

**To: California Congressional Delegation**  
**Re: Legislation to Alter Patent Litigation**  
**Date: April 27, 2015**

The more than 100 undersigned medical device, diagnostic, biotechnology and pharmaceutical companies, research universities and private, non-profit institutes, and venture capital firms are writing today to voice our serious concerns with H.R. 9, the so-called *Innovation Act*, and to respectfully urge that you oppose any effort to bring this measure to the floor in its current form.

California leads the world in life sciences research and development, which has led to groundbreaking therapies and technologies to diagnose, treat and prevent conditions such as cancer, cardiovascular disease, diabetes, HIV/AIDS, chronic pain, Alzheimer's Disease, Parkinson's Disease, and others. Moreover, the sector is an increasingly important component of our state's economic engine, employing nearly 270,300 people, paying \$27.4 billion in wages and accounting for \$22.2 billion in exports annually.

Life sciences research is an extremely expensive and lengthy endeavor, and attracting investment into companies developing the next generation of treatments, therapies, and technologies depends on a strong, reliable patent system. The biomedical industry in California consists mainly of relatively small, entrepreneurial, and venture capital-backed firms that have yet to bring products to market. For these companies, intellectual property (IP) is typically their most valuable, and sometimes only, asset.

Unfortunately, H.R. 9 contains patent litigation-related provisions that would threaten the ability of biomedical innovators to enforce their patents and fund continued R&D by inadvertently making it more difficult, time-consuming and expensive to enforce legitimate and important IP rights. Of particular concern are the **mandatory presumptive stays of discovery** in patent infringement cases; **enhanced pleading requirements** for patent infringement cases, mandating the inclusion of highly specific information, much of which is not within the ability of patent owners to know at the outset of litigation; effectively **mandatory fee shifting** for most patent litigation; and a **joinder provision** under which "interested" parties such as universities, inventors, investors, or companies could be joined in litigation as unwilling co-plaintiffs, exposing them to the cost of the defendant's attorney fees and other litigation expenses.

Further, H.R. 9 does not accurately reflect the current state of patent litigation in the United States – the legislative text has remained largely unchanged since it was introduced in the 113th Congress (H.R. 3309), despite the changed patent litigation landscape as a result of the implementation of the *America Invents Act* (AIA), recent Supreme Court cases, and key administrative changes at the US Patent and Trademark Office (PTO). At a minimum, the key provisions of the *Innovation Act* that are no longer necessary or relevant should be reconsidered to represent the developments that have occurred in the past year.

While a provision in H.R. 9 would require that the PTO use in **post-grant and inter partes review proceedings** the same claim construction standard as is used in district court – a positive change that must be retained – we continue to have substantial concerns with how post-grant and *inter partes* review proceedings have been implemented in practice. H.R. 9 does not go nearly far enough to fix the problems we now see with *inter partes* review. The procedures adopted by the PTO, institution rates, and very high patent invalidation or "kill rates" strongly support the conclusion that the proceedings are not fair to patent owners and create serious due process issues. Recent activity in which even hedge funds with no commercial interest in the patent or field to which the patent pertains have filed petitions concerning pharmaceutical patents to take advantage of such anti-patent bias raises serious concerns that should be addressed as part of any patent reform efforts.

We appreciate that there is a strong interest in addressing abusive patent litigation practices by "patent trolls," but prolonging, complicating and increasing the cost of patent litigation for patent owners across all technology areas - as we believe H.R. 9 would do - is not the right solution. We are supportive of provisions such as included in S. 632,

the *STRONG Patents Act*, which would curb abusive patent litigation practices while maintaining and strengthening important patent-holder rights and protections by proposing balanced reforms focused on cracking down on deceptive demand letters, eliminating diversion of PTO user fees, and clarifying PTO post-grant review processes. We are also supportive of the actions recently taken by the Judicial Conference of the United States to curb the litigation abuses most often faced by “patent troll” lawsuit defendants.

We believe patent litigation legislation must represent the full spectrum of different industries and sectors reliant on a well-functioning U.S. patent system and the enforcement mechanisms it provides, including California’s innovative biomedical R&D community. Unfortunately, the *Innovation Act* falls short of this goal.

Thank you for your consideration of our views, and we look forward to working with you to enact patent litigation legislation that is more supportive of the life sciences innovation ecosystem in our state. Should you have any questions or would like to speak with us on this issue in greater detail, please contact Todd Gillenwater, Executive Vice President–Advocacy and External Relations at California Healthcare Institute–CHI at [gillenwater@chi.org](mailto:gillenwater@chi.org) or (202) 974-6313.

