for their taking measures to clean up their environment. The EPA shall offer technical assistance in structuring these environmental clean up programs. If in the course of implementing these programs, the governments of the Eastern European nations need to purchase equipment as part of the clean up process, or are in need of technical advice in the implementation of these programs, they should, to the extent practical and possible, make use of American firms and advisers.

No additional funding required. Upon receipt of payment by the Soviet government of lend-lease debt by the U.S. Treasury, a like amount shall be transferred to the Secretary of State to fund the mentioned programs.

Section 11: Amend the Polish, Hungarian Aid Act (SEED).—The SEED Act shall be amended, adding two new provisions to Title II, Section 201 "Enterprise Funds for Poland and Hungary." The first provision states that in keeping with the purposes of the Enterprise Funds to promote the development of the private sector in Poland and Hungary, the Funds shall be permitted to make loans and offer grants to the governments of these nations in order for them to be able to contract with private sector economic, management, and technical advisers in making the transition to a market based economy. This shall include but not be limited to assisting with the establishment of institutions that will protect and promote the private sector, as well as with the process of privatizing parastatal industries. In addition, lending to the governments of both nations shall be permitted for use in government-sponsored infrastructure projects identified as necessary to support private sector development.

Another new provision states that it is the intent of Congress that the Enterprise Funds shall make a special effort to help in the development of small and midsized businesses and entrepreneurs in Poland and Hungary through all of its programs.

Section 12: Establish an intensive managerial, business, finance program for Eastern European businesspersons and entrepreneurs.—The Department of State in conjunction with the Department of Commerce and the National Science Foundation shall establish an intensive training program in the U.S. and abroad, ranging from six to twelve months in duration, for the training of Eastern European and Soviet managers and entrepreneurs in business, finance, and managerial skills. The purpose of this program shall be to help build the private sector expertise in these nations. To the extent possible and practical, this program shall also make use of experts from the U.S. private sector, as well as our public and private universities. This program shall be designed for implementation in the U.S. and the nations of Eastern Europe and the Soviet Union.

There is authorized to be appropriated $5 million for FY 1991 for the purpose of carrying out this program.

Section 13: Sense of Congress provision for increasing funding for the Export-Import Bank.—Sense of the Congress provision that supports increased funding for the Eximbank's direct loan program, tied aid fund, Interest Equalization Program, and administrative expenses.●

By Mr. DECONCINI (for himself, Mr. HOLLINGS, Mr. LAUTENBERG, Mr. CRANSTON, and Mr. KOHL):

S. 2326. A bill to amend title 35, United States Code, with respect to patents on certain processes; to the Committee on the Judiciary.

BIOTECHNOLOGY PATENT PROTECTION ACT

● Mr. DECONCINI. Mr. President, I rise today with my colleagues, Senator HOLLINGS, LAUTENBERG, CRANSTON, and KOHL to introduce the Biotechnology Patent Protection Act of 1990. The bill corrects the inadequacies in our patent code that limit the patentability of inventions in this emerging and important field. The bill will also provide protection from the ever increasing foreign infringement of American biotechnology ingenuity.

American scientists invented genetic engineering and America is currently the world leader in biotechnology research. However, because of the rapid advancements in this promising field, our patent and trade laws have failed to keep pace. Instead of providing incentives and the path to progress, the Patent Code and trade laws have become impediments to the commercialization of biotechnology research. We cannot sit idly by watching another American industry succumb to foreign competitors.

In its simplest terms, biotechnology is the study and application of genetic engineering techniques, sometimes referred to as recombinant DNA technology. Sections of DNA called genes contain chemical instructions that guide the cell's machinery in constructing proteins. Proteins give living things their unique characteristics. Through biotechnology drug research, scientists can discover beneficial substances that naturally occur in the body and duplicate these rare substances with gene-splicing techniques resulting in useful and commercial quantities. The end result is a whole new generation of life-saving products.

Let me provide an example of how biotechnology is revolutionizing health care. Factor VIIIc is a blood protein necessary for clotting. Hemophiliacs deficient in this protein often bleed to death from minor wounds, because their blood fails to clot. Factor VIIIc is present in small amounts in blood donated to banks and hospitals. These small amounts of the clotting factor can be extracted from donated blood and pooled to provide a sufficient quantity to treat hemophilia. Hemophiliacs must take regular injections of pooled factor VIIIc to stay alive.

