

# National Organization for Rare Disorders, Inc.<sup>®</sup>

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... out of the darkness  
into the light ...

January 10, 2000

The Honorable Q. Todd Dickinson  
 Assistant Secretary of Commerce and  
 Commissioner of Patents and Trademarks  
 US Patent & Trademark Office  
 2121 Crystal Drive  
 Crystal Park 2, Suite 906  
 Arlington, VA 22202

Re: Federal Register Notices, December 21, 1999;  
 Docket No. 991027289-9289-01 and 991027288-9288-01

Dear Commissioner Dickinson:

Few scientific topics are of more interest and concern to the public than gene patenting. To us it is quite simple: No one should be allowed to patent our genes. Genes are not inventions so we do not understand why PTO is issuing patents for human genes and sequences. You would not issue a patent for air or water so how can PTO allow a person or company to patent genes that have existed since the beginning of time? Moreover, patents on genes are delaying medical research so there is no societal benefit associated with these patents, and indeed there is a great deal of potential harm.

Because this topic is so controversial, we have been waiting for the government to initiate a true public dialogue. If there had been an open public forum focusing on gene patents, as there has been for the past decade on gene therapy, perhaps the topic would be less controversial today. However, the only opportunities for public input have been responses to *Federal Register* notices about proposed rules that are not understandable to ordinary people. Only those with medical and legal degrees can possibly understand that PTO is allowing individuals and companies to patent genes and sequences as nature designed them, and not as man engineered or altered them.

The two "Proposed Guidelines" printed in the December 21, 1999 *Federal Register* are a case in point. These notices apparently respond to several previous proposals that were published as early as 1995, and were apparently responded to primarily by people and companies with a financial interest in gene and sequence patents.

- MEMBER ORGANIZATIONS**
- Alliance of Genetic Support Groups
  - Alpha 1 Antitrypsin Deficiency National Association
  - ALS Association
  - American Brain Tumor Association
  - American Laryngeal Papilloma Foundation
  - American Porphyria Foundation
  - American Society of Adults with Pseudo-obstruction, Inc. (ASAP)
  - American Syringomyelia Alliance Project
  - Aplastic Anemia Foundation of America
  - Association for Glycogen Storage Disease
  - Balkan Disease Support & Research Association
  - Benign Essential Blepharospasm Research Foundation, Inc.
  - Charcot-Marie-Tooth Association
  - Chromosome 18 Registry and Research Society
  - Cleft Palate Foundation
  - Cornelia de Lange Syndrome Foundation, Inc.
  - Cystinosis Foundation, Inc.
  - Dysautonomia Foundation, Inc.
  - Dystonia Medical Research Foundation
  - Dystrophic Epidermolysis Bullosa Research Association (D.E.B.R.A.)
  - Ehlers-Danlos National Foundation
  - Epilepsy Foundation of America
  - Families of Spinal Muscular Atrophy
  - Foundation Fighting Blindness
  - Foundation for Ichthyosis & Related Skin Types (F.I.R.S.T.)
  - Guillain-Barre Syndrome Foundation International
  - HHT Foundation International, Inc.
  - Hemochromatosis Foundation, Inc.
  - Hereditary Disease Foundation
  - Histiocytosis Association of America
  - Human Growth Foundation
  - Huntington's Disease Society of America, Inc.
  - Immune Deficiency Foundation
  - International Fibrodysplasia Classification Progressive (ICFP) Association, Inc.
  - International Joseph Disease Foundation, Inc.
  - International Rett Syndrome Association
  - Interstitial Cystitis Association of America, Inc.
  - Lowie Syndrome Association
  - Malignant Hyperthermia Association of the United States
  - Mastocytosis Society
  - Myasthenia Gravis Foundation
  - Myotonic Dystrophy Disease Center
  - Myotonia Association of America
  - Mucopolysaccharidosis Type IV Foundation (ML4)
  - Narcicsepsy Network, Inc.
  - National Adrenal Diseases Foundation
  - National Alopecia Areata Foundation
  - National Ataxia Foundation
  - National Chronic Fatigue Syndrome and Fibromyalgia Association
  - National Foundation for Ectodermal Dysplasias
  - National Hemophilia Foundation
  - National Marfan Foundation
  - National Mucopolysaccharidoses Society, Inc.
  - National Multiple Sclerosis Society
  - National Neurofibromatosis Foundation
  - National PKU News
  - National Sjogren's Syndrome Association
  - National Spasmodic Torticollis Association
  - National Tay-Sachs & Allied Diseases Association, Inc.
  - National Tuberosclerosis Association, Inc.
  - National Urac Cyclic Disorders Foundation
  - Neurofibromatosis, Inc.
  - Obsessive Compulsive Foundation
  - Osteogenesis Imperfecta Foundation
  - Parkinson's Disease Foundation, Inc.
  - Prader-Willi Syndrome Association
  - Pulmonary Hypertension Association
  - PXE International, Inc.
  - Reflex Sympathetic Dystrophy Syndrome Association
  - Scleroderma Foundation, Inc.
  - Sickle Cell Disease Association of America, Inc.
  - Tourette Syndrome Association, Inc.
  - Trigeminal Neuralgia Association
  - United Leukodystrophy Foundation, Inc.
  - United Mitochondrial Disease Foundation
  - VHL Family Alliance
  - Wegener's Granulomatosis Support Group, Inc.
  - Williams Syndrome Association
  - Wilson's Disease Association

