



May 3, 2011

The Honorable Lamar Smith
Chairman
Committee on Judiciary
U.S. House of Representatives
Washington, D.C. 20515

The Honorable John Conyers, Jr.
Ranking Member
Committee on Judiciary
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Smith and Ranking Member Conyers:

On behalf of the Generic Pharmaceutical Association (GPhA), I am writing to express our continued strong opposition to the supplemental examination provision included in H.R. 1249, the America Invents Act. We are also concerned with the amendment adopted during the Committee's consideration of H.R. 1249 that retroactively changes the calculation of the time period to apply for patent term extensions, a retroactive fix that benefits one company. These two anti-consumer policies are significant in the context of pharmaceutical patents and will have a negative impact on access to affordable medicine. As a result we have no choice but to oppose floor consideration of the bill until these provisions are stricken or improved to ensure that the process cannot be used by dishonest actors.

The supplemental examination provision could reward patent holders that knowingly falsify information in their original patent application with the U.S. Patent and Trademark Office (PTO) or intentionally omit material information in such filings, by giving them a second chance to correct their filing without any meaningful consequences for dishonesty. This procedure threatens consumer access to affordable medicines and will fundamentally undermine the integrity of the patent system.

The committee adopted an amendment offered by Representative Goodlatte that would prohibit supplemental examination of a patent, and would suspend such an examination by the PTO, if fraud had been practiced or attempted. While we appreciate the Committee's recognition that supplemental examination should not be available to patent holders who have committed fraud, unfortunately the amendment fails to address the flawed provision in a manner that ensures a fair and honest process.

The amendment tasks PTO, which was unable to identify the original misrepresentation, with identifying deceptive conduct in a supplemental examination. Furthermore, the amendment does not give the PTO any new authorities to carry out its new mission. We are concerned that the PTO does not have the tools to uncover fraud, making it difficult to live up to the Committee's intent with the amendment. This uncertain process stands in marked contrast to the standard under current law that appropriately renders a patent unenforceable if the patent applicant knowingly lies to the PTO.

GPhA also opposes the amendment adopted by the committee modifying the calculation of the 60-day period to apply for patent term extension and applying that new definition to ongoing litigation. We are deeply concerned about the precedent of changing the rules of the patent extension process retroactively, which appears to benefit only one company – The Medicines Company. The rules and regulations that govern patents and exclusivities pertaining to both generic and brand drugs are important public policy. While it is Congress's prerogative to change or clarify statutory filing deadlines, we strongly urge you to do so in a manner that does not benefit one company's litigating position. GPhA urges you to strike the provision, or to amend it so that it does not apply to ongoing litigation.

GPhA would appreciate the opportunity to work with the Committee to make these changes before H.R. 1249 is brought to the House floor. Without further modifications, our industry stands in opposition to floor consideration of this bill and the manner in which it will undermine consumer access to affordable medicines.

Sincerely,

A handwritten signature in cursive script that reads "Robert Billings". The signature is written in black ink and is positioned to the right of the typed name.

Robert Billings
Executive Director