14-4624

United States Court of Appeals for the Second Circuit

PEOPLE OF THE STATE OF NEW YORK, by and through ERIC T. SCHNEIDERMAN, Attorney General of the State of New York,

Plaintiff-Appellee,

v.

ACTAVIS PLC, FOREST LABORATORIES, LLC,

Defendants-Appellants.

On Appeal from the United States District Court
for the Southern District of New York

BRIEF FOR INTELLECTUAL PROPERTY AND ANTITRUST PROFESSORS AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFF-APPELLEE

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STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici are professors of intellectual property (IP) and antitrust law. Their sole interest in this case is to ensure that patent and antitrust law develop in a way that serves the public interest and public health by promoting both innovation and competition.[1]

Amici[2] are among the leading scholarly experts on the application of IP and antitrust law in regulated industries. They include co-authors of the seminal treatises on IP and antitrust law and antitrust law generally, as well as authors of the primary academic articles analyzing pharmaceutical product hopping and other anticompetitive conduct in the context of the Hatch-Waxman Act. *Amici* have closely studied the underlying legal issues material to this appeal and submit this brief to assist the court in its analysis of how antitrust law may apply in the context of product hopping. In particular, *amici* explain that antitrust law is an appropriate means to protect Hatch-Waxman's carefully crafted statutory scheme – designed to promote generic competition – from predatory regulatory gaming behavior that can

[1] *Amici* certify that counsel for both appellants and appellee consented to the filing of this brief. *Amici* also certify that no party's counsel authored this brief in whole or in part, and that no person, including any party or party's counsel, contributed money that was intended to fund preparing or submitting this brief.

[2] Brief biographies of *amici*, Professors Michael A. Carrier, Stacey L. Dogan, Harry First, Herbert Hovenkamp, Mark A. Lemley, and Christopher Leslie, are included in the Appendix.

produce serious anticompetitive harm and raise drug prices for consumers, the government, and third-party payers.[3]

SUMMARY OF ARGUMENT

Seeking to correct the dearth of competition in the pharmaceutical industry that arose from duplicative and prohibitively expensive testing requirements, Congress enacted the Hatch-Waxman Act in 1984. Hatch-Waxman was intended to recalibrate the balance between innovation and competition by crafting a compromise that facilitated generic entry into the market while strengthening brand enforceability of patents. States supplemented this effort by liberalizing drug-substitution laws to reduce market friction and facilitate price competition at the pharmacy counter.

Hatch-Waxman has been largely successful at promoting meaningful competition in the pharmaceutical marketplace, but it has also created a regulatory system that brand-drug monopolists can game to produce anticompetitive effects. Because the Food and Drug Administration (FDA) approval process examines only the safety of new drugs and not their effects on competition, branded-drug manufacturers can manipulate the regulatory system to exclude generic

[3] *Amici* thank Stanford Law School Juelsgaard Intellectual Property and Innovation Clinic certified law students Brian Weissenberg, Yale Fu, Vikram Iyengar, Emily Warren, and Rachel Yu for their valuable contributions to this brief.

competitors and artificially extend the limited monopoly power created by their patent rights.

The Supreme Court has recently made clear in *FTC v. Actavis* that antitrust law applies to anticompetitive subversion of Hatch-Waxman's purpose and mechanism through one form of regulatory gaming, reverse-payment settlements. Another type of regulatory gaming, at issue in this appeal, is so-called "product hopping." In product hopping, a branded drug manufacturer restrains generic competition by switching the market away from the earlier version of its drug to which generics were equivalent, thereby effectively thwarting generic entry that would otherwise have flourished through Hatch-Waxman equivalence and state drug substitution laws. While product hopping may take various forms, *Amici* in this brief focus on the "forced switch" found by the district court below, where the earlier version of the drug is effectively withdrawn from the market. Because product hopping typically exploits the Hatch-Waxman framework to restrain generic competition and cause anticompetitive effects with no countervailing procompetitive justification, it can constitute illegal exclusionary conduct under Section 2 of the Sherman Act.

The type of product hopping at issue in this case – withdrawing drugs from the market and forced-switches to new versions – undermines the generic entry and competition intended and facilitated by the operation of Hatch-Waxman

and state drug substitution laws. This exclusionary conduct can violate Section 2 by foreclosing competition and reducing consumer choice when it is undertaken without a purpose other than eliminating competition or when its anticompetitive effect outweighs any business purpose.

ARGUMENT

I. Product Hopping Manipulates the Hatch-Waxman Regulatory Framework to Exclude the Generic Competition the Act Is Designed to Enable

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act,[4] to facilitate market entry of low-cost generic drugs while increasing the incentives for pharmaceutical companies to invest in developing new drugs.[5] The Act was squarely aimed at preventing the "practical extension of the monopoly position of

[4] 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 (2006)).

[5] The legislative history of the Hatch-Waxman Act confirms that the Act was intended to mitigate the "serious anti-competitive effects" of FDA rules on generic drug approval. H.R. Rep. No. 98-857(II), pt. 1, at 4 (1984); *see* Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 42-45 (2009) (explaining how Congress promoted generic competition through an experimental use defense, a new abbreviated approval process and a 180-day period of marketing exclusivity for the first generic to challenge a brand firm's patent; and how it fostered brand-firm innovation through patent term extensions, periods of market exclusivity not based on patents, and an automatic 30-month stay of FDA approval).

the patent holder beyond the expiration of the patent."[6] Around the same time, all 50 states passed laws that allow—and in many cases, require—pharmacists to substitute a generic drug when presented with a prescription for its branded equivalent, unless a physician directs or the patient requests otherwise.[7] Together with Hatch-Waxman, these state substitution laws "create a regulatory framework designed to reduce costs to consumers by lowering generic costs."[8] Substitution laws and Hatch-Waxman have been remarkably successful in facilitating competition in pharmaceutical markets and generating large savings for patients, health care plans, and the government.[9]

In response to these competition-promoting regulatory mechanisms mandated by Congress and the states, some branded-drug manufacturers have

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[6] H.R. Rep. No. 98-857(II), pt. 1, at 4 (1984).