Sincerely,

1R2 Diagnostics  
Moraga

Ardelyx, Inc.  
Fremont

AbbVie  
Redwood City

Arena Pharmaceuticals  
San Diego

Adamas Pharmaceuticals  
Emeryville

Armetheon, Inc.  
Santa Clara

Advanced Technology Ventures  
Menlo Park

Astellas Pharma US, Inc.  
Santa Monica

Align Technology, Inc.  
San Jose

Axiom Medical, Inc.  
Torrance

Alta Partners  
San Francisco

Bavarian Nordic, Inc.  
Mountain View

AltraVax, Inc.  
Sunnyvale

Bell Biosystems, Inc.  
San Francisco

Amgen, Inc.  
Thousand Oaks, South San Francisco

Biogen

Anvil Biosciences  
Hayward

Bullet Biotechnology  
Menlo Park

Aptus Endosystems  
Sunnyvale

Cairn Biosciences  
San Francisco

Arboretum Ventures  
Sunnyvale, Goleta, Santa Clara  
Irvine, Solana Beach, San Mateo, Tustin

Calithera Biosciences  
South San Francisco

Canaan Partners  
Menlo Park

CardiAQ Valve Technologies, Inc.  
Irvine

CareDx  
Brisbane

Cedars-Sinai Medical Center  
Los Angeles

Celgene Corporation  
San Diego, San Francisco

Cellerant Therapeutics, Inc.  
San Carlos

Cepheid, Inc.  
Sunnyvale

Cleave Biosciences  
Burlingame

Cybelle Biosciences  
San Francisco

CymaBay Therapeutics  
Newark

Delpor, Inc.  
San Francisco

DeviceFarm  
Newark

Domain Associates, LLC  
San Diego

DTOR, Inc.  
Sacramento

Direct Corporation  
Cupertino, Vacaville

Dynatronics Corporation  
Livermore

EpiBiome  
Union City

Excel Biopharm LLC  
San Francisco

ExploraMed Development, LLC  
Mountain View

Exthera Medical Corporation  
Berkeley

Farsight Genome Systems, Inc.  
Sunnyvale

Foresight Capital Management  
San Francisco

ForSight Labs  
Menlo Park

Genzyme Corporation

GlaxoSmithKline

Ground Zero Pharmaceuticals, Inc.  
Irvine

H4Y Corporation  
Santa Clarita

Innovation Pathways  
Palo Alto

InterWest Partners  
Menlo Park

ISIS Pharmaceuticals, Inc.  
Carlsbad

Jazz Pharmaceuticals, Inc.  
Palo Alto

Lightstone Ventures  
Menlo Park

Manzanita Pharmaceuticals  
Woodside

MicroCube LLC  
Fremont

Molecular Assemblies, Inc.  
San Diego

Morgenthaler Ventures  
Menlo Park

Moximed, Inc.  
Hayward

NeoTract, Inc.  
Pleasanton

NeuroPace, Inc.  
Mountain View

NeuroSave, Inc.  
San Francisco

New Enterprise Associates  
Menlo Park

New Leaf Venture Partners  
San Mateo

Nodality, Inc.  
South San Francisco

NuVasive, Inc.  
San Diego

Olema Pharmaceuticals, Inc.  
San Francisco

Oligasis  
Palo Alto

OncoMed Pharmaceuticals  
Redwood City

Organogenesis, Inc.  
La Jolla

Patient Precision  
Woodside

PaxVax  
Menlo Park

Protelica, Inc.  
Hayward

Regulus Therapeutics Inc.  
San Diego

ResMed, Inc.  
San Diego, Moreno Valley, Chatsworth

Revance Therapeutics, Inc.  
Newark

Rho Capital Partners  
Palo Alto

Rox Medical, Inc.  
San Clemente

Santé Ventures  
Goleta, La Jolla, San Francisco, Santa Rosa

Shire  
San Diego

Simplify Medical Pty Limited  
Mountain View

Sofinnova Ventures  
Menlo Park

SoundCure  
San Jose

SRI International  
Menlo Park, Fremont, Hat Creek, Huntington Beach,  
San Diego, San Luis Obispo

Sunesis Pharmaceuticals, Inc.  
South San Francisco

Sunovion Pharmaceuticals

Sutro Biopharma, Inc.  
South San Francisco

Symic Biomedical  
San Francisco

Takeda Pharmaceuticals America, Inc.

Target Discovery, Inc.  
Palo Alto

The Foundry, LLC  
Menlo Park

The Scripps Research Institute  
La Jolla

TheraBiol, Inc.  
San Francisco

TheraNova, LLC  
Redwood City

Theravance Biopharma  
South San Francisco

Topica Pharmaceuticals  
Los Altos

University of Southern California  
Los Angeles

Vanguard Therapeutics  
Half Moon Bay

Versant Ventures  
San Francisco

Vertex Pharmaceuticals  
San Diego

Vital Therapies, Inc.  
San Diego

Whole Biome, Inc.  
San Francisco

Xalud Therapeutics, Inc.  
San Francisco