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PATENT POLICY AND INNOVATION IN BIOTECHNOLOGY

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OUTLINE

Testimony of Committee Chair

Introduction:
- A Theory of Law and Progress

- Constitutional Theory of Patents
- Logistics of Patent Law
- Anti-Trust and Consumer Protection
- A Common Goal: Innovation and Progress
- A New Industry: Biotechnology
 - The Development of the Bio-Technology Industry
 - The Era of Intellectual Property
 - A Unique Framework for Development
 - Inefficiencies of the Current Patent System
- A New Economy: Intellectual Property
 - Contrasts with Production Economy
 - A New Framework for Innovation
 - New Freedoms to promote innovation
 - A Need for New Policy on Innovation
- Legislation to Promote Innovation:
 - Text of *The Biotechnology Innovation and Consumer Protection Act*
 - Eliminating Inefficiencies in the Old System
 - Promoting and Sustaining Innovation for the Future

Witness testimony

- Testimony of Consumer Advocate
- Testimony of Industry Lobbyist
- Testimony of Patent Office Representative
- Testimony of Free Market Advocate
- Testimony of Genomics Researcher
- Testimony of Economist
- Testimony of Justice Department Representative

Conclusion and Committee Recommendations:

PATENT POLICY AND INNOVATION IN BIOTECHNOLOGY

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WEDNESDAY, MARCH 21, 2001

Testimony of Committee Chair:

Good morning, ladies and gentlemen. This is a subcommittee that has in recent years devoted much of its attention to questions of the developing information technology industry. We have witnessed the development of a new industry, a true revolution in technology, which carried our nation into the new millennium. However with this

revolution we have also witnessed a failure of our current laws to effectively govern the new areas in technology. New industries have begun to change the very structure of our economy. The highly publicized Microsoft antitrust lawsuit was among the first to bring to public attention the new issues in an economy based on intellectual property. By our current legal standards, there appears to be no actual statutory violations by Microsoft. However their business practices and market outcomes seem to run contrary to the intent and spirit of our antitrust regulations, so much so that our courts have felt obligated to make rulings against Microsoft. This case calls into question, what the true substance of our legal statutes really is. Are our laws nothing more than the list of those statutory violations that constitute a crime? Or are they instead the spirit and purpose in which those laws were written, and the ends they were intended to achieve? I would contend that it is the latter. However I would quickly pre-empt critics who might say that such an interpretation of law gives government free reign to extend its power to choke developing industry and stifle the free market. This is not so. The law has no target and should not be considered the enemy of industry, but rather its partner. We have recently seen, in another highly publicized lawsuit over Napster copyright infringements, a new conflict in which industry turned to the government to seek reparations for harms. Similar to the Microsoft case these were harms that did not seem to constitute statutory violations of copyright law, but nonetheless had effects that ran contrary to the spirit in which such laws were founded. Instead of a call to arms, I today call for the various players in industry to work with us to ensure that our legal system and policy structure up remains in stride with our technology. We ensure that our society may direct the course of progress to good ends rather than allowing progress to direct the ends of society.

Today we turn our attention to another area of our blossoming intellectual property economy: the field of biotechnology. This is an industry that may have even more potential to change the way our society operates than the Internet revolution of the last century. However the industry of biotechnology also has more potential need for new government policy for two reasons. First, biotechnology, more than any other industry carries with it the weight of a revolution that could potentially reshape, not only our economy, but also our societal structure, our family structure and our personal ideals. Such invasive potential warrants careful examination. Secondly, and perhaps more practically, the government is largely responsible for the development of this industry as the commercial spin-off of government funded research. The economic policies and changes that brought about the creation of this new industry also drastically changed the system that lay the foundations for this new industry. Considering this fact the government could be said to have an interest in the development of this industry, even beyond the protection of its people. This is a government pilot program in innovation policy and its successes can be built for future policy.

The biotechnology industry currently enjoys the greatest growth of any industry. Modern science has brought new innovations, which offer the awesome potential to revolutionize the entire medical field. The Human Genome Project promises new information that will unravel the nature of human disease. Thus we have potential for a whole new generation of pharmaceuticals and genetic therapies for previously incurable diseases. Despite its currently unparalleled growth and potential for growth, the industry also faces a potential dilemma: a conflict of ideals. Our current policy on biotechnology innovation faces a potential conflict between the profit driven industry, which is

responsible for sparking the current boom and the freedom of access and information so vital to progress in research scientists. Our country is founded on the ideals, such as protections for life, liberty and property. They are written our constitution and our government is designed to promote their ends. However history illustrates that these ideals can and do come into conflict and must have their boundaries redefined in the courts, or ultimately through clarification of the statutory law. In our sessions today we will debate clarifications of our nation's technology innovation policy.

