

"Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1)."

SEC. 3. EFFECTIVE DATE.

The amendments made by section 1 shall apply to any application for patent filed on or after the date of enactment of this Act and to any application for patent pending on such date of enactment, including (in either case) an application for the reissuance of a patent.

SECTION-BY SECTION ANALYSIS AND DISCUSSION

SECTION 1. BIOTECHNOLOGICAL PROCESS PATENTS; CONDITIONS FOR PATENTABILITY; NONOBVIOUS SUBJECT MATTER

Section 1 provides a mechanism for applicants to facilitate the procurement of a patent for a biotechnological process that makes or uses a novel and non-obvious biotechnology product, overruling the decision in *In re Durden*, 763 F.2d 1406 (Fed. Cir. 1985). This section would amend section 103 of title 35, United States Code, to ensure that a biotechnological process would not be considered obvious, and thus unpatentable, if it either makes or uses a composition of matter that itself is novel and non-obvious.

The legislation has an impact on one element of patentability of biotechnological processes—the element of non-obviousness. There is no guarantee of patentability even if the process claim satisfies the non-obvious provisions of the revised section 103. The process must still satisfy all other requirements of patentability, including novelty and utility among other requirements.

To qualify as non-obvious under this section, the claims to the process and the composition of matter, to which the process is linked, must be contained in either the same application for patent or in separate applications having the same effective filing date. Additionally, the composition of matter and the process at the time it was invented, must be owned by the same person or be subject to an obligation of assignment to the same person.

Section 1 also allows an applicant to demonstrate the independent patentability of a process under current law or proceed under the non-obviousness rule established by this section. Independent patentability may be demonstrated, for example, by showing the non-obviousness of the process through proof that the process demonstrates unpredictable results.

Finally, this section provides five possible definitions of the term "biotechnological process." These definitions limit the applicability of this section to biotechnological process patents. The new definitions are broad enough to include most genetic engineering technologies that are currently being used by biotechnology researchers.

The first proffered definition explains a "biotechnological process" as a process of inducing an organism to express a characteristic not naturally associated with it through the methods of genetic engineering or other methods. Such a process may cause an organism to "express an exogenous nucleotide sequence." An example of such a method is the process by which human insulin is produced in commercial quantities. The DNA sequence for human insulin is inserted into the bacteria *E. coli* so the bacteria begins expressing, or producing, human insulin in its cellular machinery.

This second definition of a "biotechnological process" specifies that such a process could be altering an organism

to "inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence." A popular example of a product produced by such a process is the Flavr-Savr Tomato. This process involves the alteration of tomatoes to eliminate the inter-cellular production of an enzyme that causes the tomato to rot. By eliminating the expression of this "rotting" enzyme, the tomato is allowed to have a longer shelf-life.

The third qualifying definition interprets "biotechnological process" as altering an organism to "express a specific physiological characteristic not naturally associated with said organism." The Hepatitis B virus vaccine is produced utilizing such a process. The "antigen," or surface protein to which the human immune system responds, for Hepatitis B is inserted into yeast to yield commercial quantities of the protein. The expression of the protein does not occur naturally in yeast but does so because its genetic coding has been altered. The protein is then removed from the yeast and injected into humans to induce the body to safely and naturally produce an immune reaction to fight the deadly virus, which causes liver damage and cancer. The use of such a process to combat many human and animal diseases, including AIDS.

The fourth qualifying definition comprises "cell fusion procedures." An example of such a process is the method used for producing monoclonal antibodies, referred to by scientists as "hybridoma technology." This technology involves fusing spleen cells that produce certain desired antibodies to a specialized "immortal" cell—usually a cancer cell—that no longer produces an antibody of its own. The resulting fused cells, or "hybridomas," grow continuously and rapidly like a cancer cell, yet they produce the desired antibodies. Monoclonal antibodies are widely used in targeting special cells to diagnose infections and cancer. The possibility of their use in the direct treatment of cancer and immune disorders is currently a major focus of biomedical researchers.

