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**Michael A. Carrier**
***Response to Senator Grassley's Questions for the Record***
***Sen. Jud. Comm. Hearing on "IP and the Price of Prescription Drugs: Balancing Innovation and Competition"***
**May 28, 2019**

## I. PBM Industry

A. PBM industry not competitive
   1. 3 major players (CVS Health, Express Scripts, and OptumRx) control 85% of the market
   2. This concentration allows PBMs "to exercise undue market power against manufacturers and against the health plans and beneficiaries they are supposed to be representing, thus generating outsized profits for themselves."[1]

B. New competitors face high barriers to entry
   1. PBMs perform many complex services in administering plans; extremely difficult to match
   2. Given consolidation, PBMs at a severe disadvantage if not also enter at other (e.g., insurer) level
      a) Consolidated entities could harm insurers by restricting formularies, targeting rivals' customers, or not filling prescriptions
      b) Consolidated entities could harm pharmacies by reducing reimbursement, taking profitable prescriptions for themselves, or forcing conversions to their own pharmacies[2]

C. PBMs have increased prices
   1. As Department of Health and Human Services (HHS) has explained, "PBMs play an important role in negotiating with drug companies," but negotiation favoring "higher rebates instead of lower cost drugs . . . can lead to higher list prices."[3]
      a) In fact, "nearly every drug company taking a January 2019 price increase announced that all or nearly all of the increase was being paid to PBMs or insurers as rebates."[4]
      b) HHS further explained that average difference between list and net price is 26% to 30% and that rebates "are typically not used to reduce patients' cost sharing for a particular drug."[5]
   2. HHS Secretary Alex Azar has explained that rebate arrangements make it difficult to reduce price because manufacturers "fear . . . discriminat[ion] for decreasing their price."[6]
   3. Study commissioned by Texas legislature found Texas could save up to $90 million per year in Medicaid and Children's Health Insurance Program by ceasing to use PBMs[7]
   4. West Virginia saved $30 million per year by cutting PBMs out of the state's Medicaid program
   5. Ohio found that OptumRx kept $224 million through spread pricing (billing health plans at higher amounts than they reimburse pharmacies)

D. PBMs have distorted the market
   1. Because of the large rebates they receive from brand companies, PBMs have included brand drugs, rather than generics, on their formularies
   2. *E.g.*: Nearly all Medicare plans cover Sanofi's brand-name insulin-treating Lantus, while only 17% cover Eli Lilly's biosimilar Basaglar[8]
   3. *E.g.*: One study found that almost every formulary "has at least one branded drug . . . that's in a better place than the generic."[9]

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[1] COUNCIL OF ECONOMIC ADVISERS, EXEC. OFFICE OF THE PRESIDENT, REFORMING BIOPHARMACEUTICAL PRICING AT HOME AND ABROAD § 2.3 (Feb. 2018), https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf.

[2] Michael Carrier, *A Six-Step Solution to the PBM Problem*, HEALTH AFFAIRS, Aug. 30, 2018, https://www.healthaffairs.org/do/10.1377/hblog20180823.383881/full/.

[3] HHS, *Fact Sheet: Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients*, Jan. 31, 2019, https://www.hhs.gov/sites/default/files/20190131-fact-sheet.pdf.

[4] *Id.*

[5] *Id.*

[6] Gregory Twachtman, *Azar Blames PBMs for No Drop in Prescription Prices*, CHEST PHYSICIAN, June 15, 2018, https://www.mdedge.com/chestphysician/article/168282/practice-management/azar-blames-pbms-no-drop-prescription-prices.

[7] Jeff Carson, *Time to Remove Texas' Drug Middlemen*, AP, Feb. 10, 2019, https://www.apnews.com/b7bf144a415e434592fc3a35f0225d52.

[8] Jay Hancock & Sydney Lupkin, *Secretive "Rebate Trap" Keeps Generic Drugs for Diabetes and Other Ills out of Reach*, KHN, Jan. 18, 2019, https://khn.org/news/secretive-rebate-trap-keeps-generic-drugs-for-diabetes-and-other-ills-out-of-reach/.

