North Carolina Central University Science & Intellectual Property Law Review

Volume 10
Issue 1 *10th Anniversary Special Issue*

Article 3

4-1-2017

Is "Product Hopping" Anti-Competitive or Fair Game?: A Look at the Second and Third Circuit Divisions in Actavis PLC and Mylan Pharmaceuticals

Alexis S. White

IS "PRODUCT HOPPING" ANTI-COMPETITIVE OR FAIR GAME?: A LOOK AT THE SECOND AND THIRD CIRCUIT DECISIONS IN ACTAVIS PLC AND MYLAN PHARMACEUTICALS

Alexis S. White[1]

I. INTRODUCTION

The pharmaceutical industry is composed of brand-name and generic[2] drug markets.[3] Typically, generic drugs directly compete with their brand-name counterparts and are competitively priced.[4] The introduction of new drugs in both markets is heavily regulated in the United States. The Food and Drug Administration ("FDA") requires each proposed drug to submit a New Drug Application ("NDA"), a process that evaluates the drug's safety and effectiveness for public consumption.[5] NDA drugs, commonly called brand-name drugs, enjoy a period of exclusivity that prevents their generic equivalents from entering the market. Upon expiration of exclusivity rights, generic manufacturers can apply for an Abbreviated New Drug Application ("ANDA")[6]. The ANDA process allows generic drug manufacturers to "piggy-back" on approved NDAs.[7] This expedites the testing process, allowing generic drugs to enter the market more quickly.

---

1. J.D. candidate at North Carolina Central University School of Law, Class of 2018; B.S. Biology 2015, *summa cum laude*, Tuskegee University.

2. Generic drugs are copies of brand-name drugs, possessing the same active ingredients, dosage, route of administration, quality, performance characteristics and intended use. Center for Drug Evaluation and Research, Understanding Generic Drugs - *What Are Generic Drugs?* Food and Drug Administration, https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm (last visited Mar. 25, 2017).

3. International Trade Administration, *PHARMACEUTICAL AND BIOTECH SPOTLIGHT: The Pharmaceutical and Biotech Industries in the United States*, SelectUSA, https://www.selectusa.gov/pharmaceutical-and-biotech-industries-united-states (last visited Mar 09, 2017).

4. Center for Drug Evaluation and Research, *Savings From Generic Drugs Purchased at Retail Pharmacies*, Food and Drug Administration (May 3, 2004), https://web.archive.org/web/20080223131005/http://www.fda.gov/cder/consumerinfo/savingsfromgenericdrugs.htm.

5. 21 U.S.C. § 355 (2016).

6. *Id*. § 355(j).

7. F.T.C. v. Actavis, Inc., 133 S. Ct. 2223, 2228, 186 L. Ed. 2d 343 (2013) (stating that generic manufacturers may circumvent the NDA process by demonstrating bioequivalence and pharmaceutical equivalence); Donald J. Birkett, *Generics - Equal or Not?*, 26 Australian Prescriber 85 (NPS MedicineWise 2003) (adding that a generic drug is said to be pharmaceutical equivalent if it possesses the same amount of active substance, dosage, and route of administration as its brand-name competition;

The Sherman Antitrust Act (''Sherman Act"), passed by Congress in 1890, prohibits certain business activities that federal government regulators deem to be anti-competitive.[8] One pervasive tactic causing concern in the pharmaceutical industry, falling within the arena of restricted practices under the Sherman Act, is product hopping[9]. "Product hopping" is a tactic that drug manufacturers use to keep generic competitors out of the market.[10] Typically, it involves making insignificant modifications to existing brand-name drug formulations, forcing generic competitors to exit the market, and re-enter a cumbersome regulatory process. This results in monopolizations by brand-name manufacturers.[11] This note will review two cases, *Actavis PLC* and *Mylan Pharmaceuticals*, in which generic manufacturers complain of brand-name manufacturers "hard-switching"[12] their products to obstruct the generic drug market.

In *New York ex rel. Schneiderman v. Actavis PLC (2015)*, the plaintiff filed for preliminary injunction, alleging that the defendants violated Section 2 of the Sherman Act.[13] The Second Circuit upheld the lower court's decision to grant preliminary injunction.[14] However, a recent opinion from the Third Circuit rejected the reasoning in *New York v. Actavis.*

In *Mylan Pharmaceuticals Inc. v, Warner Chilcott (2016),* the plaintiff brought an action against a manufacturer, alleging the creation of an unfair monopoly and the entering into an agreement under restraint trade in viola-

---

bioequivalence describes the bioavailability of a generic drug compared to its brand-name competitor under similar experimental conditions).

