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Citation: 2 An Act to Amend Title 35 United States Code with to Patents on Biotechnological Processes Pub. L. 109 Stat. 351 S1189 1995

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(1) by striking subsection (h); and

(2) by redesignating subsections (1) through (k) as subsections (h) through (j), respectively.

o Mr. KOHL. Mr. President, I am delighted to join with Senator DUREN-BERGER in introducing this legislation. to correct what we see as a flaw in the Transportation bill we passed in 1991.

As my colleagues recall, when we debated the issue of mandatory seatbolt and helmet laws, we pretty much agreed that the Federal Government did not have the right to require State to pass them. But we also agreed that such laws might be desirable. So in the Senate version of the Transportation bill we attempted to persuade States to adopt them. Unfortunately, the final legislation attempted to coerce States into adopting them.

While the goal of the legislation may have been desirable, the tactics are objectionable. In essence we are going to force States which do not adopt mandatory helmet and seatbelt laws to waste-waste-money, money that nelther they nor we have. to the extent that the law now requires spending on education above and beyond desirable and necessary levels, to the extent that the law requires States to divert spending from more critical programs and projects, to that extent we are mandating that money be wasted.

And Mr. President, we cannot afford to do that.

As I said last year, when I drive, I wear my seatbelt; and if I rode a motorcycle. I would wear a helmet. But we all know that, as a Federal Government, we do not have the right or the ability to require States to pass the laws we might like to see in these areas. The Senate version of the legislation, while problematic, at least was acceptable because it sought to persuade States to move in a certain direction; current law coerces them. And that is unacceptable.

Again, I am delighted to join with Senator DURENBERGER in this effort. I congratulate him on his leadership and I look forward to working with him and our colleagues as we seek to find an acceptable way to resolve this problem.•  $\mathcal{T}_{1,1,2} = \mathcal{T}_{1,2}$ 

By Mr. BUMPERS (for himself. . Mr. PRYOR, Mr. KERREY, Mr. COCHRAN. Mr. BOND. Mr. WOFFORD, Mr. BOREN, Mr. KOHL, Mr. SHELBY, and Mr. REID):

S. 296. A bill to require the Secretary of Agriculture to submit monthly financial obligation and employment reports to Congress for the Food and Safety and Inspection Service, and for other purposes; to the Committee on Agriculture, Nutrition, and Forestry.

FOOD SAFETY AND INSPECTION SERVICE REPORTS

Mr: BUMPERS, Mr. President, the

" meat and poultry industry is one of the largest in the country, with annual retail value of nearly \$150 billion in products to American and international. Force Memorial Foundation to estab- industry expected to grow from \$2 bil-

million red meat animals and 6.6 bil- lumbia or its environs; to the Commitlion birds were slaughtered under Federal inspection and products undergoing further processing were reinspected in over 5,000 plants.

Not only is the meat and poultry industry a major player in moving goods through commerce, it also makes a very important contribution to direct employment of American workers. Over 400,000 people are employed in plants under the jurisdiction of Federal inspectors and many thousands of other people are employed in the breeding, raising, and transportation of food animals. In addition, thousands of other people are employed in the storage and distribution of meat and poultry products. Only a few days of industry closure would result in the loss of billions of dollars to the American economy and the disruption of a very large segment of the American work force.

Food safety, rightfully, is one of the most important responsibilities of Federal oversight in consumer affairs. American consumers are afforded the most abundant and the safest variety of food products in the world through no accident. The Food Safety and Inspection Service, an arm of the Department of Agriculture, is charged with the responsibility of closely monitoring activities in meat and poultry slaughter and processing plants across the country through the placement of highly skilled and dedicated men and women who serve as inspectors andveterinary specialists. These people not only assure the availability of safe products, they help assure American consumers that the products they want will be available in a sufficient quantity to meet demand.

The legislation I introduce today will simply provide the Congress with adeſ quate informational tools to keep us better apprised of funding levels and inspection activities of the Food Safety Inspection Service. In the recent past, funding shortfalls have required the passage of emergency supplemental appropriations bills in order to maintain the level of inspectors necessary. to meet industry and consumer demand. My legislation will do much to keep us better informed of potential shortfalls in funding and inspector vacancies to help us avoid the problems of taking emergency actions to keep slaughter and processing lines running. maintain workers on the job, and meet American and international consumers demand for meat and poultry products.