[9] *Id.*

4. *E.g.*: Another study found that from 2011 to 2015, the percentage of generic drugs on "Tier 1" (lowest out-of-pocket costs) of Medicare Part D fell from 71% to 19%[10]

## II. Consolidation Does Not Lower Costs, but Harms Small Pharmacies

A. Recent consolidation between PBMs and insurers (or other participants in the pharmaceutical supply chain) has not resulted in lower drug costs to the government (as a payer) or the consumer
B. In *theory*, consolidation could lead to reduced costs but in *reality* it has not
C. *E.g.*: Express Scripts' adjusted profit per prescription increased 500% from 2003 to 2017, and earnings per adjusted claim rose from $3.87 in 2012 to $5.16 in 2016[11]
D. Consolidation has harmed small pharmacies
   1. PBMs have "aggressively steer[ed] patients to their mail-order pharmacies," with "[c]ustomers get[ting] constant solicitations by phone or mail, enticing them to use 'Amazon-style home delivery,'" and "offering lower co-pays or larger supplies per order."[12]
   2. Steering allows PBMs to obtain data on patients, explains why PBM-owned pharmacies represent 46% of industry revenue growth, and reduces generic use since affiliated pharmacies benefit from brand rebates[13]
   3. *E.g.*: CVS Caremark breached firewall in encouraging patients to switch pharmacies at same time it reduced reimbursement to rival pharmacies and—ironically enough citing "declining reimbursements"—offered to purchase the pharmacies[14]
   4. Smaller, independent pharmacies suffer from these practices, with pharmacists not able to stock medications because they lose money in doing so
   5. *E.g.*: Some pharmacies stopped selling generic opiate-addiction-treatment Suboxone, "pushing addicts in the fragile early stages of recovery back onto the streets" because they lost $100 on each prescription[15]

## III. Rebate Walls Harmful to Patients

A. Rebate walls (or rebate traps) occur when drug manufacturers provide rebates or discounts on the condition that payors purchase bundled collection of drugs
B. In *theory*, "rebates" sound good but in *reality*, they can be used to stifle competition, preventing patients from accessing quality, lower-cost medicines
   1. HHS has explained that "[e]xcluding rival drugs with 'rebate walls' or 'bundled rebates' distorts our free market system, discourages generic competition and biosimilar adoption, and causes patients to pay more out of pocket."[16]
   2. *E.g.*: Pfizer sued J&J for threatening not to pay rebates unless insurers restricted coverage of Pfizer's Inflectra; as a result, 90% of accounts did not purchase Inflectra, which resulted in only a 4% market share for Pfizer
   3. *E.g.*: Sanofi-Aventis sued Mylan for providing rebates on condition that insurers and PBMs exclude Auvi-Q from formularies, which limited market share to 13% and allowed EpiPen's 300% (2013-16) price increase
   4. *E.g.*: Shire sued Allergan for blocking Xiidra from the market by using bundled discounts that were so aggressive that Medicare Part D plans would purchase the package even if Xiidra were provided for free
C. Congress should address rebate traps, making clear that they are not automatically procompetitive
   1. A potential framework was provided by the Third Circuit in its focus on exclusionary effects, which are especially pronounced in the pharmaceutical supply chain[17]

## IV. Patent Issuance Deficiencies

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[10] Avalere, *Seniors Pay More for Medicare Part D Generics Despite Stable Prices*, May 22, 2018, https://avalere.com/press-releases/seniors-pay-more-for-generics-in-medicare-prescription-drug-plans-despite-stable-prices.

[11] David Dayen, *The Hidden Monopolies that Raise Drug Prices*, AMERICAN PROSPECT, Mar. 28, 2017, https://prospect.org/article/hidden-monopolies-raise-drug-prices.

[12] *Id.*

[13] *Id.*

[14] Catherine Candisky et al., *Three CVS Actions Raise Concerns for Some Pharmacies, Consumers*, THE COLUMBUS DISPATCH, Apr. 15, 2018, https://www.dispatch.com/news/20180415/three-cvs-actions-raise-concerns-for-some-pharmacies-consumers.

[15] Marty Schladen & Catherine Candisky, *When Pharmacy-Benefit Manager Cuts Put Lives in Jeopardy*, THE COLUMBUS DISPATCH, May 25, 2018, https://www.dispatch.com/news/20180521/when-pharmacy-benefit-manager-cuts-put-lives-in-jeopardy/1.

