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House Energy & Commerce Committee (Subcommittee on Consumer Protection and Commerce)
Hearing on “Profits over Consumers: Exposing How Pharmaceutical Companies Game the System”
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I. Introduction

- A. Drug companies play games to increase profits
- B. One game is “product hopping,” making minor changes to keep generics off market
- C. This game cannot be justified by innovation and keeps high-priced drugs out of hands of U.S. consumers

II. My Background

- A. Have studied pharmaceutical antitrust law as co-author of leading IP/antitrust treatise; author of more than 115 articles (60 on pharmaceutical antitrust law); author of “amicus” briefs on behalf of hundreds of professors; and one frequently cited in media (1900+ times) and courts (including Supreme Court)

III. Generic Competition

- A. Generic competition crucial to affordable drugs; price can fall 90%
- B. Regulatory regime encourages competition:
 1. Hatch-Waxman Act allows generics to rely on brands’ safety/effectiveness studies
 - a) Drafters sought to ensure provision of “low-cost, generic drugs for millions of Americans” and recognized that generic competition would save consumers and government millions of dollars each year¹
 2. State substitution laws, in effect in all 50 states today, allow (and in some cases require) pharmacists to fill prescriptions for brand drugs with generic versions
 - a) Pharmacists play crucial role, as they are more price-sensitive than doctors, make greater margins on generics, and compete with other pharmacies on price
 3. Substitution laws needed because of “price disconnect” (doctors prescribe, but not pay for, drug while consumers/insurers pay for, but not select, drug)

IV. Product Hopping

- A. Product hopping occurs through different types of reformulations:
 1. Use new forms: e.g., antidepressant Prozac and cholesterol treatment TriCor (capsule to tablet); anxiety-treating Buspar (tablet to capsule)
 2. Add/remove compounds: e.g., heartburn-treating Prilosec to Nexium, allergy medication Claritin to Clarinex, antidepressant Celexa to Lexapro, heartburn medication Prevacid to Kapidex
 3. Combine previously separate compositions: e.g., migraine-treatment Treximet, high-blood-pressure medications Azor, Caduet, Exforge
- B. Reformulations often appropriate – 80% take place outside “Generic Window” when competition expected²
 1. But some switches made just to keep generic off market
- C. Product hopping combines 2 actions:
 1. Reformulating product so generic version can’t be substituted and
 2. Encouraging doctors to write prescriptions for reformulated product
 3. * No innovation reason: brand does not *expand* prescription base; just *migrates* base to block generics
- D. Product hopping does *not* include:
 1. Promoting both products without encouraging switch
 2. Introducing reformulations to fill out product line or satisfy demand
 3. Expanding prescription base by competing with other branded products or growing market
- E. Every time brand changes drug slightly, generic cannot be substituted
 1. Substitution requires “AB rating”: generic “therapeutically equivalent” to brand (same active ingredient, form, dosage, strength, safety/efficacy profile) and “bioequivalent” (absorbed into body at same rate)³
 2. Product hopping exploits this regulation – minor changes (capsule to tablet, 10-mg to 12-mg dose) prevents generic from obtaining AB rating needed for substitution
 3. Generic must then start all over again: reformulate drug, get FDA approval, and fight new set of patents (litigation, automatic 30-month stay)

¹ 130 CONG. REC. 24,410, 24,427, 24,456 (1984).

² Steve Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L. J. 1, 26-27 (2009).

³ FDA, *Orange Book Preface*, <https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface>.

- F. Harms from both “hard switches” (original drug pulled from market) and “soft switches” (original drug remains)
- G. Greater harms when brand switches before generic enters market (promotion/marketing more effective in convincing doctors to prescribe reformulated version)

V. Harms: General

- A. Product hopping has massive effect on consumers
 - 1. Most recent (2009) empirical analysis found \$28 billion worth of drugs subject to product hopping, including Advair, Allegra, Augmentin, Caduet, Clarinex, Kapidex, Lexapro, Nexium, Prozac, Risperdal⁴
 - a) For \$1 billion blockbuster drug, consumers pay extra \$765 million each year from delayed competition⁵
 - 2. Consumers have overpaid \$1.7 billion for Namenda, \$200 million for Effexor, \$700 million/year for TriCor, and (according to legal complaints) \$11.5 billion for Nexium and \$650 million annually for Suboxone⁶
 - 3. Brand firms have charged significantly more each month for drugs like Adasuve (\$4500 vs. \$45), Zytiga (\$10,000 vs. \$3,300), and Treximet (\$695 vs. \$21)⁷
 - 4. Consumers unable to afford high prices cut pills in half, choose between paying for drugs and food/rent, and do not take needed medicines