8. Gregory J. Werden, *Competition, Consumer Welfare, & the Sherman Act,* 9 Sedona Conf. J. 87 (2008) ("The Sherman Act was designed to be a comprehensive charter of economic liberty aimed at preserving free and unfettered competition as the rule of trade.").

9. Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry,* 108 Colum. L. Rev. 1471, 1472–73 (2008).

10. *Id*.

11. *Id*.

12. Brief for FTC at 19, Mylan Pharm., Inc. v. Warner Chilcott, Pub. Co., No. 12-3824 (E.D. Pa. Nov. 21, 2012) [hereinafter FTC Mylan Brief], https://www.ftc.gov/system/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.warner-chilcott-plc-et-al./151001mylanamicusbrief.pdf (discussing how taking an extra step by removing a brand-name drug from the market whose patent is approaching expiration while simultaneous introducing a new formulation coerces consumers; however, the popularity and success of the new formulation is not based on merit, but based on manufacturers artificially extending their monopoly in the market by impeding competition).

13. N.Y. ex rel. Schneiderman v. Actavis PLC*,* 787 F.3d 638 (2d Cir.), *cert. dismissed sub nom.* Allergan PLC v. N.Y. ex. rel. Schneiderman, 136 S. Ct. 581, 193 L. Ed. 2d 421 (2015) (discussing the State's antitrust action against drug manufacturer, alleging that drug manufacturer introduced Namenda XR, an Alzheimer's disease medication, at the end of the patent exclusivity period for the twice-daily version, Namenda IR and removed Namenda IR off the shelves in order thwart competition from generic competitors; the United States District Court for the Southern District of New York issued a preliminary injunction, ordered manufacturer to keep Namenda IR on the shelves until generic product entry and the manufacturer appealed).

14. *Id*.

tion of Sections 1 and 2 of the Sherman Act. [15] The Third Circuit in *Mylan* found that the manufacturer's actions did not obstruct the plaintiff from entering the market and thus were not anti-competitive.[16]

Through the review of relevant anti-trust legislation and case law, this note reconciles the courts' split decisions by creating a test that preserves the intent of the Sherman Act, while preserving brand-name manufacturers' right to be competitive.

II. THE HATCH-WAXMAN ACT AND STATE SUBSTITUTION LAWS

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, an act to amend the Federal Food, Drug and Cosmetic Act ("FDCA"), better known as the Hatch-Waxman Act.[17] The Hatch-Waxman Act is a method of enabling competition between brand-name and generic pharmaceutical markets while also incentivizing the development of new drugs.[18] The 1962 amendments to the FDCA imposed burdensome requirements that made the approval process costly and lengthy.[19] Moreover, only 15% of top-selling branded drugs with expired patents had generic competition before the passing of the Hatch-Waxman amendments.[20]

The Hatch-Waxman amendments sought to cure these unintended consequences by extending patent exclusivity,[21] while also simplifying the process for generic drugs to enter the market.[22] Prior to 1984, the FDA required that both brand-name drug manufacturers and generic drug manufacturers submit a New Drug Application ("NDA"),[23] which was "a long, compre-

15. Mylan Pharmaceuticals Inc. v. Warner Chilcott PLC et al., No. 15-2236, 2016 WL 5403626 (3d Cir. Sept. 28, 2016).

16. *Id.* (explaining the generic manufacturer's filed action against brand-name manufacturer of acne medication, alleging that they violated the Sherman Act by changing the formulation of their product and marketing and selling the new formulation as the expiration date for its older formulation's patent approached; the United States District Court for the Eastern District of Pennsylvania granted summary judgment for brand-name name manufacturer and the generic manufacturer appealed).

17. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

18. *Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments)*, U.S. Food and Drug Administration (before Senate Committee on the Judiciary) (Aug. 1, 2003), http://www.fda.gov/newsevents/testimony/ucm115033.htm.