[16] HHS, *Fact Sheet*.

[17] *LePage's v. 3M*, 324 F.3d 141 (3d Cir. 2003).

A. U.S. Patent Office does not *intend* to grant patents for "tweaks" to inventions, but cannot *ensure* no invalid patents granted because of (1) limited time, (2) warped incentives, and (3) *ex parte* nature of process

B. Examiners have only 19 hours to review each application[18]
   1. Within this period, examiner must read application, search for prior art, compare prior art with application, write rejection, respond to applicant's arguments, and (often) conduct interview with attorney[19]
   2. Michael Frakes & Melissa Wasserman found that as a patent examiner is promoted (and given less time to review applications), "the less active she becomes in searching for prior art, the less likely she becomes to make time-intensive rejections, and the more likely she becomes to grant the patent."[20]
      a) As a result, the grant rate is 13% to 29% higher for promoted examiners[21]
      b) Based on a comparison with foreign offices, these marginal patents are "of questionable legal validity."[22]
   3. Examiners themselves have lamented that they are "fighting for their lives" and are "not [given] enough time to do a proper job."[23]
   4. The period for patent review has not been reevaluated since the 1970s, and the General Accounting Office and Office of the Inspector General have recommended reassessing examination time[24]

C. Examiners have incentives to grant patents
   1. Frakes & Wasserman have shown that "the vast majority of the PTO's budget is gained through fees that the Agency collects only if a patent is granted."[25]
      a) This result is particularly likely in industries where patents are more likely to be renewed (like pharmaceuticals), as "the PTO stands to gain more financially" in those settings[26]
      b) As a result, "the PTO's current fee schedule likely biases the Agency to grant patents."[27]
   2. Frakes & Wasserman also have demonstrated that the PTO's "inability to finally reject a patent application" contributes to the agency's "bias[] toward granting patents."[28]
      a) In particular, "an aggrieved patent applicant can always choose to start the examination process over by filing a repeat application" that takes the form of a continuation application or a request for continued examination (RCE)[29]
      b) Repeat filings can "seriously undermine the examination process," as they make up a "substantial portion" of the backlog in patent applications[30]
      c) As a result, the PTO "allow[s] additional patents early in the examination process," which "extinguishes the incentive of patent applicants to refile" and thus "turn[s] off the spigot of repeat filings, in the process reducing its backlog[31]

D. Examiners hampered by *ex parte* nature of process, with the examiner only able to communicate with the applicant, who is not required to search for prior art
   1. This challenge is particularly acute in areas in which it is difficult to locate prior art
   2. PTO examiners are required to rely on the agency's computer systems, which do not offer comprehensive databases of product sales or unpatented published materials

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[18] Michael D. Frakes & Melissa F. Wasserman, *Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents?: Evidence form Micro-Level Application Data*, NBER, at 18, July 2014, https://www.nber.org/papers/w20337.pdf.

[19] *Id.*

[20] Michael D. Frakes & Melissa F. Wasserman, *Irrational Ignorance at the Patent Office*, 72 VAND. L. REV. 975, 984 (2019).

[21] *Id.*

[22] *Id.* at 986.

[23] *Id.* at 979 (citation omitted).

[24] USPTO, *Examination Time and the Production System*, https://www.uspto.gov/sites/default/files/documents/Examination%20Time%20and%20the%20Production%20System.pdf#page=4.

[25] Michael D. Frakes & Melissa F. Wasserman, *Does Agency Funding Affect Decisionmaking?: An Empirical Assessment of the PTO's Granting Patterns*, 66 VAND. L. REV. 67, 79 (2013).

[26] *Id.* at 88.

[27] *Id.* at 124.

[28] Michael D. Frakes & Melissa F. Wasserman, *Does the U.S. Patent and Trademark Office Grant Too Many Bad Patents?: Evidence from a Quasi-Experiment*, 67 STAN. L. REV. 613, 676 (2015).

[29] *Id.* at 625.

[30] *Id.* at 627.

[31] *Id.* at 628.