Among the founding ideals of our nation was the promotion of progress. Article I Section 8 of our constitution provides congress the power “to promote the progress of science and useful arts by securing for limited times ...inventors the exclusive rights to their...discoveries.” Essentially Congress is granted the power to confer exclusive rights, in the form of patents and copyrights, as a tool to promote innovation. Patents and copyrights grant authors and inventors virtual monopolies for a limited period, for the purpose of allowing the inventor or innovator exclusive rights for a time necessary to recover their development costs. From the time of our founding the patent concept has been an invaluable tool for the promotion of innovation. However despite the timeless utility of patents the logistics of the patent system are must continue to evolve with our economy as now industries change bring drastic changes in the way our system works. The current patent system is one that evolved in “the golden age” of twentieth century America: The Industrial Age. As the production economy developed the process mass production and new innovative technologies to serve its ends, it became necessary to protect innovators and their inventions from being undercut by competitors. Thus the

patent system was structured to allow these individuals or industries exclusive rights for a limited time to allow them to recover their development costs.

The Patent Act of 1952 was designed to promote industrial innovation by providing industry with a means to recover the development costs on new technological innovations. The act established four basic statutory requirements necessary to obtain a patent. A claimed invention must have ‘utility,’ it must be ‘novel,’ it must be ‘non-obvious,’ and it must be ‘fully disclosed’ in the patent application. I will further clarify these four requirements, which constitute the basis of modern patent law, in case any of them seem as “non-obvious” to you as they did to me. However I can only clarify their meanings as to their original legislative intent, as the definitions are not as solid as the statutory language may initially seem. The disclosure requirement is the most straightforward. It simply requires inventors to spell out, in plain, unambiguous language, the purpose of the invention as a support of the utility requirement. The disclosed information is used to promote technology transfer and further the goal of innovation through open access to these inventions. The non-obvious is probably the most nebulous requirement as of now. It is clarified in the language of the statute as an invention “not obvious to any person of ordinary skill in the art at the time the invention was made.” The requirement is intended to limit patents on process steps and any “inventions” that could have been arrived at accidentally or in the ordinary course of work. The novelty and the utility requirements have by recent regulations combined into a single enforcement rule, stated in Title 35 of the US Code. Any person who “invents, or discovers any useful... composition of matter, or any new or useful improvement thereof, may obtain a patent.” These statutory requirements were written to address the

issues of the industrial production economy by allowing individuals to patent new inventions and discoveries to encourage the marketing of new products. Despite the universal language of the statute, the scope of their applicability is in fact quite limited as the last decade has proven their inability to regulate our current intellectual property based economy. Eventually new policy for the promotion of innovation will be necessary.

Ironically the industrial age, which produced legislation for the promotion of the American ideal of innovation through granting of limited monopolies, also brought legislation to regulate monopolies to protect another age old American ideal: the free market. The Sherman Antitrust Act of 1890 was first legislation enacted to prevent monopolistic practices that interfered with economic competition. The industrial age soon brought new amendments to the antitrust regulations in order to curb new abuses of power and monopolistic practices that developed with the industrial revolution. The Clayton Antitrust Act of 1914 was intended to strengthen the intent of the Sherman Act. The new act defined various types of illegal business practices that are conducive to the formation of monopolies, including holding companies, discriminatory contracting, collective agreements and market fixing. It was passed in response to new monopolistic practices, which did not specifically violate the provisions of the Sherman Act, but had the effect of creating monopolies including as market control stemming product and process patents.

Government policy in these areas may seem contradictory. On the one hand we ban monopolistic market practices in protection of consumers and a free market, and yet on the other hand we grant monopoly power as an incentive to industry to innovate. Yet

within this seeming contradiction there is a common goal: progress. Government policies particularly in the economic development often rely on striking a difficult balance. In the this case, the balance is between a profit incentive of patents to encourage individuals to innovate and encourage companies to invest in such innovation, and the discouraging monopolistic practices which hurt consumer confidence and can stifle innovation by preventing effective technology transfer. The ultimate goal of progress is best served if we use the profit incentive to encourage individual innovation and yet protect the free market so as not to stifle the innovation process.

The value of the patent system as a tool for the promotion of technological innovation is empirically proven. However it is also empirically proven that the nature of this system is such that to be effective it must continue to evolve with economic development. I contend that we are currently entering a new age in economic and technological development that breaks the paradigm of the industrial production economy. This shift is evidenced in the clashes the between the information technology industry and the government regulatory structure and also the inability our current system of laws to even classify let alone regulate the biotechnology industry. While our developing cannot yet be given a classification, which is usually left for history to do, it can be observed that new economy places high value on information and innovation rather than on mass product. In light of these observed changes we must develop a patent policy to effectively meet the needs of this new paradigm.

