Prepared Statement ofThe Federal Trade Commission

Before the

Committee on Judiciary
United States Senate

Washington, D.C.

August 1, 2003

Introduction

Mr. Chairman, I am Tim Muris, Chairman of the Federal Trade Commission. I am pleased to appear before the Committee today to testify on behalf of the Commission regarding the Senate's and House of Representatives' versions of the "Greater Access to Affordable Pharmaceuticals Act." This statement supplements the Commission [redacted]rovisions that govern the generic drug approval process, its vigorous enforcement of the antitrust laws with respect to generic drug competition, and the Commission's industry-wide study of generic drug entry prior to patent expiration entitled: Generic Drug Entry Prior to Patent Expiration: An FTC Study.[1]

[redacted]

Earlier this year, both the Senate and House passed versions of the Greater Access to Affordable Pharmaceuticals Act that reform the Hatch-Waxman generic drug approval process. The reforms are nearly identical to the FTC Study's recommendations. We70.88 1g2t69ocd2ys rhA T2(elen)13(dat)2 h8 1g2t69 drarl dr datcctar rguama3(d))4()4(,)2(c)-3bi1(c)-3(a

generic applicant may argue that the patent claims neither the drug for which the brand-name drug was approved, nor an approved method of using the drug.

The patent listing statute also requires that the patent holder list patents only "for which a claim of patent infringement could reasonably be asserted." The bills, however, do not include this prong as a basis for the counterclaim. The Commission suggests that Congress consider modifying the counterclaim provision to parallel the bases for listing patents in the Orange Book.

Declaratory Judgment/Case or Controversy Provisions

The Senate bill adds a provision clarifying that if the brand-name company fails to bring an infringement action within 45 days of receiving notice of an ANDA containing a paragraph IV certification, the generic applicant can bring a declaratory judgment action that the patent is invalid or not infringed. To overcome possible jurisdictional limits to bringing such an action, the bill adds a provision stating that the failure of the patent owner to bring an action for patent infringement before the expiration of the 45-day period shall establish a controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in the courts of the United States.

The House bill does not include a similar provision establishing a controversy between the 8(w)19(een t1 a7v ( )Tj 0.0)19(R6(oa)15(he)

Minor Recommendation #1 that clarifies marketing of the brand-name drug product by the first generic applicant constitutes commercial marketing to trigger the 180-day period.

The bills also contain a forfeiture provision that attempts to safeguard against the possibility that first generic applicants will delay the start of commercial marketing. When a forfeiture event occurs, the 180-day exclusivity would not roll to the next generic applicant. The forfeiture events include: (a) failing to market within prescribed time periods (described more below); (b) withdrawing the ANDA application; (c) changing a paragraph IV to a paragraph III certification; (d) failing to obtain tentative approval within 30 months; and (e) entering into an agreement with the brand-name company, or another generic applicant, that an FTC or court decision, from which no appeal can be taken, finds violates the antitrust laws.

The Commission believes that the bills ensure that the first generic applicant will receive the 180-day exclusivity, unless it faces significant problems obtaining final approval of its ANDA. The 180-day exclusivity near-guarantee arises because the "failure to market" forfeiture provision to obt-13(ay)11(scn 7-1(o2(t)e)1g)17(i) mThe arise "f8f86-2(t)d 1 Tf 9 -0 0 9 7