3. In most cases, due to security concerns, examiners cannot use the Internet for research[32]
4. Difficulties in prior art searching are confirmed by a study that concluded that examiners were at a "strong comparative disadvantage" in searching for prior art that appeared in nonpatent prior art or foreign patents[33]
5. Examiners accounted for 41% of citations to U.S. patents but only 10% of citations to nonpatent prior art[34]

E. These deficiencies have an effect, with post-patent reviews in the Patent Office showing that not all issued patents are valid:
1. For second-look reviews (inter partes review (IPR), post grant review (PGR), and covered business method review (CBM), Patent Trial and Appeal Board (PTAB) found only 1/5 of patents valid in their entirety
   a) PTAB found that for 63% of patents, all claims were unpatentable, and for 18%, some claims were[35]
2. One example is provided by the Humira patents, with one IPR leading to the conclusion that all of the claims of 3 AbbVie patents were unpatentable
   a) PTAB rejected secondary considerations of nonobviousness based on previous statements by AbbVie highlighting reasons for commercial success other than the ones recited in the patents at issue
3. For Orange Book-listed patents, PTAB overturned initial findings of patentability in roughly half the cases
   a) PTAB found all claims unpatentable in 46% of cases, and some claims unpatentable in 3%[36]
4. An exhaustive FTC report found that generics prevailed in 73% of patent infringement cases[37]
5. The courts have overturned roughly half of all issued patents
   a) According to one oft-cited study, courts found that 46% of patents litigated to judgment are invalid[38]

## V. Patent Quality Proposal

A. Given the number of invalid patents issued, Congress should ensure that IPR and PGR procedures remain robust
B. Legislation that weakens critical post-patent review should not be enacted
C. For that reason, Congress should not enact the Hatch-Waxman Integrity Act of 2018, which forces generics to choose between using IPR/PGR and obtaining the protections of the Hatch Waxman Act (HWA)
1. Such legislation would mark the death knell for IPR in the pharmaceutical industry
2. Generics would never pursue IPR given that they could not use the foundational HWA procedures that allow them to offer low-cost alternatives by not replicating costly and lengthy brand clinical trials
3. A principal HWA drafter explained that "IPR proceedings enhance the integrity" of HWA by providing a pathway for cancelling invalid patents before they can be listed in the Orange Book[39]
4. The drafter also explained that "[i]nsulating pharmaceutical patents from the quality control review created by the America Invents Act will only serve to encourage the procurement and enforcement of non-meritorious patents to delay legitimate generic competition."[40]

D. Congress could consider providing resources to PTO for more thorough examinations
1. Frakes & Wasserman find that doubling the amount of time examiners have for review would result in the PTO's grant rate falling roughly 19 percentage points, which equals 80,000 fewer patents per year[41]
   a) Doubling the amount of hours would lead to $660 million in costs each year (but would yield more than $900 million in annual savings)

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[32] *See* USPTO, MANUAL OF PATENT EXAMINING PROCEDURES § 904.02(c) (2018) (examiners must "restrict search queries to the general state of the art" unless the PTO has established "a secure link over the Internet with a specific vendor to maintain the confidentiality of the unpublished patent application").

[33] Bhaven N. Sampat, *Determinants of Patent Quality: An Empirical Analysis*, at 2-3, 11, Sept. 2005, http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.382.8290&rep=rep1&type=pdf.

[34] *Id.* at 8.

[35] USPTO, *Trial Statistics: IPR, PGR, CBM*, at 10, Mar. 2019, https://www.uspto.gov/sites/default/files/documents/trial_statistics_mar_2019.pdf (figures from 2012 to 2019).

[36] USPTO, *Chat with the Chief: New PTAB Studies in AIA Proceedings: Expanded Panels and Trial Outcomes for Orange Book-listed Patents*, Mar. 13, 2018, at 45, https://www.uspto.gov/sites/default/files/documents/chat_with_the_chief_march_2018.pdf (figures from 2012 to 2017).

[37] FTC, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 13 (July 2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf.

[38] John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205 (1998).

[39] Alfred B. Engelberg, *Hatch Amendment Would Delay Generic Competition And Increase Drug Costs*, HEALTH AFFAIRS BLOG, Nov. 9, 2018, https://www.healthaffairs.org/do/10.1377/hblog20181106.747590/full/.

[40] *Id.*

[41] Frakes & Wasserman, *Irrational Ignorance*, at 985.

