July 9, 2015

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

The Honorable Robert Goodlatte
Chairman
House Judiciary Committee
2138 Rayburn Building
Washington, D.C. 20515

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

The Honorable John Conyers
Ranking Member
House Judiciary Committee
B-351 Rayburn Building
Washington, D.C. 20515

Dear Chairmen Grassley and Goodlatte and Ranking Members Leahy and Conyers:

As organizations representing consumers, health insurance plans, and pharmacy benefits managers, we write to express our strong support for your efforts through the bipartisan Protecting American Talent and Entrepreneurship (PATENT) Act of 2015 to address abuses in the patent system that unnecessarily drive up the cost of health care.

However, we are seriously concerned with efforts to modify the PATENT Act by including a special carve-out for brand name drug manufacturers from the inter partes review (IPR) process before the U.S. Patent and Trademark Office. The IPR process—implemented in 2012 under the America Invents Act (AIA)—is intended to improve the patent system by creating an expedited, less expensive alternative to challenging weak patents through the courts. It is a critical consumer protection against abusive patent extensions that limit patient access to more affordable treatment options, delay market entry of less expensive generic therapies, and drive up drug costs. Simply, exempting branded drug manufacturers from the IPR process is unwarranted and harmful to consumers. To that end, **we strongly oppose any exemption from the IPR process for drug and biologic patents.**

We are particularly concerned that such an exemption would provide little protection against a widely-used practice known as "evergreening" where manufacturers make minor modifications to existing products in order to extend patent protection for years. Evergreening results in substantial additional spending on prescription drugs that do not measurably improve quality of care. Exempting drug patents from the IPR process would make it easier for manufacturers to engage in this behavior. As a result, consumers, payers, and public programs like Medicare and Medicaid will face even higher drug costs at a time when such spending is already unsustainable.[1],[2]

[1] Kaiser Health Tracking Poll, "The Public Says Prescription Drug Prices Are Unreasonable," June 16, 2015, http://kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-june-2015/
[2] Morning Consult Polling, "Sponsored Poll from the Campaign for the Sustainable Rx Pricing: High Prescription Drug Costs a Major Concern for Voters," June 23, 2015, http://morningconsult.com/polls/sponsored-poll-from-the-campaign-for-the-sustainable-rx-pricing-high-prescription-drug-costs-a-major-concern-for-voters/

While manufacturers claim the IPR process makes invalidating drug patents too easy, the data show that IPR challenges to pharmaceutical patents represent a small fraction of the challenges submitted to the PTO. Consequently, it is premature to make drastic changes to IPRs until more data are available to truly evaluate how the process is working. Further, every indication is that IPR process works in harmony—not in conflict—with the goals of Hatch-Waxman. It encourages challenges to weak patents to expedite generic drug entry to the benefit of the U.S. healthcare system. When it comes to price, there is a significant difference between generic and brand name drugs. On average, generic drug prices are 80 to 85 percent lower than comparable branded drug prices.[3] Overall, generic drugs have saved the U.S. health care system nearly $1.5 trillion over the past 10 years.[4]

IPR challenges will also become increasingly important to encourage the development of the emerging biosimilar market. The IPR process should accelerate the availability of these lower cost therapies. The Biologics Price Competition and Innovation Act (BPCIA) already provides for 12 years of statutory market exclusivity for new biologics from the date of FDA approval. Reference biologics are often covered by hundreds of patents, which could lead to significant extensions of exclusivity well beyond the statutory period. Biosimilar developers have no simple way to determine what patents are covered, but the IPR process offers a path to legal certainty earlier in the biosimilar development cycle.

As you know, the daily costs associated with biologics are enormously higher—approximately 22 times higher—than those for small-molecule drugs.[5] With annual or treatment regimen costs that can exceed $400,000[6], the cost of biologics adversely affects consumers, health plans, PBMs, and taxpayers. Studies suggest that the price savings from biosimilars could be 10 to 50 percent versus branded biologics. Given the focus by manufacturers on biologics, IPR challenges may be critical to realizing future biosimilar savings.

In sum, we believe that the IPR process is largely working as intended by providing a more cost-effective avenue to challenge weak patents that extend monopolies for high cost prescription drugs. As such, we oppose any exemption from the IPR process for brand name drug manufacturers. In addition, we ask the Committee to fully consider the implications of any such exemption in terms of increased spending for payers, including Medicare and Medicaid, and higher prices for consumers. It would be unfortunate if this issue was to impede progress of the larger patent reform effort.

Thank you for considering our views on this important issue that will have an impact on consumers, taxpayers and the entire U.S. healthcare system.

Sincerely,

Joyce A. Rogers
Senior Vice President, Government Affairs, AARP

Matthew D. Eyles

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[3] Facts about Generic Drugs, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm

[4] Generic Pharmaceutical Association, Generic Drug Savings in the U.S, Sixth Annual Edition: 2014, http://www.gphaonline.org/media/cms/GPhA_Savings_Report.9.10.14_FINAL.pdf

[5] A.D. So and S.L. Katz, "Biologics Boondoggle." New York Times, March 7, 2010.

[6] M. Herper, "The World's Most Expensive Drugs," Forbes, February 22, 2010.

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Kristin Bass
Senior Vice President, Policy and Federal Affairs, PCMA

cc: All House and Senate Judiciary Committee Members

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