Finally, the fifth definition of a qualifying "biotechnological process" is described as any method of using a final product that has been produced by a process defined by any of the other four definitions provided or a combination of the processes thereof.

SECTION 2. PRESUMPTION OF VALIDITY

This section provides that if a patent claim to a composition of matter—either the starting material or the final product—is held invalid because the Patent and Trademark Office determines that it is non-obvious, the patent process application that is dependent on that composition of matter will no longer be entitled to rely on that composition of matter for a presumption of non-obviousness. In such a case, the inventor must show that such a process is non-obvious without relying on this legislation.

SECTION 3. EFFECTIVE DATE

The amendments made by this act are effective on the date of enactment. The amendments will apply to all patents filed on or after the date of enactment and all patent applications, including applications for the reissuance of a patent, pending on the date of enactment.

MESSAGES FROM THE HOUSE

At 2:24 p.m., a message from the House of Representatives, delivered by Ms. Goetz, one of its reading clerks, announced that the House has passed the following bill, in which it requests the concurrence of the Senate.

H.R. 2405. An act to authorize appropriations for fiscal years 1996 and 1997 for civilian

science activities of the Federal Government, and for other purposes.

At 6:09 p.m., a message from the House of Representatives, delivered by Ms. Goetz, one of its reading clerks, announced that the House has passed the following bills, without amendment.

S. 227. An act to amend title 17, United States Code, to provide an exclusive right to perform sound recordings publicly by means of digital transmissions and for other purposes.

S. 268. An act to authorize the collection of fees for expenses for triploid grass carp certification inspections, and for other purposes.

S. 1111. An act to amend title 35, United States Code, with respect to patents on biotechnological processes.

The message also announced that the Speaker appoints Mr. OBERSTAR as a conferee in the committee of conference on the disagreeing votes of the two Houses on the amendment numbered 4 of the House to the bill (S. 395) to authorize and direct the Secretary of Energy to sell the Alaska Power Administration, and to authorize the export of Alaska North Slope crude oil, and for other purposes; to fill the vacancy resulting from the resignation from the House of Representatives of Mr. Mineta.

The message further announced that the House disagrees to the amendment of the Senate to the bill (H.R. 1655) to authorize appropriations for fiscal year 1996 for intelligence and intelligence-related activities of the U.S. Government, the Community Management Account, and the Central Intelligence Agency Retirement and Disability System, and for other purposes, and agrees to the conference asked by the Senate on the disagreeing votes of the two Houses thereon; and appoints the following Members as the managers of the conference on the part of the House:

From the Permanent Select Committee on Intelligence, for consideration of the House bill, and the Senate amendment, and modifications committed to conference: Mr. COMBEST, Mr. DORNAN, Mr. YOUNG of Florida, Mr. HANSEN, Mr. LEWIS of California, Mr. GOSS, Mr. SHUSTER, Mr. MCCOLLUM, Mr. CASTLE, Mr. DICKS, Mr. RICHARDSON, Mr. DIXON, Mr. TORRICELLI, Mr. COLEMAN, Mr. SKAGGS, and Ms. PELOSI.

From the Committee on National Security for the consideration of defense tactical intelligence and related activities: Mr. SPENCE, Mr. STUMP, and Mr. DELLUMS.

As additional conferees from the Committee on International Relations, for consideration of section 303 of the House bill, and section 303 of the Senate amendment, and modifications committed to conference: Mr. GILMAN, Mr. SMITH of New Jersey, and Mr. BERMAN.

MEASURES REFERRED

The following bill was read the first and second times by unanimous consent and referred as indicated:

H.R. 2405. An act to authorize appropriations for fiscal years 1996 and 1997 for civilian science activities of the Federal Government, and for other purposes; to the Committee on Commerce, Science, and Transportation.

