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MYLAN V. WARNER CHILCOTT: A STUDY IN PHARMACEUTICAL PRODUCT HOPPING

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INTRODUCTION

On June 11, 2013, a district court in the Eastern District of Pennsylvania denied Defendant Warner Chilcott's motion to dismiss in the ongoing pharmaceutical litigation suit, *Mylan Pharmaceuticals, Inc. v. Warner Chilcott Public Limited Co.*[1] The Plaintiff in the suit, Mylan Pharmaceuticals, alleged that when Warner Chilcott "switched the market" for their acne drug, Doryx, from tablets to capsules, solely to avoid generic competition, it engaged in "product hopping" and broke the antitrust laws.[2] In its order, denying Warner Chilcott's motion-to-dismiss, the court stated that because the defendant's antitrust defense required it to consider facts that were well outside the complaint, it could not address the defendant's arguments "without going beyond the pleadings."[3]

However, although the court denied Warner Chilcott's motion to dismiss, its characterization of Mylan's product hopping theory as "'novel' at best" and failing to state "an antitrust injury"[4] is troubling in light of the precedent. While the "court's dismissal decision" sends a "promising sign to those who oppose antitrust scrutiny" of regulatory gaming in general and product hopping in particular, it "does little to clarify the law."[5] Moreover, the court's stance on product hopping can have grave consequences for consumers, health care plans, and the government if the court ultimately refuses to submit Warner Chilcott's conduct to antitrust scrutiny.

In this Note, I explain how product hopping—making non-substantial changes to branded drugs to delay the entry of generic alternatives to the market—is a form of regulatory gaming. Product hopping defeats the intended purpose of the Hatch-Waxman Act, which was intended to expedite competition and the entry of generics.[6] Although in *Mylan*, no branded-drug patent is implicated, product hopping can occur even when a patent is in force and a generic competitor challenges it as invalid.[7] In such a case, a brand firm

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1. Order on Motion to Dismiss, Mylan Pharms., Inc. v. Warner Chilcott Pub. Co., No. 12-3824 (E.D. Pa. Jun. 12, 2013), [hereinafter *Mylan Order on Motion to Dismiss*] (denying motion).

2. *Id.* at 2.

3. *Id.* at 3–4 (stating that "[d]efendants' Motions are premature. Although I am skeptical that the "product hopping" alleged here constitutes anticompetitive conduct . . . I cannot definitively address that question without going beyond the pleadings.").

4. *Id.* at 3 (stating that "[d]efendants' contentions, if correct, appear compelling. I agree that Plaintiffs' theory here is 'novel' at best.")

5. M. Sean Royall, Ashley E. Johnson & Jason C. McKenney, *Antitrust Scrutiny of Pharmaceutical "Product Hopping,"* 28 ANTITRUST 71, 75 (2013) [hereinafter *Royall*].

6. *See* Lisa Barons Pensabene et al., *Hatch-Waxman: An Overview*, PRAC. L. COMPANY (2013), http://www.fitzpatrickcella.com/DB6EDC/assets/files/News/Hatch-Waxman%20Act%20Overview%20lpensabene_dgregory.pdf.

7. *See Mylan Order on Motion to Dismiss*, *supra* note 1.

can manipulate Hatch-Waxman's regulatory framework to increase the amount of litigation and Food & Drug Administration (FDA) delay in approving the generic alternative to the detriment of consumers. Therefore, the consequences of the court's final decision in *Mylan* has implications reaching far beyond the facts of the suit to cases where invalid patents in combination with product hopping could hold up generic entry.

This Note is organized as follows. In Part I, I begin by describing the Hatch-Waxman regulatory framework, state drug substitution laws, and pharmaceutical product hopping. In Part II, I state the relevant facts and procedural history of the *Mylan* case, and describe the district court's decision and reasoning. In Part III, I present the legal background in this area before *Mylan*. In Part IV, I analyze whether Mylan's sought generic entry to the market was indeed free-riding as Warner Chilcott characterizes it, and whether Warner Chilcott's conduct sought to manipulate the Hatch-Waxman regulatory framework and frustrate Congress's stated intent.

I. THE HATCH-WAXMAN REGULATORY FRAMEWORK AND PRODUCT HOPPING

In this Part, I describe the regulatory framework established by Hatch-Waxman and state drug substitution laws. Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984—commonly known as the Hatch-Waxman Act[8]—in 1984 in order to "facilitate market entry of low-cost generics while incentivizing pharmaceutical companies to invest in developing new drugs."[9] Moreover, all fifty states have passed laws that allow pharmacists to substitute a generic when presented with a prescription for its branded equivalent, unless a physician directs, or the patient requests otherwise.[10] These state substation laws together with Hatch-Waxman "create a regulatory framework designed to reduce costs to consumers by lowering

8. Brief of Intellectual Property and Antitrust Law Professors as *Amici Curiae* at 3, Mylan Pharms., Inc. v. Warner Chilcott Pub. Co. (E.D. Pa. Jun. 12, 2013) (No. 12-3824) [hereinafter *Professors Amicus*] (citing 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 (2006))).

9. The Hatch-Waxman Act's legislative history "confirms that the Act was intended to mitigate the 'serious anti-competitive effects' of FDA rules on generic drug approval and prevent the 'practical extension of the monopoly position of the patent holder beyond the expiration of the patent.'" Professors Amicus, *supra* note 8, at 3 n.5 (citing H.R. Rep. No. 98-857(II), pt. 1, at 4 (1984)). The Act safeguards patent rights by affording a patent holder the opportunity to trigger a 30-month stay on FDA approval of a generic drug so that it may attempt to enforce its patents through litigation. *Id.* (citing 21 U.S.C. § 355(j)(5)(B)(iii)). It also provides a term extension for human drug products subject to FDA approval. A patent's term can be extended by a maximum of five years or fourteen years of effective patent life, whichever is less, for the time the FDA was reviewing the first drug application. *Id.* (citing 35 U.S.C. § 156).

