. U. L.* Rev. 174 (1991).

36/ The so-called Hatch-Waxman amendments are found in Pub. L. No. 98-417, 98 Stat. 1585 (1984).

37/ *See, e.g.*, *Amgen Inc. v. Chugai Pharmaceutical Co.*, 927 F. 2d 1200 (Fed. Cir. 1991) (addressing the enabling of DNA sequences); *Regents of the University of California v. Eli Lilly and Co.*, 119 F. 3d 1559 (Fed. Cir. 1997) (addressing written description requirements for biotechnology inventions that led to the PTO's Interim Written Description Guidelines); *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (addressing the obviousness of preparing DNA sequences from fragments). *See also Festo Corp. v. Shoketsu Kinzohu Kabushiki Co.*, 234 F.3d 558 (Fed. Cir. 2000), *cert. granted*, 121 S. Ct. 2519 (2001), a pivotal case on the "doctrine of equivalents" pending in the Supreme Court. Regardless of the outcome of *Festo,* there will likely be an alteration in the law in this area. The net effect in *Festo* and related cases has been to increase the degree of scrutiny courts have applied to assertions of "equivalents" and a more careful examination of patent prosecution history. These developments, taken together, are likely to improve the scope and quality of patents upon issuance, because applicants will be more careful in refining their claims in the patent prosecution process. This development should, in turn, decrease the risk of overly broad claims (or equivalents) thereby limiting the risk of creating a patent thicket.

38/ Process Patent Amendments Act of 1988, Pub. L. No. 100-418, 102 Stat. 1563 (1988).

39/ *See Operations of the U.S. Patent and Trademark Office, Including Review of Agency Funding: Hearings Before the Subcomm. on Courts, the Internet, and Intellectual Property of the House Comm. on the Judiciary*, 107th Cong. (2001).

40/ For example, the Director (formerly Commissioner) of the Patent and Trademark Office was an Administration appointee but not at the same level as an Assistant Secretary; now the Director of the Patent and Trademark Office is also Under Secretary of Commerce for Intellectual Property. American Inventors Protection Act of 1999, Pub. L. No. 106-113, 113 Stat. 1501 § 4732 (1999) More importantly, with the enactment of Public Law 106-113, the PTO became a performance-based organization, which should increase accountability, service and quality of patent examination and issuance.

41/ In FY 1999, the PTO budget was $806 million. U.S. Dep't. of Commerce, *FY 2000 Corporate Plan for the United States Patent & Trademark Office: Moving into the 21st Century* (Feb. 23, 1999), p. 3. *Available at* <http://www.doc.gov/bmi/budget/PB2000/BROWSE/PTO.PDF>. In FY 2001, the PTO's enacted budget was $1.039 billion; the PTO's requested FY 2002 budget is $1.128 billion. U.S. Dep't. of Commerce, *Budget in Brief: Fiscal Year 2003*, p. 117. *Available at* <http://www.doc.gov/bmi/budget/FY%202003%20DOC%20Budget%20in%20Brief.pdf.

42/ For criticism of business method patents, *see, e.g., Hearing on Gene Patents and Other Genomic Inventions of the Subcomm. on Courts and Intellectual Property of the House Comm. on the Judiciary*, 106th Cong. 128-56 (2000) (testimony of Harold Varmus, M.D.); James Gleick, "Patently Absurd," *New York Times Magazine*, 12 March 2000, 44; *and* R. Dreyfuss, "Are Business Method Patents Bad for Business?" 16 *Santa Clara Computer & High Tech. L.J.* 263 (2000). So-called business method patents arose out of *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F. 3d 1368 (Fed. Cir. 1998).

43/ Uruguay Round Agreements Act (URAA), Pub. L. 103-465, 108 Stat. 4809 1994. Congress, as a part of implementing an international agreement, provided for a 20-year patent term from filing.

44/ The American Inventor Protection Act, Pub. L. No. 106-113, 113 Stat. 1501 (1999) (which contains provisions sometimes called the Patent Term Guarantee Act of 1999) changes the law, in relatively complex ways, to permit patent term extensions for delays at the PTO that are outside the control of the applicant after an expiration of three years of pendency.