**Associate Members**

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| <ul style="list-style-type: none"> <li>And Metase Deficiency Association</li> <li>Acid Syndrome Newsletter, Inc.</li> <li>ALS Association/Greater Philadelphia Chapter</li> <li>American Autoimmune Related Diseases Association</li> <li>American BMCA's Disease Association, Inc.</li> <li>American Pseudo-obstruction &amp; Mesenteric Disease Society, Inc.</li> <li>American Self-Help Clinics/Institutes</li> <li>Amnegen Interservice Group</li> <li>Angel View-Crippled Children's Foundation</li> </ul> | <ul style="list-style-type: none"> <li>A-T Project</li> <li>Alaska Tetrahydroam Children's Project</li> <li>CDGS Family Network</li> <li>Canadian Organization for Rare Disorders</li> <li>Children's Hospital Medical Center, Akron, Ohio</li> <li>Children's Leukemia Foundation/Michigan</li> <li>Children's Medical Library</li> <li>Children's PKU Network</li> <li>Chromosome Deletion Outreach, Inc.</li> <li>Chronic Granulomatous Disease Association, Inc.</li> <li>Consortium of Multiple Sclerosis Centers</li> <li>Contact A Family</li> </ul> | <ul style="list-style-type: none"> <li>Conley's Anemia Foundation</li> <li>Cushing Support &amp; Research Foundation</li> <li>Earl Conberg Aplastic Anemia Foundation</li> <li>Family Caregiver Alliance</li> <li>Family Support System for North Carolina</li> <li>Fretzner-Shelton Parent Support Group</li> <li>Hydrocephalus Association</li> <li>International Foundation for Alternating Hemiplegia of Childhood</li> <li>JUMP Foundation</li> <li>Kippel-Tremburg Support Group</li> <li>Late Onset Tay-Sachs Foundation</li> <li>Late Onset ALS Foundation, Inc.</li> </ul> | <ul style="list-style-type: none"> <li>National Association for Pseudotumor Euphorium</li> <li>National Coalition for Research in Neurological &amp; Communicative Disorders</li> <li>National Cougher's Foundation</li> <li>National Lymphedema Network</li> <li>National Niemann-Pick Disease Foundation</li> <li>National Patient Air Transport Hotline</li> <li>National Spasmodic Dysphonia Association</li> <li>Organic Acidurias Association</li> <li>Osteoporosis and Related Bone Diseases National Resource Center</li> <li>Parents Available to Help (PATH)</li> </ul> | <ul style="list-style-type: none"> <li>Parent to Parent of Georgia, Inc.</li> <li>Parent to Parent of New Zealand</li> <li>Rare and Expensive Disease Management Program</li> <li>Recurrent Respiratory Papillomatous Foundation</li> <li>Research Trust for Metabolic Diseases in Children/United Kingdom</li> <li>Reelase Legs Syndrome Foundation</li> <li>Smock Networking Association</li> <li>Shwachman Syndrome Support Group</li> <li>Sickle Cell Disease Association of Texas Gulf Coast</li> </ul> | <ul style="list-style-type: none"> <li>Society For Progressive Supranuclear Palsy, Inc.</li> <li>Sturge-Weber Foundation</li> <li>Treacher Collins Foundation</li> <li>Vanderbilt Metabolic Lysosomal/Ferrous</li> </ul> <p>* Associations are joining continuously. For current listing, please contact the NORD office.</p> |
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Dedicated to Helping People with Orphan Diseases

The Honorable Q. Todd Dickinson

January 10, 2000

Page Two

Americans with genetic diseases, especially those represented by national health charities, are quite concerned that if one person or company patents the gene that causes their disease, other scientists and companies will not be allowed access to that gene without the patent holders permission (and payment of royalties). We are not scientists or attorneys; we are ordinary people concerned that our property (our genes) will be owned by others, and progress in biomedical research will be delayed or prevented. If one company patents a gene, other companies and/or scientists will be unable to study it and develop improved genetic tests or medicines. Nor will they be able to publish the results of their research if the patent holder does not allow them. However, scientific advancements are based on building bricks of knowledge, one placed on top of another, and gene patents will interfere with this essential process. This will have devastating consequences for humanity.

In general, consumers have no objection to the patenting of products that will be useful in the diagnosis or treatment of diseases, nor patenting of engineered genes that have been altered from nature's design. However, the proposed guidelines appear to allow patenting of genes and gene fragments of undisclosed, or partially disclosed, biological function. Patents will be permitted with a very broad scope on *theoretical* functions rather than requiring the patent seeker to actually *invent* a commercial product and prove its *utility*. Moreover, the guidelines put the burden of proof on the PTO to prove that a gene or sequence is not useful, rather than requiring the applicant to prove that there is a use for his/her discovery.

When we began reading the *Federal Register* notices, we were hoping that the government would raise the bar and make it more difficult for such patents to be issued. Unfortunately, this does not appear to be the case. Under the December 21 proposals, anyone who discovers a gene will be allowed to get a broad patent on the gene covering any number of possible applications, even though those uses may be unattainable and unproven. If the applicant wants a patent, the burden of proof should be on them to actually invent a marketable product and prove its utility. Patents should be awarded for tangible inventions, not discoveries of items that already exist in nature. Genes are discovered. Genetic tests are invented. Therefore, genetic tests should be patentable, but genes should not be patentable.

We would like the government to revise the utility standards reflected in the December, 1999 *Federal Register* notice, and raise the bar much higher before a person or company will qualify for genetic patents. We believe the public should be given a reasonable opportunity to debate gene patenting (in terms they can understand) with government officials before PTO finalizes the guidelines. The government should not set definitive public policy on this issue until you understand how strongly the public feels about ownership of human genes. Few will object to patenting of useful inventions; but genes are not inventions, and they should not be patented because the resulting monopolies will be harmful to society.

Very truly yours,



Abbey S. Meyers  
President

ASM:aa

cc: President William Clinton  
Dr. Francis Collins

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A/C FOR PATENTS