To develop an effective patent policy for the twenty-first century we must first examine the unique needs of our developing economy. While our innovation inherently entails giving companies the incentive for development, the ends of industry are often

different than the ends which an effective patent policy seeks to promote, namely the ends of society. Progress is major end of society, and is undoubtedly linked to the profit motive for companies with their innovations. This after all is what patent policy was designed to do: play to the profit motive. However in doing so we must recognize that the nature of patents is essentially monopolistic, an end which is not good for society, because it hurts consumers, and because it also may ultimately impede future progress. While our new technology paradigm is one that will require new patent policy to give certain deference to innovators, at the same time we must recognize the potentially monopolistic tendencies of some of these an intellectual property based technologies. We must develop regulations to ensure that promotion of innovation does not backlash into stifled innovation through monopolistic practices.

The development of our biotechnology industry is a true experiment in government innovation policy. Modern patent policy is designed to promote innovation in two ways, first by protecting industry investments from being undercut, and second by promoting startup innovation by providing a profit incentive to bring innovative ideas to market. While the production economy tended to focus on the former, the biotechnology industry largely focuses on the latter. The biotechnology industry is the product of the conjunction of research science and the commercial industry as the result of significant changes in economic policy particularly in the last two decades. The passage of the Bayh-Dole act in 1980 began this by establishing uniform patent regulations for all products of federally funded research produced by nonprofits and small businesses. This allowed for the first time universities and researchers to patent research results and products from federal projects, and established a basis for the transfer of research results

to the private sector. The year 1980 also brought a landmark Supreme Court decision on the patentability of biological products in *Diamond v. Chakrabarty*, in which a researcher for General Electric sought a patent for a the development of a bacteria genetically designed to degrade hydrocarbons. In this case the court found that genetically engineered microorganisms were in fact patentable, provided the invention met all statutory requirements. A famous quote from Chief Justice Burger in the decision of the court set the tone for future patents in the area of biological research. “Congress intended the statutory subject matter to include ‘anything under the sun that is made by man’.” These developments were key to the rise of biotechnology industry. Two simultaneous changes in American economic policy, bringing profit incentives to federal research and the patentability of biological products, combined to promote a wave of innovation and lead to the development of a booming industry.

When applying our current patent laws to a new field such as biotechnology, the key criteria for patent determinations have been the first two standards of the Patent Act uniqueness and utility. Recent changes in enforcement of patent law, based on the stipulations of Title 35, have tended to give deference to inventors in biotechnology by allowing the ‘purposeful human intervention’ as a standard to meet uniqueness and utility. This standard for utility as based on human intervention, began as an extension of the patent policy to include pure cultures or pure minerals, which were judged to have utility because of their pure state. The issue however has become much more complex in subject of gene patents. Gene patents have become highly politicized in the public eye because of the moral uncertainty that surrounds this debate. However the focus of this committee is not to address those particular issues, but instead to examine the effects of

gene patents on the research and innovation. Gene patents have also become controversial in the research sector and even the industry sector due to a recent dramatic increase in number of gene patents granted on sequenced human genes. The debate over gene patents highlights a unique aspect of research science, which necessitates changes from current paradigm in patent law.

The nature of the research science is such that it progresses linearly, to develop the tools necessary to continue its progress and to eventually develop marketable products. Because of the linear nature of research it often happens that researchers can develop the same process or results, after beginning from the same starting point. This is generally considered a benefit of the laboratory research that it is duplicable, because it allows for peer review and comparison of results. However if we grant patents to processes or tools in the development of a process we may cut off this means of peer review by leaving it to the deference of the company's and individual researchers. The result is that we now have researchers and biotechnology firms seeking patents on the most basic tools and information, often gene patents, as an exclusionary practice to limit competition in their field. To grant patents on genes with potential applications is essentially to grant patents on a process before it is developed, and also on all corollary processes yet undiscovered. Both of these run contrary to the interests of research science and in fact could be considered monopolistic practices. However the current standards of enforcement, allow such patents to slip through, and necessitate clarification of the patent law to prevent such practices.

The current requirements of uniqueness and utility are too relaxed, at least at their current standards of enforcement. The patent office currently grants patents for genes if

the patentee can claim a single purpose for that sequence or alternatively can show unique human intervention and potential utility, such as application in research. These standards are not strict enough for they allow patenting of information before its utility or at least the full potential of its utility is disclosed. This opens tremendous potential for abuse and also potential for complications of the research process such as overlapping patents, and unknowing infringements which hurt the progress of research. It is obvious that these standards need clarification.