45/ When Congress enacted the Drug Price and Patent Term Restoration Act of 1984, Pub. L. No 98-417, 98 Stat. 1585 (1984), it established a complex regime for determining patent term restoration rules. In sum, the Congress acted to permit companies to receive full -- or day-for-day -- restoration for the entire period of time that a company's application is before the Food and Drug Administration awaiting final commercial marketing approval. The Congress, however, provided for three other rules that limit both what other regulatory delays can justify a patent restoration and the maximum overall time for which a company receive an extension. The Congress determined that companies could only receive patent restoration credit for one half of the time that the product was in human clinical trials. This limitation can be quite significant because most of the drug development time occurs during this period of time. The human clinical trial phase can last up to 10 years. The other caps on total patent term restoration have also prevented innovator companies from receiving full patent restoration. The first limitation is that a company, regardless of the total clinical trial development time, and its due diligence cannot receive a total patent extension of more than five years. The second limitation is that no company may, as result of the combination of the original patent term plus any permissible extension, result a total patent term from issuance of more than 14 years. For a more detailed description of the statute and how it has operated, *see* Congressional Research Service Report to Congress, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ('The Hatch-Waxman Act')*, Dec. 18, 2000; Sheila Schulman, Joseph DiMasi and Kenneth Kaitlin, "Patent Term Restoration: The Impact of the Waxman-Hatch Act on New Drugs and Biologics Approvals 1984-1995," 2 *J. Biolaw & Bus.*, 63 (1999).

BIO has previously testified in favor of altering the terms of the Hatch-Waxman statute to permit patent term restoration for all of the time that a biotechnology firm is conducting human clinical trials. *See* Statement of the Biotechnology Industry Organization (BIO) Submitted to the Subcommittee on Courts and Intellectual Property of the House Judiciary Committee Regarding Reform of the Hatch Waxman Law, July 1, 1999. <http://www.bio.org/laws/tstm070199.html>
For reasons that are inexplicable, current law limits patent term extensions to compensation for only one-half of the time that a product is involved with human clinical trials. This denial of patent term, due to federal regulatory denial, unfairly discriminates against products regulated by the Food and Drug Administration. As the FDA requirements to establish safety and efficacy have changed over time by requiring more and more clinical data, the actual patent term for some products has eroded over time.

46/ *Patent Restoration Act and Drug Price Competition*, "Testimony of David Beier on behalf of the Biotechnology Industry Association before the Senate Judiciary Committee Regarding Loss of Patent Term Due To Delays At The Food & Drug Administration and Amendments To The Hatch-Waxman Patent Term Restoration Act." Mar. 5, 1996.

47/ *See, e.g.,* Mark A. Lemley, "Intellectual Property and Shrinkwrap Licenses," 68 *So. Cal. L. R.* 1239, n.169 (1995).

48/ *See* "To Promote the Progress of...Useful Arts" in an Age of Exploding Technology, Report of the President's Commission on Patent System (1966) (the President's Commission on the Patent System was created by President Johnson through Executive Order 11125; the Commission's report was followed by President Johnson's legislative recommendations in Patent Reform Act of 1967, U.S. Dept. of Commerce, Communication from the President of the United States, A Draft of Proposed Legislation for the General Revision of the Patent Laws, Title 35 of the United States Code and for Other Purposes, H.R. Doc. No. 90-59 (1967)). *See also* Domestic Policy Review of Industrial Innovation (1978-79) (instituted by President Carter); Hearings on H.R. 6033, H.R. 6934, H.R. 3806 and H.R. 2414 before the Subcommittee on Courts, Civil Liberties and the Administration of Justice, House Committee on the Judiciary 797, 96th Cong., 2d Sess. (1980).

49/ Drug Price and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

50/ *See* DiMasi, J.A. *Patent Term Restoration for Drugs and Biologicals Under the Drug Price Competition and Patent Term Restoration Act of 1994: A Report Prepared for the Subcommittee on Courts and Intellectual Property of the United States House Judiciary Committee*. May 21, 1998.