My legislation has the support of the meat and poultry industries and will help the Food and Safety Inspection Service maintain the highest capability possible to meet the demands of food safety for consumers. The safety of our food supply and the security of our work force should demand no less.

### By Mr. STEVENS:

S. 297. A bill to authorize the Air

tee on Energy and Natural Resources.

AIR FORCE MEMORIAL ESTABLISHMENT ACT • Mr. STEVENS. Mr. President, the U.S. Air Force was established as a separate service in 1947. Since that time, the men and women of the U.S. Air Force have distinguished themselves as an integral part of our Nation's defense in times of peace and war. The men and women of the Air Force have dem-onstrated bravery and effectiveness during such historical events as the Berlin airlift and, most recently, Operation Desert Storm.

The 50th anniversary of the founding of the Air Force will be 1997. Today, I am introducing a bill to authorize the erection of a memorial to the Air Force and to the men and women who have honorably served our country within this extraordinary institution. Congress must begin the process now if a memorial is to be completed in time for the 50th anniversary celebration...

The memorial will also be dedicated to those men and women who served in the Army Air Corps, the predecessors to the Air Force, who fought valiantly 'in World War I, and provided the Allies: with their greatest advantage in Europe and the Pacific during World War II.

This bill requires that funds will be raised privately and expressly prohibits any taxpayer funding for the Air Force Memorial. The process for the establishment of a memorial must be in accordance with all existing standards for erecting such works as laid out in 40 U.S.C. 1001.

I urge my colleagues to assist me in establishing a long awaited monument honoring this great institution and our fellow citizens who have served in the U.S. Air Force.

By Mr. DECONCINI (for himself, Mr. HATCH, Mr. HEFLIN, Mr. KENNEDY, Mr. KOHL, Mr. LAU-TENBERG, Mr. SPECTER, Mr. GRASSLEY, Mr. BROWN, and Mr. DOMENICI):

S. 298. A bill to amend title 35, United States Code, with respect to patents on certain processes; to the Committee on the Judiciary.

THE BIOTECHNOLOGY PATENT PROTECTION ACT Mr. DECONCINI. Mr. President, I rise to introduce with my colleagues Senators HATCH, HEFLIN, KENNEDY, KOHL, LAUTENBERG. SPECTER. GRASSLEY. BROWN. and DOMENICI the Biotechnology Patent Protection Act of 1993. This legislation passed the Senate last year, but unfortunately, the House did not have time to act upon the bill before the 102d Congress adjourned. Representatives BOUCHER and MOOR-HEAD are introducing a companion version in the House today.

The Biotechnology Patent Protection Act is critical to the continued success of the United States biotechnology industry. The United States is currently the world leader in biotechnology, an consumers. In 1992, approximately 117 lish a memorial in the District of Co- lion to \$5 billion by the year 2000. In

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## CONGRESSIONAL RECORD - SENATE

addition to the billions of dollars this field generates for our economy, biotechnology offers a potential panacea to seemingly hopeless problems. Currently, biotechnology researchers are developing new energy sources, cures for cancer and heart disease, and healthier food products.

Patents are the lifeblood of the biotechnology industry. They are used to attract the venture capital necessary to finance research and development. Patents also motivate inventors to devote their energies to the discovery and realization of technological innovations. In order to encourage these - scientific breakthroughs, as well as to stimulaté commercial development, we need strong patent protection for our innovations. Our current patent system, however, fails to sufficiently safeguard the biotechnology industry.

The Biotechnology Protection Act provides a rather simple solution to this very complex area of law. Specifically, it amends the Patent Code to provide additional patent protection to the biotechnology industry through two provisions. The first provision overrules the troublesome 1985 Federal circuit case of In re Durden, which has been a serious obstacle for the biotechnological industry in obtaining process patent protection. The second provision closes a loophole in the Patent Code which currently permits a competitor to exploit a patented host cell by importing the resulting product into the United States.