[7] See, e.g., N.Y. EDUC. LAW § 6816-a (McKinney 2014). *See also* Michael A. Carrier, *A Real World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 Fla. L. Rev. 1010, 1017 (2010).

[8] Br. for Fed'l Trade Comm'n as *Amicus Curiae* at 7, Mylan Pharms., Inc. v. Warner Chilcott Pub. Co., (No. 12-3824), 2013 WL 5692880 (hereinafter "FTC Amicus").

[9] In 2012 alone, the use of generic drugs saved consumers $217 billion. Generic Pharmaceutical Association, *Generic Drug Savings in the U.S.* (5th ed. 2013) at 2, *available at* http://www.gphaonline.org/media/cms/2013_Savings_Study_12.19.2013_FINAL.pdf. *See also* C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 Antitrust L.J. 947, 952 (2011) (stating that "once multiple generic firms enter the market, prices fall, often dramatically" and providing supporting empirics to show that prices for a cholesterol-reducing drug dropped from $150 pre-generic entry to $7 post-entry).

employed strategies to delay or effectively exclude the intended generic competition. One strategy brand manufacturers use to game this carefully tailored regulatory system is product hopping, forcing the market to switch to a new, protected (either by patent or FDA approval) version of their brand drug, for which generics do not have Hatch-Waxman equivalence, thereby thwarting Hatch-Waxman and substitution laws and restraining generic competition.[10]

A. Congress Created the Hatch-Waxman Framework to Promote Generic Competition Following Patent Expiration

Congress enacted Hatch-Waxman in response to the high costs of pharmaceuticals resulting from patent monopolies on branded drugs and from delayed generic market entry.[11] Before the Act, generics could not cost-effectively enter markets to compete because of the need for expensive duplicative testing.[12] As a result, branded drugs continued to reap monopoly profits long after patents expired because of the de facto extension of their patent term. Congress therefore

[10] See Section II.B., *infra*.

[11] In 1983 alone, the Federal Government spent $2.4 billion for drugs through Medicaid and in veterans and military hospitals. Then-President Ronald Reagan stated that the Hatch-Waxman Act would enable "the Federal Government, the largest single consumer of drugs, [to] be able to purchase generic drugs at significantly lower cost." Ronald Reagan, President of the United States, Remarks on Signing S. 1538 into Law (Sep. 24, 1984). Congress noted that prices of generic versions of ten popular drugs were "on average 50 [%] less than their brand name equivalent[s]." H.R. Rep. No. 98-857(II), pt. 1, at 32 (1984).

[12] H.R. Rep. No. 98-857(II), pt. 1, at 5 (1984) (stating that "the inability of generics to obtain approval . . . without enormous expenditures of money for duplicative tests" resulted in a practical extension of the patent monopoly).

sought to increase the availability of generic substitutes to reduce both healthcare costs and the high percentage of individual income spent on pharmaceuticals.[13] The Supreme Court recently confirmed that Hatch-Waxman's purpose was to "speed the introduction of low-cost generic drugs to market, thereby furthering drug competition." *FTC v. Actavis*, 133 S.Ct. 2223, 2228 (2013).

The proponents of the Hatch-Waxman legislation urged its adoption as the best possible compromise between the competing economic interests of patentees and generic manufacturers.[14] On one hand, Hatch-Waxman granted generic manufacturers expedited entry to the market.[15] Rather than submitting full safety and efficacy data to the FDA, a generic manufacturer can now obtain much faster and cheaper approval by filing an Abbreviated New Drug Application (ANDA), which certifies the bioequivalence of its generic to an existing branded

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[13] The legislative history notes that the reduction in drug prices would be "especially important to the poor, the under-insured, and the elderly. The government itself, as purchaser of prescription drugs, [would] also save money as a result." H.R. Rep. No. 98-857(II), pt. 1, at 29 (1984).

[14] Hemphill & Lemley, *supra* note 9, at 947 ("The Hatch-Waxman Act gave additional protection to the inventors of new drugs, both by lengthening patent terms and by providing guaranteed terms of data exclusivity. In exchange, Hatch-Waxman made it easier for generic drug manufacturers to enter the market with a copy of the drug.").

[15] H.R. Rep. No. 98-857(II), pt. 1, at 11 (1984); Herbert Hovenkamp, Mark D. Janis, Mark A. Lemley, & Christopher R. Leslie, *IP & Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* § 15.3c, at 15-77 (2d ed. Supp. 2013) [hereinafter "*IP & Antitrust*"].

drug.[16] This path for expedited entry represents Hatch-Waxman's mechanism to correct the market failures of the highly regulated pharmaceutical market that effectively prevented generic competition. In return, Hatch-Waxman provided substantial benefits for branded manufacturers, including extending the terms of certain drug patents, "creat[ing] incentives for increased research expenditures" by patentees.[17] The very nature of the highly regulated market necessitated the compromise.[18]

B. State Generic Substitution Laws Effectuate Hatch-Waxman's Purpose

One unique element of the highly regulated pharmaceutical market is the prescription system. Unlike in other markets where consumers have direct access to products in the marketplace, pharmaceutical products only reach consumers through physician prescriptions that are filled by pharmacists. Physicians prescribe drugs they are aware of and usually hesitate to change

[16] 21 U.S.C. § 355(j) (2006).
[17] H.R. Rep. No. 98-857(II), pt. 1, at 10 (1984) (Congress noted in the legislative history that "[i]n most cases the bill affords greater protection for patent holders than current law.").
[18] H.R. Rep. No. 98-857(II), pt. 1, at 9 (1984) (stating that the Hatch-Waxman Act was designed to "implement the policy objective of getting safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent."); *id.* at 30 ("The nature of the interference with patent rights created by [Hatch-Waxman] is necessitated by the very nature of the industry involved.").

prescriptions for patients who have a productive routine.[19] Physicians often become familiar with the brand name drug and continue to prescribe it by name, even following patent expiration and entry of generics.[20] Given these factors, pharmaceutical markets historically suffered from a high degree of market friction and product "stickiness" that had little correlation to product value or competitive efforts.

