

Legislation Alert

To: California Congressional Delegation
Re: H.R. 3309 – The Innovation Act

The California Healthcare Institute (CHI), the public policy association representing California's statewide life sciences sector – biotechnology, pharmaceutical, medical device and diagnostics companies, universities and private research institutions, and venture capital firms – is writing to voice our concerns with recently introduced patent reform legislation (H.R. 3309, The Innovation Act) and to respectfully request that you withhold your support of the measure as introduced.

California's more than 2,300 biomedical companies and institutions, clustered throughout the state, lead 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, Parkinson's Disease, and others. Just as important, the sector is an increasingly important component of our state's economic engine, employing nearly 270,000 people, paying \$15.5 billion in wages and accounting for \$20 billion in exports annually.

Life sciences research is extremely expensive, 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 – sometimes only – asset. Thus, the ability to rely on patents once they are issued and enforce those patents is a top priority for California's research universities, institutes and biomedical companies large and small.

This was the case leading up to enactment of the 2011 Leahy-Smith America Invents Act (AIA) where early proposals and provisions that would have dramatically weakened patent certainty and enforcement throughout the life of a patent were, following years of debate and deliberation, ultimately rejected for a package that better reflected the composition of sectors, including California's innovative biomedical R&D community, that heavily rely and depend on the U.S. patent system and the enforcement mechanisms it provides.

And this is the case today with H.R. 3309 which, while not as comprehensive as the AIA, 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.

For example, provisions of H.R. 3309 would routinely defer or suspend discovery and litigation on the merits in patent infringement cases and require unreasonable amounts of disclosure and public recordation of patent ownership, litigation interests, and other business or confidential

information. The bill would also repeal 35 U.S. Code Section 145, which allows patent holders to appeal decisions about a patent by the U.S. Patent and Trademark Office (USPTO) to U.S. District Court where, for example, new evidence can be entered in to the patent application file to further the issuance of valid enforceable patents; this is an important safeguard that should be retained. With regards to the measure's fee shifting provisions, given the U.S. Supreme Court's announced review of the issue, we believe it is premature for Congress to act legislatively.

Particularly problematic, H.R. 3309 would make permanent and expand the purview of Section 18 of the AIA pertaining to the USPTO's "Covered Business Method Patent" program (CBMP program). AIA's CBMP program established transitional post-grant review proceedings for "covered business method patents" allowing the USPTO to review a patent again after its grant or reissuance, in order to determine its validity. A CBMP is a patent that relates to a "financial product or service." Unlike regular post-grant review proceedings, which require that a proceeding must be requested no later than nine months from a patent's grant date or reissuance date, a request for a CBMP proceeding can be made at any time until September 16, 2020 – the date the transitional program is scheduled to sunset. During congressional consideration of the AIA, proponents of Section 18 argued that it was a necessary and temporary measure to review a very narrow class of financial-services-related patents.

However, H.R. 3309 proposes to remove the sunset for transitional proceedings under Section 18, and to codify an expansive definition of "covered business method patent" that was established in an administrative decision of the USPTO's Patent Trial and Appeal Board. By some accounts, the USPTO's administrative interpretation sweeps in an unexpectedly broad range of patents, such as patents for data processing software and other technologies that aren't limited to financial services. This administrative patent decision has not yet undergone judicial review, and no court has had an opportunity to construe the scope of Section 18 of the AIA. Legislation on the matter would therefore be premature. To hastily codify an ambiguous administrative decision would invite unnecessary litigation over the applicability of the CBM proceeding to innovative patent holders outside the financial services sector.

The end result is additional patent-related uncertainty and risk in the already high-risk, high-expense, high-uncertainty field of biopharmaceutical and medical technology product research and development. Therefore, while other provisions of H.R. 3309 (such as changing the USPTO's broadest reasonable interpretation in claim construction) would complement and strengthen reforms enacted under the AIA, due to provisions including but not limited to those outlined above, CHI cannot offer its endorsement and we would respectfully urge you to refrain from co-sponsoring or supporting the bill at this time.

Thank you for your consideration of our views.