In Durden, the Federal Circuit denied a process patent under the nonobvious standard of the Patent Code. The patent applicant in Durden admitted the familiarity of the general nature of the chemical reaction involved in his application, but asserted that because a new compound was produced from a new starting material, a patent should be issued. The Federal circuit disagreed, holding that, in this case, the use of a different starting material in an otherwise known process did not constitute a patentable process. The court indicated that each process patent must be evaluated on a case-by-case basis.

As a result of Durden, the Patent Office now routinely denies process claims, thereby diminishing patent protection in the U.S. biotechnology industry. The Durden decision is exacerbated by its inconsistent application by patent examiners.

Title I of the Biotechnology Protection Act resolves the Durden predicament by utilizing more appropriate criteria for assessing patentability. The bill provides that a biotechnological process of making or using a product will not be considered nonobvious if the starting material or resulting product is novel. Such a provision is necessary to afford predictability to the patent procedure and to ensure equal and adequate access to patent protection.

Title II closes the loophole which currently allows foreign exploitation of patented biotechnological material.

Under current law, a U.S. patent holder of a genetically engineered host cell is unable to prevent a competitor from using the patented invention overseas and then exporting the product to the United States to compete with the patentee. Such piracy enables a competitor to circumvent established patent law, encouraging businesses to go overseas to evade U.S. law.

Furthermore, this abuse undermines continued investment in the research and development phase of scientific advancements. Not only may scientists abandon meritorious experiments on patented material they fear will be taken overseas, developed, and imported into the United States, but investors may withdraw financial backing from such projects as well.

Mr. President, this legislation moves U.S. biotechnology in the right direction-forward. It is time to end the uncertainty in this area of law that hinders the essential progress of the biotechnology industry. It is time to stop intellectual property pirates from abridging the spirit of U.S. patent laws. Time and time again, we hear of a U.S. industry losing its global lead to another country willing to provide the tools for that industry to succeed. Time and time again, we have been forced to look back in retrospect, lamenting what little needed to be done to maintain U.S. dominance in a particular high-technology industry. If we act now on this legislation, we will not lose the U.S. lead in biotechnology.

Mr. President, in light of the fact that this bill passed the Senate last Congress and in light of the urgent need for the protection this bill provides, I would like to move quickly on this legislation. I ask unanimous consent that the full text of the bill be printed in the RECORD at this point.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

#### S. 299

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled.

TITLE I-BIOTECHNOLOGICAL PROCESS PATENTS

SEC. 101. CONDITIONS FOR PATENTABILITY; NONOBVIOUS SUBJECT MATTER.

Section 103 of title 35, United States Code,

is amended-(1) in the first unnumbered paragraph by inserting "(a)" before "A patent";

(2) in the second unnumbered paragraph by inserting "(b)" before "Subject matter"; and (3) by adding at the end thereof the following new subsections:

(c) Notwithstanding any other provision of this section, a claimed process of making or using a machine, manufacture, or composition of matter is not obvious under this section if-

"(1) the machine, manufacture, or composition of matter is novel under section 102 of this title and nonobvious under this section:

"(Ż) claimed the process is я biotechnological process as defined in subsection (d); and

"(3)(A) the machine, manufacture, or composition of matter, and the claimed process invention at the time it was made, were owned by the same person or subject to an obligation of assignment to the same person; and

"(B) claims to the process and to the machine, manufacture, or composition of matter-

"(1) are entitled to the same effective filing date; and

"(ii) appear in the same patent application, different patent applications, or patent which is owned by the same person and which expires or is set to expire on the same data.

"(d) For purposes of this section, the term 'biotechnological process' means any method of making or using living organisms, or parts thereof, for the purpose of making or modifying products. Such term includes recombinant DNA, recombinant RNA, cell fusion including hybridoma techniques, and other processes involving site specific manipula-tion of genetic material.".

SEC. 102. NO PRESUMPTION OF INVALIDITY.

