

IP and Competition: Context, Test, and Balance

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I. Context: Importance of regulatory regime

- A. In pharmaceutical industry, Hatch Waxman Act and state substitution laws promote competition
- B. FTC lawsuits
 - 1. Litigation challenging pay-for-delay settlements key in developing caselaw, including *Actavis*
 - a) FTC's lawsuits can show how payment for "services" is really for delay
 - b) As courts (like *Nexium* and *Wellbutrin*) require private plaintiffs to prove patent invalidity, FTC—not confronting causation hurdles—can play vital role
 - 2. REMS litigation (not just amicus briefs) would be useful
 - a) FTC lawsuits challenging sample denials, refusal to participate in shared REMS would be helpful, as private cases often settle after motion to dismiss denied
 - b) Litigation would support FDA's actions and speeches targeting "shenanigans" and could increase pressure to pass CREATES Act
 - 3. Section 5 litigation could advance "frontier" cases challenging:
 - a) PBM contracts, rebates, and other arrangements that block competition
 - b) Rebates/bundling like that challenged in Sanofi-Aventis/Mylan, Pfizer/J&J, and Shire/Allergan suits
 - c) A pattern of conduct that includes thickets such as Humira's 100+ patents
- C. FTC hearings
 - 1. As courts confronting product hopping focus on "coercion" (inapt because of unique markets characterized by market disconnect) and assume legality of "soft" switches (in which old product remains on market), hearings essential
 - a) Could show how behavior accompanying soft switches makes no sense other than harming generic and stifles competition
- D. FTC 6(b) study
 - 1. FTC can play unique role in shining light on secretive PBM model involving rebates, fees, "pharmacy spread," "clawbacks," and "gag clauses"

II. Test: Consumer welfare standard

- A. Neo-Brandeisian jettisoning of consumer welfare standard could lead to higher prices, unmanageable economic vs. noneconomic balancing, and harms to innovation and consumers
- B. Big Tech is not walking antitrust violation; attention must be paid to innovation and remedy
- C. Concerns with EC's Google Search and Android cases, which seem to protect competitors at cost to consumers

III. Balance: IP and competition (not IP trumps competition)

- A. *Actavis*: Patent and antitrust both play role in determining "scope of . . . patent monopoly"
- B. Multigenerational innovation key – not just initial invention
- C. Patent is utilitarian, not absolute right, and infringement should not result in automatic injunction
- D. In standards context, obtaining market power by breaching promise to reasonably license can lead to holdup and present antitrust concern
 - 1. Harms from holdup acknowledged in 2007 and 2011 agency reports
 - 2. Courts awarding patentees tiny fraction of demanded royalties reveals holdup
 - 3. Holdup presents antitrust concern more than (absent concerted conduct) holdout

IV. Conclusion

- A. Context critical, especially where companies undercut regulatory regime with conduct making sense only by harming rival
- B. Consumer welfare test flexible and avoids more severe harms from abandonment
- C. IP/competition balance key