Additionally the new biotechnology patents have raised a complex debate over the non-obvious standard, and forces us to define what the parameters of this standard are. Often tools of biotechnology such as genetic information constitute steps in a certain process, which can even be used without knowledge of the patent infringement until after the experimentation is complete. Thus the Patent Office is caught in a dilemma of enforcement, and must decide between enforcing patent infringements or repealing the patent on basis of 'non-obviousness.' The preference has been for the former, or else to take no action at all, as there are currently no standards, legislated or otherwise, to make determinations of 'non-obviousness.' This is a second area that requires our address.

Gene patents are considered by many to be inherently detrimental to research because they shift too much focus on the sequencing aspect of gene research and not on the analysis of the genes. When the goal in a patent becomes beating competition to the patent office, we often find that patents are being requested with only minimal preliminary information, rather than full disclosure of results. Such patents do not help the research community because they do not disclose any new information, but instead grant a specific research group exclusive rights to pursue a specific line of research

absent competition or even review. In the progress of research science this is inherently detrimental because it prevents open access to information and collaborative efforts which are essential in research.

Furthermore the nature of gene patents creates may be conducive to monopolistic practices which are particularly detrimental to research and stifle innovation. Because the actual gene sequence is really a tool, a data reading of information to allow researchers to discover its purpose or purposes. If we allow researchers to have exclusive rights to such a valuable resource as the sequence of a gene they essentially have exclusive rights to all products and processes which may stem from that gene. The analogy that I've heard is to patenting a rainforest. We don't know anything about it except where it is and what it looks like, it contains a world of unexplored potential, and anyone who has exclusive rights has a monopoly on all discoveries that occur because of it. This is detrimental to the research process and to innovation.

The grant of gene patents creates procedural inefficiencies on two levels. First, companies and researchers don't know if at some step in the linear process of research if they have developed and used a patented tool and are liable to be sued or for royalties. The result is that many biotechnology firms have been forced to engage in defensive patenting practices, by which they patent tools so that they will be able to file a counter suit if they are ever sued. This is not the purpose of gene patents and creates incredible inefficiency because researchers must worry about which tools they use along they way rather than simply pursuing the course of research. Second, ambiguities over the meaning and scope of gene patents causes disputes in patent ownership and may lead to monopolistic practices. If a company owns a step in the process they can make claim to

own all of the tools a products after that by default to process patents in effect yield an unfair monopoly. For example in a recent legal conflict, Chiron and Genetech independently developed a process for the production of insulin, and arrived at it by different processes essentially. However the essence of the process was defined by a tool step which was a fusion step which Genetech beat Chiron to the punch on patenting. However Chiron was able to obtain a patent for the whole process first so the question was who owns the process with these two conflicting patents. Based on Genetech's argument we allow a patent for a process step to grant the owner the rights to all tools and products thereafter. Taken to an extreme companies could potentially use strategic use of patented information firms could force others out by denying could deny use of tools to another company and prevent them from achieving the ends of their research and instead pursue all such research for their own gain. This would stifle research because it would remove profit incentives on those discoveries for all others and allow these companies to engage price fixing.

These inefficiencies must be addressed if we are to develop a policy for sustained technological progress. It is perhaps the case that if the true spirit of the laws was enforced correctly and to the letter of the law, that the currently established distinctions would be sufficient to protect against the types of potential infringements and potential harms of unnecessary and unjustified patents on the research process. However the laws have recently been enforced to relatively weak standards and allowed many of these gene patents to go through with minimal review. Thus in order to make this law effective in regulating the biotechnology industry we must go back to the original purpose of the law to define it's parameters to have to specifically define which of the types of intellectual

property and biotechnology innovations justify patents and which don't. This position thus stated I would like to again preempt critics and say that this should not be seen as an law targeting business freedoms, but rather as an attempt to work with industry to achieve the goals of efficiency and innovation.

The intellectual property based economy constitutes a distinct departure from the industrial production based economy and warrants changes in innovation policy to carry us forward into a new era technological development. In the case of biotechnology this policy should build on the policies that produced the industry as a product of government research. On its current course the biotechnology industry threatens to stifle its own progress by destroying the base of its success: the research community. The combination of the research community and commercial industry has proved a potent combination. However this combination is extremely volatile, because the policies that produce a strong research community and those that produce a strong business community. While it was necessary to grant new freedoms to spark the development of this revolutionary new industry it is also necessary to maintain the strength of the research industry so that we can continue to produce the wealth of intellectual property that makes our industry the strongest in the world. The profit motive is only valuable for encouraging the transfer of established research into marketable products, but is not conducive to supporting the basic science research itself. Business relies on immediate results and new profits, but science requires time and background research in order to produce the basis for any type of marketable innovation, and to ensure the opening of new fields. The profit motive can harm research science by shifting the focus from discovery to product and also shifting

the atmosphere from one of cooperation and peer review to one of competition. Thus it is necessary to keep these areas separate.