E. Congress also can ensure that follow-on patents for drug improvements are only granted for true innovations by supporting the robust application of antitrust enforcement through legislation that would target questionable patents without harming innovation:
   1. Pay-for-delay settlements (Preserve Access to Affordable Generics and Biosimilars Act)
   2. Sample denials (CREATES Act)
   3. Citizen petitions (Stop STALLING Act and/or Efficiency and Transparency in Petitions Act)
   4. Product hopping and patent thicketing (Affordable Prescriptions for Patients Act of 2019)

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***Response to Senator Klobuchar's Questions for the Record***
***Sen. Jud. Comm. Hearing on "IP and the Price of Prescription Drugs: Balancing Innovation and Competition"***
**May 28, 2019**

## I. Citizen Petitions

A. Meant to raise legitimate concerns, but really used to delay generic entry, with my empirical study showing FDA denies 92% of 505(q) petitions, 98% of late-filed petitions[1]
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[2]
C. FDA has evidenced "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"[3]
    1. FDA "remains concerned" that the resources it is forced to incur come "at the expense of completing the other work of the Agency."[4]

## II. Stop STALLING Act Beneficial

A. Legislation finding that delaying conduct is sham could help courts cut through firewall of *Noerr-Pennington* immunity
B. Helpful to include as "sham" petitions not only 505(q) petitions but also "series" of such petitions
C. Beneficial to give FTC Section 5 authority and put congressional stamp of disapproval on abusive citizen petitions
D. Useful deterrent to impose penalty of drug revenue (while petition under review) or (if larger) $50,000 a day

## III. Stop STALLING Act Could Be Stronger in 2 Ways: (1) List Sham Factors and (2) Address Subjective Inquiry

A. Focus on general "sham" conduct without specific supporting detail would be lost opportunity
    1. Because of importance of petitioning, courts set very high bar before finding "sham" exception to *Noerr* immunity
    2. Legislation could make clear that this is not just general "sham" conduct but bears specific markers of abusive behavior in the form of a list of factors
B. Factors relevant to determining sham appear in FDA draft guidance[5] that sheds light on "primary purpose of delay":
    1. Unreasonable length of time to submit petition
    2. Multiple petitions challenging conduct that reasonably could have been known at time of earlier petition
    3. Petition submitted close in time to date on which application could be approved
    4. Petition submitted without supporting data/information
    5. Petition raising same or substantially similar issues as prior petitions that have received response
    6. Petition addressing standards for which there is opportunity for public input but for which petitioner did not comment
    7. Petition requesting that other applicants meet standards more rigorous than petitioner did
    8. Petitioner's history
C. These factors common in abusive petitions
    1. In my empirical studies, I did not come across sham petitions not covered by these categories

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[1] *See* Michael A. Carrier & Carl J. Minniti III, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 AMERICAN UNIVERSITY LAW REVIEW 305 (2016), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2832319.

[2] *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), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2841445

[3] 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 (2016), http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ReportsBudgets/UCM517279.pdf.

[4] *Id.*

[5] FDA, *Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act*, Oct. 2018, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/citizen-petitions-and-petitions-stay-action-subject-section-505q-federal-food-drug-and-cosmetic-act-0.

2. The factors also appear in the Lower Health Care Costs Act and Ensuring Timely Access to Generics Act of 2019

D. The Stop STALLING Act reflects the caselaw's "subjective" prong in emphasizing the use of the governmental process, as opposed to the outcome, to interfere with a rival
   1. But it is difficult to know why a petition is filed, and this information is often shielded by privilege issues
   2. For that reason, the court in *FTC v. AbbVie* made clear that:
      a) Because of the difficulty of proving state of mind, intent "is usually a matter of inference."[6]
      b) Subjective-intent finding could be shown by actions of experienced attorneys who file objectively baseless suits, which makes it "reasonable to conclude that they intended the natural and probable consequences of acts they knowingly did."[7]

E. Like *AbbVie*, the Stop STALLING Act could provide that:
   1. Evidence of intent can be shown not only through direct evidence but also through indirect evidence
   2. Experienced actors engaged in objectively baseless conduct could demonstrate subjective element

