

**Congress of the United States**  
**Washington, DC 20515**

July 24, 2015

The Honorable John Boehner  
Speaker  
U.S. House of Representatives  
H-232 The Capitol  
Washington, D.C. 20515

The Honorable Nancy Pelosi  
Minority Leader  
U.S. House of Representatives  
H-204 The Capitol  
Washington, D.C. 20515

The Honorable Kevin McCarthy  
Majority Leader  
U.S. House of Representatives  
H-107, The Capitol  
Washington, D.C. 20515

The Honorable Steny Honyer  
Minority Whip  
U.S. House of Representatives  
H-148, The Capitol  
Washington, D.C. 20515

Dear Speaker Boehner, Majority Leader McCarthy, Minority Leader Pelosi, and Minority Whip Hoyer:

The House Judiciary Committee recently approved H.R. 9, the Innovation Act, and we understand that the bill's sponsors would like to have the legislation considered on the House floor in the coming weeks. We support the original objective of the legislation, and we commend Chairman Goodlatte for attempting to combat so-called patent trolls in our system. At the same time, however, any patent litigation legislation must represent the views of the full spectrum of different industries and sectors reliant on a well-functioning U.S. patent system. Accordingly, before H.R. 9 is brought to the floor, we believe that, in addition to the current changes to the inter partes review (IPR) system contained in the bill and several other changes that have been requested by the life sciences community, language should also be included to preserve the integrity of the Drug Price Competition and Patent Term Restoration Act (commonly known as Hatch-Waxman), and the Biologics Price Competition and Innovation Act (BPCIA). Congress established Hatch-Waxman and BPCIA to strike a balance between access to lower cost versions of medicines and preserving incentives for continued innovation. This unique patent litigation system has been working for decades. However, the patent challenge system created under the America Invents Act, specifically the IPR system, threatens to undermine these specialized patent resolution frameworks in a way that was not intended when Congress created it.

Patents are critically important for developing FDA-approved biopharmaceutical products. Unlike companies in other sectors, biopharmaceutical companies are not able to immediately capitalize on the value of their patents. Instead, they must spend almost a decade and, on average, \$2.6 billion, before they can receive approval from the FDA to bring new medicines to market. In recognition of these unique circumstances, Congress established separate patent dispute resolution frameworks for approved drugs and biologics. Hatch-Waxman and BPCIA are designed, among other things, to create an incentive for generic and biosimilar competition, while balancing the need to preserve incentives for innovation.

Hatch-Waxman has had a profound impact on the prescription drug market since its inception 30 years ago. Today, 88 percent of prescriptions filled in the U.S. are for generics – up from just 19 percent before the law’s enactment – and the use of generics generated nearly \$1.5 trillion in savings to the U.S. health care system from 2004-2013. At the same time, investment in research and development (R&D) is at an all-time high and there were a record number of new medicines approved by the FDA in 2014, allowing patients to live longer healthier lives. The IPR process, as implemented by the Patent and Trademark Office (PTO), must not be allowed to upset this delicate balance.

Fortunately, Congress has a chance to address this concern, by including language in H.R. 9 to make clear that the IPR process does not apply to biopharmaceutical patents that are subject to challenge under Hatch-Waxman and BPCIA. Doing so would build on language in the underlying bill, which already exempts Hatch-Waxman and BPCIA challenges from changes the bill makes to certain patent litigation proceedings. Including this language would protect the delicate balance Congress struck in Hatch-Waxman and BPCIA while in no way harming the intent behind the IPR process. We should address this issue, which is crucial to maintaining the substantial R&D investments needed to develop new treatments and cures for U.S. patients, before the bill comes to the House floor.

We look forward to working with you and with Chairman Goodlatte to address this issue before H.R. 9 is considered.

Sincerely,



RYAN COSTELLO  
Member of Congress



SCOTT PETERS  
Member of Congress



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Member of Congress



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Member of Congress



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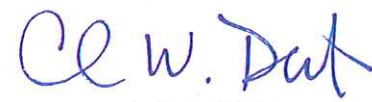
  
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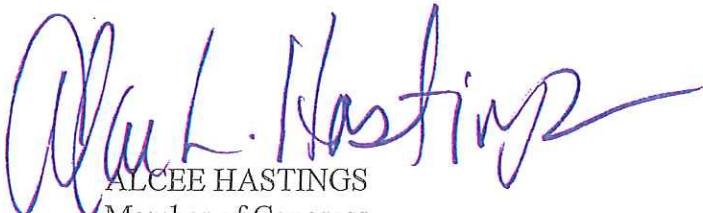
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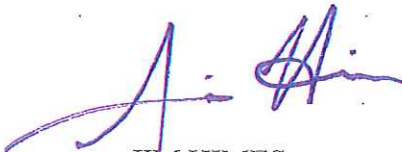
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RYAN ZINKE  
Member of Congress

cc: The Honorable Robert Goodlatte, Chairman, House Committee on the Judiciary  
cc: The Honorable John Conyers, Jr., Ranking Member, House Committee on the Judiciary