10. Brief for Fed'l Trade Comm'n as *Amicus Curiae* at 6, Mylan Pharms., Inc. v. Warner Chilcott Pub. Co., No. 12-3824 [hereinafter *FTC Amicus*].

generic costs."[11] This pairing "have been remarkably successful in facilitating generic competition and generating large savings for patients" and third-party payers.[12]

A. The Hatch-Waxman Act

"Congress enacted Hatch-Waxman in response to the high costs of pharmaceuticals resulting from patent monopolies on branded drugs and delayed generic entry."[13] Previously, generics faced limited incentives to enter a market because of the need for expensive duplicative testing.[14] As a result, branded drugs continued to reap monopoly profits long after patents expired because of the effective extension of their monopoly term. Congress therefore sought to increase the availability of generics to reduce both healthcare costs and the high percentage of individual incomes spent on pharmaceuticals.[15] "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.'"[16] A central provision of the Hatch-Waxman Act is the introduction of the Abbreviated New Drug Application (ANDA) procedure for generic manufacturers.[17]

1. Abbreviated New Drug Application Procedure

To introduce a new drug to market, a pharmaceutical company must

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11. Professors Amicus, *supra* note 8, at 3 n.5 (citation omitted).

12. In 2012 alone, the use of generic drugs saved consumers $217 billion. Professors Amicus, *supra* note 8, at 3 n.8 (citations omitted); *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).

13. Professors Amicus, *supra* note 8, at 4. In 1983 alone, the Federal Government spent $2.4 billion for drugs through Medicaid and in veterans and military hospitals. Ronald Reagan, U.S. President, *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]." Professors Amicus, *supra* note 8, at 4, n.10 (citation omitted).

14. *Id.* at 4; *see also id.* at 4 n.11 (citing H.R. Rep. No. 98-857(II), pt. 1, p. 4 (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)). Moreover, earlier the Carter administration had urged Congress to act because "the requirements of duplicative tests on humans unnecessarily endangered human health." *Id.* at 4 n.11 (citation omitted).

15. The legislative history states 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, p. 29 (1984).

16. Professors Amicus, *supra* note 8, at 4 (citing FTC v. Actavis, 133 S.Ct. 2223, 2228 (2013)).

17. *See* H.R. Rep. No. 98-857(II) (1984).

provide detailed evidence of safety and efficacy tests, and also a listing of any relevant patents.[18] Hatch-Waxman expedites the approval process for generics that follow a branded drug.[19] "Rather than submitting full safety and efficacy data, a generic manufacturer can obtain FDA approval by filing an ANDA, which certifies the bioequivalence of the generic to an existing branded drug."[20] Once approved, the generic receives an "AB-rating," which allows pharmacists to substitute the generic when presented with a prescription for the branded product.[21]

2. Patent Suits and ANDA Stays

However, to protect the rights of patent holders, the Hatch-Waxman Act also requires generic manufacturers to identify any patents potentially relevant to their ANDA.[22] The patentee then has forty-five days to sue for infringement.[23] A patent suit at this stage leads to an automatic thirty-month stay of the ANDA.[24] The FDA has no mandate or discretion to reduce this stay.[25] Only a final court judgment of non-infringement or invalidity can truncate the stay.[26] As Professor Hovenkamp points out, "The effect of this rather remarkable rule is to delay drug price competition for several years even when a patent is clearly invalid, by granting what is akin to an automatic preliminary injunction whenever a pharmaceutical patent owner files suit against a generic manufacturer."[27]

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18. Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 709–10 n.99 (2009) [hereinafter *Dogan & Lemley*] (internal citations omitted). From animal testing and clinical trials, through full FDA approval, the process for drug approval can take up to ten years. 21 U.S.C. § 355(b)(1) (2008).

19. 21 U.S.C. § 355(j)(5)(A) (requiring that the approval process be completed within 180 days of the filing of the application).

20. Professors Amicus, *supra* note 8, at 5; 21 U.S.C. § 355(j)(2)(A)(iv).

21. *Demystifying Generic Substitution: Knowing the Law*, 2013 PHARMACIST'S LETTER (2013) http://pharmacistsletter.therapeuticresearch.com/ce/ceCourse.aspx?cs=&s=PL&pv=1&pc=13-307&quiz=&AspxAutoDetectCookieSupport=1 ("In order for a drug to have an AB rating, the drug must . . . show that it is therapeutically equivalent (meaning that it is bioequivalent AND pharmaceutically equivalent) to the reference drug.").

22. 21 U.S.C § 355(j)(2)(A)(vii) (requiring the generic manufacturer to certify one of the following: (1) no relevant patent is listed; (2) the patent is expired; (3) the ANDA only seeks approval after the expiration date of the patent; or (4) the ANDA does not infringe the patent or the patent is invalid).

23. 21 U.S.C. § 355(j)(2)(B); 21 U.S.C. § 355(j)(5)(B)(iii).

24. 21 U.S.C. § 355(j)(5)(B)(iii).

25. Dogan & Lemley, *supra* note 18, at 711.

26. *Id.*

27. Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, IP & ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 15.3, at 22 (Supp. 2010) [hereinafter *Hovenkamp et al.*].

B. State Drug Substitution Laws

Around the same time that Hatch-Waxman was passed, all 50 states passed drug substitution laws designed to lower prices for consumers.[28] These laws allow—and in many cases require—pharmacists, in the absence of a doctor's contrary instructions, to substitute generic versions of brand-name prescriptions.[29] State drug substitution laws are designed to address the disconnect in the industry between prescribing doctors, who are not directly responsive to drug pricing, and paying insurers and consumers, who do not directly select the prescribed drug.[30] State drug substitution laws therefore carve out a role for pharmacists, who are much more sensitive to prices than doctors.