## IV. Administrative Changes

A. In addition to addressing antitrust liability for sham behavior, legislature could make helpful administrative changes, such as those offered in S. 660, the Efficiency and Transparency in Petitions Act[8]

B. Because of delayed and serial petitions, legislation could require petition to be filed within a specified period (60 days to 1 year) of learning of safety/efficacy issue
   1. Legislation also could require subsequent petitions to explain why the information or allegations was not in the initial petition

C. Because of lack of transparency, legislation could mandate that FDA include comprehensive list of 505(q) petitions in annual reports to Congress, including:
   1. Timing of petition in relation to patents listed in Orange Book
   2. Time FDA expended on petition
   3. Delay (if any) in generic approval caused by petition and determination of how delay calculated

D. Such provisions very helpful because FDA does not maintain easily searchable list of 505(q) petitions, nor does it explain what is "delayed" petition
   1. FDA claims one petition each year is delayed, but considers delay only if response comes after 150-day response period[9]
   2. FDA not consider that there could be delay in not approving generic until it resolves petition

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[6] FTC v. AbbVie, Case 2:14-cv-05151-HB (E.D. Pa. June 29, 2018).

[7] *Id.*

[8] *See also* Michael A. Carrier, *Five Actions to Stop Citizen Petition Abuse*, 118 COLUMBIA LAW REVIEW ONLINE 81 (2018), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3043541.

[9] *See* 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 9 (2015) (finding that "a petition answered within the [150-day] statutory deadline does not delay approval of a pending application").

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## I. Patent Thicketing and Product Hopping Pervasive

A. Issues of patent thicketing and product hopping pervasive
B. Patent thicketing becoming common
   1. Humira has 138 patents, including 53 obtained in 2015-16, just before the active-ingredient patent expired[1]
      a) Humira patents cover indication/method of treatment (24), formulation (14), manufacturing (24)
   2. J&J's Remicade also protected by more than 100 patents
   3. I-MAK analysis of 12 best-selling U.S. drugs found 125 applications and 71 patents per drug, including
      a) Avastin (86 patents), Eliquis (27), Enbrel (41), Eylea (51), Herceptin (108), Lantus (49), Lyrica (68), Revlimid (96), Rituxan (94), Xarelto (30)[2]
C. Product hopping common
   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, Risperdal[3]

## II. Impact on Consumers

A. Patent thicketing and product hopping have significant effect on consumers
B. By delaying generics, conduct forces consumers to pay high monopoly prices instead of low competitive prices
   1. Consumers unable to afford monopoly prices do not take needed medicines, cut pills in half, and choose between paying for medications and food/rent
C. I-MAK found average 68% price increase from 2012 to 2017, including double-digit increases for:
   1. Avastin (16%), Eliquis (69%), Enbrel (155%), Humira (144%), Lantus (114%), Lyrica (163%), Revlimid (79%), Remicade (18%), Rituxan (25%), Xarelto (87%)
D. Even though patent term lasts only 20 years (and FDA exclusivity is shorter), each of the 12 drugs studied blocked competition for much longer:
   1. Avastin (43 years), Eliquis (34), Enbrel (39), Eylea (34), Herceptin (48), Humira (39), Lantus (37), Lyrica (32), Remicade (32), Revlimid (40), Rituxan (47), Xarelto (31)

## III. Legislation to Address

A. Affordable Prescriptions for Patients Act of 2019 would address these issues
B. Patent thicketing legislation would give FTC power to challenge concerning behavior
   1. Obtaining a patent is not a Section 5 violation, so need rigorous requirements
   2. Legislation meets this test in limiting scrutiny to (1) patents in same patent family or portfolio filed after FDA application or (2) underlying composition-of-matter patent found invalid with manufacturer obtaining additional patents that can't be avoided and FTC finding improper restriction of competition
   3. Factors for FTC to consider highlight worrisome aspects of patent thicketing like identical claims, invalidated patents, and intent to "unduly limit competition"
   4. Could prevent next 100+ patent portfolio
C. Product hopping
   1. Legislation targets reformulations made at a time that generic entry is anticipated
   2. Legislation addresses "hard switches" (in which original drug pulled from market) and "soft switches" (in which original drug remains on market) where no safety- or financial-based explanation

## IV. Priority

A. Patent thicketing and product hopping should be high on Congress's priority list
B. Not many options for addressing patent thicketing
   1. Until recently, every biosimilar manufacturer with a version of Humira had settled with AbbVie, agreeing not to enter U.S. market until 2023

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[1] Cynthia Koons, *This Shield of Patents Protects the World's Best-Selling Drug*, BLOOMBERG, Sept. 7, 2017, https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug.