51/ Pub. L. No. 103-465, 108 Stat. 4809 (1994).

52/ *See* Testimony of Paul B. Crilly, Ph.D. Before the House Judiciary Committee, Subcommittee on Courts and Intellectual Property, Nov. 1, 1995 ("Using pendency figures from a 1994 issue of the *Patent Gazette*, the average pendency is seven years. In a June 1994 letter from BIO, a biotechnology industry trade group, they suggest it takes an average of ten years for a biotechnology patent to issue."). *See also* Mark A. Lemley, "An Empirical Study of the Twenty-Year Patent Term, 22 *Am. Intell. Prop. L. Ass'n Q.J.* 369, 405 (Summer/Fall 1994).

53/ American Inventors Protection Act of 1999 (AIPA), Pub. L. No. 106-113, 113 Stat. 1501 (1999).

54/ *See* n. 45, *supra*.

55/ Under the terms of Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) <http://www.wto.org/english/docs_e/legal_e/27-trips.pdf> portion of the WTO treaty, it is not permissible for countries to discriminate between technologies by refusing to patent certain products. *See* n.93, *infra*. This element of TRIPS was a substantial improvement for innovators over the previous international standard of the Paris Convention, which had permitted that form of discrimination.

56/ The uniform approach taken in the United States towards the various categories of technology has worked well. *See The Advisory Commission on Patent Law Reform, A Report to the Secretary of Commerce* at 192 (August 1992) ("The patent laws have successfully adapted to new

technologies for over two hundred years, and in each instance have fulfilled their role in promoting the technological innovation and commercial application of such technologies."); *and also Diamond v. Chakrabarty*, 447 U.S. 303, 315 (1980) ("The subject matter provisions of the patent law have been cast in broad terms to fulfill the constitutional and statutory goal of promoting 'the Progress of Science and the useful Arts' with *all* that means for the social and economic benefits envisioned by Jefferson" (emphasis added). In contrast to the non-discrimination uniformity across subject matter, the *sui generis* protection called for by the Semiconductor Protection Act has not fulfilled its billing to provide a well balanced set of protection schemes for semiconductor technology. *See Patenting Business Methods: A White Paper of the American Intellectual Property Law Association* (2000), *available at* <http://www.aipla.org/html/whatsnew/patentingbusiness2.pdf>.

The United States should continue to follow such a non-discrimination policy because altering the domestic patent laws with respect only to certain technologies would disadvantage American inventors as compared to their international counterparts still bound by the TRIPS anti-discrimination article and would pose problems with defining what technologies would be subject to the changes and deciding how to distinguish between inventions closely on either side of the border.

57/ To the extent that commentators criticized the PTO for earlier decisions or guidelines relating to either so-called gene patents or business method patents, these issues have been addressed administratively. In each instance the reaction from affected parties has been positive. *See* text at pp. 5-7.

The obligation of the Patent and Trademark Office to update their procedures is spelled out by the Court of Appeals for the Federal Circuit in the case of *In re Lundak*, 773 F. 2d 1216, 1220, n.1 (Fed. Cir. 1985).

58/ For a description of the problem, *see* C. Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting* (March 2001), *available at* <http"//haas.berkeley.edu/~shapiro/thicket.pdf>.

59/ For a discussion of the research tool issue from the perspective of a leading academic commentator, *see* R. Eisenberg, "*Bargaining Over the Transfer of Proprietary Research Tools: Is this Market Failing or Emerging, in* R. Cooper Dreyfuss, D. Zimmerman, H. First, eds. EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY (2001). *See also* Report of the National Institutes of Health (NIH) Working Group on Research Tools, Presented to the Advisory Committee of the Director, June 4, 1998. *Available at* < http://www.nih.gov/news/researchtools/.>

For a discussion of the value of "research tool" patents *see* Testimony of Randall Scott, CEO of Incyte before the Subcommittee on Intellectual Property, Committee on the Judiciary, United States House of Representatives, July 13, 2000. *Available at* <www.house.judiciary.gov>.