However, the Hatch-Waxman Act and state substitution laws have created a complex regulatory framework with certain loopholes that can enable brand firms to game the system in a way that extends their period of exclusivity, to the detriment of the public and generic rivals.[31] The FDA has neither the mandate nor the power to close these loopholes because it does not consider generic competition concerns when approving new products.[32] One strategy brand firms have turned to is product-hopping, making non-substantial changes to their branded products and taking advantage of the resulting time required for FDA approval to impede generic substitution and exclude competition.[33]

C. Pharmaceutical Product Hopping

When brand firms are faced with the possibility of generic competition once a patent expires or is held invalid, they can make trivial alterations to their approved drugs, get FDA approval for those trivial alterations, and then replace the old product with the new product.[34] For example, a brand firm might switch from selling a drug in capsule form to selling the same formulation of the same drug as a tablet. While the change will not matter

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28. Michael A. Carrier, *A Real World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 109, 1017 (2010).

29. *Id.*

30. FTC Amicus at 6 ("The physician—who selects the drug product but does not pay for it – has little incentive to consider price when deciding which drug to prescribe.").

31. Dogan & Lemley, *supra* note 18, at 709.

32. *Id.*; Hovenkamp et al., § 15.3, at 79 (stating that "[m]aking matters worse, the [FDA] regulators can do nothing to thwart this obvious abuse of their administrative function.").

33. *See, e.g.*, Abbott Labs. v. Teva Pharms. USA, Inc., 432 F. Supp. 2d 408, 409 (D. Del. 2006) (describing allegations that Abbott Laboratories changed the formulation of a drug to prevent a generic drug from entering the marketplace).

34. Hovenkamp et al., *supra* note 27, § 15.3 at 74.1.

much to consumers, it can be sufficient to require a generic manufacturer to restart the ANDA filing process, delaying the date of generic entry, and triggering an entirely new round of patent litigation and thirty-month stays.[35]

Product-hopping is therefore an effort by a brand firm "to manipulate the lag times inherent in the FDA's generic-approval process in a way that, when combined with state drug substitution laws, excludes generic entry and the competition and lower prices that entry would bring."[36] Product-hopping delays generic competition in several ways. First, where the branded drug's patent is still in force, product hopping can prompt a whole new set of litigation-triggered thirty-month stays.[37] Second, by making trivial modifications to its branded product, the brand firm can require its generic rival to start the ANDA process all over again, repeating the same 180-day (and usually longer) FDA review.[38] "Third, product-hopping prevents pharmacists from substituting generic versions according to state substitution laws until the generic's new ANDA is approved."[39] If the brand firm has pulled its old product from pharmacy shelves and convinced doctors to write scripts for its new product, the market for the generic collapses.[40] Thus, the generic cannot compete because under state substitution laws, pharmacists may only prescribe generic alternatives when the FDA certifies them as bioequivalent.[41] If doctors only prescribe the new version of the branded drug, generics must await completion of the ANDA approval process to even be considered for substitution.[42]

"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."[43]

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35. *Id.*

36. Professors Amicus, *supra* note 8, at 6 (citing Dogan & Lemley, *supra* note 15, at 709; Hovenkamp et al., § 15.3, at 23–24).

37. *Id.* (citing Dogan & Lemley at 711–12).

38. *Id.* (internal citations omitted).

39. *Id.* (citing Carrier, *supra* note 28, at 1017–18 (discussing how product reformulations further delay generics' attempts to achieve bioequivalence, sometimes by years); Hovenkamp et. al., *supra* note 28, § 15.3, at 25 ("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.")).

40. Professors Amicus, *supra* note 8, at 6 (citing Dogan & Lemley, *supra* note 18, at 712); Hemphill & Lemley, *supra* note 12, at 960 (stating that 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.").

41. 21 U.S.C. § 355(j).

42. Professors Amicus, *supra* note 8, at 6 (citing Carrier, *supra* note 28, at 1018); *see also* Hovenkamp et al., § 15.3, at 24 (citing *Abbott Labs*, 432 F. Supp. 2d 408 to reveal how product hopping creates anticompetitive effects by delaying generic substitution).

43. Hovenkamp et al., § 15.3 at 25.

Without the FDA's long approval process, generics could quickly enter the market with competing versions of branded drugs upon expiration of a patent.[44] "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 excludes such competition."[45] As Professor Hovenkamp describes the problem, "product-hopping seems clearly to be an effort to game the rather intricate FDA rules. . . . The patentee is making a product change with no technological benefit solely in order to delay competition."[46]

II. WARNER CHILCOTT'S MOTION TO DISMISS

In this section, I describe the relevant facts and procedural history of the *Mylan* case, and then discuss the district court's decision and reasoning.

A. Mylan's Complaint

Mylan Pharmaceuticals's complaint alleges that Warner Chilcott engaged in a conscious strategy to prevent or delay generic competition for the company's branded Doryx medication by executing at least three distinct product hops: (1) first from a capsule to a tablet; (2) then from 75 mg and 100 mg tablets to a single 150 mg dosage strength; and finally (3) from a single-scored version of the 150 mg tablet to a dual-scored version.[47] "[T]hese switches," the complaint alleges, provided "little or no therapeutic benefit to consumers," but "devastated the market for the prior versions of Doryx."[48] The defendant ceased marketing the old versions of its drug and eventually withdrew it from the market, thereby "forc[ing] generic manufacturers such as Mylan to change their products in development" in an effort to align their generic offerings with the newly promoted version of the branded drug.[49]

B. Defendant's Motion to Dismiss

In moving to dismiss, Warner Chilcott argued that Mylan's claims implied that brand firms have a duty to continue promoting outdated formulations to

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44. Professors Amicus, *supra* note 8, at 7.

45. *Id.*; *see also* Hovenkamp et al., § 15.3, at 23–24.

46. Hovenkamp et al., *supra* note 28, § 15.3, at 75.

47. Royall, *supra* note 5, at 74 (citing Complaint and Demand for Jury Trial at ¶¶ 2–5, Mylan Pharms. v. Warner Chilcott, Pub. Co. (No. 03824) (E.D. Pa. July 6, 2012) [hereinafter *Mylan Complaint*]).

