RUTGERS Law School

Rutgers, The State University of New Jersey
217 N. Fifth Street
Camden, NJ 08102-1203

Michael A. Carrier
Distinguished Professor

mcarrier@camlaw.rutgers.edu
Tel: (856) 225-6380

Statement by Michael A. Carrier
Distinguished Professor, Rutgers Law School
May 7, 2019
to Senate Judiciary Committee
on "Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition"

I. Introduction

A. Drug prices too high
   1. Brand drug companies abuse system by delaying generic entry
   2. Brands withhold samples, pay generics not to enter, and exploit citizen petitions, product hopping, and patent thickets
B. This conduct cannot be justified by patents or innovation
C. Congress can address these abuses

II. My Background

A. I 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 (1500+ times) and courts (including Supreme Court)

III. Sample Denials

A. Generics need samples to reach market but brands have denied them
   1. FDA has received more than 170 inquiries from generics unable to obtain samples; costs $5+ billion/year
   2. FDA powerless: its "generics are safe" letters ineffective; agency not examine competition issues
   3. Sample denials violate legislative provision that brands not use Risk Evaluation and Mitigation Strategies (REMS) to "block or delay" generics
B. Brands have abused Single Shared REMS program, applicable when brand, generic each have REMS
   1. Have slow-walked negotiations, sometimes for years (*e.g.*, Suboxone, Xyrem)
      a) FDA acts "after substantial delay" and "ha[s] to try and try and try and try, and then finally . . . declare defeat and . . . go ahead and let the generics have their own system."[1]
C. There's also concern outside the REMS setting; *e.g.*, Martin Shkreli's 5000%-price-hiked Daraprim
   1. 62 years after approval and for no apparent reason, Turing restricted distribution system; official "would block [generic] purchase" and company "do[es] [its] best to avoid generic competition."[2]
D. Antitrust law uncertain – even if should be violation for conduct making no economic sense, courts could accept brands' arguments based on safety, product liability, and lack of duty to deal with rivals
E. CREATES Act offers simple fix, allowing targeted lawsuits and deterrent remedy

IV. Pay-for-Delay Settlements

A. Brands have colluded with generics, paying them to delay entering the market
B. Legislation provides that generic receiving "anything of value" for delayed entry is presumptively illegal
C. Standard makes clear that pay-for-delay settlements anticompetitive and helps FTC prove cases in court
D. Legislation addresses judicial errors relating to payment, "scope of patent," and risk aversion. *E.g.*:
   1. *AbbVie*: Brand provided generic with drug at price "well below what is customary" but court (despite recognizing deal's "large value") concluded it "was not a reverse payment."[3]
   2. *AbbVie* and Administrative Law Judge in *Impax*: Assumed entry before patent expiration procompetitive (despite Supreme Court's overturning of scope-of-patent test).[4]
   3. *Wellbutrin*: Relied on risk aversion defense (rejected by Supreme Court) to dismiss argument that size of payment reflects patent weakness.[5]

---

[1] *See* Michael A. Carrier, *Sharing, Samples, and Generics: An Antitrust Framework*, 103 CORNELL LAW REVIEW 1, 41-47 (2017).

[2] *See* Michael A. Carrier, Nicole L. Levidow, & Aaron S. Kesselheim, *Using Antitrust Law to Challenge Turing's Daraprim Price Increase*, 31 BERKELEY TECHNOLOGY LAW JOURNAL 1379, 1400 (2017).

[3] *FTC v. AbbVie Inc.*, 107 F. Supp. 3d 428, 436 (E.D. Pa. 2015).

[4] *In the Matter of Impax Labs., Inc.*, Dkt. No. 9373, at 144, 146 (FTC ALJ Chappell May 18, 2018).

[5] *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 165 (3d Cir. 2017).

V. Citizen Petitions

A. Meant to raise legitimate concerns, but really used to delay generic entry, with my empirical study showing that FDA denies 92% of "505(q)" petitions (against pending generic), 98% of late-filed petitions.[6]
B. Concerning examples: Shire ViroPharma's 46 filings, Teva's multiple Copaxone petitions, Bayer's Mirena petition 1 day before patent expiration, Mylan's delayed filing of petition on EpiPen alternative.[7]
C. From 2011 to 2015, 118 petitioners filed 505(q) petitions: 108 brand firms, 4 generic firms, 4 law firms or consultants, *only 2* public interest groups, and *0* individuals
D. Legislation helpful in giving FTC authority to bring Section 5 claim (and obtain strong penalties) against sham petitions

VI. Product Hopping

A. Brands have switched drugs so generics can't be substituted and migrated patients before generic entry
   1. Examples: capsule to tablet, different dosage, single- and dual-scored tablet
B. Each switch slows generic: must reformulate, face patent litigation (& 30-month stay), can't be substituted
C. Antitrust liability appropriate for conduct that makes no sense other than harming generic
   1. For example, why would brand voluntarily pull *$1.5 billion* drug off market?[8]
   2. And why would brand disparage *own* product?[9]

VII. Patent Thickets

A. Biologic manufacturers have obtained more than 100 patents on single product to extend protection
   1. Many of the patents are related and extend protection beyond main patent & 12-year exclusivity
B. *E.g.*: AbbVie's 130+ Humira patents, including 53 obtained in 2015/16, just before main patent expired
   1. AbbVie has settled with all biosimilars except one, delaying U.S. entry until 2023 (while biosimilars have already entered in Europe)
   2. From 2013 to 2016, AbbVie raised price 68%

VIII. Conclusion

A. Anticompetitive behavior costs consumers billions in unnecessary payments and untold suffering when patients go without food or rent, split pills in half, or don't take needed medicines
B. Legislation on samples, settlements, citizen petitions, product hopping, and patent thickets would make patients' lives better without affecting innovation

---

[6] *See* Michael A. Carrier & Carl J. Minniti III, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 AMERICAN UNIVERSITY LAW REVIEW 305 (2016).

[7] *See* Carrier & Minniti, *Citizen Petitions*, at 344-47; Michael A. Carrier & Carl J. Minniti III, *The Untold EpiPen Story: How Mylan Hiked Prices by Blocking Rivals*, 102 CORNELL LAW REVIEW ONLINE 53, 64-66 (2017).

[8] *New York ex rel. Schneiderman v. Actavis PLC* (*Namenda*), 787 F.3d 638, 647 (2d Cir. 2015).

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