As part of the regulatory movement that motivated Hatch-Waxman, all fifty states enacted generic substitution laws to correct these market failures. These laws give pharmacists the option (or require them, in some states) to fill prescriptions for a brand drug with a bioequivalent AB-rated generic drug. This substitution retains an FDA assurance of safety (to be AB-rated, generics must be therapeutically equivalent to FDA-approved drugs) while allowing generics the

[19] *See, e.g.*, SA-55-56 (district court's finding that any alterations to the medical routine of patients taking Appellants' drug could cause them to move to a care facility).

[20] Douglas A. Lundin, *Moral Hazard in Physician Prescription Behavior*, J. Health Econ. 19; 5, 639-62 (Sept. 2000) (physicians may continue prescribing brand drugs after patent expiration for a number of reasons, including brand loyalty from marketing and moral hazard); William H. Shrank et al., *The Consequences of Requesting 'Dispense as Written'*, Am. J. Med. 124; 4, 309-17, 315 (Apr. 2011), *available at* http://www.amjmed.com/article/S0002-9343(10)01087-9/pdf ("[p]hysicians with a strong preference for branded medications may not be aware of whether a generic is available").

ability to compete at the only place they can cost-effectively access the market: the point of sale.[21]

Substitution laws do not "stack the deck" against brand manufacturers who have already availed themselves of a patent term's worth of monopoly profits; they merely ensure access to "cheaper generic drugs in lieu of more expensive brand name drugs" if the patient does not specifically need the more expensive drug. *Pharmaceutical Soc. of State of New York, Inc. v. Lefkowitz*, 454 F. Supp. 1175, 1178 (S.D.N.Y. 1978), *aff'd* 586 F.2d 953 (2d Cir. 1978). The laws remove unnecessary transaction costs in marketing and physician-pharmacist communication that would occur each time a consumer wanted a cheaper generic drug, thereby reducing market friction and enhancing consumer choice and market competition. And they are part and parcel of the Hatch-Waxman compromise.[22]

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[21] *See, e.g.*, *In re Suboxone Antitrust Litig.*, 2014 WL 6792663, at *12 (E.D. Pa., Dec. 3, 2014) ("[V]arious market forces unique to the pharmaceutical industry make generic substitution the cost-efficient means of competing for companies selling generic pharmaceuticals.").

[22] *See, e.g.*, *Drug Legislation: Hearing on H.R. 1554 and 3605 Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce*, 98th Cong. 6 (1983) (statement of Mark Novitch, M.D., Deputy Comm'r., Food and Drug Admin.) ("In 1980, [the FDA] began to publish a list of all approved drugs with therapeutic equivalence evaluations to aid States and purchasers of generic drugs to substitute such drugs with confidence."); H.R. Rep. No. 98-857(II), pt. 1, at 11 (1984) (noting that enacting Hatch-Waxman could produce savings if "generic copies of these drugs are substituted").

C. "Piggy-Back" Generic Entry Is Central to Hatch-Waxman's and Substitution Laws' Purposes and Mechanisms for Facilitating Competition in the Pharmaceutical Industry

What Appellants seek to disparage as unfair "free riding"[23] is in fact precisely the balanced mechanism for facilitating generic competition that Hatch-Waxman and state drug substitution laws have carefully and deliberately created.[24] The Supreme Court recently recognized the important role that Hatch-Waxman's abbreviated approval procedures play in allowing generics to "obtain approval while avoiding 'the costly and time-consuming studies'" needed for a pioneer drug and to "piggy-back on the pioneer's approval efforts, 'speed[ing] the introduction of low-cost generic drugs to market' . . . thereby furthering drug competition." *FTC v. Actavis, Inc.*, 133 S.Ct. 2223, 2228 (2013) (internal citations omitted). The same piggy-back principle applies to marketing efforts.[25] The Hatch-Waxman framework thus positions generic drugs as low-cost alternatives that do not have to

[23] *See* Page Proof Br. for Defs.-Appellants 5 ("All that Forest's plans to reduce sales of Namenda IR would do is reduce its future rivals' ability to use state generic substitution laws to free-ride on Namenda IR prescriptions"). *See also id.* at 43.

[24] Hatch-Waxman was intended to improve the system for approval of generic drugs that the House Report described as "too cumbersome and expensive." H.R. Rep. No. 98-857(II), pt. 1, at 5 (1984).

[25] SA-78 ("Generics compete on price and avoid marketing to physicians because the costs of such marketing severely impact their ability to offer the significantly lower prices upon which they compete.").

rely on expensive and time-consuming promotional efforts by their producers.[26] State drug substitution laws operate in a similar way, recognizing that, after patent expiration, speeding price competition into the marketplace has great value.

This mechanism for facilitated generic entry and substitution solves the price disconnect between "prescribing doctors, who are not directly responsive to drug pricing, and paying insurers and consumers, who do not directly select the prescribed drug."[27] As a result, drugs are much cheaper and more widely available today than they were before Hatch-Waxman.[28] Without these laws and the procompetitive mechanisms they create, generics could not compete cost-effectively in this highly regulated marketplace. The ability of generics to succeed in the market by expedited approval and substitution on brand prescriptions is precisely the sort of procompetitive "piggy-backing" to lower prices for consumers that these regulatory regimes are specifically designed to enable.

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[26] *See* H.R. Rep. No. 98-857(II), pt. 1, at 4 (1984) (stating that Congress enacted Hatch-Waxman to allow generics to compete via "following on" branded drugs because other paths to get generics to market are not cost-effective).

