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House Committee on Energy and Commerce, Subcommittee on Health
Hearing on "Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs"

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I. Introduction

A. Drug prices too high; consumers unable to afford needed medicines. Why?
   1. Brand drug companies abuse system by delaying generic entry
      a) Two examples: pay-for-delay settlements, citizen petitions
      b) This conduct cannot be justified by patents or innovation
B. Congress can address these anticompetitive abuses through legislation

II. My Background

A. I have studied pharmaceutical antitrust law as co-author of leading IP/antitrust treatise; author of more than 130 articles (65 on pharmaceutical antitrust law); drafter of 20 "amicus" briefs on behalf of hundreds of professors; and one frequently cited in media (2000+ times) and courts (including Supreme Court)

III. Pay-for-Delay Settlements: Harm

A. Brand firms have colluded with generic companies, paying them to delay entering the market
   1. Alone among anticompetitive pharmaceutical conduct, settling generics align with brands against consumers
B. Patients harmed from collusion, not innovation
   1. FTC has calculated that pay-for-delay settlements cost consumers $3.5 billion a year.[1]
   2. Brand firm delays competition from payment, not patent
   3. Generics agree to delay entry in return for dropping patent challenge
      a) But most (89%) of the patents at issue in settlements are secondary patents on which the brand firm is less likely to win (32%), as compared to active-ingredient (92%) patents.[2]
      b) Examples of settlements on secondary patents: Actos, AndroGel, Cephalon, Effexor, K-Dur, Lidoderm, Loestrin, Niaspan, Opana, Solodyn, Wellbutrin
   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

IV. Pay-for-Delay Settlements: Solution

A. H.R. 153, the Protecting Consumer Access to Generic Drugs Act of 2021, would play a critical role in stopping anticompetitive settlements
   1. Legislation provides that generic receiving "anything of value" for delayed entry is illegal
      a) Common-sense approach supports Supreme Court's *Actavis* ruling, which broadly considered payment.[3]
      b) Helpful to include not just "direct[]" but also "indirect[]" compensation, which reflects increasingly complex arrangements between the settling parties
      c) Important to recognize that "anything of value" includes "a license"
         (1) Settling parties have claimed that subjecting licenses to potential antitrust liability would be "extraordinary" and "call[] into question the continued viability of any patent litigation settlement."[4]
         (2) To the contrary, as the Third Circuit has explained, defendants seek not "a patentee's right to grant licenses" but "a right to use valuable licensing in such a way as to induce a patent challenger's delay."[5]
   2. Legislation offers beneficial provisions for defendants:

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[1] FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS (2010).

[2] C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1387 (2013).

[3] *FTC v. Actavis*, 570 U.S. 136 (2013).

[4] Petition for a Writ of Certiorari, *SmithKline Beecham Corp. v. King Drug Co.*, at 1, 14 (U.S. filed Feb. 19, 2016).

[5] *King Drug Co. v. SmithKline Beecham Corp.*, 791 F.3d 388, 405–06 (3d Cir. 2015).

a) Exception when payment for goods/services
b) Exclusion from liability for right to market, payment of reasonable litigation expenses, and covenant not to sue

B. Benefit 1: Standard makes clear that pay-for-delay settlements anticompetitive and helps FTC prove cases in court
1. Payments have migrated from cash to compensation hidden in increasingly obscure corners
2. Treating pay-for-delay settlements as anticompetitive will deter blatantly illegal conduct that courts do not always recognize and that bogs down the FTC for years in resource-intensive litigation
a) *E.g.*: The FTC's *Actavis* litigation, which did not even involve a trial, took *10 years* to settle.[6]

C. Benefit 2: 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 that it "was not a reverse payment."[7]
2. *AbbVie* and Administrative Law Judge in *Impax*: Assumed entry before patent expiration procompetitive (despite Supreme Court's overturning of scope-of-patent test).[8]
3. *Wellbutrin*: Relied on risk aversion defense (rejected by Supreme Court) to dismiss argument that payment size reflects patent weakness.[9]

D. Potential strengthening amendment 1: Extend reporting requirements under Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to settlements at Patent Trial and Appeal Board (PTAB)
a) Empirical evidence finds that roughly 75% of settlements of PTAB proceedings involve payment.[10]
b) Nearly half of the settlements occur after PTAB judge "institutes" inter partes review, which indicates that challenged patent is "reasonably likely" to be invalid.[11]
c) Absence of reporting requirements means that anticompetitive settlements can evade detection
(1) Parties simultaneously settling district court litigation and Patent Office proceedings can hide payment in PTAB settlement

