

HEINONLINE

Citation: 2 An Act to Amend Title 35 United States Code with
to Patents on Biotechnological Processes Pub. L.
109 Stat. 351 E946 1995

Content downloaded/printed from
HeinOnline (<http://heinonline.org>)
Tue Mar 19 17:43:08 2013

-- Your use of this HeinOnline PDF indicates your acceptance
of HeinOnline's Terms and Conditions of the license
agreement available at <http://heinonline.org/HOL/License>

-- The search text of this PDF is generated from
uncorrected OCR text.

ence of human toxic risk assessment. New methods developed by CIIT have been adopted by many laboratories across the country and the world. This is truly science in the public interest, and I want to commend CIIT for playing such a vital role in our Nation's public health.

THE BIOTECHNOLOGY PATENT PROTECTION ACT

HON. RICK BOUCHER

OF VIRGINIA

IN THE HOUSE OF REPRESENTATIVES

Wednesday, March 13, 1991

Mr. BOUCHER. Mr. Speaker, the Biotechnology Patent Protection Act of 1991, which I am introducing today, will strengthen the protection afforded to products produced through biotechnology and stimulate development of new drugs through this innovative process. I am pleased to be joined by the gentleman from California, Mr. Moorhead, and 19 of our colleagues in offering this measure.

The legislation is a response to the impediments American inventors face in obtaining adequate patent protection for products and processes produced using biotechnology. Biotechnology is an immensely important industry, invented in the United States. In the decades ahead, it will improve the lives and health of virtually every American family. It will put people to work. It will save people's lives. In this decade, it will make a major contribution to America's positive balance of trade.

The promise of biotechnology has been noted by President Bush who has said that breakthroughs in the field "offer unprecedented opportunities for improving the Nation's productivity, health, and well-being." Similarly, the National Academy of Engineering last year acknowledged that the development of biotechnology products is one of the 10 leading engineering accomplishments of the past 25 years.

Biotechnology allows us to replicate beneficial substances that naturally occur in minute quantities and produce them in sufficiently large amounts to make them available to treat serious and life threatening disease. Despite these impressive achievements—and the explosive growth in the industry—deficiencies in our patent law grant unfair advantages to foreign competitors and threaten the long term viability of the industry.

The Biotechnology Patent Protection Act puts American companies on an even footing with their Japanese and European competitors by providing patent protection for the production process, so long as the starting material is novel. If we continue to deny such process patent protection, we will dampen American invention and initiative, jeopardizing future drug development and the economic and medical benefits that come with it.

The United States had only just begun to tap the potential of biotechnology, which produces billions of dollars in annual sales for our Nation's economy. Currently, American companies are spending up to \$2 billion in biotechnology research and development each year. The industry employs tens of thousands of highly trained scientists and engineers. More than 30 States are involved in the active promotion of biotechnology efforts.

One of the biggest impediments to the achievement of the full potential of the industry is inadequate intellectual property protection. Our legislation remedies the largest such problem.

The U.S. Patent Office has taken the position that it is barred from issuing appropriate patent protection for biotechnology processes because of an aberrant court case, the rule of which the Patent Office agrees should be reversed through legislation. This situation is especially unfair because the denial of such patent protection in the United States is contradicted by the extension of such patent protection by our trading partners in Japan and Europe.

The current problem arises—in the relatively common situation—where the starting material used in an invention is novel, but the steps used in the process, and often the final product itself, are not. In modern biotechnology, an inventor often may develop a novel starting material, such as a host cell, DNA sequence or vector, and use a process previously used in another context to create a nonpatentable final product. In these cases, Europe and Japan would grant process patents. The U.S. Patent Office frequently grants no effective patent protection, leaving U.S. biotechnology at a competitive disadvantage.

The Patent Office denies many patent applications in reliance on a court case that has been widely criticized. Last Congress, when the Committee on the Judiciary conducted a hearing on a similar measure, the Patent Commissioner strongly urged Congress to change the result of that case.

Our legislation has the strong support of the administration, the business community—including the pharmaceutical and biotechnology industries—and the university community. This support stems from a recognition that stronger patent laws stimulate research and development.

The Biotechnology Patent Protection Act of 1991 will promote industrial innovation and enhance fair trade.

CONGRESSMAN KILDEE PAYS TRIBUTE TO REPRESENTATIVE BUS SPANIOLA

HON. DALE KILDEE

OF MICHIGAN

IN THE HOUSE OF REPRESENTATIVES

Wednesday, March 13, 1991

Mr. KILDEE. Mr. Speaker, I rise today to pay tribute to the long and distinguished career of Francis R. (Bus) Spaniola who has served as State representative for Michigan's 87th State House District for the past 16 years. Representative Spaniola has recently retired from public life, leaving behind a legacy of service which will long be remembered in Shiawassee and Livingston Counties. Representative Spaniola will be honored at a roast to be held on March 21, 1991 at the Knights of Columbus Hall in Owosso, MI.

Although I know Representative Spaniola will continue to serve humanity in whatever activities he pursues in retirement, I also know that his colleagues and his constituents will miss his strong moral presence in the Statehouse. I had the good fortune to have served in the Statehouse with Representative Spaniola. As an observer of his consistent and

continual courage to stand and speak out for what is right, regardless of the potential criticisms, I have become a better person as well as a better legislator. His steadfast commitment and dedication to the welfare of the people of Michigan have made a major difference in the lives of many people, particularly in an area held most dear in my heart—education. Literally millions of students have benefitted from his commitment to the improvement of our State's system of education.

Mr. Speaker, I look back on the career of Representative Spaniola with fond memories of accomplishment and friendship amidst sometimes stormy waters. My respect and admiration for Representative Spaniola can only be expressed by emulating his committed and courageous service. Indeed, our society needs more public servants like Representative Spaniola.

Mr. Speaker, it is an honor and a privilege to pay tribute to this highly respected and distinguished gentleman. I ask that my colleagues join me in congratulating Representative Francis R. (Bus) Spaniola on the occasion of his retirement.

TRIBUTE TO DR. CLEO DAWSON SMITH

HON. E de la GARZA

OF TEXAS

IN THE HOUSE OF REPRESENTATIVES

Wednesday, March 13, 1991

Mr. DE LA GARZA. Mr. Speaker, I respectfully request a few moments to say that south Texas recently lost one of its last remaining pioneers. I would like to take a moment to remember this incomparable individual. I'm talking about the late Dr. Cleo Dawson Smith, who a few weeks ago passed away. All of us are sadder for her loss, but there is no question that the legacy she leaves behind is a rich one.

Dr. Dawson, as she was commonly referred to, came to south Texas as a small child by covered wagon. With her family she helped to build a town beside the railroad where a trail from the Rio Grande crossed the track—a town newly named Mission. This was back in the very early 1900's and long before Mission was incorporated into a city.

Cleo Dawson grew up to be an example of how invigoratingly one can live life and how limitless are its possibilities. In all of her endeavors she shined brightly.

First and foremost, I would call her an educator. In fact, because of her years of work in this field her name, particularly in south Texas, became synonymous with education. This eventually resulted in the street crossing in front of Mission High School being named in her honor.

She was also an author, well read and widely published. One of her most successful endeavors, "She Came To The Valley," a tribute to her pioneer family's contribution to the growth of the lower Rio Grandé Valley, became a movie. The true story dealt with the formation of the city of Mission, the border raids by Mexican bandits, the arrival of the United States soldiers, and her mother's life in what was truly a frontier town.

These are only but two of the hats worn so well by Dr. Dawson. Also included among her

40)