48. Royall, *supra* note 5, at 74–75 (citing *Mylan* Complaint ¶¶ 2, 9).

49. *Id.*

permit generic competitors to take advantage of automatic substitution laws.[50] But nothing in the antitrust laws suggests that such a duty either does or should exist.[51] Warner Chilcott further argued that antitrust law suggests that this type of "free riding" is "'the antithesis of competition.'"[52]

Warner Chilcott also maintained that Mylan's complaint alleged nothing more than "innovation by the defendants, and the marketing of those innovations once government approvals were obtained."[53] Because neither the Sherman Act nor state drug substitution laws impose a duty on a firm to assist a rival with the firm's innovations, Mylan's claims that were based on "the timing and speed of Warner Chilcott's innovation" should be dismissed.[54] Finally, the Defendant used its motion to make a pointed attack against Mylan and its generic business model.[55] "In the opening paragraphs of [its] motion, [Warner Chilcott] contended that Mylan is one of the world's largest pharmaceutical companies, fully twice the size of Warner Chilcott, and that the company has ample resources to actively promote its generic products without relying entirely on state substitution laws, if it so chose."[56]

C. The Court's Order

On June 11, 2013, U.S. District Judge Paul S. Diamond in Pennsylvania denied Warner Chilcott's motion to dismiss, saying the motion was premature.[57] The court stated that the antitrust allegations against Warner Chilcott, raised by Mylan and retailers such as Walgreen and Safeway, were sufficient to survive the motion to dismiss at this early stage in the litigation.[58]

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50. Memorandum of Law in Support of Defendant Warner Chilcott's Motion to Dismiss at 16, Mylan Pharms. v. Warner Chilcott Pub. Co., No. 03824 (E.D. Pa. Oct. 1, 2012) [hereinafter *Warner Chilcott Motion to Dismiss*] ("Plaintiffs argue that Defendants owed Mylan a duty to continue marketing older versions of Doryx, so that Mylan's generic Doryx could be automatically substituted for Doryx prescriptions and Mylan would take the sale.").

51. *Id.* at 1 (stating that "the Sherman Act certainly does not impose a duty on Defendants to assist a larger rival, Mylan, with its innovations.").

52. *Id.* at 23–24 (stating that "antitrust law recognizes the peril of free riders and the legitimate business concern of avoiding the free rider problem.") (citations omitted).

53. *Id.* at 1.

54. *Id.* (stating that "[p]laintiffs allege that Defendants improved their anti-acne products too quickly. But rapid innovation is the lifeblood of competition, and Defendants' outpacing of Mylan cannot provide grounds for an antitrust action. . . .").

55. *Id.* at 3 (stating that "Mylan is the third largest generic and specialty pharmaceuticals company in the world, in terms of revenue, reporting $6.13 billion in total revenues in 2011 . . . Mylan markets a global portfolio of approximately 1,100 different products.") (citations and quotation marks omitted).

56. Royall, *supra* note 5, at 75 (citations omitted).

57. *Mylan Order on Motion to Dismiss*, *supra* note 1, at 3 (stating that "[p]laintiffs' allegations are sufficient to survive Defendants' Rule 12 Motions.").

58. *Id.*

The court expressed skepticism, however, toward Mylan's claims that Warner Chilcott tried to ward off competition by switching the market from Doryx tablets to Doryx capsules so pharmacists would not be able to substitute in generics automatically. "Although I am skeptical that the 'product hopping' alleged here constitutes anti-competitive conduct under the Sherman Act, I cannot definitively address that question without going beyond the pleadings," the court said.[59] "Accordingly, I will deny defendants' motions to dismiss without prejudice. They may renew these arguments at summary judgment."[60]

Moreover, the court stated that "[d]efendants' contentions, if correct, appear compelling."[61]

> I agree that plaintiffs' theory here is 'novel' at best. Nevertheless, defendants' arguments require me to consider 'facts' that are well outside the complaints in this matter. I am not prepared to consider these facts at the Rule 12 stage.[62]

While the court's order may comfort brand firms who oppose antitrust scrutiny of regulatory gaming in general and product hopping in particular, it "does little to clarify the law."[63] Because the court placed no reliance on the only two pharmaceutical product hopping cases to date that have resulted in substantive court decisions,[64] the validity of the approaches adopted by those prior decisions is now unclear. Moreover, the court's dismissive stance on the dangers of product hopping can have grave consequences for consumers, health care plans, and the government if the court rules in favor of Warner Chilcott at the upcoming summary judgment stage. The public has come to rely on Hatch-Waxman's effectiveness in expediting the entry of generics to market and the lower prices that entry brings. Allowing brand firms to continue regulatory gaming of Hatch-Waxman using product hopping undermines that effectiveness.

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59. *Id.*

60. *Id.*

61. *Id.*

62. *Id.*

63. Royall, *supra* note 5, at 75.

64. Royall, *supra* note 5, at 72 (The first of these cases involved the cholesterol drug TriCor24, Abbott Labs v. Teva Pharms. USA, Inc., 432 F. Supp. 2d 408 (D. Del. 2006) (denying defendant's motion to dismiss), and the other involved the heartburn medications Prilosec and Nexium25, Walgreen Co. v. AstraZeneca Pharm. L.P., 534 F. Supp. 2d 146 (D.D.C. 2008) (granting defendant's motion to dismiss). The two cases dealt with mirror image facts and led to opposite conclusions, one denying a motion to dismiss and the other granting dismissal.).