The first unnumbered paragraph of section 282 of title 35, United States Code, is amended by inserting after the second sentence "A claim issued under the provisions of section 103(c) of this title on a process of making or using a machine, manufacture, or composition of matter shall not be held invalid under section 103 of this title solely because the machine, manufacture, or composition of matter is determined to lack novelty under section 102 of this title or to be obvious under section 103 of this title.". SEC. 103. EFFECTIVE DATE.

The amendments made by this title shall apply to all United States patents granted on or after the date of the enactment of this Act and to all applications for United States patents pending on or filed after such date of enactment, including any application for the reissuance of a patent.

TITLE II-BIOTECHNOLOGICAL MATERIAL **PATENTS** 

SEC. 201. INFRINGEMENT BY IMPORTATION, SALE OR USE.

(a) INFRINGEMENT .- Section 271 of title 35. United States Code, is amended by adding at the end the following new subsection:

"(h) Whoever without authority imports into the United States or sells or uses within the United States a product which is made by using a biotechnological material (as defined under section 154(b)) which is patented in the United States shall be liable as an infringer if the importation, sale, or use of the product occurs during the term of such patent.'

(b) CONTENTS AND TERM PATENT .- Section 154 of title 35, United States Code, is amended-

(1) by inserting "(a)" before "Every"

(2) by striking out "in this title," and inserting in lieu thereof "in this title (1)"

(3) by striking out "and, if the invention" and inserting "(2) if the invention";

(4) by inserting after "products made by that process," the following: "and (3) if the invention is a biotechnological material used in making a product, of the right to exclude others from using or selling throughout the United States, or importing into the United States the product made or using such biotechnological material,"; and (5) by adding at the end thereof the follow-

ing:

"(b) For purposes of this section, the term 'biotechnological material' is defined as any material (including a host cell, DNA se-quence, or vector) that is used in a biotechnological process as defined under. section 103(d)."

(c) EFFECTIVE DATE .--

(1) IN GENERAL.-The amendment made by this section shall take effect six months after the date of enactment of this Act and. subject to paragraph (2), shall apply only with respect to products made or imported

after the effective date of the amendments made by this section. (2) EXCEPTIONS.-The amendments made by this section shall not abridge or affect the right of any person, or any successor to the business of such person-

(A) to continue to use, sell, or import products in substantial and continuous sale or use by such person in the United States on the date of enactment of this Act; or

(B) to continue to use, sell, or import products for which substantial preparation by such person for such sale or use was made before such date, to the extent equitable for the protection of commercial investment made or business commenced in the United States before such date.

Mr. HATCH. Mr. President, today I am pleased to cosponsor the Biotechnology Patent Protection Act of 1993 with my colleagues, Senator DECONCINI.

This legislation is the result of a great deal of work by numerous Members of Congress over the past two Congresses. The problem it addresses was best summarized by the Council on Competitiveness in a report it issued nearly 2 years ago:

The uncertainties in intellectual property rights for innovations in the biotechnology area continue to hamper the industry. Changes in U.S. law have been suggested as a way of improving patent protection. Legislation has been introduced to overturn a court case (In re Durden) that suggests that use of a novel starting material in combination with a known chemical process is not eligible for a process patent. The application of Durden in the biotechnology area could deny protection to innovations that only can be protected through process patents. If Durden were overturned, patenting these processes would permit the patent holder to exclude the importation into this country of product produced by using a patented biotechnological material.

The administration should support | States by the patented process. passage of legislation to provide necessary process patent protection for products, such as those in the biotechnology area, that can be protected only through process patents.

The key elements of this legislation are the protection of major scientific breakthroughs involved in the methods of making and using new products. The best examples of the types of processes that will benefit from this legislation are those that arise in the biotechnology industry.

As noted by the Council on Competitiveness, for a variety of reasons, the patent position of the biotechnology industry is not as strong as that available to traditional pharmaceuticals. This means that under current law it is possible for a major innovation, such as creation of the first commercially effective process for making a recombinant human therapeutic, to be without adequate patent protection. In some instances there may be no product patent protection available for the end product, no process protection for the method of making the product, and no ability to prevent foreign manufacture of the end product using the patented intermediate or host cell. In bio-

technology, the use of an intermediate. most frequently a host cell or organism, is the modern equivalent of creating a miniature factor for the production of a product. Thus, the inability to prevent the transportation of a patented host cell offshore and the subsequent importation of an end product is a serious defect in our current patent system. Our bill addresses this problem directly by extending process patent protection to cover the inventor's process of making the product. Such process patents may be enforced under the current law to stop importation of a product made by a patented process. Thus, this bill will give inventors the full promise of the process patent amendments Senator DECONCINI and I authored in the 1988 omnibus trade bill.