The most comprehensive and detailed assessment of these issues of patenting research tools is found in a study prepared for the Science, Technology and Economic Policy Board of the National Academy of Sciences, J. Walsh, A. Arora, W. Cohen, " The Patenting of Research Tools and Biomedical Innovation," (Oct. 9, 2000), *available at* <http://www4.nationalacademies.org/PD/step.nsf/files/walsh2.pdf/$file/walsh2.pdf>.

60/ *Pioneer Hi-Bred Int'l, Inc. v. J. E. M. A G Supply, Inc.*, 200 F. 3d 1374, 1376 (Fed. Cir. 2000), *aff'd*, 122 S. Ct. 593 (2001)(court has a duty to update the laws to meet new technologies).

61/ American courts have long recognized a common law research exception to statutory patent infringement. *See e.g., Whittemore v. Cutter*, 29 F. Cas., 1220 (C.C.D. Mass. 1813). This exception, however, has been correctly reserved for non-commercial activities. *See Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984). Notwithstanding some vague proposals to legislate in this area, there has been only narrow legislative consideration of this issue within the United States. *See, e.g.,* 7 U.S.C. 2544 (Congress excepted *bona fide* research from exclusive rights granted to developers of new and unique plant varieties) (here the exception does not apply to patents *per se* but to the Plant Variety Protection Act) *and* Drug Price Competition and Patent Term Restoration Act, Public Law 98-417, 202, 98 Stat. 1585, 1603 (1984); 35 U.S.C. 271(e)(1) (Congress excepted from infringement the use of a patented drugs and biological products, other than new animal drugs or veterinary biological products prepared by certain biotechnological means, when such use is related to the preparation of a regulatory submission to the Food and Drug Association). There is good reason for the lack of a broad statutory research exception: there is no evidence of a serious problem, and the possible remedies in creating a statutory exception are virtually impossible to overcome. To the extent that research activity is genuine experimentation and non-commercial there seems little controversy, *see* J. Walsh, A. Arora, W. Cohen, "The Patenting of Research Tools and Biomedical Innovation," (2000) (Prepared for the Science, Technology and Economic Policy Board of the National Academy of Sciences), and once the activity leaves that sphere and becomes commercial it should not be protected because to do so would substantially undermine the property rights of the innovator.

62/ For a description of *voluntary* patent pools *see* Clark, Jeanne, *et al.*, U.S. Patent & Trademark Office, "Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?," Dec. 5, 2000 (hereinafter "PTO White Paper – Patent Pooling"), *available at* <http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf>.

63/ The United States Patent and Trademark Office (PTO) receives about 260,000 patent applications per year and issues 170,000. *See* n. 16, *supra*.

In contrast, even large biotechnology firms like Genentech, Chiron and Amgen only hold a *total* of hundreds of patents. The number of gene-based patents issued to biotechnology firms as of year-end 1999 is as follows: Incyte Pharmaceuticals (356), SmithKline Beecham (197), Genentech (175), Eli Lilly (145), Novo Nordisk (142) and Chiron (129). Biotechnology Industry Organization (BIO). "Primer: Genome and Genetic Research, Patent Protection and 21st Century Medicine." July 2000. (hereinafter "BIO Primer") <www.bio.org/genomics/primer.html>.

64/ There has been a dramatic increase in the number of patents issued to the university community. According to the National Science Board, 44% of all United States patents issued to universities for the 25-year period from 1969 to 1994 were issued in the last five years of that period. *See* National Science Board, "Science and Engineering Indicators – 1996" at 5-42**.** In fiscal year 1998, universities filed more than 4,800 patent applications. BIO Primer. <www.bio.org/genomics/primer.html> Moreover, university patents accounted for 25% of the total patents awarded in molecular biology and microbiology and drugs. *See* National Science Board, "Science and Engineering Indicators – 1996" at 5-43, Fig. 5-31. The typical licensees of such patents have been *small* pharmaceutical, biotechnology or medical businesses. *Id.* at 5-43.

