July 8, 2015

The Honorable Charles Grassley
Chairman
Senate Judiciary Committee
Washington, D.C. 20510

The Honorable Patrick Leahy
Ranking Member
Senate Judiciary Committee
Washington, D.C. 20510

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

On behalf of the Generic Pharmaceutical Association (GPhA), I am writing to express our concerns with efforts to impede timely patient access to affordable medicines by limiting the current ability of generic and biosimilar manufacturers to utilize the Inter Partes Review (IPR) process to challenge patents. GPhA opposes any amendments to patent reform legislation that would carve out pharmaceutical patents from the IPR process.

Generic drugs have saved the U.S. health care system nearly $1.5 trillion over the past 10 years, including $239 billion in savings in 2013 alone. A 2014 study conduct by RAND Corporation found that biosimilars will lead to a $44.2 billion reduction in spending on biologics over the next decade.

The America Invents Act (AIA) introduced the IPR process to quickly and cost-effectively weed out weak patents. The purpose behind this particular aspect of the AIA is closely aligned with the legislative purposes behind the Hatch-Waxman Act and the Biologic Price Competition and Innovation Act (BPCIA) – increasing competition by encouraging challenges to weak patents and expediting generic drug and biosimilar market entry.

GPhA supports the Committees’ efforts to address abuse of the court system by patent trolls. Prior to passage of the AIA, trolling was not a major concern of the pharmaceutical industry. It is clear that one of the unintended consequences has been the involvement of non-pharmaceutical manufacturer entities in the challenging of patents for the purposes of affecting stock prices or seeking millions of dollars from settlements. However, the proposed carve out of pharmaceutical patents goes beyond what is reasonably needed to address abusive tactics.

Eliminating the ability of those intending to bring affordable medicines to market from using the IPR process to cull weak branded drug patents would be counter to the purpose of the IPR. A pharmaceutical exemption or carve out would unfairly shield only one industry from challenges at the PTO. The statutory deadlines attendant to the IPR proceedings further accelerate the timeframe for disposing of weak patents and securing final approval of generics and biosimilars.

GPhA
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The Honorable Robert Goodlatte
Chairman
House Judiciary Committee
Washington, D.C. 20515

The Honorable John Conyers
Ranking Member
House Judiciary Committee
Washington, D.C. 20515
Generic manufacturers can more effectively bring products to the market by being able to utilize both district court litigation and IPR proceedings, since brand drugs usually have multiple patents listed as covering a product in the Orange Book.

The Purple Book does not list which patents cover biologic products, but biosimilar manufacturers can use a patent identification process established by the BPCIA. Biosimilar manufacturers may not be able to determine what patents the reference product sponsor believes covers its product until years after the initial investment, during the “patent dance” that occurs only after an application has been filed. Biosimilar applicants can use the IPR process at the PTO to obtain patent information earlier, which is vital since the investment needed to develop a biosimilar can be as much as $300 million. Preserving access to the IPR process for biosimilar manufacturers will help increase competition and patient access to lower-cost medicines.

Thank you for your leadership and tireless work on this important issue. We look forward to continuing to work with you as the process moves forward.

Sincerely,

Ralph G. Neas
President and CEO

cc:

The Honorable Lamar Alexander, Chairman, Senate HELP Committee
The Honorable Patty Murray, Ranking Member, Senate HELP Committee
The Honorable Fred Upton, Chairman, House Energy and Commerce Committee
The Honorable Frank Pallone, Jr., Ranking Member, House Energy and Commerce Committee