

**ROLL CALL
ATTENDANCE/QUORUM CALL
111th CONGRESS
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON COMMERCE, TRADE, AND CONSUMER PROTECTION**

Subject AMDT 2 - FTC - Radanovich HR 1706

Gavel : _____
Adjournment : _____

Date : June 3, 2009

YEAS	NAME	NAYS
	Mr. RUSH, Chairman	✓
	Ms. SCHAKOWSKY, Vice Chair	✓
	Mr. SARBANES	✓
	Ms. SUTTON	✓
	Mr. PALLONE	✓
	Mr. GORDON	✓
	Mr. STUPAK	✓
	Mr. GREEN	✓
	Mr. GONZALEZ	NR
	Mr. WEINER	✓
	Mr. MATHESON	NR
	Mr. BUTTERFIELD	✓
	Mr. BARROW	✓
	Ms. MATSUI	✓
	Ms. CASTOR	✓
	Mr. SPACE	✓
	Mr. BRALEY	✓
	Ms. DEGETTE	✓
✓	Mr. RADANOVICH, Ranking Member	
✓	Mr. STEARNS	
✓	Mr. WHITFIELD	
✓	Mr. PITTS	
✓	Ms. BONO MACK	
✓	Mr. TERRY	
	Ms. MYRICK	NR
	Mr. SULLIVAN	NR
✓	Mr. MURPHY	
✓	Mr. GINGREY	
✓	Mr. SCALISE	
	Mr. BARTON, ex officio	NR
	Mr. WAXMAN, ex officio	NR
	Mr. DINGELL, ex officio	

AMENDMENT TO H.R. 1706
OFFERED BY MR. RADANOVICH

Strike subsection (a) through (e) of section 2 and insert the following:

1 (a) ENFORCEMENT ACTIONS RELATING TO SETTLE-
2 MENTS OF CERTAIN PATENT INFRINGEMENT CLAIMS.—
3 Before commencing any enforcement action under section
4 5 of the Federal Trade Commission Act relating to an
5 agreement resolving or settling a covered patent infringe-
6 ment claim between an NDA holder and an ANDA filer
7 instigated by the filing of an ANDA pursuant to section
8 505(j)(2)(A)(vii)(IV) of the Food, Drug, and Cosmetic Act
9 (21 U.S.C. 355(j)(2)(A)(vii)(IV)), the Federal Trade
10 Commission shall consider the following factors to deter-
11 mine whether the agreement in question constitutes an un-
12 fair and deceptive act or practice or an unfair method of
13 competition:

14 (1) The length of time remaining on the NDA
15 holder's right to sell the NDA product prior to the
16 expiration of the relevant patent or statutory exclu-
17 sivity, compared with the agreed upon entry date for
18 the ANDA filer.

1 (2) The form and amount of consideration re-
2 ceived by the ANDA filer in light of the fair market
3 value of any consideration received by the NDA
4 holder from the ANDA filer.

5 (3) The likelihood that the agreement will in-
6 crease the ANDA filer's ability to enter the market
7 earlier and more effectively.

8 (4) Whether the purposes of the Drug Price
9 Competition and Patent Term Restoration Act (Pub-
10 lic Law 98-417) in facilitating the early entry of ge-
11 neric drugs and promoting incentives for innovation,
12 are advanced by permitting such a settlement.

13 (5) Any orders entered by the court hearing the
14 covered patent infringement claim construing the
15 patent claims, addressing the validity, enforceability,
16 or infringement of any patent, or preventing the
17 ANDA filer from commercially marketing the ANDA
18 product until final judgment has been entered in the
19 patent action.

20 (6) Any other factors relevant to considering
21 whether the proposed agreement is pro-competitive
22 and in the public interest.

23 (b) EXPEDITED REVIEW.—With respect to any en-
24 forcement action described in subsection (a) and brought
25 by the Federal Trade Commission after considering the

1 factors set forth in such subsection, if such enforcement
2 action includes a filing by the Commission for an injunc-
3 tion against such a violation, the district court shall accord
4 such filing a priority in its disposition ahead of all other
5 civil actions except for actions challenging the legality and
6 conditions of confinement.

Page 3, line 13, strike “(d)” and insert “(c)”.

Page 4, after line 5, insert the following new para-
graphs (and redesignate subsequent paragraphs accord-
ingly):

7 (5) NDA.—The term “NDA” means a new
8 drug application, as defined under section 505(b) of
9 the Federal Food, Drug, and Cosmetic Act (21
10 U.S.C. § 355(b)).

11 (6) NDA HOLDER.—The term “NDA holder”
12 means—

13 (A) the party that received FDA approval
14 to market a drug product pursuant to an NDA;

15 (B) a party owning or controlling enforce-
16 ment of the patent listed in the Approved Drug
17 Products With Therapeutic Equivalence Eval-
18 uations (commonly known as the “FDA Orange
19 Book”) in connection with the NDA; or

1 (C) the predecessors, subsidiaries, divi-
2 sions, groups, and affiliates controlled by, con-
3 trolling, or under common control with any of
4 the entities described in subparagraph (A) or
5 (B) (such control to be presumed by direct or
6 indirect share ownership of 50 percent or great-
7 er), as well as the licensees, licensors, succes-
8 sors, and assigns of each of the entities.

Strike section 3 and redesignate sections 4 and 5 as
sections 3 and 4, respectively.