The most common licensing practice in the university community in this sector is a non-exclusive license (339 out of 536 reviewed by the National Science Board). *See* National Science Board, "Science and Engineering Indicators – 1996" at 5-42 – 5-43. This is not surprising given the evident financial success of Stanford University with the Cohen-Boyer that it licensed on a non-

exclusive basis. *Id. See also* Scherer, F.M. *New Perspectives on Economic Growth and Technological Innovation.* Washington, DC: Brookings Inst. Press, 1999: 55-56 (noting that the Cohen-Boyer basic biotechnology patent generated $75 million in revenue for the university between 1991 and 1994).

65/ Heller, Michael A. and Rebecca S. Eisenberg. "Can Patents Defer Innovation? The Anticommons in Biomedical Research." *Science* 280 (May 1, 1998): 698-701.

66/ *Id.*

67/ *Id.*

68/ C. Shapiro, *supra* n. 58.

69/ J. Walsh, A. Arora, W. Cohen, " The Patenting of Research Tools and Biomedical Innovation," (Oct. 9, 2000) presented to the STEP of the National Academy of Sciences, n. 54, *available at* <http://www4.nationalacademies.org/PD/step.nsf/files/walsh2.pdf/$file/walsh2.pdf>.

70/ *Id.* at p. 1.

71/ *See* Robert P. Merges, *Institutions for Intellectual Property Transactions: The Case for Patent Pools* (Aug. 1999) <www.law.berkeley.edu/institutes/bclt/pubs/merges>. See *generally* Steven Carlson, "Patent Pools and the Antitrust Dilemma," 16 *Yale J. on Reg.* 359 (1999).

72/ *Available at* <www.pto.gov/web/offices/com/speeches/01-06.htm>.

73/ *See* U.S. Dep't. of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (1995) ("*IP Guidelines*") *available at* <http://www.usdoj.gov.atr.public/guidelines/ipguide.htm>.

74/ PTO White Paper – Patent Pooling, at 6. *See also* Steven Carlson, "Patent Pools and the Antitrust Dilemma," 16 *Yale J. on Reg.* 359, 379-382 (1999).

75/ For example, anticompetitive concerns may arise if: (1) excluded firms cannot effectively compete in the relevant market for the good incorporating the licensed technologies, (2) the pool participants collectively possess market power in the relevant market, and (3) the limitations on participation in the patent pool are not reasonably related to the efficient development and exploitation of pooled technologies. PTO White Paper – Patent Pooling, at 6.

76/ For example, competitive concerns can be reduced if: (1) the patents need to be valid and unexpired, (2) there should be no aggregation of competitive technologies and setting of a single price for them, (3) an independent expert should be used to determine whether a patent is essential to complement technologies in the pool, (4) the pool agreement should not advantage competitors in downstream product markets, and (5) the pool participants must not collude on prices outside the scope of the pool (that is with respect to downstream products). PTO White Paper – Patent Pooling, at 7.

77/ *See generally* Timothy Muris, "The Federal Trade Commission and the Rule of Reason: In Defense of Massachusetts Board," 66 *Antitrust L. J.* 773 (1998); Sheila F. Anthony, "Antitrust and Intellectual Property Law: From Adversaries to Partners," 28 *AIPLA Quarterly Journal* 1 (Winter

2000); Willard K. Tom and Joshua A. Newberg, "Antitrust and Intellectual Property: From Separate Spheres to Unified Field," 66 *Antitrust L. J.* 167 (1997).

78/ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), *available at* <http://www.wto.org/english/docs_e/legal_e/27-trips.pdf>.

79/ TRIPS Art. 27(1) states that in WTO member states that "patents shall be available for any inventions, whether products or processes, *in all fields of technology*, provided that they are new, involve an inventive step and are capable of industrial application . . . patents shall be available and patent rights enjoyable without discrimination as to the place of invention, *the field of technology* and whether products are imported or locally produced." (Emphasis added.) Article 27(3), however, allows WTO member states to exclude from patentability methods of surgery, therapy, and diagnosis, non-microbiological plants and animals, and processes for the production of non-microbiological plants and animals.