VI. Harms: Examples

- A. Cholesterol-treating TriCor: capsule to tablet
 - 1. Abbott switched from capsule to tablet, (slightly) lowered drug’s strength, bought back drugs, stopped selling capsules, and changed code for capsules in national drug database to “obsolete.”⁸ Then it did all this again.
 - 2. *Made no sense*: Abbott discouraged doctors from prescribing \$200-million drug, incurring costs to make switch...despite projections showing no new sales or profits⁹
- B. Heartburn-treating Prilosec to Nexium
 - 1. Almost no difference between drugs, but AstraZeneca aggressively promoted Nexium to doctors while stopping promotion of Prilosec, switching market to receive additional 13 years of patent protection¹⁰
 - 2. *Made no sense*: Stopped marketing most profitable (\$4 billion) drug...even though sales increased less than for other drugs in class, and expert told doctors they “should be embarrassed” if prescribe “same drug” Nexium¹¹
- C. Opioid-dependence-treating Suboxone: tablets to sublingual (under-the-tongue) film
 - 1. Reckitt publicly announced removal of tablets for safety reasons (even though tablets safer), waited 6 months to remove, disparaged (and raised price of) Suboxone tablets, and promoted Suboxone film to doctors¹²
 - 2. *Made no sense*: Raising price of tablets (even though film more expensive) was costly, as was warning of false safety concerns, for result of...“substantially reduced profit margins” on \$700 million in annual sales!¹³
- D. Acne-treating Doryx: capsule to tablet
 - 1. Warner Chilcott stopped selling capsules, removed capsules from website, “auto-referenced” tablets, informed wholesalers/retailers/dealers that capsules replaced by tablets, and bought back and destroyed capsules¹⁴
 - 2. *Made no sense*: Capsules earned at least \$50 million in revenues; reformulated version “more costly and difficult” to manufacture, with brand...“not expect[ing] . . . increased sales or profits.”¹⁵
- E. Alzheimer’s-treating Namenda: IR (2x/day) to XR (1x/day)
 - 1. To obtain 14 more years of patent protection, Forest stopped actively marketing IR, significantly promoted XR, sold XR at discount, announced discontinuance of IR, and published letters urging switch to XR¹⁶

⁴ Steve Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L. J. 1 (2009).

⁵ FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 8 (2010), <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf> (multiple generics take 90% of sales at average 85% discount).

⁶ 787 F.3d 638, 661 (Namenda); <http://theconversation.com/explainer-evergreening-and-how-big-pharma-keeps-drug-prices-high-33623> (Effexor); <https://www.motherjones.com/kevin-drum/2012/04/how-keep-healthcare-costs-high-one-easy-lesson/> (TriCor); 2007 WL 1480480 (Nexium); <https://www.hilliardshadowenlaw.com/images/uploads/banner/Suboxone-2015.04.13-149 - End-Payor Plaintiffs Second Amended Complaint.pdf> (Suboxone).

⁷ <https://www.consumerreports.org/drug-prices/product-hopping-drives-up-drug-prices-but-you-can-still-save-on-your-meds/> (Adasuve); <https://consumer.healthday.com/cancer-information-5/prostate-cancer-news-106/a-light-breakfast-might-cut-cost-of-pricey-prostate-cancer-drug-732344.html> & <https://www.drugs.com/price-guide/abiraterone#oral-tablet-250-mg> (Zytiga); https://www.washingtonpost.com/national/health-science/nine-tips-for-paying-less-for-doctor-visits-drugs-and-medical-treatments/2018/03/16/f5862014-1b09-11e8-ae5a-16e60e4605f3_story.html (Treximet).

⁸ *Abbott Labs. v. Teva*, 432 F. Supp. 2d 408, 415-18 (D. Del. 2006).

⁹ Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 223 (2016).

¹⁰ *Walgreen v. AstraZeneca Pharmaceuticals*, 534 F. Supp. 2d 146, 148-49 (D.D.C. 2008).

¹¹ Carrier & Shadowen, at 224.

¹² *In re Suboxone Antitrust Litigation*, 64 F. Supp. 3d 665, 674 (E.D. Pa. 2014).

¹³ *Id.*

¹⁴ *Mylan Pharmaceuticals v. Warner Chilcott*, 838 F.3d 421, 429-31 (3d Cir. 2016).