However a policy to promote long term innovation within the biotechnology industry must ensure the maintenance of this combination. To do so requires a balance between free market innovation and promotion of research science. This balance is more difficult to strike than it may seem, because it essentially is attempting to maintain a bridge between a laissez faire style free market and an independent or government sponsored research community. Government programs combining aspects of regulation and deregulation have not had much success. The current California energy crisis is blamed on attempts at such a combination. So the challenge before us is daunting, to succeed where others have failed in the face of skepticism. However we have the advantage of having a proven track record. The policies of the last two decades, which promoted the rise of the biotechnology industry, are perhaps the greatest success in government innovation policy. The next great success will be to ensure its survival.

In order to develop a successful policy for innovation we must develop a policy that keeps the interests of research science and industry essentially separate and yet allows for technology transfer. Technology transfer is the key point of intersection is between tools based research and products based industry, taking the products of development and bringing them to market. The purpose of free market competition is that it provides the economic incentive for companies to bring products to market quickly. However government and university-funded projects have the efficiency of innovation and the incentive to make research breakthroughs rather than monetary profit. Thus we observe a distinct division between the profit incentives which encourage the

development of marketable products and the research incentives which encourage scientific progress and breakthrough.

In developing a new innovation policy to ensure the long-term development of biotechnology and other intellectual property based industries, it is necessary to sustain a strong research base to produce valuable intellectual property separate from the free market. It seems that the most effective and most efficient way to achieve this would be to separate their incentives. Our patent policy should have distinct incentives, tailored to the products of commercial industry and tools of research science. The profit incentive can serve a purpose in both research and in commercial market. In the commercial sector free-market competition is the best innovation policy. Government should essentially remain out. However in research the profit incentive cannot be allowed to stifle free information exchange and the research process. Thus any profit incentives from the tools of science should be subject to government regulation to set fair royalties and ensure the open access to new research tools. This would ensure a strong research base, while promoting continued innovation in the biotechnology industry.

In the spirit of long-term innovation we propose the following amendments to the 1952 patent act, to define legal distinctions between patents on research tools and industrial products, and set clearer requirements for patent to protect against abusive or monopolistic practices.

Text of the *Biotechnology Innovation and Consumer Protection Act*:

In order to serve our nation's interests for long innovation for the future, we propose the following policy as an amendment to the 1952 Patent Act.

I. Any invention seeking a patent must meet the following criteria:

- (a) Must be novel, involving some combination of natural resources and human intervention

(b) Must not be obvious such that it could not be arrived at by anyone in the field by the natural progress of science or a to a person of ordinary skill in the field

(c) Must have stated and fully disclosed utility, and patent rights will be limited to claimed utility, and any directly corollary purposes

II. The patent office will grant patents in one of two types based on claimed utility:

(a) Product Patents - must have a marketable real world application

(b) Tool Patents and - tools can be marketed as tools and subject to regulation

Product Patents will be granted exclusive marketing rights for a period of 11 years. Tool Patents will be granted exclusive rights a period of 7 years and must be subject to standard licensing fees and must be entered into a joint sharing database of tools coordinated through the patent agency.

III. In recognition of the inherent monopolistic aspects of tools or process patents the Patent Office reserves the power to rescind patents that upon independent review prove to have monopolistic effects.

Testimony of Consumer Advocate:

Needless to say I am pleased with the progress that the current legislation makes.

It is a big first step, to get some meaningful legislation geared to regulating the specifics of the biotechnology. I have always been confused by the difficulty in getting any legislation passed to regulate any aspect of this industry, because it is one filled with so much uncertainty and yet so much potential to change all of our lives. I always thought that we would want to direct the course of such momentous change. However after working in Washington politics I have come to understand some of the logistics of the legislative process that make it difficult.

It is specifically because of this uncertainty that the biotech industry has been so difficult to regulate. We are unsure of the real world effects of such regulation. And an industry of such great importance to our economy wields a great amount of political power in Washington to resist any kind of change that could even potentially have a

negative effect on industry. Thus in order to make changes we the industry must support its regulation of itself. This is often a difficult goal to obtain because an industry is unlikely to support any government action unless it somehow stands to gain from it. However as the industry has allowed these uncertainties to loom with no government involvement to protect against potential harms, the public has become increasingly skeptical. While these fears are in many cases worst case scenarios or even exaggerations, they are serious enough to warrant government protections to ensure that these are not paths that we ever find ourselves on. Public opinion is a powerful bargaining tool as I'm sure the biotechnology industry has realized. If you don't have the trust of the public, your market base disappears because people are uncertain about doing business with you. Public uncertainty is currently fueled by uncertainties on issues such as genetic ownership and genetic discrimination. In order to legitimize this industry these fears must be addressed.

