AMENDMENT TO H.R. 965

Offered by M_.

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

1	SEC. 5. DUPLICATIVE PROCEEDINGS AS A RESULT OF
2	INTER PARTES REVIEW.
3	(a) Brand Name Drugs.—Section 505(b)(2) of the
4	Federal Food, Drug, and Cosmetic Act (21 U.S.C.
5	355(b)(2)) is amended—
6	(1) in subparagraph (A)(iv), by striking "and"
7	at the end;
8	(2) in subparagraph (B), by striking the period
9	at the end and inserting "; and"; and
10	(3) by adding at the end the following:
11	"(C) in each certification required under
12	subparagraph (A) with respect to a patent, a
13	certification that—
14	"(i) neither the applicant nor any
15	party in privity with, related to, or cooper-
16	ating with the applicant has filed, or will
17	file, a petition to institute inter partes re-
18	view or post-grant review of that patent
19	under chapter 31 or 32, respectively, of
20	title 35, United States Code; and

1	"(ii) in making the certification re-
2	quired under subparagraph (A), the appli-
3	cant is not relying in whole or in part on
4	any decision issued by the Patent Trial
5	and Appeal Board in an inter partes re-
6	view or post-grant review under chapter 31
7	or 32, respectively, of title 35, United
8	States Code.".
9	(b) Generic Drugs.—Section 505(j)(2)(A) of the
10	Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11	355(j)(2)(A)) is amended—
12	(1) in clause (vii)(IV), by striking "and" at the
13	end;
14	(2) in clause (viii), by striking the period at the
15	end and inserting "; and";
16	(3) by inserting after clause (viii), as amended
17	by paragraph (2), the following:
18	"(ix) in each certification required
19	under clause (vii) with respect to a patent,
20	a certification that—
21	"(I) neither the applicant nor
22	any party in privity with, related to,
23	or cooperating with the applicant has
24	filed, or will file, a petition to institute
25	inter partes review or post-grant re-

1	view of that patent under chapter 31
2	or 32, respectively, of title 35, United
3	States Code; and
4	"(II) in making the certification
5	required under clause (vii), the appli-
6	cant is not relying in whole or in part
7	on any decision issued by the Patent
8	Trial and Appeal Board in an inter
9	partes review or post-grant review
10	under chapter 31 or 32, respectively,
11	of title 35, United States Code."; and
12	(4) in the flush text following clause (ix), as
13	added by paragraph (3), by striking "(viii)" and in-
14	serting "(ix)".