¹⁵ Carrier & Shadowen, at 227.

2. *Made no sense*: Forest pulled one of its best-selling drugs (\$1.5 billion in annual sales) to suffer... “20% franchise disruption” and loss of “tens if not hundreds of millions of dollars”!¹⁷

VII. Harms: Innovation

- A. No empirical evidence has shown innovation would be deterred by applying antitrust analysis to product hopping
- B. Brand firms often withhold incremental innovations from market to use later as part of product hop:
 1. TriCor: Abbott delayed seeking new indication for original product, reserving it for reformulation, even though “data necessary to get the new indication was available much earlier.”¹⁸
 2. Neurontin: Warner-Lambert conceded that “principal reason[] for not seeking FDA approval” for off-label uses was that it “wanted to reserve them for a later promotional campaign for its reformulated product.”¹⁹
 3. Namenda: Forest waited until generic competition for twice-daily Namenda imminent before introducing once-daily version (even though obtained FDA approval three years earlier!)²⁰
 4. If value of “innovation” to consumers was greater than value to brand of delaying generic, would immediately introduce innovation to reap increased gains
- C. Not valuable innovation when product hopping makes sense only by harming generic
 1. *Namenda* court found that defendants “presented no evidence to support their argument that antitrust scrutiny of the pharmaceutical industry will meaningfully deter innovation.”²¹
 2. *Namenda* court also noted that “immunizing product hopping from antitrust scrutiny may deter significant innovation” by encouraging brands to “switch[] the market to trivial or minor product reformulations rather than investing in the [R&D] necessary to develop riskier, but medically significant innovations.”²²
 3. In recent years, drug companies have increasingly sought “ancillary patents on chemical variants, alternative formulations, methods of use, and relatively minor aspects of the drug.”²³

VIII. Solutions

- A. In June, Senate Judiciary Committee passed (by 22-0 vote) the Affordable Prescriptions for Patients Act of 2019
 1. Gives FTC power under Section 5 to challenge anticompetitive hard and soft switches
 - a) Hard switch = (1) withdraw drug or destroy inventory and impede competition + (2) sell follow-on drug
 - b) Soft switch = (1) unfairly disadvantage original and impede competition + (2) sell follow-on drug
 - c) Drug company can offer justifications based on showing (1) would have taken actions regardless of effect on competition and (2) had safety, supply-disruption, or procompetitive reasons for switch
 - d) Differential analysis accepts all legitimate reasons in context of conservative (“no economic sense”) test
 2. One benefit: Ensure courts recognize harms of soft switches when only reason for change is to harm generic
 - a) *Walgreen’s* court ignored price disconnect in finding no allegation AstraZeneca “eliminated any consumer choices” but claiming it “added choices,” with superiority determinations “left to the marketplace.”²⁴
 - b) *Doryx* court focused on competitor rather than consumer (even though company “made . . . ‘hops’ primarily to ‘delay generic market entry’”).²⁵
- B. FDA
 1. Allow “therapeutic substitutability” (at FDA and states) unless safety/effectiveness concerns
 - a) Require bioequivalence but not mandate same route of administration, dosage form, or strength
- C. FTC Report
 1. Provide report (see S. 771 § 406 (115th Cong.)) covering types of product hops, timing, patents/exclusivities, cost to consumers/insurance, and effect on brand profits and generics

IX. Conclusion

- A. Drug companies call product hopping “life-cycle management” but just keeps gravy train of trivial tweaks running
- B. Congress can play crucial role, encouraging legitimate innovation and helping consumers afford prescription drugs

¹⁶ *New York ex rel. Schneiderman v. Actavis*, 787 F.3d 638, 648 (2d Cir. 2015).

¹⁷ *Carrier & Shadowen*, at 228.

¹⁸ Steve Shadowen et al., *Bringing Market Discipline to Pharmaceutical Product Reformulations*, 42 IIC 698, 710 (2011) (data “used to get approval for the new indication had been developed in studies for the original product”).

¹⁹ *Id.* (noting that Warner-Lambert “was concerned” that generics “would undermine sales” of the new drug).

²⁰ 787 F.3d at 647.

²¹ *Id.* at 659.

²² *Id.*

²³ C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 JOURNAL OF EMPIRICAL LEGAL STUDIES 613, 615 (2011).

²⁴ 534 F. Supp. 2d at 151.

²⁵ 838 F.3d at 431.