[27] Carrier, *supra* note 7, at 1017 (noting that drug substitution laws "carve out a role for pharmacists, who are much more sensitive to prices than doctors.").

[28] The first generic to enter the market is typically 20% to 30% cheaper than the branded drug. Subsequent generic entry creates greater price competition, with discounts of 85% off the branded price. A recent study of 5.6 million prescriptions revealed that patients and insurers paid an average of $17.90 and $26.67, respectively, for generics and an average of $49.50 and $158.25 for brand drugs where no generic existed. FTC Amicus, *supra* note 8, at 7 (internal citations omitted).

D. Product Hopping By Branded-Drug Manufacturers Contravenes These Regulatory Frameworks and Harms Competition from Generics

The kind of product hopping at issue in this case – essentially withdrawing an existing drug from the market and forcing patients to switch to a newer version – thwarts the procompetitive benefits intended by Hatch-Waxman and substitution laws, and precludes effective generic entry and the competition and lower prices that entry would bring.[29]

Product hopping delays generic competition in several ways. First, by making modifications to its branded product, the firm can require its generic rival to start the ANDA process over again, repeating the FDA review for the new drug.[30] Second, where the branded drug's patent is still in force, the new ANDA can prompt a fresh litigation-triggered stay.[31] Third, product hopping prevents pharmacists from substituting generic versions for the new drug pursuant to state substitution laws until the generic's new ANDA is approved.[32] Where, as the

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[29] Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 Tex. L. Rev. 685, 709 (2009); *IP & Antitrust* § 15.3c, at 15-78.
[30] Dogan & Lemley, *supra* note 29, at 712; *IP & Antitrust* § 15.3c, at 15-78.
[31] Dogan & Lemley, *supra* note 29, at 711-12.
[32] Carrier, *supra* note 7, at 1017-18 (discussing how product reformulations further delay generics' attempts to achieve bioequivalence, sometimes by years); *IP & Antitrust* § 15.3c, at 15-78.4 ("until the ANDA for that new product is approved . . . state laws limit the ability of pharmacists to substitute the 'old' generic for the 'new' branded drug.").

district court found in this case,[33] the branded-drug firm plans to withdraw its previous drug from the market and thus force most doctors to write prescriptions for the new version, the market for generics will collapse.[34] With doctors prescribing only the new branded drug, generics must await completion of the additional ANDA approval process to even be considered for substitution, since substitution laws only allow FDA-certified equivalent generics to be prescribed.[35]

Product hopping "therefore presents a paradigmatic case of a regulatory game. . . . [It] exploits the product-approval process precisely because of its exclusionary effects and converts it into a tool for suppressing competition."[36] Without the FDA's lengthy product-approval process, generic firms could quickly go to market with competing versions of branded drugs when branded-drug patents expire. But the regulatory framework prevents them from doing so, and the ability of branded-drug firms to exploit Hatch-Waxman and force generics into multiple ANDAs before they can reach the market powerfully

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[33] *See, e.g.*, SA-67 (Appellants' limited distribution plan would "largely eliminate the use of [IR, the previous drug]") (internal quotations omitted); SA-118.

[34] Dogan & Lemley, *supra* note 29, at 712; Hemphill & Lemley, *supra* note 9, at 960 (while the generic firm waits for its new ANDA approval it may still sell its version of the old drug, "but that is often small comfort because pharmacists cannot substitute the old drug for the new brand-name drug.").

[35] Carrier, *supra* note 7, at 1018. *See also IP & Antitrust* § 15.3c, at 15-78.2 (citing *Abbott Labs*, 432 F. Supp. 2d at 422, to show how product hopping creates anticompetitive effects by delaying generic substitution).

[36] *IP & Antitrust* § 15.3c, at 15-78.4-79.

excludes such competition.[37] As some of the *amici* describe this problem in their treatise, "product hopping seems clearly to be an effort to game the rather intricate FDA rules."[38]

II. Product Hopping Can Constitute Exclusionary Conduct That Violates Section 2 of the Sherman Act

Standard antitrust monopolization analysis is well-suited to evaluate product design changes for effects on competition under Section 2 of the Sherman Act. *See, e.g.*, *United States v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001) (en banc) (change in versions of Windows). The Supreme Court has specifically approved antitrust scrutiny in the pharmaceutical industry for reverse-payment settlements, another form of Hatch-Waxman regulatory gaming. *Actavis*, 133 S. Ct. at 2225. Like reverse-payment settlements, product hopping can create a danger of exclusion of generic competition and is appropriately subject to antitrust scrutiny under Section 2.

A. Section 2 of the Sherman Act Is Well Suited to Address Product Hopping Through Its Straightforward Analytical Approach to Monopolization

A firm with market power illegally monopolizes if it willfully acquires or maintains that power through exclusionary conduct rather than "growth or development as a consequence of a superior product, business acumen, or

[37] *Id.*
[38] *Id.* at 15-78.

historical accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966); *see In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 133 (2d Cir. 2014). Exclusionary conduct by a monopolist impairs opportunities for rivals to compete and "does not further competition on the merits or does so in an unnecessarily restrictive way." *Aspen Skiing Co. v. Aspen Highlands Corp.*, 472 U.S. 585, 605 n.32 (1985). It is conduct "without a legitimate business purpose that makes sense only because it eliminates competition." *Adderall*, 754 F.3d at 133. Essentially, exclusionary conduct enables the monopolist to "prevent[] actual or potential rivals from competing or impair[] their opportunities to do so effectively."[39]

Courts have developed and successfully applied an appropriate standard to determine whether a product change constitutes illegal monopolization. Once a plaintiff demonstrates that the change has anticompetitive effects and harms competition, the defendant must present a "procompetitive justification" for its conduct, "a nonpretextual claim that its conduct is indeed a form of competition on the merits." *Microsoft*, 253 F.3d at 59. The plaintiff must then rebut the procompetitive justification or demonstrate that, even if it is valid, it is outweighed by the anticompetitive harm of the conduct. *Id*. at 58-59.[40]

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[39] 3 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 651 (4th ed. 2013).