EXECUTIVE AND OTHER COMMUNICATIONS

The following communications were laid before the Senate, together with accompanying papers, reports, and documents, which were referred as indicated:

EC-1506. A communication from the Chairman of the International Trade Commission, transmitting, pursuant to law, the report entitled, "Caribbean Basin Economic Recovery Act: Impact on U.S. Industries and Consumers"; to the Committee on Finance.

EC-1507. A communication from the Assistant Secretary of State for Legislative Affairs, transmitting, pursuant to law, notice of a Presidential determination relative to Serbia and Montenegro; to the Committee on Foreign Relations.

EC-1508. A communication from the Assistant Secretary of State for Legislative Affairs, transmitting, pursuant to law, notice of a Presidential determination relative to Mongolia; to the Committee on Foreign Relations.

EC-1509. A communication from the Assistant Secretary of State for Legislative Affairs, transmitting, pursuant to law, notice of a Presidential determination relative to Rwanda and Burundi under the Migration and Refugee Assistance Act of 1962; to the Committee on Foreign Relations.

EC-1510. A communication from the Assistant Secretary of State for Legislative Affairs, transmitting, pursuant to law, notice of certification for fiscal year 1996 relative to the United Nations; to the Committee on Foreign Relations.

EC-1511. A communication from the Assistant Legal Affairs Adviser for Treaty Affairs, the Department of State, transmitting, pursuant to law, the text of the international agreements, other than treaties, and background statements; to the Committee on Foreign Relations.

EC-1512. A communication from the Secretary of Agriculture, transmitting, pursuant to law, the management report for the period October 1, 1994 to March 31, 1995; to the Committee on Governmental Affairs.

EC-1513. A communication from the Chief Financial Officer, the Assistant Secretary for Administration, the Department of Commerce, transmitting, pursuant to law, the annual report under the Freedom of Information Act for calendar year 1994, to the Committee on the Judiciary.

EC-1514. A communication from the Chief of the Retirement Branch Directorate of Force Management and Personnel, the Department of Air Force, transmitting, the annual report for the Air Force Nonappropriated Fund Retirement Plan; to the Committee on Governmental Affairs.

EC-1515. A communication from the Comptroller General, transmitting, pursuant to law, reports and testimony for the month of August 1995; to the Committee on Governmental Affairs.

PETITIONS AND MEMORIALS

The following petitions and memorials were laid before the Senate and were referred or ordered to lie on the table as indicated:

POM-344. A resolution adopted by the Governing Board of the Northeast Ohio Areawide

Coordinating Agency relative to the Environmental Protection Agency; to the Committee on Appropriations.

POM-345. A joint resolution adopted by the Legislature of the State of California; to the Committee on Appropriations:

"JOINT RESOLUTION NO. 29

"Whereas, the Congress of the United States is expected to consider funding for additional Air Force B-2 Stealth Bombers beyond the 20 currently authorized; and

"Whereas, international challenges persist, and the availability of stealth bomber technology will enable the Air Force to respond quickly and decisively; and

"Whereas, the United States' ability to respond effectively would be greatly undermined if the Air Force's current fleet of bombers is allowed to become obsolescent; and

"Whereas, according to the 1995 defense appropriations bill, 'Independent studies have concluded that the 20 B-2 aircraft currently on order are simply not enough to provide a militarily-significant and cost-effective long-rang conventional bomber force . . .'; and

"Whereas, the B-2 is the only aircraft currently in production that incorporates advanced stealth technology, developed in California, that unlike the current fleet of bombers, gives the United States superiority over any adversary in the world; and

"Whereas, the B-2 program employs 9,000 people in California at Northrop Grumman Corporation, the prime contractor, and more than 2,000 suppliers throughout the state, and helps support thousands of additional jobs at local businesses: Now, therefore, be it

Resolved by the Assembly and Senate of the State of California, jointly, That the B-2 Stealth Bomber is acknowledged as a key element of the military strategy for the defense of the United States; and be it further

Resolved, That the Legislature of the State of California respectfully urges the President and the Congress of the United States to provide the necessary funding in the 1996 fiscal year for additional production of the Air Force B-2 Stealth Bomber, an important national resource; and be it further

Resolved, That the Chief Clerk of the Assembly transmit copies of this resolution to the President and the Vice President of the United States, to the Speaker of the United States House of Representatives, and to each Senator and Representative from California in the Congress of the United States."

