AMENDMENT TO H.R. 965

OFFERED BY M__. _____

At the end of the bill, add the following new section:

SEC. 5. DUPLICATIVE PROCEEDINGS AS A RESULT OF INTER PARTES REVIEW.

(a) BRAND NAME DRUGS.—Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2)) is amended—

(1) in subparagraph (A)(iv), by striking ''and'' at the end;

(2) in subparagraph (B), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(C) in each certification required under subparagraph (A) with respect to a patent, a certification that—

''(i) neither the applicant nor any party in privity with, related to, or cooperating with the applicant has filed, or will file, a petition to institute inter partes review or post-grant review of that patent under chapter 31 or 32, respectively, of title 35, United States Code; and

''(ii) in making the certification required under subparagraph (A), the applicant is not relying in whole or in part on any decision issued by the Patent Trial and Appeal Board in an inter partes review or post-grant review under chapter 31 or 32, respectively, of title 35, United States Code.''.

(b) GENERIC DRUGS.—Section 505(j)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(A)) is amended—

(1) in clause (vii)(IV), by striking ''and'' at the end;

(2) in clause (viii), by striking the period at the end and inserting ''; and'';

(3) by inserting after clause (viii), as amended by paragraph (2), the following:

''(ix) in each certification required under clause (vii) with respect to a patent, a certification that—

''(I) neither the applicant nor any party in privity with, related to, or cooperating with the applicant has filed, or will file, a petition to institute inter partes review or post-grant re-

view of that patent under chapter 31 or 32, respectively, of title 35, United States Code; and

''(II) in making the certification required under clause (vii), the applicant is not relying in whole or in part on any decision issued by the Patent Trial and Appeal Board in an inter partes review or post-grant review under chapter 31 or 32, respectively, of title 35, United States Code.''; and

(4) in the flush text following clause (ix), as added by paragraph (3), by striking ''(viii)'' and inserting ''(ix)''.

☒