This legislation is a victory for consumers as a first step towards setting parameters for industry and in having some of their fears addressed. This legislation protects consumers by preserving a free market and protecting public access to genetic information and protecting ownership rights of genetic information from patent. However this is not a one sided victory for industry because also stands to gain public confidence. This is a big step for both sides and sets the stage for future compromise towards further public protections and greater legitimization of the developing industry.

Testimony of Patent Office:

A representative of the U.S. Patent and Trademark Office previously testified before this committee in 1995 hearings on policy for scientific progress. At the time my

office made recommendations that the patent laws in the area of biotechnology be left as they are on the books and any adaptations could be made by in agency regulation. We have generally taken the position that changes in the patent law are difficult because they create not only specific statutory changes, but also changes in regulatory mandate. So our decision today to support the bill before us today is somewhat of a reversal of position.

Recent years have brought developments that have proved the need for some legislative clarification on certain points of ambiguity. While we still maintain that the strength of the current patent system is it's universal applicability to all innovations, and we would be opposed to any change in the basic standards, we have come to recognize that statutory meanings must indeed evolve with the technological paradigm. The paradigm of the industrial age has changed and the patent office has been faced with new products raising new questions of utility and uniqueness standards, and recently become tangled in a new debate over the non-obvious standard. A recent legal dispute between Chiron and Genetech brought to light the issue of overlapping patents. Chiron developed a genetic process, which Genetech claimed it already had patent rights to through a previous gene patent. The debate over non-obviousness is yet unresolved as the overlap, which this standard is meant to protect against, seem difficult to enforce in the area of biotechnology. Previous standards of enforcement have relied on examination of utility and uniqueness, however we have not as yet developed a standard for determining what the extent of a patent should be granted. In the area of genetics the utility of a gene can be claimed and accurate, but the gene itself may have far more utility than initially claimed. Furthermore when such predicaments arise we face a dilemma for which there

are no guiding legislative standards, and that is reparations. We have been reluctant to seek straight revocations of patents, and thus far have simply been allowing both sides to slide. However this is only a temporary situation, and without the scientific tools to make better utility assessments, we must have a change in policy to solve this dilemma.

This bill offers just such a policy solution. It first ensures that the damages of any overlapping patents would be minimal by setting fixed royalties for tools and process patents, making the legal disputes over ownership not worth the expense. Furthermore the bill grants our agency the power of independent review and to rescind any patents that prove unjustified or conducive to monopolistic practices. The Patent and Trademark office offers its strong endorsement of this bill as a tool to aid us in continuing our mission to promote progress.

Testimony of Biotechnology Industry Lobbyist:

Generally being in a position of lobbying against any changes in the patent laws, my firm is in the unfamiliar position of supporting these particular changes. Most proposed changes to the patent code are detrimental to business because they have the effect of changing the rules of the game midstream. However the amendments to the patent law set forward in this bill do not result in full scale changes in the patent regulation, but instead bring much needed clarification to an ambiguous area of patent law. Under the current statute the law is unclear as to what qualifies for a patent and what doesn't, creating a great deal of uncertainty for the industry. Uncertainty is always bad for business. The result is severe market inefficiencies where corporations and researchers are in the dark as to which of their inventions are patentable and also what actions constitute patent infringements. This has developed a pervasive practice within

the industry of defensive patenting, where corporations are forced to hold patents as to defend against potential lawsuits. The clarifications offered by this bill go a long way towards eliminating these and other inefficiencies. Further the bill promises increased market efficiency by encouraging tool sharing and tech transfer, while maintaining the profit incentive for start-ups, protections for corporate holdings and incentives for researcher to bring products on the market. The public will benefit from an innovative industry and also now with added security against infringements on personal property or future abuses of an undirected industry. This bill ensures that the biotechnology will continue to move in only one direction, forward!

Testimony of Genomics Researcher:

I believe that I can speak for most members of the research community when I express my endorsement of this bill. I believe it goes a long way to ensuring the long-term strength of our research base. Despite the incredible success of the past two decades in the development of the biotechnology industry, many researchers have been worried about the prospect of too much corporate direction of research. Corporations usually fund projects expecting specific results, and if they don't get them they pull the funding. This is not conducive to good science.

