AMENDMENT NO._________ Calendar No.______

Purpose: To prohibit inter partes review for certain patents.

IN THE SENATE OF THE UNITED STATES—114th Cong., 1st Sess.

S.1137

To amend title 35, United States Code, and the Leahy-Smith America Invents Act to make improvements and technical corrections, and for other purposes.

Referred to the Committee on ____________________ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. TILLIS

Viz:

On page 46, between lines 12 and 13, insert the following:

(D) by adding at the end the following:

“(f) DRUG OR BIOLOGICAL PRODUCT PATENTS.—An inter partes review shall not be instituted or maintained for a patent that claims a drug or biological product, method of use, or method of manufacturing a drug or biological product approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262), including any patent listed in the Food and Drug Administration publication Approved Drug Products with Thera-
1. The petition owner is required to submit timely evidence of bioequivalence or identify a bioequivalence evaluation submitted to the patent owner in a certification in its response to the petition.”