III. LEGAL BACKGROUND FOR REGULATORY GAMING IN PHARMACEUTICALS

The Hatch-Waxman legislation has led to an enormous amount of antitrust litigation.[65] The most prevalent suits have centered around claims that brand firms have (1) improperly invoked Hatch-Waxman 30-month stays through "sham" patent litigation;[66] and (2) essentially "conspired" with their generic rivals through "pay-for-delay" patent settlements to forestall the onset of generic competition.[67]

A. Patent Settlements

Patent settlement agreements or reverse-payment settlements between brand firms and generic manufacturers have taken place to delay the entry of generic products into the market. They involve a payment from the brand firm to the generic manufacturer in exchange for delayed entry into the market.[68] In the 2013 case, *FTC v. Actavis*, the Supreme Court questioned whether it was illegal for brand firms to use reverse payment settlements to keep generic competitors out of the market, even if the brand firm held a patent on the drug.[69] While the Court did not hold such settlements presumptively illegal, five members of the Court declared that the FTC could not be prevented from bringing an antitrust suit against the Defendant.[70] The Court lamented that "payment in return for staying out of the market . . . simply keeps prices at patentee-set levels," which leads to gains for the patentee and challenger and losses for the consumer.[71]

However, the dissent in *Actavis* rejected the application of antitrust law, arguing that it was a "novel approach" and "without any support in any statute."[72] It is interesting to note how similar this language in the *Actavis* dissent is to Judge Diamond's language in *Mylan*.[73] The dissenting opinion in *Actavis* further argued that only when a patent holder acts beyond the scope of

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65. Royall, *supra* note 5, at 72 (citations omitted).

66. *See* M. Sean Royall & Joshua Lipton, *The Complexities of Litigating Generic Drug Exclusion Claims in the Antitrust Class Action Context*, 24.2 ANTITRUST, Spring 2010, at 22.

67. FTC v. Actavis, 133 S.Ct. 2223, 2228 (2013).

68. *Id.* at 2227.

69. *Id.* at 2229.

70. *Id.* at 2237 (stating that "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects . . . a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent . . .").

71. Michael Carrier, *Payment After* Actavis, 100 IOWA L. REV. 1, 17 (2014), forthcoming (citing *Actavis*, 133 S.Ct. at 2235).

72. *Actavis*, 133 S.Ct. at 2238 (dissenting opinion) (stating that "[a] patent carves out an exception to the applicability of antitrust laws.").

73. *See id.* at 2238–47; *Mylan Order on Motion to Dismiss*, *supra* note 1.

its granted monopoly should antitrust scrutiny be applicable.[74] The danger of Mylan following the *Actavis* dissent is that while there was no patent at issue in *Mylan*, product hopping can have serious anticompetitive consequences when used to game the Hatch-Waxman system when a patent is indeed in force. For example, Hatch-Waxman encourages generic manufacturers to file an ANDA when they believe the patent on the branded drug is invalid.[75] In such a case, product hopping followed by 30-month stays can delay generic entry indefinitely even when the patent is invalid, effectively defeating the very purpose of the patent system.[76]

While the law related to reverse-payment settlements is reasonably well settled since *Actavis*, product-hopping allegations—the latest antitrust outgrowth of Hatch-Waxman—are a relatively recent phenomenon, and the law remains very much in flux.[77]

B. Product Hopping Caselaw

Prior to *Mylan*, there were only two pharmaceutical product-hopping cases that resulted in court decisions.[78] From those two, it is possible to infer that antitrust claims based on product-hopping turns largely on the strength of the facts, especially whether the brand firm withdrew its prior formulation from the marketplace and limited consumer choice.[79]

First, in *Abbott Labs*, the plaintiff asserted that Abbott changed its formulation for its branded drug TriCor24 twice, strategically timed to thwart imminent generic competition.[80] Teva alleged that Abbott not only stopped selling the prior versions, but also removed them from the National Drug Data File (NDDF),[81] a private database of FDA-approved drugs.[82] This effectively prevented pharmacies from filling prescriptions for the superseded versions or

74. *Actavis*, 133 S.Ct. at 2238–39.

75. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

76. *See* U.S. CONST. art I, § 8 (stating that "[t]he Congress shall have power to . . . promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries").

77. Royall, *supra* note 5, at 72.

78. *Id.* at 72–3 (citing Abbott Labs v. Teva Pharms. USA Inc., 432 F. Supp. 2d 408 (D. Del. 2006); Walgreen Co. v. AstraZeneca Pharm. L.P., 534 F. Supp. 2d 146 (D.D.C. 2008)).

79. *Id.* at 72–73.

80. *Id.* at 73 (citing *Abbott Labs*, 432 F. Supp. 2d at 416–17).

81. The NDDF plus (now known as FDB MedKnowledge) guides pharmacists in determining substitution. It is the most widely relied upon drug knowledge base in the United States and Canada. It is integrated within healthcare information systems serving hospitals, physician practices, and retail pharmacies, and enables solutions that range from e-prescribing and pharmacy dispensing to drug pricing analysis. FDB MedKnowledge (NDDF), http://www.fdbhealth.com/fdb-medknowledge (last visited Feb 2, 2015).

82. Royall, *supra* note 5, at 73 (citing *Abbott Labs*, 432 F. Supp. 2d at 416–17).

any generic equivalents.[83] The *Abbott Labs* court rejected Abbott's arguments that a product change which introduces an improvement is per se lawful under antitrust considerations.[84] The court determined that dismissal was inappropriate, because of the allegations that Abbott removed the prior drug formulations from the market and changed the NDDF codes.[85] "[S]uch conduct," the court declared, "results in consumer coercion" and "is potentially anticompetitive."[86]

Second, in *Walgreen v. AstraZeneca*, Walgreen alleged that AstraZeneca began aggressively promoting a newly approved prescription heartburn medication, Nexium, just as its longstanding heartburn drug, Prilosec, was nearing the end of its patent protection and beginning to face generic competition.[87] However, although AstraZeneca began marketing Nexium to doctors, it did not withdraw Prilosec from the market. In granting AstraZeneca's motion to dismiss, the *Walgreen* court relied on the reasoning in *Abbott Labs*, especially on the "critical factor" of consumer choice.[88] Because AstraZeneca had "added choices" by introducing a new drug to compete with its alternative drug, Prilosec, with generic substitutes to Prilosec, and with heartburn medications offered by other manufacturers, the product hop was not enough to support a monopolization complaint.[89]

But in *Mylan*, the court puzzlingly departed from this precedent, raised fundamental questions about the merits of product-hopping allegations, and signaled skepticism whether a brand firm's shift to a new formulation could ever constitute an antitrust violation.[90] Therefore, the *Mylan* court's order, when considered in the light of *Abbott Labs* and *Walgreen*, muddies the law on product hopping, leaving many questions unanswered.

