

CAPITOL OFFICE
1119 LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
PHONE: (202) 225-6235
FAX: (202) 225-2202



COMMITTEE ON WAYS AND MEANS
SUBCOMMITTEE ON HEALTH
SUBCOMMITTEE ON OVERSIGHT
SUBCOMMITTEE ON SOCIAL SECURITY

DISTRICT OFFICE
1910 SUNSET BOULEVARD, #560
LOS ANGELES, CA 90026
PHONE: (213) 483-1425
FAX: (213) 483-1429

BECERRA.HOUSE.GOV

Congress of the United States
House of Representatives

XAVIER BECERRA
31ST DISTRICT, CALIFORNIA

COMMITTEE ON THE BUDGET

ASSISTANT TO THE
SPEAKER OF THE HOUSE

A large, stylized handwritten signature in black ink, appearing to read 'Xavier Becerra', written over the text 'ASSISTANT TO THE SPEAKER OF THE HOUSE'.

ON THE INTRODUCTION OF
THE GENOMIC RESEARCH AND ACCESSIBILITY ACT

Hon. XAVIER BECERRA (CA-31)
Friday, February 9, 2007

Mr. BECERRA. Madame Speaker, I rise today with the hope of fixing what I believe to be a regulatory mistake – a mistake that at first glance may seem minor in scope, but upon further examination has dramatic, costly and harmful implications for every American.

I speak of the practice of gene patenting, where private corporations, universities and even the federal government are granted a monopoly by the United States Patent and Trademark Office on significant sections of the human genome.

It is my belief that this practice is wrong, ill-conceived and stunts scientific advancement. And it is for this reason that today I introduce the Genomic Research and Accessibility Act to put an immediate end to this practice.

Fifty-four years ago this month James Watson and Francis Crick discovered the structure of Deoxyribonucleic acid (DNA), the molecule that contains the genetic information of nearly all living organisms. Few discoveries have matched theirs in the understanding of the make up of the human species. This discovery led to the 1990 founding of the Human Genome Project, a U.S.-initiated and funded undertaking through the Department of Energy and the National Institutes of Health and in collaboration with geneticists from China, France, Germany, Japan and the United Kingdom. Its goal was to code three billion nucleotides contained in the human genome and to identify all the genes present in it. This dramatic undertaking has given us a greater grasp of many of life's most basic – and dramatic – questions.

The Project's efforts have led to the discovery of approximately 35,000 genes.

Madame Speaker, 20 percent of these genes have already been patented. Put another way, one-fifth of the blueprint that makes you ... me ... our children ... all of us ... who we are is owned by someone else. And we have absolutely no say in what those patent holders do with our genes.

This cannot be what Watson and Crick intended.

Here are a few examples of the implications of gene patenting:

1. Gene patents interfere with research on diagnoses and cures. Half of all laboratories have stopped developing diagnostic tests because of concerns about infringing gene patents. One laboratory in four has had to abandon a clinical test in progress because of gene patents.
2. In countries where genes are not patented patients get better tests for genetic diseases than in the United States.
3. Forty-seven percent of geneticists have been denied requests from other faculty members for information, data, or materials regarding published research. The practice of withholding data detrimentally affects the training of the next generation of scientists. Almost one fourth of doctoral students and postdoctoral fellows reported they have been denied access to information, data and materials.
4. Disease-causing bacteria and viruses have now been patented. The genome of the virus that causes Hepatitis C, for example, is owned. This can lead to major problems, for if someone else wants to introduce inexpensive, timely public health testing for this (or another) common infectious disease, the patent holder can prevent it.
5. Few in this chamber would ever forget the SARS epidemic. From November 2002 to July 2003, this respiratory disease spread to 24 countries, killing 774 of the 8,096 people who contracted it. Scientists were apprehensive about vigorously studying the disease because three patent applications were pending and they were fearful of possibly facing charges of patent infringement and subsequent litigation.

This is a serious problem and it is growing.

My legislation, the Genomic Research and Accessibility Act, is straight forward: it ends the practice of gene patenting. It gives guidance to the United States Patent and Trademark Office (PTO) on what is not patentable – in this case, genetic material, naturally-occurring or modified. It is not retroactive – it does not rescind the patents already issued. But, fortunately, the Framers of our Constitution in their infinite wisdom made the point that any recognized invention deserved a monopoly for only a limited time. Congress has defined that scope of protected status to be 20 years from the point the patent application was filed. Thus, if we enact this bill into law quickly, we will reach balance in less than two decades – a patent-free genome that does not hinder scientific research, business enterprise, or human morality.