[40] *See IP & Antitrust* § 15.3c, at 15-78.1 (suggesting that plaintiffs can establish antitrust liability by demonstrating that anticompetitive harm outweighs procompetitive benefit even when defendants establish a valid business reason for

1. Antitrust Laws Apply to the Pharmaceutical Industry

The mere fact that an industry is heavily regulated or features patent-protected products does not immunize behavior in that industry from antitrust scrutiny. Antitrust analysis "must always be attuned to the particular structure and circumstances of the industry at issue" and it may be considerably more important in industries where "nothing built into the regulatory scheme . . . performs the antitrust function." *Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411-12 (2004) (internal citations omitted); *see also United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 189 (3d Cir. 2005) (antitrust analysis must be guided by the economic realities of the industry at issue); *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056 (3d Cir. 1978) (in a pharmaceutical bundling case, holding that antitrust analysis must be specifically attuned to the special circumstances of the pharmaceutical industry).

Scholars, including some of the *amici* here, have described *Trinko* as advocating an inverse relationship between the regulatory scheme's effectiveness at protecting competition and the need for antitrust intervention.[41] Under *Trinko*, antitrust analysis is particularly important in the pharmaceutical context because

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their conduct); Dogan & Lemley, *supra* note 29, at 716-17. This weighing of anticompetitive effects against procompetitive justifications is similar to the rule-of-reason analysis in Section 1 cases. *See Microsoft*, 253 F.3d at 59.

[41] *See, e.g.*, Herbert Hovenkamp, *Antitrust and the Regulatory Enterprise*, 2004 Colum. Bus. L. Rev. 335, 353 (2004); Carrier, *supra* note 5, at 68-71.

the regulatory scheme fails to perform an antitrust function on its own. Further, regulatory tolerance of potentially anticompetitive behavior does not compel antitrust to "get out of the way to avoid interference in the regulatory scheme."[42]

The Supreme Court's most recent decision in this area upheld antitrust liability for patent-holding pharmaceutical companies, even where the challenged conduct occurred squarely within the Hatch-Waxman "drug-regulatory framework" and the alleged "anticompetitive effects fall within the scope of the exclusionary potential of the patent." *Actavis*, 133 S. Ct. at 2230 (reverse-payment settlements engineered to delay generic entry under Hatch-Waxman can violate the Sherman Act).[43]

Product hopping, like the reverse-payment settlements at issue in *Actavis*, can manipulate the provisions of the regulatory framework to exclude generic entry in a way not intended by that framework. *See id.* at 2234 (relying on

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[42] Dogan & Lemley, *supra* note 29, at 717; *see* C. Scott Hemphill, *Paying for Delay, Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1557 (2006) ("A particular regulatory regime sets the boundaries of feasible anticompetitive conduct.").

[43] Antitrust scrutiny of regulatory gaming of Hatch-Waxman is hardly novel. *See, e.g.*, *In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 351 n.14 (D.N.J. 2009) ("Antitrust claims are, moreover, frequently based on allegations of manipulation of the Hatch-Waxman regulatory framework."); *Walgreen Co. v. Organon, Inc.* (*In re Remeron Antitrust Litigation*), 335 F. Supp. 2d 522, 532 (D.N.J. 2004) ("Within the maze of Hatch-Waxman, if a patent-holder's actions unlawfully maintain otherwise lawful monopoly power or use a lawful patent to manipulate the ANDA process, such actions could lead to anticompetitive effects in the relevant market.")

the "general procompetitive thrust" and specific entry-promoting provisions of the Hatch-Waxman Act as reasons to recognize antitrust liability for reverse-payment settlements). Moreover, the FDA is not able to prevent this regulatory gaming because it explicitly avoids consideration of competition effects when approving pharmaceuticals. *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 241 (4th Cir. 2002) (describing the FDA's approach to Hatch-Waxman as "focus[ing] on its primary task of ensuring that drugs are safe and effective" while letting private parties sort out their respective rights).[44] The patent system likewise does nothing to mitigate regulatory gaming because patents are granted to new drugs without regard for their potential anticompetitive uses.

2. Appellants' Patents Do Not Confer Sweeping Antitrust Immunity

The Supreme Court in *Actavis* rejected the notion that the existence of a patent precludes antitrust scrutiny of any conduct involving that patent. Rather, the fact that the alleged "anticompetitive effects fall within the scope of the exclusionary potential of the patent" did not "immunize the agreement from antitrust attack." 133 S.Ct. at 2230. The Court rejected the contrary "scope of the patent" rule and instead stated that, in light of the specific circumstances of

[44] *See also IP & Antitrust* § 15.3c, at 15-79 ("Making matters worse, the [FDA] regulators can do nothing to thwart this obvious abuse of their administrative function.").

settlements in the Hatch-Waxman context, "it would be incongruous to determine antitrust legality by measuring the settlement's effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well." *Id*. at 2231.

Patent rights simply do not result in "an absolute and unfettered right to use [one's] intellectual property as [one] wishes . . . ." *Microsoft*, 253 F.3d at 63. Such a claim "is no more correct than the proposition that use of one's personal property, such as a baseball bat, cannot give rise to tort liability." *Id*.

Nor does 35 U.S.C. § 271(d)(4) (1988) provide the broad antitrust immunity appellants claim;[45] rather, that provision simply codified existing case law regarding the separate doctrine of patent misuse. This case is not about patent misuse, but instead about product hopping involving a patented product that can violate Section 2 under well-established antitrust case law.