IV. MANIPULATION OF THE HATCH-WAXMAN REGULATORY FRAMEWORK

In this Part, I first examine whether Warner Chilcott's contention that Mylan sought to free-ride on the Defendant's innovations is truly

83. *Id.*

84. *Id.* (citing *Abbott Labs*, 432 F. Supp. 2d at 420).

85. *Id.*

86. *Abbott Labs*, 432 F. Supp. 2d at 424.

87. Royall, *supra* note 5, at 74 (citing Walgreen Co. v. AstraZeneca Pharm. L.P., 534 F. Supp. 2d 146, 148 (D.D.C. 2008)).

88. *Id.* (citing *Walgreen*, 534 F. Supp. 2d at 151).

89. *Walgreen*, 534 F. Supp. 2d at 152 (stating that "[t]he fact that a new product siphoned off some of the sales from the old product and, in turn, depressed sales of the generic substitutes for the old product, does not create an antitrust cause of action.").

90. Royall, *supra* note 5, at 73.

"compelling."[91] Then, I discuss Warner Chilcott's conduct in light of the Hatch-Waxman compromise. Finally, I examine the district court's order in light of the product hopping precedent, especially related to withdrawal of older branded-drug versions by brand firms.

A. Was Mylan's Generic Entry Free-Riding?

In its motion to dismiss, Warner Chilcott asserted that antitrust law does not impose a duty on brand firms to promote outdated formulations, such that generic manufacturers may take advantage of automatic substitution laws.[92] Warner Chilcott further described the generic business model as anticompetitive free-riding.[93] And Judge Diamond, in his order denying the motion, stated that

> [i]n Defendants' view, Plaintiffs' allegation that generic firms cannot advertise their products to compete successfully with Doryx may reveal a problem with the generics' business models or demonstrate the regulatory regimes' inability to control generics' costs through forced 'free-riding' . . . Defendants' contentions, if correct, appear compelling."[94]

However, faster and cheaper generic entry is the intended result of the Hatch-Waxman Act and state substitution laws; it is not, as Warner Chilcott asserted, somehow undesirable free-riding.[95] What Warner Chilcott characterized as free-riding by generics is in fact the mechanism for introducing faster and more effective generic competition that Hatch-Waxman and state drug substitution laws have deliberately created.[96]

"As the Supreme Court recently recognized, Hatch-Waxman's abbreviated approval procedures allow generics to 'obtain approval while

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91. *Mylan Order on Motion to Dismiss*, *supra* note 1, at 3 (stating that "[i]n Defendants' view, Plaintiffs' allegation . . . demonstrate the regulatory regimes' inability to control generics' costs through forced "free-riding" . . . Defendants' contentions, if correct, appear compelling.").

92. *Id.* at 23.

93. *Id.* (stating that "[t]he Supreme Court's antitrust case law has recognized the legitimate concerns of manufacturers in avoiding the 'free rider' effect.")

94. *Id.* at 3.

95. *Id.* at 23.

96. FTC Amicus, *supra* note 10, at 7. Hatch-Waxman was intended to expedite the system for approval of generic drugs by the FDA that the House Report described as "too cumbersome and expensive." Professors Amicus, *supra* note 8, at 7 n.30 (citing H.R. Rep. No. 98-857(II), *Pt. 1*, *supra* note 14, at p.5 (1984)). The House Judiciary Committee estimated that there were 150 drug products approved after 1962 that were off-patent, but for which no generics existed. Generics for these branded drugs would become available using the ANDA procedure. Professors Amicus, *supra* note 8, at 7 n.30 (citation omitted).

avoiding "the costly and time-consuming studies"' needed for a pioneer drug and let generics 'piggy-back on the pioneer's approval efforts, "speed[ing] the introduction of low-cost generic drugs to market" . . . thereby furthering drug competition.'"[97]

Further, the Hatch-Waxman framework positions generics as low-cost alternatives that "[should] not [have to] compete with the promotional efforts of brand firms."[98] "State drug substitution laws eliminate the need for generics to undertake financially crippling marketing costs that could prevent generic viability."[99] The facilitated generic entry and enabled point-of sale generic substitution is hardly free-riding. It was deemed important by Congress to facilitate quicker public access to affordable medicines.[100] "The combined mechanism for facilitated generic entry and substitution also 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.'"[101] "As a result, drugs are much cheaper and more widely available today."[102] Without these laws, generics would be unable to compete cost-effectively. Far from free-riding, "the ability of generics to succeed in the market without equivalent approval processes and marketing expenses is precisely the sort of procompetitive 'piggy-backing' . . . these laws carefully facilitate."[103]

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97. Professors Amicus, *supra* note 8, at 7 (citing *Actavis*, 133 S.Ct. at 2228 (citations omitted)).

98. FTC Amicus, at 10; *see* H.R. Rep. No. 98-857(II), at Pt. 1, p. 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).

99. Professors Amicus, *supra* note 8, at 8. For example, Pennsylvania's drug substitution law states that its purpose is to "permit consumers to secure necessary drugs at the most economical costs." Professors Amicus, *supra* note 8, at 8 n.32 (citing 35 PA. CONS. STAT. Ann. § 960.1 (2014)).

100. Mylan Pharmaceutical's Memorandum in Opposition to Defendant's Motions to Dismiss at 7–8, *Mylan* (E.D. Pa. Oct. 1, 2012) [hereinafter *Mylan Opposition*] (citing Teva Pharms. USA, Inc. v. Novartis Pharms. Corp., 482 F.3d 1330, 1344 (Fed. Cir. 2007) ("A central purpose of the Hatch-Waxman Act . . . is 'to enable competitors to bring cheaper, generic . . . drugs to market as quickly as possible.'") (quoting 149 Cong. Rec. S15885 (Nov. 25, 2003))).