E. Potential strengthening amendment 2: Make clearer that courts should not presume that entry will not occur until patent expires and that pre-expiration entry is procompetitive

F. Potential strengthening amendment 3: Expand H.R. 153 to private plaintiffs (who litigate most settlement cases), which could address overly strict causation standards so that plaintiffs need not definitively prove patent invalidity (as *Wellbutrin* and *Nexium*[12] courts required)

G. Potential strengthening amendment 4: Expand H.R. 153 to open 180-day bottleneck, which would have even stronger effect on settlements
1. *E.g.*: H.R. 1506, Fair and Immediate Release (FAIR) of Generic Drugs Act, enlarges category of "first applicants" to include generics obtaining judicial invalidity/noninfringement decision
2. This addresses perversion of Hatch-Waxman Act by which 180-day period has morphed from incentive to invalidate patents to bottleneck blocking entry

[6] FTC, *Last Remaining Defendant Settles FTC Suit that Led to Landmark Supreme Court Ruling on Drug Company "Reverse Payments,"* Feb. 28, 2019.

[7] *FTC v. AbbVie*, 107 F. Supp. 3d 428, 436 (E.D. Pa. 2015), *aff'd*, 976 F.3d 327 (3d Cir. 2020).

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

[9] *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 165 (3d Cir. 2017). For a discussion of additional errors in settlement cases, see Michael A. Carrier, *Three Challenges for Pharmaceutical Antitrust*, 59 SANTA CLARA L. REV. 613 (2020).

[10] Erik Hovenkamp & Jorge Lemus, *Delayed Entry Settlements at the Patent Office*, 54 INT'L REV. L. & ECON. 30, 37-38 (2018); Erik Hovenkamp & Jorge Lemus, *Reverse Payment Settlements and Holdup Under PTAB*, IP WATCHDOG, July 31, 2016.

[11] Hovenkamp & Lemus, *Delayed Entry Settlements*, at 31.

[12] *In re Nexium Antitrust Litig.*, 842 F.3d 34, 63 (1st Cir. 2016). *See generally* Kevin B. Soter, *Causation in Reverse Payment Antitrust Claims*, 70 STAN. L. REV. 1295 (2018).

V. Citizen Petitions: Harm

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.[13]
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.[14]
C. From 2011 to 2015, 118 petitioners filed 505(q) petitions: *108* brand firms, 4 generic firms, 4 law firms or consultants, but only *2* public interest groups and *0* individuals
D. FDA has shown "concern[] that section 505(q) may not be discouraging the submission of petitions that are intended primarily to delay the approval of competing drug products and do not raise valid scientific issues."[15]
    1. FDA "remains concerned" that the resources it is forced to incur come "at the expense of completing the other work of the Agency."[16]

VI. Citizen Petitions: Solution

A. H.R. 2387, the STOP GAMES Act of 2019, is helpful in challenging abusive petitions and offers several substantial benefits.
B. Benefit 1: Disjunctive structure of summary disposition
    1. Disjunctive structure makes it possible for first time for FDA to grant summary disposition
    2. FDA currently is required to demonstrate two factors before using this power:
        a) Petition "submitted with the primary purpose of delaying" generic and
        b) Petition "does not on its face raise valid scientific or regulatory issues."[17]
    3. But provision is too strict; it "has neither curbed the filing of petitions submitted with the primary purpose of delay" nor "permitted FDA to dispose of such petitions without expending substantial amounts of resources."[18]
        a) As FDA has explained, the standards for summary disposition are "extremely difficult to meet."[19]
    4. Primary purpose prong difficult
        a) FDA cannot determine primary purpose based on petition itself
            (1) Merely reviewing such a document, which includes safety or effectiveness concerns, cannot reveal the filer's purpose, let alone its primary purpose
    5. Scientific/regulatory prong difficult
        a) Even a petition that ultimately is denied will tend not to reveal "on its face" that it "does not . . . raise valid scientific or regulatory issues."
            (1) Petitions will include language and sometimes documentation challenging a drug's safety or efficacy that at first glance may sound plausible
            (2) Because erroneously granted summary dispositions could result in safety mishaps years down the road, FDA hesitant to rule in cursory review that petition does not raise valid issues
C. Benefit 2: Supporting detail fleshing out "primary purpose"
    1. As discussed above, challenging to show primary purpose
    2. Legislation helpfully links this concept to specific markers of abusive behavior
    3. Relevant factors mirror FDA draft guidance[20] on "primary purpose of delay": (a) unreasonable length of time to submit petition; (b) multiple petitions challenging conduct that reasonably could have been known at time of earlier petition; (c) petition submitted close in time to date on which application could be approved; (d) petition submitted without supporting data/information; (e) petition raising same or substantially similar issues as prior petition that has received response; (f) petition addressing standards for which FDA provided opportunity for public input but petitioner did not comment; (g) petition requesting that other applicants meet standards more rigorous than petitioner; (h) petitioner's history

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[13] Michael A. Carrier & Carl J. Minniti III, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 AM. U. L. REV. 305 (2016).