[2] I-MAK, *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices*, https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf.

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

2. The last holdout, Boehringer Ingelheim (which had robustly litigated, uncovering evidence of anticompetitive behavior and advancing an "unclean hands" defense) recently also settled for a 2023 entry date
3. Obtaining patents is not typically viewed as an antitrust violation, and biologic manufacturers will claim that the Patent Office has lawfully granted each of the patents
4. But at some point, it becomes clear that the reason for amassing the thicket is not to protect innovation but to harm rivals
5. FTC is the expert agency in the pharmaceutical industry; giving it authority to challenge this conduct helpful

C. Legislation beneficial to address product hopping
1. Courts recognize anticompetitive harms of hard switch, not always recognize soft switch
   a) *Walgreen's* court concluded that 2 products automatically better than 1[4]
2. Courts sometimes distracted and neglect antitrust goals
   a) *Doryx* court focused on competitor rather than consumer[5]
3. Legislation highlights concerning aspects of product hopping: reformulation at time when generic entry anticipated, with no reason for the reformulation other than harming the generic

**V. Killer Acquisitions**

A. "Killer acquisitions" worrisome
1. Empirical study showed a 29% reduced likelihood that a drug will be developed after incumbent with overlapping drug acquires[6]
   a) Also 47% less likely that drug project will enter Phase II if acquired during Phase I by company with overlapping drug
2. *E.g.*: Questcor had monopoly on infant-seizure-treating ACTH, acquired rights to competing Synachten, and increased price 85,000% (from $40/vial in 2001 to $34,000/vial in 2017)
3. Related concept is "innovation markets," or markets for research and development
   a) The concern is that a merger between the two firms most advanced in R&D have a heightened incentive to suppress one of the research paths
   b) Antitrust agencies have challenged mergers in innovation markets, like (1) Glaxo and Wellcome, (2) Upjohn and Pharmacia, (3) GlaxoWellcome and SmithKline Beecham, and (4) Baxter and Immuno[7]

B. Concerning that pharmaceutical companies merging with potential competitors in deals structured to avoid Hart-Scott-Rodino Act's pre-merger notification requirements
1. Empirical analysis found "clear bunching of deals right below the review threshold," but only for "deals in which the target has projects that overlap with the acquirer" (i.e., "killer acquisition")[8]
2. Study found that "survival rate of below-threshold acquisitions is drastically lower than those right above the threshold."
   a) Analysis found that below-threshold acquisitions led to lower product launch rate (1.8% vs. 9.1%) and higher discontinuation rate (94.6% vs. 83.3%).

C. Congress could consider HSR adjustments in pharmaceutical industry
1. Adjustments could lower thresholds by a certain percentage for size-of-person and size-of-transaction tests
2. Size of percentage reduction would depend on tradeoff between (a) greater chance of finding anticompetitive deals and (b) increased burden of heightened reporting requirements
3. Legislation could require agencies to provide guidance on how to adjust thresholds to balance these objectives in the pharmaceutical industry

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[4] *Walgreen Co. v. AstraZeneca Pharmaceuticals*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008) (ignoring "price disconnect" between doctors prescribing drugs and patients/insurers paying for drugs by stating that brand "added choices," with determination of product superiority "left to the marketplace").

[5] *Mylan Pharmaceuticals v. Warner Chilcott*, 838 F.3d 421, 438 (3d Cir. 2016) (rejecting possibility of antitrust violation since "Mylan was not foreclosed from the market").

[6] Colleen Cunningham et al., *Killer Acquisitions*, Aug. 28, 2018, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3241707.

[7] Michael A. Carrier, *Two Puzzles Resolved: Of the Schumpeter-Arrow Stalemate and Pharmaceutical Innovation Markets*, 93 IOWA L. REV. 393 (2008).

[8] Cunningham, *Killer Acquisitions*.