

September 8, 2015

The Honorable Chuck Grassley  
Chairman  
Senate Committee on the Judiciary  
224 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Patrick J. Leahy  
Ranking Member  
Senate Committee on the Judiciary  
224 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Bob Goodlatte  
Chairman  
House Committee on the Judiciary  
2138 Rayburn House Office Building  
Washington, DC 20510

The Honorable John Conyers  
Ranking Member  
House Committee on the Judiciary  
B-351 Rayburn House Office Building  
Washington, DC 20510

Dear Chairman Grassley, Ranking Member Leahy, Chairman Goodlatte, and Ranking Member Conyers:

Soon, Congress could vote on the Innovation Act (H.R. 9), legislation that would make reforms to our U.S. patent system. As organizations representing millions of patients across the country, we are concerned that, as currently written, H.R. 9 falls short of preserving important patent protections for the biopharmaceutical innovation our communities rely on to achieve a better quality of life. We commend the House Judiciary Committee for its work to combat the problem of patent trolls, but remain concerned that the bill does not address some forms of abuse in our patent system that, left unaddressed, could undermine the investments that sustain medical research into lifesaving treatments and cures.

At a time when we need to be incentivizing investment in innovative therapies, Congress is considering patent reform legislation that could make future advances in treating chronic and rare conditions all too rare. A strong and secure patent system that encourages investments in innovative treatments and devices is critical for the millions of Americans who are waiting for breakthrough therapies to help them live their lives to their fullest potential.

The Inter Partes Review (IPR) proceedings were intended to be a more efficient way to address patent challenges, but IPR opened the door to abuses that threaten the unique and specialized mechanisms under the Drug Price Competition and Patent Term Restoration Act (commonly referred to as the Hatch-Waxman Act) and the Biologics Price Competition and Innovation Act (BPCIA). Congress established these carefully-crafted patent dispute resolution frameworks to balance the interests of innovators, generic and biosimilar manufacturers, and, most importantly, the individuals waiting for a treatment or cure. This system generally works well. Many generic medications are entering the market while, at the same time, innovative R&D is delivering new treatments to patients. These trends are helping individuals with chronic and complex conditions live longer, healthier lives.

Developing new medical treatments can cost billions of dollars and take more than a decade of research and development. Both small and large research and development companies rely

heavily on the certainty of their patents to justify the significant long-term, risky investments needed to obtain approval from the U.S. Food and Drug Administration, often many years after a patent is granted. Current abuses in the IPR proceedings could ultimately undermine the ability to raise capital and recoup development costs needed to fund future research, leading to a chilling effect on the therapy development pipeline impacting the millions of Americans waiting for a new treatment or cure.

Congress never intended for the IPR proceedings to undermine the patent dispute resolution frameworks in Hatch-Waxman and BPCIA. We urge Congress to include language in H.R. 9 that would preserve the highly-detailed and sophisticated systems designed by Hatch-Waxman and BPCIA to avoid weakening the patents that sustain medical research. Strong patents will ensure that innovative ideas make it from the lab to the people who need them most.

In an environment where research funding is hard to secure and results take years to achieve, we urge Congress to ensure that we can rely on the patent system to protect the promise of future medical breakthroughs and fuel American innovation.

Sincerely,

Action CF

Addario Lung Cancer Foundation

AIDS Delaware, Inc.

Alabama Lifespan Respite Resource Network

Allergy & Asthma Network

Alliance for Patient Access

Alzheimer's Association

American Autoimmune Related Diseases Association

Asthma & Allergy Foundation of America, New England Chapter

Asthma and Allergy Foundation of America

Benign Essential Blepharospasm Research Foundation

Bladder Cancer Advocacy Network

Brain Injury Association of Nebraska

Bridge the Gap - SYNGAP Education and Research Foundation

California Hepatitis C Task Force

California Senior Advocates League

Caregiver Action Network

Chris4Life Colon Cancer Foundation

Community Health Charities of Nebraska

Cure SMA

Delaware HIV Consortium

Dystonia Medical Research Foundation

Elder Care Advocacy of Florida

Epilepsy California

Epilepsy Foundation

Epilepsy Foundation New England  
Epilepsy Foundation of Connecticut  
Epilepsy Foundation of Florida  
Epilepsy Foundation of Greater Chicago  
Epilepsy Foundation of Kentuckiana  
Epilepsy Foundation of Michigan  
Epilepsy Foundation of Mississippi  
Epilepsy Foundation of Nevada  
Epilepsy Foundation Heart of Wisconsin  
EveryLife Foundation for Rare Diseases  
Florida State Hispanic Chamber of Commerce  
Global Colon Cancer Association  
Global Genes  
Hannah's Hope Fund  
HEALS (Hepatitis Education Awareness & Liver Support) of the South  
HealthHIV  
Healthy Women  
Hepatitis Foundation International  
ICAN, International Cancer Advocacy Network  
Immune Deficiency Foundation  
International Essential Tremor Foundation  
International Foundation for Autoimmune Arthritis  
Kentucky and S. Indiana Stroke Association  
Kidney Cancer Association  
Lupus and Allied Diseases Association, Inc.  
Lupus Foundation of America  
Lupus Foundation of Florida  
Lupus Foundation of Northern California  
Lupus Foundation of Southern California  
Massachusetts Association For Mental Health, Inc.  
Men's Health Network  
Mental Health America of Indiana  
Michigan Lupus Foundation  
Minnesota State Grange  
MLD Foundation  
NAMI Alabama  
NAMI Greater Des Moines  
NAMI Indiana  
Nashville CARES  
National Alliance on Mental Illness  
National Association of Hepatitis Task Forces  
National Association of Social Workers, NC Chapter  
National Council for Behavioral Health

National Grange  
National Hispanic Council on Aging  
National Minority Quality Forum  
National MS Society  
National Prostate Cancer Awareness Foundation  
National Psoriasis Foundation  
Neurofibromatosis, Inc. Mid-Atlantic  
New England Community for Cancer Survivorship  
New Jersey Association of Mental Health and Addiction Agencies, Inc.  
Ovarian Cancer National Alliance  
Parent Project Muscular Dystrophy  
Parkinson's Action Network  
Prevent Cancer Foundation  
Rare and Undiagnosed Network (RUN)  
RetireSafe  
Rio Grande Valley Diabetes Association  
Rocky Mountain Stroke Center  
Rush to Live  
Rx Partnership  
Salud USA  
Solidarity Project Access Network  
St. Baldrick's Foundation  
ST/Dystonia, Inc.  
Texas Nurse Practitioners  
The AIDS Institute  
The ALS Association  
The Playing For Life Foundation  
Tuberous Sclerosis Alliance  
United Spinal Association  
US Pain Foundation, Inc.  
Veterans Health Council  
Vietnam Veterans of America  
Wellness and Education Community Action Health Network  
ZERO - The End of Prostate Cancer

cc: Speaker of the House John Boehner  
House Minority Leader Nancy Pelosi  
Members, House Committee on the Judiciary  
Members, House Energy and Commerce Committee  
Senate Majority Leader Mitch McConnell  
Senate Minority Leader Harry Reid  
Members, Senate Committee on the Judiciary  
Members, Senate Committee on Health Education, Labor and Pensions