[14] *See id.* at 344–47; Michael A. Carrier & Carl J. Minniti III, *The Untold EpiPen Story: How Mylan Hiked Prices by Blocking Rivals*, 102 CORNELL L. REV. ONLINE 53, 64–66 (2017).

[15] FDA, REPORT TO CONGRESS: EIGHTH ANNUAL REPORT ON DELAYS IN APPROVALS OF APPLICATIONS RELATED TO CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION FOR FISCAL YEAR 2015, at 8 (2016) [FDA, 2015 REPORT].

[16] *Id.*

[17] 21 U.S.C. § 355(q)(1)(E).

[18] FDA, REPORT TO CONGRESS: SEVENTH ANNUAL REPORT ON DELAYS IN APPROVALS OF APPLICATIONS RELATED TO CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION FOR FISCAL YEAR 2014, at 10 (2015) [FDA, 2014 REPORT].

[19] *Id.*

[20] FDA, *Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act*, 2018.

4. These factors are common in abusive petitions
   a) In my empirical studies of every citizen petition filed between 2001 and 2015, I found that these categories captured the range of petitions that raise concern.[21]
5. FDA's determination of primary purpose of delay appropriately results in referral to the FTC
   a) Such cross-agency collaboration allows competition-focused FTC to take advantage of FDA's health expertise

D. Benefit 3: Time limit
1. Legislation requires a petitioner to file a petition "not later than 60 days after the information upon which the petition is based first became known to the party on whose behalf the petition is submitted"
2. Limit makes sense as legitimate petitions should be filed within a reasonably short time of discovering the safety or efficacy concern
3. Late-filed petitions raise concern that petitioner is gaming system, often by waiting until generic is about to enter market to file even though it was long aware of information forming basis of petition
4. One example is provided by Mylan, notorious for its price increases on the life-saving epinephrine-autoinjector EpiPen device, which filed a petition challenging Teva's EpiPen alternative at least five years after it most likely was aware of details about the generic product.[22]

E. Benefit 4: Reporting to Congress
1. Because of lack of transparency, important to require FDA to include comprehensive list of 505(q) petitions in annual reports to Congress, including:
   a) Time and resources FDA expended on petition
   b) Timing of petition in relation to expiration of patents listed in Orange Book
   c) Quantification of delay (if any) in generic approval caused by petition and determinations of how delay calculated and when delayed approval would have been granted absent petition
   d) Simultaneous determinations: When generic application and petition disposed of on same or nearly same date, statement of when FDA would have disposed of generic application absent petition
      (1) Information would reveal if (a) generic would have been approved earlier absent petition or (b) FDA delays announcing ruling on petition until it approves generic application
2. These reporting provisions would be helpful in shining light on black box of petitions
   a) FDA does not maintain an easily searchable list of 505(q) petitions
      (1) The government website reglations.gov is difficult to navigate, leading to dependence on the privately-compiled collection at FDALawBlog.[23]
      (2) The difficulty of uncovering information obscures the prevalence of the conduct and the full extent of the delay
   b) FDA does not explain what constitutes a "delayed" petition
      (1) Since 2016, FDA has not listed in its annual reports the number of delayed petitions
      (2) In its most recent treatment (FY14 report submitted in 2015), FDA found "delayed approvals" on only ten occasions between 2008 and 2015,[24] but it did not specify the petitions, nor did FDA consider a petition delayed if it responded within the statutorily required 150-day period for addressing petitions.[25]

VII. 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 pay-for-delay settlements and citizen petitions would make patients' lives better without harming innovation

[21] Carrier & Minniti, *Citizen Petitions* (2011 to 2015); Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 CARDOZO L. REV. 249 (2012) (2001 to 2010).

[22] Carrier & Minniti, *How Mylan Hiked Prices*, at 65.

[23] FDA Law Blog, https://www.fdalawblog.net (FDA Citizen Petition Tracker link in right margin).

[24] FDA, 2015 REPORT, at 8.

[25] FDA, 2014 REPORT, at 9.