80/ TRIPS Art. 31 provides WTO members the authority to grant compulsory licenses, but only after the hurdles of the article's twelve subsections are cleared. Those subsections limit the use of compulsory licenses to situations where the use is authorized only on an ad hoc basis, where the IP owner is compensated for the use, where the use is non-exclusive, where the use is non-assignable, where the use is authorized predominately for the supply of the member state's market only, where the grant of the use is subject to review by a higher authority in the member state, and other limitations.

81/ Presently, TRIPS Art. 31(b) allows member states, that otherwise would be required under the WTO agreement to only grant compulsory licenses where the IP owner was initially but unsuccessfully engaged with a commercial offer for the use of its rights, to forgo any initial contact of the IP owner in situations of a "national emergency or other circumstances of extreme urgency." Developing nations undergoing public health crises may attempt to at least claim their health situations as emergencies under the agreement such that they could grant compulsory licenses for patented pharmaceuticals or other treatments, if they do not pass on TRIPS outright for the sake of not allowing the patent protection of such pharmaceuticals and treatments in the first place. Many developing nations advocated at the November 2001 Doha Ministerial Conference by way of a Declaration on the TRIPS Agreement and Public Health to recognize certain flexibilites in the agreement, which would allow the members greater abilities to provide unencumbered access to patented pharmaceuticals and treatments in the wake of domestic epidemics, especially those of HIV/AIDS, tuberculosis, and malaria. The Declaration also requests the developed members to "promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2 [of TRIPS]." "Declaration on the TRIPS Agreement and Public Health," World Trade Organization Ministerial Conference, Fourth Session, WT/MIN(01)/DEC/W/2 (November 2001).

82/ Richard J. Gilbert and Willard K. Tom, "Is Innovation King at the Antitrust Agencies? The Intellectual Property Guidelines Five Years Later," 69 *Antitrust L. J.* 43, 48 (2001). This compares with 4 cases (3% of the challenges) in the preceding 5-year period.

83/ *In re Roche Holding, Ltd.*, 113 F.T.C. 1086 (1990).

84/ *See, e.g., Glaxo Wellcome plc*, FTC Dkt. No. C-3990 (Jan. 26, 2001); *Novartis AG*, FTC Dkt. No. C-3979 (Dec. 15, 2000); *Pfizer Inc. and Warner-Lambert Co.*, FTC Dkt. No. C-3957 (June 19, 2000); *Hoechst AG and Rhone-Poulenc S.A.*, FTC Dkt. No. C-3919 (Jan. 18, 2000); *Zeneca Group plc*, FTC Dkt. No. C-3880 (June 7, 1999); *Merck & Co.*, FTC Dkt. No. C-3853 (Feb. 18, 1999); *Roche Holding Ltd.*, 125 F.T.C. 919 (1998); *Ciba-Geigy Ltd.*, 123 F.T.C. 842 (1997); *The Upjohn Co.*, 121

F.T.C. 44 (1996); *Hoechst AG*, 120 F.T.C. 1010 (1995); *Glaxo plc*, 119 F.T.C. 815 (1995); *American Home Products Corp.*, 119 F.T.C. 217 (1995).

85/ *IP Guidelines* at § 3.2.3.

86/ *See e.g.* Richard J. Gilbert, Steven C. Sunshine, "Incorporating Dynamic Efficiency Concerns in Merger Analysis: The Use of Innovation Markets," 63 *Antitrust L. J.* 569 (1995); Richard T. Rapp, "The Misapplication of the Innovation Market Approach to Merger Analysis," 64 *Antitrust L. J.* 19 (1995); Robert J. Hoerner, "Innovation Markets: New Wine in Old Bottles?," 64 *Antitrust L. J.* 49 (1995); Richard J. Gilbert and Steven C. Sunshine, "The Use of Innovation Markets: A Reply to Hay, Rapp and Hoerner," 64 *Antitrust L. J.* 75 (1995).