101. Professors Amicus, *supra* note 8, at 8 (citing Carrier, *supra* note 29, at 1017 (stating that in particular, drug substitution laws "carve out a role for pharmacists, who are much more sensitive to prices than doctors.")).

102. *Id.* at 8 n.34. The first generic to enter the market is typically 20% to 30% cheaper than the branded drug. Professors Amicus, *supra* note 8, at 8 n.34. Subsequent generic entry creates greater price competition, with discounts of 85% or more off the price of the branded drug. *Id.* A recent study of 5.6 million prescriptions revealed that patients and their insurance plans respectively paid an average of $17.90 and $26.67 for generic drugs and an average of $49.50 and $158.25 for branded drugs where no generic existed. *Id.* (citing FTC Amicus, *supra* note 10, at 7 (internal citations omitted)).

103. Professors Amicus, *supra* note 8, at 8.

B. The Effect of Product Hopping on the Hatch-Waxman Compromise

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.[104] On the one hand, Hatch-Waxman allowed generic manufacturers, such as Mylan, expedited entry to the market.[105] "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 drug."[106] Hatch-Waxman requires that the FDA complete its ANDA review within 180 days (but sometimes it can take longer).[107] On the other hand, Hatch-Waxman extended the terms of certain drug patents "create[ing] incentives for increased research expenditures" by patentees.[108]

"This compromise was designed to facilitate the introduction of low-cost generic[s] into the market for the benefit of consumers, health care plans, and the government."[109] The very nature of the highly regulated market necessitated the compromise.[110] "In a different industry like automobiles for example, there would be no need for similar provisions because—unlike the FDA—there is no government regulatory agency that would delay marketing of a new product after patent expiry."[111]

Here, because Warner Chilcott reformulated (but did not improve) Doryx, and then withdrew the existing formulation from the market allegedly to impede generic substitution, its conduct deprived the public of the benefits of

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104. *Id.* at 4–5 (citing Hemphill & Lemley, *supra* note 12, 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.")).

105. H.R. Rep., *supra* note 14, at 5 (1984) (stating that "H.R. 3605 provides that a generic manufacturer may request FDA approval to begin marketing before the patent on the drug has expired.").

106. Professors Amicus, *supra* note 8, at 4–5 (citing 21 U.S.C. § 355(j)).

107. *See* Office of Inspector Gen., Dep't of Health & Human Servs., THE FOOD AND DRUG ADMINISTRATION'S GENERIC DRUG REVIEW PROCESS, 13 (2008), *available at* http://www.oig.hhs.gov/oei/reports/oei-04-07-00280.pdf (noting that the FDA review process for ANDAs often exceeds the 180-day statutory maximum).

108. Congress noted in the legislative history that "[i]n most cases the bill affords greater protection for patent holders than current law." H.R. Rep., *supra* note 14, at p. 10 (1984).

109. Professors Amicus, *supra* note 8, at 5 (citing H.R. Rep., *supra* note 9, at p. 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.")).

110. Professors Amicus, *supra* note 8, at 5 (citing H.R. Rep., *supra* note 9, at p. 30 (1984)).

111. *Id.*

the Hatch-Waxman compromise. Moreover, the Defendant appears to have enhanced the anticompetitive effects of its product hopping strategy by precisely timing the introduction of scoring on the tablets in order to erect barriers to generic entry.[112] In fact, Warner Chilcott's internal documents appear to admit to an "anti-generic strategy" meant to increase profits at the expense of the public and third-party payers.[113] Therefore, because Warner Chilcott's product hopping deprived the public of the pro-competitive goals of the Hatch-Waxman compromise, it should be liable to antitrust scrutiny.

C. Withdrawal of Older Branded Versions in Mylan

Finally, the intended goals of Hatch-Waxman and state substitution laws are thwarted when brand firms engage in product-hopping strategies involving withdrawal of the branded product from the market. "When a brand [is] withdrawn, there can be no generic substitution because there is no product for which the generic can be substituted."[114] By discontinuing its existing versions of Doryx, Warner Chilcott reduced, rather than expanded, consumer choice. A similar reduction in consumer choice was deemed critical by the court in *Abbott Labs*: "[H]ere, according to Plaintiffs, consumers were not presented with a choice between [] formulations. Instead, Defendants allegedly prevented such a choice by removing the old formulations from the market while introducing new formulations."[115]

The *Abbott Labs* court's rationale "was also essential to the court's decision in *Walgreen* [], in which AstraZeneca introduced Nexium, but did not remove Prilosec from the market or seek to prohibit generic substitution of Prilosec."[116] The *Walgreen* court distinguished *Abbott Labs* on the facts, explaining that there was "no allegation that AstraZeneca eliminated any consumer choices. Rather, AstraZeneca added choices."[117]

In *Mylan*, Warner Chilcott appears to have reduced competitive choices to Doryx by removing prior formulations of the drug as well as by suppressing generic competition.[118] In fact, Professor Hovenkamp also notes that the

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112. *Mylan* Complaint at ¶¶57–60.

113. *Id.* at ¶¶47–49. In discussing the hop from capsules to tablets, the Defendant's internal documents reveal that "[t]he tablet is to be used as an anti-generic strategy" and that "[i]t is [Warner Chilcott's] intention to discontinue the Doryx capsule as soon as the tablet is available to eliminate generic competition." *Id.* at ¶49.

114. *Mylan* Opposition, *supra* note 100, at 8.

115. *Abbott Labs*, 432 F. Supp. 2d at 422.

116. *Mylan* Opposition at 21 (citing *Walgreen*, 534 F. Supp. 2d 146).

117. *Walgreen*, 534 F. Supp. 2d at 151.