Any researcher will tell you that progress in science is made by a few successes in a sea of failures. We always produce results, just not necessarily the ones desired. Whatever the results we can always build on them to eventually make breakthrough discoveries. However you must understand that this process is long-term, while profits are only calculated in the short term, the next quarter. The trend towards results based research became even more disconcerting in recent years as even government

sponsorship, traditionally made in block grants, began to come with strings and directives. Science cannot be directed in this way, we must simply allow it to progress in the direction that it does. There is no greater mistake a researcher can make than to try to push his results in a certain direction to try to please his sponsor. Such a debacle is evidenced by the research into the causes of lung cancer sponsored by the cigarette makers, or the research into global warming sponsored by the fossil fuel industry. We must not make the same mistake in an area as revolutionary as biotechnology.

The bill before you today will ensure that our research in biotechnology continues to progress forward with its own unique breakthroughs. This bill in fact ensures greater efficiency in the progress of science because it removes competition and corporate directives from the lab environment and allows such vital aspects of research as information exchange and peer review to continue to serve the ends of scientific progress. The very purpose of the bill is to maintain the research community as a separate entity from the commercial industry. We must trust the science community if left to its own with its own methods to produce marketable results, and from that point on the commercial industry can take over.

Testimony of Economist:

The last decade has seen our nation rise from the market losses of the early nineties in the semiconductors industry to our competitors in Japan and Germany, rise to be the leader in this industry and the worlds leader in the new biotechnology industry. The rebirth of the American industry base and our currently unparalleled competitiveness can likely be attributed to the strength of our research base in our universities. The new economy is run by knowledge, and our research base has produced a great wealth of

intellectual property. This knowledge has then been brought to market through favorable economic policy encouraging technological innovation through the profit incentive of the patent system. The result has been that America has quickly become the strongest economy in the world and also the economy with the greatest potential. We must now shift our focus to sustainable growth.

While the profit incentive was undoubtedly vital to sparking the transfer of knowledge from research to the commercial sector, it is also notable that the profit incentive has had negative effects, particularly on the progress and focus of our research base. We must not allow desire for short term profit allow us to shift the focus of genetics research to short term profits but must continue to promote forward looking innovations. This legislation is a major step towards striking a balance between market innovation and continued development of our research base, both of which are vital to the long-term survival of the industry and maintaining our global competitiveness.

Testimony of the Justice Department:

I am a representative of the justice department and today I testify on a very important relationship between patent law and antitrust law, raised in proposed amendments to the Patent Act. Before I go into the logistics of the changes, I would like to offer up front the full endorsement of the Justice Department on the proposed changes to the Patent Code. We believe, in light of recent legal conflicts, that they are important and much needed clarifications, and also that these changes will help us to better regulate a developing industry. It is even somewhat surprising that such changes were not proposed earlier as these are all changes in the spirit of the current patent law as well as the history of court rulings on this matter. Yet the enforcement of the patent laws with

respect to biological products has somehow diverged from this original intent, such that statutory clarification has become necessary.

The basic legal effects of this law are to make clarifications to the granting of patents on biological products to protect against those patent practices, which could be conducive to monopolistic practices, such as preliminary gene patents. As an additional safeguard against potential threats to the free market this bill establishes by establishing a system for independent review by the patent office of the effects of specific patents and the power to rescind the patent rights if necessary. This is clearly a goal in the spirit of current patent law as it has already been established that patent arrangements only grant limited monopolies to the patent holder, and beyond that all effects are subject to general law. The case of *Mercoid Corp. v. Mid-Continental Invention Co.* establishes the power to nullify patents as a protection of the public interest in free enterprise. Patent rights are not intended to grant their holder any privilege to organize any kind of monopoly power.

The Sherman Act grants the patentee only limited exception to patent laws aimed at the protection of free enterprise and imposes strict limitations on the rights of a patentee to engage in certain types of activities. A patentee may lawfully engage in licensing of the patented invention, and impose restrictions as to the licensee as to conditions of use, unless these restrictions lead to an enlargement of the monopoly powers of the patentee. Section 3 of the Clayton Act prohibits from making contracts, which extend beyond the monopoly power granted in the patent. This statute holds true whether the consequences of the law are intended or unintended, as in the case of the inherent monopoly power granted by the process and tool patents, such as preliminary gene patents. Such patents are subject to review, because the effects of the patent, though

consequential, fall outside the scope of the patent agreement and are subject to the regulation of antitrust law.

The changes to the current patent code proposed in this bill, to set distinctions between the product patents and tool patents, and to establish new enforcement mechanisms, are clearly justified in the intent of our current patent legislation to protect against potential monopolies. Title 35 of the U.S. Code provides for all patent regulations to be construed relative to the to antitrust laws. Patents are not to be considered an absolute right. The current bill proposes changes in the interest of preserving the free-market and ultimately in the maintenance of long term innovation to promote progress. Both of these goals are in the best interest of society and the power to seek these goals is granted to Congress by our constitution. Having examined the legal justifications for the proposed amendments the Justice Department wishes to offer our strong endorsement of the bill and of the goals it seeks to achieve.

