

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