118. *Mylan* Opposition, *supra* note 100, at 22 (citing Hovenkamp et al., *supra* note 27, § 15.3 at 77 (stating that " '[U]nlike *Abbott* [*Labs*], AstraZeneca did not withdraw Prilosec from the market or seek to prohibit generic substitution of Prilosec. . . . *Walgreen* represents a case in which the

decisive anticompetitive act in *Abbott Labs* was the same as here: withdrawal of older versions after the introduction of reformulations with little or no patient benefit.[119]

However, unlike in *Abbott Labs*, in *Mylan*, the Plaintiff did not allege that Warner Chilcott changed NDDF codes in a manner that might prevent generic substitution.[120] "In fact, the complaint appears to acknowledge that Mylan successfully developed and at least initially launched several generic formulations."[121] From the court's order in *Mylan*, it appears therefore that Judge Diamond may have distinguished *Abbott Labs* in giving judicial deference to a pharmaceutical product shift that did not openly disrupt consumer choice by changing NDDF codes.[122] But the borders of this NDDF safe harbor to antitrust scrutiny of product hopping are not well defined.[123] For example, under *Abbott Labs*, it is unclear whether a brand firm could successfully win dismissal if the challenged formulation change was not accompanied by a change in NDDF codes.[124] Moreover, it is not clear whether there would be grounds for dismissal if the prior formulation was not removed from the market.[125]

Had Judge Diamond followed the approach of *Abbott Labs* and *Walgreen*, he might have considered the Defendant's alleged decisions to phase out prior formulations and the extent to which this deprived consumers of choices.[126] But the *Mylan* court made no mention of these concepts in its order denying Warner Chilcott's motion to dismiss.[127] The court instead summarized the Defendant's principal arguments for dismissal, including claims that "their product changes . . . did nothing to block generic firms from competing" but "merely precluded generic firms from taking advantage of automatic

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patentee introduced a new product but did not take advantage of the regulatory scheme to interfere with the introduction of a generic drug by the patent challenger.'")).

119. Hovenkamp et al., *supra* note 22, § 15.3 at 74.1.

120. Royall, *supra* note 5, at 75.

121. *Id.* (citing *Mylan* Complaint at ¶32).

122. *Id.* at 73.

123. *Id.*

124. *Id.*

125. *Id.* Another open question left by *Abbott Labs* and *Mylan* are whether it would be enough for a plaintiff to defeat dismissal if it alleged that the prior formulation, while still available, was no longer being actively marketed by the brand firm. *Id.* Finally, is there another variation of alleged coercion, besides withdrawing support for old branded versions that a plaintiff could argue interferes with "free choice" in this context?. *Id.* (stating that *Abbott Labs* "provides no real answers to these questions, which is somewhat troubling, considering that it offers the most detailed judicial commentary to date on this subject.").

126. *Id.* at 75.

127. *Id.*

substitution laws."[128] "This was, to say the least, a marked departure from *Walgreen* and *Abbott Labs*."[129]

While the *Mylan* court's dismissal decision may send a promising sign to brand firms who oppose antitrust scrutiny of product hopping, it does little to clarify the law. In fact, the dramatically different tone struck by the court's decision, making no reference to the Defendant's withdrawal of its previous drug versions, in comparison to *Abbott Labs* and *Walgreen* poses a serious challenge to the formation of a judicial consensus.[130] Finally, the use of the terms "'novel' at best" and fails to state "an antitrust injury"[131] to characterize Mylan's product-hopping theory portends grave consequences for public access to low-cost generics and Congress's pro-competitive intent in enacting Hatch-Waxman if the court ultimately does not consider Mylan's antitrust claim.

CONCLUSION

Because the FDA has no authority to consider competition issues in its regulatory activities and does not review product changes for anything other than safety and efficacy,[132] courts must step in. This is in contrast to regulated industries, such as telecommunications, where regulations provide for competition concerns.[133] In the pharmaceuticals industry, however, brand firms can make small modifications to their products and then "withdraw the earlier [versions], which forces the ANDA applicant to restart the application process in order to secure an AB rating."[134] The FDA's regulations can therefore be easily gamed by brand firms to anticompetitive effect.[135]

In *Mylan*, the determination of whether the Defendant's product hopping was exclusionary would be properly evaluated under the antitrust rule of

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128. *Id.* (citing *Mylan Order on Motion to Dismiss*, *supra* note 1, at 2–3).

129. *Id.*

130. *Id.* at 75.

131. *Mylan Order on Motion to Dismiss*, *supra* note 1, at 3.

132. *See* 21 U.S.C. § 355(d) (enumerating factors agency may consider in product approval); *see generally* Dogan & Lemley, *supra* note 18, at 709 (stating that "[The FDA] has neither the mandate nor the power to take competition concerns into account in approving particular pharmaceutical products.").

133. *Mylan* Opposition, *supra* note 100, at 9 (citing Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 405–06 (2004) (describing competition regulations in telecommunications)).

134. *Id.* (citing *Abbott Labs*, 432 F. Supp. 2d at 420-24; Dogan & Lemley, *supra* note 14, at 709–17).

135. *Id.* (citing *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522, 530–31 (D.N.J. 2004); Dogan & Lemley, *supra* note 18, at 709 ("The pharmaceutical industry presents a perfect storm for regulatory gaming.").

reason.[136] In fact, as the *Abbott Labs* court held: "[p]laintiffs are not required to prove that the new formulations were absolutely no better than the prior version or that the only purpose of the innovation was to eliminate [a rival] product of a rival. . . . if [p]laintiffs show anticompetitive harm from the formulation changes, that harm will be weighed against any benefits presented by Defendants."[137] The *Mylan* court should therefore subject Warner Chilcott's product hopping strategy to antitrust scrutiny at the upcoming summary judgment stage.

136. *Mylan* Opposition, *supra* note 100, at 20 (citing United States v. Microsoft Corp., 253 F.3d 34, 65 (D.C. Cir. 2001) (*en banc*).

137. *Abbott Labs*, 432 F. Supp. 2d at 422.