Conclusions and Recommendations of the Committee Chair:

We find ourselves in a new era of innovation and economic development, where intellectual property forms the base of our developing industries. Information Technology and Biotechnology are currently the driving force behind our economy, as it has become the strongest in the world. However we find that the strength of our industry relies on a careful balance between ideals. The proposed *Biotechnology Innovation and Consumer Protection Act* seeks to promote the basic ideals of our nation: progress, innovation, free enterprise, and consumer protection by striking such a delicate balance. This legislation will achieve this end by forging a balanced relationship between the commercial enterprise and the research community.

The act proposes through three basic changes in the patent law. First, it clarifies and consolidates the criteria for granting patents to apply universally to the production and intellectual property based economies. All patents must now prove unique human intervention, non-obviousness is made a distinct standard with respect to the scientific process, and utility must be tailored to the precise invention patented, and patent rights will be limited to claimed utility. Second, the bill establishes a distinction between product patents, and tool or process patents, and guards against monopolist use of these processes by regulating the licensing terms. Additionally this part of the bill is structured to promote open access to patented tools, through full disclosure of tools and uses and licensing under set royalties, to thus promote the innovation while preventing process monopolies. Finally, the bill provides a mechanism for independent review and the power to rescind patents, which are found to have monopolistic tendencies. Thus we provide a procedural safeguard to give the Patent Office the power to make retrospective judgements about the effects of patents on certain types of technology.

I believe that this legislation represents a first important step in developing our policy on innovation to carry us into the twenty-first century. While this act does not, by any stretch, represent a complete revolution in technology policy, I believe that the targeted nature of the changes, is the very key to its success. We have through simple clarification of the current patent laws, provided the means to regulate a developing area of the economy and even built in procedural safeguards giving the Patent Office limited power to make decisions on future developments. We have drawn practically universal support, as this bill serves the interests of consumers and industry alike while not imposing any undue burden on any member of the industry or government. I urge the

committee to recommend this bill to Congress as a vital piece of legislation to ensure our continued economic growth and competitiveness in the future.

Thank you.

Sources

“*Patent Interference: Genetech Inc. v. Chiron Corp.*,” *Intellectual Property Litigation Reporter*. September 27, 2000, Vol. 7; No. 5; Pg. 10, Lexis Law Publishing, a division of Reed Elsevier Inc.

Title 35. Patents part III. Patents and Protection of Patent Rights. Ownership and assignment 35 uscs § 261, 2001. United States Code Service Copyright 2001, Lexis Law Publishing, a division of Reed Elsevier Inc.

Sibley, Kenneth D. *The Law and Strategy of Biotechnology Patents*. Boston: Butterworth-Heinemann, 1994

Sterckx, Sigrid. *Biotechnology, Patents and Morality*. Brookfield: Ashgate Publishing. 1997

Allen Buchanan, Dan W. Brock, Norman Daniels, & Daniel Wikler. *From Chance to Choice: Genetics and Justice*. Cambridge: Cambridge University Press, 2000

Kornberg, Aurthur. *Inside Biotechnology Ventures*. Sausalito:University Science Books, 1995

United States. Information Infrastructure Task Force. Working Group on Intellectual Property Rights. *Intellectual property and the National Information Infrastructure : the report of the Working Group on Intellectual Property Rights* / Bruce A.Lehman, chair. 1995

United States Congress. House Committee on the Judiciary. Subcommittee on Intellectual Property and Judicial Administration. *Biotechnology development and patent law: hearing before the Subcommittee on Intellectual Property and Judicial Administration of the Committee on the Judiciary*, House of Representatives, One Hundred Second Congress, first session, November 20, 1991. 1993.

United States Congress. Senate Committee on the Judiciary. Subcommittee on Patents, Copyrights, and Trademarks. *The Bayh-Dole Act, a review of patent issues in federally funded research: hearing before the Subcommittee on Patents, Copyrights, and Trademarks of the Committee on the Judiciary*, United States Senate, One Hundred Third Congress, second session, on Public Law 96-517, to examine the implementation of the Government Patent Policy Act, which allows universities to patent the results of research funded by the federal government and license their inventions in the marketplace, April 19,1994.

United States Congress. House Committee on Science. *Is today's science policy preparing us for the future?* : Hearing before the Committee on Science, U.S. House of Representatives, One Hundred Fourth Congress, first session, January 6, 1995.