The Supreme Court in *Actavis* did not hesitate to find antitrust liability for patent conduct due to any concerns about § 271(d)(4); in fact, it did not consider the provision at all. The U.S. Department of Justice Antitrust Division and the FTC, on the other hand, in their 2007 Antitrust and Intellectual Property Report, carefully considered arguments about the impact of § 271(d)(4) on

[45] *See* Page Proof Br. for Defs.-Appellants 36 (arguing that § 271(d)(4) "insulates non-use of a patent from antitrust liability").

potential antitrust liability.[46] The agencies relied upon "the well-established principle that immunity from antitrust laws is both exceptional and disfavored" and noted that, "absent 'clear, express Congressional intent to immunize conduct or . . . repugnancy between some other body of law and antitrust,' a finding of immunity is unwarranted."[47] They concluded that they "do not read the statute to create antitrust immunity for such refusals to license" patents.[48]

3. A Monopolist's Product Changes May Be Anticompetitive

Although courts generally "are properly very skeptical" that product design changes harm competition, it is well established that in certain circumstances a monopolist's product changes can do precisely that. *Microsoft*, 253 F.3d at 65 (holding unanimously that Microsoft's software-design changes constituted exclusionary conduct because "through something other than competition on the merits" they restricted rivals' ability to compete).[49] Product or

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[46] U.S. Dep't of Justice & Fed. Trade Comm'n, Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition (2007) 25-26, *available at* http://www.ftc.gov/sites/default/files/documents/reports/antitrust-enforcement-and-intellectual-property-rights-promoting-innovation-and-competition-report.s.department-justice-and-federal-trade-commission/p040101promotinginnovationandcompetitionrpt0704.pdf.

[47] *Id*. (internal citations omitted).

[48] *Id*. at 26.

[49] *See* Areeda & Hovenkamp, *supra* note 39 at ¶ 776a (Although "product improvement without more is protected and beyond antitrust challenge[,] . . . strategic creation of incompatibility can have serious anticompetitive consequences, particularly in 'network' industries where compatibility itself is

design changes are anticompetitive where they have no purpose "other than protecting [the] monopoly" and where they "unfairly tend[] to destroy competition itself." *Microsoft*, 253 F.3d at 67; *id.* at 58 (quoting *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993)).

Deference to product innovation "does not mean that a monopolist's product design decisions are per se lawful." *Id.* at 65; *see also C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1382 (Fed. Cir. 1988) (upholding jury verdict finding redesign of patented product violated Section 2). As some of the *amici* conclude in their treatise:

> While monopolists have no general duty to help their competitors, they do have an obligation to refrain from acts that have no purpose or effect except to exclude competition. And while distinguishing between the two can be tricky, courts have proven themselves up to the task, even in cases involving product design. It makes no sense to immunize patently anticompetitive behavior because of the risk that some cases might prove tough to decide. The proper standard requires deference to innovation, but not complete abdication.[50]

Product changes in the pharmaceutical industry such as the introduction of new drugs with significant benefits that increase patient choice can represent genuine innovation that furthers competition on the merits. Other

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often an essential ingredient to product success.") Given the regulatory framework for pharmaceuticals, incompatibility arises when branded drugs are modified to avoid bioequivalence with generics.

[50] *IP & Antitrust* § 15.3c, at 15-79 (citations omitted).

changes, however, such as the withdrawal of a successful drug from the market and forced switch of patients and doctors to a new version, particularly when made with no legitimate business justification and even at a profit sacrifice[51] (and, as in this case, with the clear intent and effect of avoiding imminent generic competition[52]), have no purpose but to exclude competition and are anticompetitive.[53] Such changes exploit the regulatory framework of Hatch-Waxman and state substitution laws to protect the branded firm's monopoly position by keeping out generic competition via substitution laws.

Anticompetitive conduct in product hopping cases does not require total foreclosure of competitors from the market; it only requires barring them "from their cost-efficient means of competing." *Abbott Labs v. Teva Pharms. U.S.A., Inc.*, 432 F. Supp. 2d 408, 423 (D. Del. 2006) (citing *Microsoft*, 253 F.3d at 64); *see Dentsply*, 399 F.3d at 191 ("[I]t is not necessary that all competition be

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[51] Profit sacrifices to restrict competition in the long run can indicate anticompetitive purpose and effect. *Trinko*, 540 U.S. at 409.

[52] The district court found that Appellants undertook their forced-switch strategy specifically to exclude competitors from meaningful, cost-effective access to the market after patent expiration. *See, e.g.*, SA-49 (quoting Appellants' executive: "We need to transition volume to XR to protect our Namenda revenue from generic penetration in 2015 when we lose IR patent exclusivity."); SA-51 (quoting another executive: "[I]f we do the hard switch . . . it's very difficult for the generics then to reverse-commute back, at least with the existing Rxs. They don't have the sales force. They don't have the capabilities to go do that. . . . [I]t just becomes very difficult and it is an obstacle . . .").

[53] *See* Carrier, *supra* note 7, at 1020.

removed from the market. The test is not total foreclosure but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit."). Because the only cost-effective means of competition for generic drugs under the Hatch-Waxman framework is through substitution laws,[54] foreclosing these channels means effective exclusion, even if generics could theoretically engage in expensive marketing and reach doctors directly. *See Abbott Labs*, 432 F. Supp. 2d at 423-24; *see Microsoft*, 253 F.3d at 70 (excluding Netscape from the most efficient channels of distribution, and "relegat[ing] it to more costly and less effective methods" can violate Section 2, even if less than 40% of the market is foreclosed).

Thus, deference to pharmaceutical product changes is especially inappropriate because of the regulatory barriers and market factors that restrict consumer choice between products and eliminate market competition when a product switch occurs.[55] In pharmaceutical markets, "the success of a product switching scheme does not depend on whether consumers prefer the reformulated

[54] *See* Section I.C., *infra*. *See also, e.g.*, SA-78 ("Generics compete on price and avoid marketing to physicians because the costs of such marketing severely impact their ability to offer the significantly lower prices upon which they compete."); SA-50-51; *In re Suboxone Antitrust Litig.*, 2014 WL 6792663 at *12 ("[V]arious market forces unique to the pharmaceutical industry make generic substitution the cost-efficient means of competing for companies selling generic pharmaceuticals.").