87/ *See United States v. Marine Bancorp.*, 418 U.S. 602, 624-625 (1974); *United States v. Siemens Corp.*, 621 F.2d 499, 505 (2d Cir. 1980).

88/ National Cooperative Research and Production Act of 1993, Pub. L. No. 103-42, 107 Stat. 117 (1993) (codified at 15 U.S.C. § 4301-05 (1994)).

89/ *In re Independent Service Organizations Antitrust Litigation,* 203 F.3d 1322, 1327 (Fed. Cir. 2000), *cert. denied*, 531 U.S. 1143 (2001).

90/ 125 F.3d 1195, 1219-1220 (9th Cir. 1997).

91/ 35 U.S.C. § 154(a)(1).

92/ Agreement Establishing the World Trade Organization, Annex 1C: Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, WTO No. LT/UR/A-1C/IP/1. The general rule barring discrimination against biotechnology patents is found in Article 27 which states that "…patents **shall** (emphasis added) be available for any inventions …" with certain very limited exceptions. The exceptions in Article 27, para. 2 (e.g. those necessary to protect public morality, human life or health, or to avoid serious prejudice to the environment) do not serve as a justification for excluding biotechnology inventions as a category. The exceptions found in Article 27 (3)(permitting the exclusion of "plants and animals other than micro-organism, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes") have been read --- because of the context of the legislative drafting --- in a manner that does not permit the exclusion of modern biotechnology-related pharmaceutical patents.

Under the requirement of Article 27 of TRIPS, the WTO is obligated to review the patent rules with respect to biotechnology inventions. This review is underway and is designed to assist member States in evaluating how their laws compare to the requirements of the TRIPS, but does not contemplate substantive revisions.

93/ For a discussion of the patent laws of other countries, especially developing countries, see Harvey E. Bale, Jr., "Patent Protection and Pharmaceutical Innovation," 29 *N.Y.U.J. Int'l L. & Pol.* 95 (1996-1997). For a more detailed discussion of the benefits of patent protection in developing countries, *see* Harvey E. Bale, Jr., "Patent Protection for Pharmaceuticals: A Platform for Investment, Markets and Improved Health in the Americas." *Paper presented to Workshop ID, Cartagena,* March 1996, *available at* <www.scie.oas.org/ip/pharma_e.asp>.

94/ National Science Foundation, "Science and Engineering Indicators – 1998," Appendix Table 6-6. Available at <http://www.nsf.gov/sbe/srs/seind98/pdfstart.htm>.

95/ Some in Congress have suggested that the United States freely permits compulsory license to the government of private sector-held patents on pharmaceuticals. *See* Sen. Charles E. Schumer, *Schumer: New Cipro Source Could Dramatically Increase Supply* (visited Jan. 2, 2002). <http://www.senate.gov/~schumer/> (stating that "Federal law . . . allows the United States to purchase products like ciproflocaxin for official use from manufacturers other than the patent holder."). These claims do not withstand scrutiny.

Uncompensated government use of patented products is not explicitly authorized by federal statute. Rather, Congress has chosen to provide judicial procedure for those extremely rare instances in which the Government has advertently or inadvertently used a patent without permission. *See* 28 U.S.C. § 1498 (2001). Specifically, 28 U.S.C. § 1498(a) provides:

> Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for recovery of his reasonable and entire compensation for such use and manufacture. . . .

Although § 1498 does not specifically limit its application to times of war or national emergency, legislative history suggests that it was meant primarily to address such a situation. In fact, the 1918 amendment (Naval Appropriations Act of July 1, 1918, ch. 114, 40 Stat. 705) which instituted § 1498 was "necessary and urgent" because it would "expedite the manufacture of war materials." *Leesona Corporation v. United States*, 202 U.S.P.Q. 424, 433 (Ct. Cl. 1979) (quoting 56 Cong. Rec. 7961 (1918) (remarks of Rep. Padgett)).

This procedure requires the federal government to make "reasonable and entire" compensation for any governmental patent infringement. This limited form of guaranteed compensation is not, as some have argued, a full-blown compulsory licensing scheme.