In recent years, biotechnology researchers have been successful in placing human factor VIIIc genes into microorganisms. These microorganisms can be induced to secrete factor VIIIc in quantities sufficient to treat hemophiliacs. Because this genetically engineered factor VIIIc is not a blood product, it will not be contaminated with impurities such as the AIDS virus.

Despite the progress that biotechnology researchers have achieved, our patent code as interpreted by the courts has failed to provide the necessary protection to these recombinant processes. The first section of this measure addresses the problem that biotechnology inventors have had with the decision of In re Durden. Durden involved the asserted patentability of a process for producing a new and patentable compound from a new and patentable starting material using a known chemical reaction. The patent applicant in that case admitted that the nature and conduct of the chemical reaction as it related to the change made in the molecules was known for other, analogous, starting materials to make other corresponding products. The Federal circuit held in Durden that although the starting material and the resulting product were nonobvious and novel, the process to make the product could not be patented.

The Durden decision has been applied in an inconsistent manner by the Patent Office in denying process patents to various useful recombinant versions of naturally occurring proteins. The denials continue to occur although there are indeed patent cases supporting the proposition that a process to make a product will not be considered unpatentable if the starting material is novel. However, as long as Durden is controlling, there is no assurance that patent examiners will not continue to deny biotechnological process patent applications worthy of patent protection.

Section I of this bill will resolve the Durden dilemma and provide the proper criteria for recombinant processes. The section provides that a process to make a product will not be considered unpatentable if the starting material or resulting product is novel. This section will give guidance to the Patent Office for biotechnology-derived process applications and end the inconsistent application of Durden.

The Biotechnology Patent Protection Act also provides a solution to another deficiency in our law that has created an obstacle for the U.S. biotechnology industry. Before the 1988 Trade Act, a patent infringer could take a patented process offshore, make a product from the process, and then ship the product back into the United States. The owner of the patented process had no recourse from this form of infringement. The 1988 Trade Act amended the Patent Code and section 337 of the 1930 Tariff Act to prevent offshore process patent infringement. In that important piece of legislation, Congress adopted the principle that no one should be allowed to import a product manufactured offshore that would constitute patent infringement if it had been manufactured in the United States. Unfortunately, the language of the bill as interpreted did not mirror our intent.

Contrary to the intention of the 1988 amendments to section 337 and the Patent Code, the International Trade Commission has recently ruled that foreign manufacturers are still permitted to take patented biotechno-

logical materials offshore to produce a product to ship back into the United States without legal recourse to the patentee. This practice has had a deleterious effect on the American biotechnology industry. If, after a long, costly, and uncertain period of discovery of an innovative drug product, an American biotechnology company has to watch helplessly as infringing foreign imitators pilfer the remuneration to which it is entitled, then the economic incentive intended to encourage the efforts of these American companies will dry up.

Presently, the biotechnology industry produces billions of dollars annually for our Nation's economy. President Bush recognized the importance this field has on our economic growth by designating biotechnology research as a funding priority in his proposed budget. The budget proposal notes how the recent breakthroughs in the biotechnology field "offer unprecedented opportunities for improving the Nation's productivity, health, and well-being."

This legislation will increase the incentive to invest in biotechnology research and commercial development by correcting the inadequacies in our patent laws and ending the foreign infringement. All Americans will benefit from a prosperous biotechnology sector as the patenting of new drugs will dramatically improve the quality of all our lives.

A companion bill to this legislation has already been introduced in the House by Representative BOUCHER, differing only in the effective date of the legislation. This distinguishing factor in the bills evinces a need for negotiation between all parties concerned on how best to proceed with this legislation. As chairman of the Subcommittee on Patents, Copyrights and Trademarks, I plan to hold a hearing on this measure in the future so that we arrive at the best possible solution to the growing problems this bill addresses. As I have always done on legislation dealing with such complex areas of science and law, I encourage suggestions from industry and all interested parties.

Mr. President, I ask unanimous consent that the full text of the bill be printed in the RECORD.

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

S. 2326

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

SECTION 1. PATENTABILITY OF CERTAIN PROCESSES.

Section 103 of title 35, United States Code, is amended by adding at the end the following new paragraph:

"A process of making a product shall not be considered obvious under this section if an essential material used in the process is novel under section 102 and otherwise nonobvious under section 103.".

SEC. 2. IMPORTATION PROHIBITION; INFRINGEMENT BY IMPORTATION, SALE, OR USE.