[55] *IP & Antitrust* § 15.3c, at 15-79.

version of the product over the original, or whether the reformulated version provides any medical benefit."[56] Product reformulations accompanied by withdrawal of the previous versions prevent "consumers from weighing the relative merits of competing products."[57]

Forced product switches like those in this case eliminate both consumer choice and drug competition. Because the previous version of the drug is removed from the market, patients are denied choices (both about which branded drug to choose and about whether to choose the branded drug or a generic), not given greater choice.[58] *See Abbott Labs*, 432 F. Supp. 2d at 422-24.

B. Forced Product Switches That Harm Competition Without Procompetitive Business Justification Violate Section 2

Forced product switches and similar types of product hopping that harm competition and have no procompetitive business justification constitute exclusionary conduct that violates Section 2 of the Sherman Act. *See Abbott Labs*, 432 F. Supp. 2d at 422; *In re Suboxone Antitrust Litig.*, 2014 WL 6792663, at *12 (E.D. Pa., Dec. 3, 2014). In the three primary cases that have previously addressed product hopping antitrust claims, the particular effects on competition and consumer choice in the market were determinative.

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[56] FTC Amicus, *supra* note 8, at 12-13.
[57] *Id.* at 13.
[58] SA-67 (Appellants' actions are "largely eliminating" the original drug's availability in the market).

In *Abbott Labs*, the court held that the plaintiffs properly alleged that product hopping defendants illegally excluded generic competition by introducing new drug formulations, withdrawing prior versions, and changing prior versions' National Drug Data File codes to "obsolete." *Abbott Labs*, 432 F. Supp. 2d at 424. These actions prevented pharmacists from filling prescriptions with generic alternatives because the drug to which those alternatives were AB-certified was no longer available to be prescribed. *Id.* at 415-16. Meanwhile, pharmacists were also unable to substitute prior-version generics on new branded-version prescriptions because the generics had not yet received AB-certification for the new branded formulation. Consumer choice and competition were eliminated; there was no "open market where the merits of any new product [could] be tested by unfettered choice." *Id.* at 422. In effect, the brand firm functionally excluded generics from the market since the generics could not compete cost-effectively on either version of the drug. Consumers had no access to the prior version – whether brand or generic – and were forced into the new brand version.

Abbott's "hard" or forced switch is distinguishable from a branded company merely introducing a new product version but not removing the old product from the market. In *Walgreen Co. v. AstraZeneca Pharmaceuticals L.P.*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008), another product hopping case, the manufacturer introduced and began vigorously marketing a newly patented drug,

but kept the original drug on the market at the same level of availability (though it ceased marketing it). The court found that, unlike in *Abbott Labs*, the manufacturer did not "deliberately limit rather than expand consumers' choices by merely changing the formulation of the drug." *Id.* The new product introduction in that case, the court found, did not saddle generics with a product withdrawal and forced switch that essentially prevented substitution. *Id.*[59]

The third product hopping case, decided two months ago, further illustrates the centrality of consumer choice and the anticompetitive effects of product withdrawals and forced switches. In *In re Suboxone Antitrust Litig.*, 2014 WL 6792663 (E.D. Pa., Dec. 3, 2014), the branded manufacturer allegedly fabricated safety concerns about its existing version that was soon to lose patent exclusivity in order to remove it from the market in favor of a new patented version. The court found this conduct coercive to patients because a patient preferring the existing version might be persuaded to switch "believing that their favored product would soon be removed from the market." *Id.* at *11. The switch would lock consumers into the new non-substitutable brand version once the old brand version was removed. Generic competitors thus would effectively be

[59] *See Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 287 & n.39 (2d Cir. 1979) (finding no liability for introducing new product but stating that "the situation might be completely different" if the defendant stopped producing old products or removed them from the market).

excluded even though they had nominal access to the market through selling outside of the substitution system, because the switch would bar their cost-efficient means of distribution (through substitution). *Id.* at *12 (citing *Microsoft*, 253 F.3d at 64).

A nuanced analysis of pharmaceutical markets, the Hatch-Waxman Act, and drug substitution laws, as applied by the courts in the above cases, makes clear that product hopping can constitute anticompetitive conduct under Section 2 if it excludes generic cost-effective competition and reduces consumer choice. When, as here, branded-drug manufacturers facing the expiration of patent exclusivity introduce a product change and effectively withdraw their prior patented version, they prevent generics from being substituted for the prior version while their new version is protected from competition by patents or FDA approval timelines. Consumers, insurers and the government all will pay higher prices for drugs for a longer time. This exclusionary conduct deprives consumers of competitive choices and, in the absence of a procompetitive business justification, violates Section 2.

The anticompetitive effects of product hopping can be particularly pronounced when the conduct includes, as in this case, changes timed to occur before generic entry, proferred justifications for the changes that are pretextual or lacking in evidentiary support, “smoking gun” documents that demonstrate the

actual intent and effect of the product switch are to protect monopoly revenue from generic competition, rather than a legitimate business purpose, or other evidence demonstrating an exclusionary objective and impact.

CONCLUSION

Product changes such as forced switches and other forms of product hopping can thwart Hatch-Waxman's and state substitution laws' purpose of promoting generic pharmaceutical competition. The product changes found in this case, including product withdrawals and a related course of exclusionary conduct, prevent manufacturers from bringing generics to market and cost-effectively offering competition to branded drugs. Hatch-Waxman sought to promote innovation through its bargain between prolonged patent protection and expedited generic entry, and product hopping can upset this bargain. Competition is stifled, and consumers, insurers, and the government pay the (substantial) price. As an antitrust matter, a company's forced product switches or other product hopping to impede generic competition is precisely the sort of behavior that Section 2 condemns.[60]

[60] *IP & Antitrust* § 15.3c, at 15-79.