Any abrogation of a patent during its term should be very reluctantly undertaken. The current legal system in the United States permits compulsory licensing (the unauthorized use of a patent) in only limited instances either relating to competition policy concerns or unusual fact patterns. On rare occasions federal agencies involved in competition policy or merger reviews have ordered that an allowance be made to permit the use of a patent as a form of punishment or remedy for anti-competitive behavior or ordered divestiture to prevent undue concentration. *See, e.g.,* United States v. 3D Systems Corporation and DTM Corporation: Proposed Final Judgment and Competitive Impact Statement, 66 Fed. Reg. 49,200-211 (Dep't of Justice September 26, 2001) (requiring 3D Systems to license its rapid photocopying patents to competing third-parties to alleviate anti-competitive effects of 3D Systems' acquisition of DTM Corporation).

While there have been situations in which the Government has been found to have used a patent held by a private sector entity without permission, there appear to be only rare instances in which the Government infringed a patent purposefully. *See, e.g., Brunswick Corp. v. United States*, 34 Fed. Cl. 532 (Ct. Cl. 1995) (unpublished decision); *Gargoyles Inc. v. U.S.*, 32 Fed. Cl. 157 (Ct. Cl. 1994); *Hughes Aircraft Co. v. U.S.*, 219 U.S.P.Q. 493 (Fed. Cir. 1983). These cases do not state explicitly that the U.S. government's infringement was unintentional, but imply as much. In *Hughes*, *supra*, for example, the government disputed ownership of the patent, implying that its infringement was not willful since it thought it was the rightful owner of the patent. In *Gargoyles*, *supra*, the fact that the U.S. offered defenses of patent invalidity, also shows that it was not a

knowing, purposeful infringer. In most of these cases, in fact, it was a Government contractor who unintentionally used a private sector patent, rather than a purposeful Government taking. *See, e.g., Brunswick Corp. v. United States*, 34 Fed. Cl. 532 (Ct. Cl. 1995) (holding that U.S. government infringed the plaintiff's patent for camouflage screens by procuring infringing screens from third-party supplier) (unpublished decision); *Gargoyles Inc. v. U.S.*, 32 Fed. Cl. 157 (Ct. Cl. 1994) (holding that U.S. government infringed the plaintiff's patent for ballistic eyewear by procuring infringing eyewear from third-party supplier); *Hughes Aircraft Co. v. U.S.*, 219 U.S.P.Q. 493 (Fed. Cir. 1983) (holding that U.S. government infringed the plaintiff's patent for an apparatus that stabilizes the spin axis of space vehicles by procuring infringing apparatus from third-party supplier).

In those handful of instances in which the Federal Government has acted explicitly to use a patent owned by a private sector entity, the courts have generally avoided an explicit Government taking by either invalidating the patent (*see, e.g.*, *Carter-Wallace, Inc. v. United States*, 496 F.2d 535 (Ct. Cl. 1974) (finding that plaintiff is estopped from asserting the validity of patent against the U.S. government where the patent was held invalid in a prior litigation to which the plaintiff was a party) or declining to grant an injunction to enforce the patent. In the later instance, the Government has still been obligated to pay entire compensation to the patent holder. It is the payment of reasonable and entire compensation, in part, which has deterred the Government from using this power frequently, because such compensation could be similar or equal to the cost of purchasing the patented product in the first instance. Thus, in practice the United States does not have a compulsory licensing scheme of a kind as exists in some other countries – or as contemplated by some in Congress.

Currently the Government is seeking the cooperation of the pharmaceutical and biotechnology industry to engage in basic research as well as in creating new vaccines and treatment to address the risks of bioterrorism. The worst signal to send to the industry would be to suggest that the creation of such new products and vaccines will not receive meaningful patent protection. Such a signal would indicate that the Government intends to expropriate future research results from all these contracts. "Taking" a patent in the current environment is likely to deter many firms from actively cooperating in the basic research tasks that the government needs to address bioterrorism. If the Government could act years later to seize the fruits of basic research unrelated to a real national emergency there will be far greater risks to such cooperation.