I do not wish to lay blame on anyone who has sought out a gene patent, for they all saw an opportunity and capitalized on it. But that opportunity should never have existed in the first place, and thus, it is time that we as a legislative body put an end to this practice.

Nor do I find fault with the Patent and Trademark Office. These days, it should not surprise anyone that innovative technology often outpaces innovative policies. Quite frankly, I don't know if the Patent and Trademark Office or anyone else for that matter had the technical expertise to fully understand the implications when the PTO granted the first gene patents. Those first patents set the precedent. The precedent created the practice. And the practice has now proliferated. This would not be the first time in our nation's history where government has had to play catch up in order to properly understand technological innovation, and it certainly won't be the last.

Madame Speaker, precedent does not and should not simply guarantee continued practice. Indeed, Congress has the constitutional right to proliferate and reward the advancement of

invention, but it also has the responsibility to intervene should that advancement be misdirected or incorrect. Article I, Section 8 of the United States Constitution states that we must “promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.” But implicit in those words is the power of discretion – Congress’ charge to offer guidance on what exactly merits an exclusive right.

I make the argument that the human genome was not created by man, but instead is the very blueprint that creates man. The genome and the approximately 35,000 genes it encompasses has existed for millions of years, predating the human species; and suffice to say that it will certainly post date us as well.

If you agree with me that genes have existed beyond the full grasp of human knowledge and indeed before the dawn of human kind, then you must conclude as I have that they are a product of nature and thus not patentable. Patenting the gene for breast cancer or any other gene is the analogous equivalent to patenting water, air, birds or diamonds.

But don’t take my word for it, Madame Speaker. One need only read the Supreme Court’s *Diamond v. Chakrabarty* decision of 1980 to receive guidance on what is truly not patentable. In this landmark decision, Chief Justice William Burger wrote that “The laws of nature, physical phenomena, and abstract ideas have been held not patentable ... Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are ‘manifestations of . . . nature, free to all men and reserved exclusively to none.’”

Proponents of gene patenting have said they are not patenting genes but instead are patenting “isolated and purified” genetic sequences. This is mere wordplay. In practice, these patents are patents on products of nature. For example, a patent on the supposedly isolated and purified breast cancer sequence prohibits a woman’s doctor from looking for the breast cancer gene in her blood without paying \$3,000 to the patent holder. It prohibits the same woman from donating her breast cancer gene to other researchers because the holder of the patent has the exclusive right to prevent anyone else from doing research on any individual’s breast cancer gene. Such restrictions make clear that in effect, patents on isolated and purified sequences are patents on the actual genes found in nature.

We have overstepped our bounds. We have made a regulatory mistake. We have allowed the patenting of a product of nature.

Fortunately, we have the power to end the practice expeditiously and for the benefit of all. This bill will allow all doctors and researchers to have access to the genetic sequence, consisting of the chemical letters A (adenine), T (thymine), C (cytosine) and G (guanine). Just as we would never allow a patent on the alphabet that would permit the patent holder to charge people a royalty every time they spoke, we should not allow a patent on the genetic alphabet that comprises our common genome.

I want to thank my friend, the Honorable Dr. Dave Weldon of Florida, for agreeing to join me in writing and introducing this critical piece of legislation. I am appreciative for the support that this legislation has found in the science and medical communities. The Medical Association, the College of American Pathologists, the American College of Medical Genetics, the American Society of Human Genetics, the Association for Molecular Pathology, the Academy of Clinical

Laboratory Physicians and Scientists and a host of others have all made public their wish to see the practice of gene patenting come to an immediate end. I applaud their steadfast support and encourage them to stay vocal until such time as their wish becomes reality and the Genomic Research and Accessibility Act becomes law.

Enacting the Genomic Research and Accessibility Act does not hamper invention, indeed, it encourages it. Medical innovation and economic advancement will occur if the study of genes is allowed to happen unabated. Incredible manifestations of intellectual property will result: medicines, machines, processes – most deserving of recognition, some potentially life-saving, and all worthy of a patent.

Madame Speaker, let us take up and pass in short order the Genomic Research and Accessibility Act.

I thank you for your consideration and yield back the balance of my time.