(a) AMENDMENT TO TARIFF ACT OF 1930.—Section 337(a)(1)(B) of the Tariff Act of 1930 (19 U.S.C. 1337(a)(1)(B)) is amended—

(1) in clause (i) by striking "or" after the semicolon;

(2) in clause (ii) by striking out the period at the end and inserting "; or"; and

(3) by adding at the end the following:

"(iii) are made, produced, or processed under, or by means of, the use of an essential biotechnological material (as defined under section 154(b) of title 35, United States Code) covered by a valid and enforceable United States patent.".

(b) AMENDMENTS TO TITLE 35, UNITED STATES CODE.—

(1) 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 an essential 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.".

(2) CONTENTS AND TERM OF PATENT.—Section 154 of title 35, United States Code, is amended—

(A) by inserting "(a)" before "Every";

(B) by inserting "(1)" after "in this title,";

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

(D) by inserting after "products made by that process," the following: "and (3) if the invention is an essential 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, that product,"; and

(E) by adding at the end the following:

"(b) For purposes of this section, the term 'essential biotechnological material' means a biologically engineered organism that is essential for the production of a product. Such term includes any host cell, DNA sequence, or vector.".

SEC. 3. EFFECTIVE DATE.

(a) SECTION 1.—The amendment made by section 1 shall apply to all United States patents granted before, 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.

(b) SECTION 2.—(1) The amendment made by section 2(a) shall apply only to articles imported, or sold for importation, on or after the date of the enactment of this Act.

(2)(A) Subject to subparagraph (B), the amendments made by section 2(b) shall take effect on the date of the enactment of this Act.

(B) With respect to any article which is imported before the date of enactment of this Act, and which, but for the amendment made by section 2(b), could be sold or used within the United States, no person shall be liable for infringement under section 271(h) of title 35, United States Code, for such sale or use.●

By Mr. KERRY (for himself, Mr. RIEGLE, Mr. METZENBAUM, Mr. GARN, Mr. BOND, Mr. BRYAN and Mr. HATCH):

S. 2327. A bill to authorize Federal depository institutional regulatory agencies to revoke charters, terminate deposit insurance, and remove or suspend officers and directors of depository institutions involved in money laundering or monetary transaction reporting offenses; to the Committee on Banking, Housing, and Urban Affairs.

DEPOSITORY INSTITUTION MONEY LAUNDERING AMENDMENTS

● Mr. KERRY. Mr. President, last month the Foreign Relations Subcommittee on Narcotics and Terrorism released a report "Drug Money Laundering, Banks and Foreign Policy." In that report the subcommittee recommended that:

Federal regulators should consider revocation of a bank's charter whenever there is evidence that the bank's senior officals or directors had knowledge of or participated in money laundering violations to the extent that the operational integrity and viability of the institution is compromised.

Today I am introducing the Depository Institution Money Laundering Amendments Act of 1990, which will give Federal regulators that power. I am pleased to be joined in this effort by the chairman of the Senate Banking Committee, Senator RIEGLE; the chairman of the Subcommittee on Antitrust, Monopolies and Business Rights, of the Judiciary Committee, Senator METZENBAUM; the ranking minority member of the Banking Committee, Senator GARN, as well as Senators BOND and BRYAN.

The laundering of illegal drug profits is estimated to be a $300 billion global problem, with a least a third of the illegal activity located in the United States alone. Money laundering is a central part of the drug trade, directly involving those at the top of the drug heirarchy. It is becoming increasingly clear that with the proper laws and enforcement, money laundering could prove to be the Achilles heel of the drug trade.

Although banks in this country are showing an increasing willingness to cooperate in the war on drugs, we still have some distance to travel. Bank money laundering continues to be a significant problem.

This legislation will give the appropriate Federal depository institution regulatory agencies the power to revoke charters, terminate deposit insurance, and remove or suspend officers and directors of depository institutions involved in money laundering or monetary transaction reporting offenses.

The Government already has the power to shut down a corrupt institution. Under 12 U.S.C. 1818(a), the FDIC can terminate an institution's insured status on the basis that the institution has violated the law or upon finding that unsafe and unsound practices or conditions are prevalent within an institution. We are adding another weapon for the regulators to punish illegal conduct.

Specifically, the appropriate bank regulator must order a pretermination hearing on the forfeiture of a franchise of a bank, provided, the institution itself was convicted of an offense

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