The other important reason that this bill makes sense is that it will produce an international patent norm that no longer leaves our inventors at a competitive disadvantage. Under current law, it is possible for innovators to face unfair foreign competition from parties who would be barred from using a patented host cell in the United States. This legislation will correct that anomaly by granting process patent protection. In my view, this approach is preferable to attempting the creation of a new set of remedies for the making, using, or selling of products of host cells. This bill removes a courtcreated barrier resulting from an anomalous interpretation of the patent laws. Removal of this barrier will result in: First, process patent allowance; and second, application of existing process patent laws to enforce the newly allowed process patents to stop the importation into the United States of products made outside the United

> By Mr. RIEGLE (for himself, Mr. y Mr. Rifster Jeffords, Mr. Simon Mra. Boxer, SIMON. Mr. Ms. MOSELEY-BRAUN. and Mr DODD):

S. 299. A bill to amend the Housing and Community Development Act of 1974 to establish a program to demonstrate the benefits and feasibility of redeveloping or reusing abandoned or substantially underutilized land in economically and socially distressed communities, and for other purposes; to the Committee on Banking, Housing, and Urban Affairs.

ABANDONED LAND REUSE ACT OF 1993 • Mr. RIEGLE. Mr. President, today I rise to introduce the Abandoned Land Reuse Act of 1993.

This legislation is a more comprehensive version of S. 3164, that I introduced last session along with Senators Jім **JEFFORDS** and JOE LIEBERMAN. The legislation addresses a basic issue of community development and economic policy in this country; what to do with abandoned industrial and commercial land. The Abandoned Land Reuse Act of 1993 is different from S. 3164 in a number of respects, most notably in providing more assistance to distressed neighborhoods and creating new jobs where old jobs have been lost.

Abandoned industrial and commercial sites are a major problem for many communities. Taking steps to reuse and rehabilitate these areas will increase the tax base, rehabilitate distressed neighborhoods, and provide a new start for communities that are currently locked in economic decline. and lack the resources to address these and other key issues.

The legislation authorizes grants by the Secretary of Housing and Urban Development to local governments or local nonprofit community development corporations to carry out a program to redevelop or rehabilitate abandoned industrial and commercial facilities that are located in economically and socially distressed communities. This is especially important where the existing owners of the facilities lack the resources to accomplish the rede-' velopment or rehabilitation.

The Abandoned Land Reuse Act of 1993 authorizes the appropriation of \$100 million for each of the next 3 fiscalyears. The legislation enables the HUD Secretary to approve the demonstration grant proposals or to delegate this responsibility to a State's Governor with respect to demonstration project sites in that State. The grants would cover 75 percent of the costs of site redevelopment or rehabilitation and would be subject to repayment, if the grantee recovered from site disposition an amount exceeding its 25 percent share of the costs, or the grantee failed to carry out the redevelopment or rehabilitation project in a timely manner.

For several years now the U.S. Congress has been debating the need to reinvest in the infrastructure that supports the efficient operation of our economy.

This country cannot afford to abandon the sites that have employed thousands of our Nation's workers. We do not have the capital to be so extravagant. We also cannot ignore the impact upon our economy of the large-scale abandonment of large portions of our communities to nonproductive use.

Additionally, this legislation responds to our need to reinvest in our Nation. In my home State of Michigan, the marketability and reuse of thousands of sites are impaired by past industrial or commercial land use practices. These sites, which are in some kind of economic limbo, need rehabilitation to make them viable for reuse. This legislation provides assistance for that economic and community regeneration.

In fact, the Michigan State Legislature has created a special committee to consider what initiatives the State might take to facilitate the reuse of these sites for contemporary uses that will attract or retain private employers. Other levels of government in Michigan and other Michigan organiza-