POM-346. A joint resolution adopted by the Legislature of the State of California; to the Committee on Armed Services.

"JOINT RESOLUTION NO. 40

"Whereas, the most recent base closure and realignment recommendations forwarded to the President by the federally-appointed Defense Base Realignment and Closure Commission now include an additional 20 California defense facilities; and

"Whereas, Presidents Franklin D. Roosevelt, John F. Kennedy, and Ronald Reagan led the charge in rebuilding American's defenses in the 20th Century and in practicing a policy of 'peace through strength'; and

"Whereas, the fruits of this policy were realized with the collapse of the Soviet empire, America's victory in the Cold War, and the military's stunning victory in the Persian Gulf War; and

"Whereas, Americans have a profound respect for the men and women of the United States military who faithfully serve the country; and

"Whereas, we believe that, if the men and women of the military are sent into harm's way, they must be equipped with whatever is necessary to ensure their safety and to get the job done; and

"Whereas, the world remains a dangerous place, with military involvements recently in Iraq, Haiti, and now Bosnia, and the maintenance of our defense should be a top priority; and

"Whereas, downsizing and streamlining military operations are important goals—but only as long as the security of the United States is not compromised; and

"Whereas, the bases in California, especially McClellan Air Force Base and the Long Beach Naval Shipyard, are vital national assets on the Pacific Rim; and

"Whereas, it was recently learned that technology from McClellan Air Force Base was used in the rescue of downed Air Force pilot Scott O'Grady in Bosnia; and

"Whereas, the radio beacon and transmitter, as well as the E3A AWACS aircraft equipment and radio communication system used by O'Grady and his rescuers, were repaired and serviced at McClellan Air Force Base; and

"Whereas, California has been forced to endure up to 50 percent of all national economic impact from base closures; and

"Whereas, the closure of these California facilities would represent direct and indirect job losses of up to 46,000 jobs, and since the California economy is highly reliant upon the high technology associated with national defense expenditures, these closures will only exacerbate that devastation; and

"Whereas, the California economy, already suffering from the strain of previous base closures, would be further injured by these additional closures, which would represent the loss of an estimated additional \$10,200,000,000 in annual income: Now, therefore, be it

Resolved by the Assembly and Senate of the State of California, jointly, That the Legislature of the State of California memorializes the President of the United States and the United States Congress to reject the entire base-closure list to be submitted on or before July 1, 1995, by the Defense Base Closure and Realignment Commission; and be it further

Resolved, That the President, in consultation with the Congress, is urged to develop a more balanced policy with regard to the security needs of the United States; and be it further

Resolved, That a more balanced national security policy should take into consideration the strong military strategic concerns of the United States Defense Department and the Joint Chiefs of Staff; and be it further

Resolved, That the Chief Clerk of the Assembly transmit copies of this resolution to the President and Vice President of the United States, to the Speaker of the United States House of Representatives, and to each Senator and Representative from California in the Congress of the United States."

POM-347. A resolution adopted by the Chamber of Commerce of the City of San Angelo, Texas relative to trust fund accounts; referred jointly, pursuant to the order of August 4, 1977, to the Committee on the Budget, and to the Committee on Governmental Affairs.

POM-348. A resolution adopted by the Board of Commissioners of Caswell County, North Carolina relative to tobacco; to the Committee on Labor and Human Resources.

POM-349. A resolution adopted by the Military Chaplains Association of the United States of America relative to the Impact Aid Program; to the Committee on Labor and Human Resources.

POM-350. A joint resolution adopted by the Legislature of the State of California; to the Committee on Labor and Human Resources:

"JOINT RESOLUTION NO. 25

"Whereas, the Congress of the United States, acknowledging the fiscal burden