Dated: February 19, 2015

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CERTIFICATE OF COMPLIANCE WITH
FEDERAL RULE OF APPELLATE PROCUDURE 32(a)

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) as modified for amici by Fed. R. App. P. 29(d) because this brief contains 7000 words, excluding the parts of this brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).
2. This brief complies with the typeface limitation of Fed. R. App. P. 32(a)(5) and the style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2013 in 14 point Times New Roman font.

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CERTIFICATE OF SERVICE

I hereby certify that, on this 19th day of February, 2015 I filed the foregoing Brief for Intellectual Property and Antitrust Professors as Amicus Curiae in Support of Plaintiff-Appellee with the Clerk of the United States Court of Appeals for the Second Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

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APPENDIX

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[i] Michael A. Carrier, *Provigil: A Case Study of Anticompetitive Behavior*, 3 Hastings Sci. & Tech. L.J. 441 (2011); Michael A. Carrier, *A Real World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 Fla. L. Rev. 1010 (2010); Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37 (2009); Michael A. Carrier, *Of Trinko, Tea Leaves, and Intellectual Property*, 31 J. Corp. L. 357 (2005).

[ii] Br. *Amici Curiae* of 118 L., Econ., & Bus. Professors & the Am. Antitrust Inst., No. 12-416, *FTC v. Actavis*, 133 S. Ct. 2223 (2013).

[iii] Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 Tex. L. Rev. 685 (2009)

Harry First is the Charles L. Denison Professor of Law at New York University School of Law and Co-Director of the law school's Competition, Innovation, and Information Law Program. He has written on numerous issues involving antitrust law and competition policy, including articles[iv] and books[v] relating to various aspects of intellectual property and innovation. He is most recently the co-author, with Andrew Gavil, of "The Microsoft Antitrust Cases: Competition Policy for the Twenty-first Century" (2014). He serves as a contributing editor of the *Antitrust Law Journal* and Foreign Antitrust Editor of the *Antitrust Bulletin*. From 1999-2001 he served as Chief of the Antitrust Bureau of the Office of the Attorney General of the State of New York.

Herbert Hovenkamp is the Ben and Dorothy Willie Chair at the University of Iowa College of Law. He is co-author of the seminal treatises on antitrust law and on the intersection of IP and antitrust law,[vi] and has written

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[iv] Harry First, *Antitrust and Trade Secrets*, in *The Law and Theory of Trade Secrecy: A Handbook of Contemporary Research* (Rochelle Dreyfuss & Katherine Strandburg eds.) (2011); Harry First, *Controlling the Intellectual Property Grab: Protect Innovation, Not Innovators*, 38 Rutgers L. J. 365 (2007); Harry First, Microsoft *and the Evolution of the Intellectual Property Concept*, 2006 Wis. L. Rev. 1369, reprinted, 39 Intellectual Prop. L. Rev. 711 (2007).

[v] Harry First, *Working Within the Boundaries of Intellectual Property* (with Rochelle Dreyfuss and Diane Zimmerman, eds.) (2010); Harry First, *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (with Rochelle Dreyfuss and Diane Zimmerman, eds.) (2001).

[vi] 3 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* (4th ed. 2013); Herbert Hovenkamp, Mark D. Janis, Mark A. Lemley, & Christopher R. Leslie, *IP &*

numerous books and articles on the topic of antitrust law and its interaction with innovation.[vii] In 2008, he received the John Sherman Award from the Antitrust Division of the Department of Justice, an award presented only once every three years to an individual for their outstanding achievements in antitrust law.

Mark A. Lemley is the William H. Neukom Professor of Law at Stanford Law School. He is the author of seven books and is among the world's most-cited law review authors.[viii] His scholarship focuses on intellectual property law, antitrust law and technology and the law. He is a co-author of the seminal IP and antitrust law treatise and has written extensively on the topic of regulatory gaming in the pharmaceutical context, including specifically on the issue of product hopping.[ix] His works have been cited over 140 times by courts, including

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Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law (2d ed. Supp. 2013).

[vii] See, e.g., Herbert Hovenkamp, *Innovation and Competition Policy: Cases and Materials* (2d ed. 2013); Christina Bohannon & Herbert Hovenkamp, *Creation Without Restraint: Promoting Liberty and Rivalry in Innovation* (2012); Herbert Hovenkamp, *The Antitrust Enterprise: Principle and Execution* (2006); Herbert Hovenkamp, *Consumer Welfare in Competition and Intellectual Property Law*, 9 Competition Policy Int'l J. 53 (2014); Herbert Hovenkamp, *Markets in IP and Antitrust*, 100 Geo. L.J. 2133 (2012); Herbert Hovenkamp, *Antitrust and the Regulatory Enterprise*, 2004 Colum. Bus. L. Rev. 335 (2004).

[viii] Fred R. Shapiro & Michelle Pearse, *The Most-Cited Law Review Articles of All Time*, 110 Mich. L. Rev. 1483 (2012) (finding that Lemley has authored or co-authored 9 of the 100 most-cited law review articles).

[ix] Herbert Hovenkamp, Mark D. Janis, Mark A. Lemley, & Christopher R. Leslie, *IP & Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* (2d ed. Supp. 2013); Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and*

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Regulatory Gaming, 87 Tex. L. Rev. 685 (2009); C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 Antitrust L.J. 947 (2011); Mark. A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 Tex. L. Rev. 1031 (2005).

[x] Herbert Hovenkamp, Mark D. Janis, Mark A. Lemley, & Christopher R. Leslie, *IP & Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* (2d ed. Supp. 2013).

[xi] Christopher R. Leslie, *Antitrust Law & Intellectual Property Rights: Cases and Materials* (2011).