19. 21 U.S.C. § 355(b)(1) (2012); 21 U.S.C. § 355(c) (2012) (stating that ANDA requires the applicant to: submit full reports of investigations, showing whether the drug is safe for use and whether the drug is effective; provide a list of the components of the drug, a statement of the composition of the drug, and a full description of the method and facilities used to manufacture, process, and package the drugs; and submit assessments supporting claims that drug is safe and effective for use).

20. D Reiffen and MR Ward, *Generic drug industry dynamics*, TC Bureau Economics Working Paper No. 248,37–49 (2002); *See* RE Caves, *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, Brookings paper on economics activity, 1-66 (1991).

21. 35 U.S.C. § 156 (2016).

22. 21 U.S.C. § 355(j) (2016).

23. 21 U.S.C. § 355(2016).

hensive, and costly testing process"[24] that required filing scientific literature to support the safety and efficacy of a drug before market entry was allowed.[25] An approved brand-name drug enjoys a twenty-year patent exclusivity period in the market, at the end of which one or more generic drugs that exhibit the same characteristics as the brand-name drug may enter the market at a lower price to compete with the brand-name drug.[26]

The Hatch-Waxman Act introduced the ANDA[27] to expedite the process of introducing lower cost generic drugs to the market. Under the ANDA, generic manufacturers can piggyback on the application of brand-name comparable drugs if they can demonstrate bioequivalence and pharmaceutical equivalence.[28] Once approved, the generic drug receives an "AB-rating,"[29] which allows pharmacists to fill prescriptions for brand-name drugs with its generic doppelganger.[30]

By the time Hatch-Waxman was passed, many states enacted drug substitution legislation, further facilitating generic drug competition.[31] Today, drug substitution laws are present in all fifty states[32] and permit pharmacists to substitute subscriptions for brand-name drugs with generic drugs.[33] In over thirty states, drug substitution laws require not only that generic drugs be bioequivalent[34], but also pharmaceutically equivalent[35] in accordance with FDA AB-rating standards.[36] However, because AB-rating requirements are so stringent, the Hatch-Waxman Act and state substitution laws create loopholes for brand-name drug manufacturers to extend their periods

---

24. *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013).

25. Garth Boehm et. al., *Development of the Genetic Industry in the US After the Hatch-Waxman Act of 1984*, 3 Acta Pharaceutica Sinica, 297, 297 (2013).

26. *New York v. Actavis PLC*, 787 F.3d 638, 643 (2d Cir. 2015).

27. 21 U.S.C. § 355(j) (2016).

28. *Id*.

29. FDA, Orange Book: Approved Drug with Therapeutic Equivalence Equations 7, 1-1400 (2017), http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm.

30. Gerald Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 Food and Drug L. J., 187, 190 (1999).

31. Alison Mason & Robert L. Steiner, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws* 1 (1985), http://1.usa.gov/1IS44Ju.

32. Jessie Cheng, Note, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 Colum. L. Rev. 1471, 1480 (2008).

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

34. Drugs are said to be bioequivalent when "the rate and extent of absorption" of the drugs are not significantly different; Kamal K Midha & Gordon McKay, *Bioequivalence; Its History, Practice, and Future,* 11 AAPS Journal 664–670, 664 (2009).

35. "[P]roducts are considered pharmaceutical equivalents if they contain the same active ingredient(s), are of the same dosage form, route of administration and are identical in strength or concentration"; U.S. Dept. of Health and Human Services, Therapeutic Equivalence-Related Terms, *in* Approved Drug Products with Therapeutic Equivalence Evaluations vii (37 ed. 2004).

36. *Id.* at 8.

of exclusivity.[37] One way in which brand-name manufacturers extend their exclusivity is by product hopping; this is accomplished by making trivial changes to the brand-name drug in order to force its genetic equivalent back into the regulatory process.[38]

III. PRODUCT HOPPING

The most significant threat to brand-name drug profitability is generic drug entry.[39] This is inevitable once a brand-name manufacturer loses its ability to market exclusively to the public. When generic products enter the market, the price of brand-name drugs drops dramatically. This incentivizes brand-name firms to delay the entry of generic competition for as long as possible.[40]

Most product hopping antitrust claims allege that a brand-name drug manufacturer has manipulated the FDA system.[41] When brand-name drug manufacturers are confronted with the likelihood of rivalry once a patent lapses or is held invalid, they can make minor changes to their endorsed drugs, get FDA approval for those paltry modifications, and supplant the old formulation with the new one.[42]

Product hopping can be achieved through several methods. Manufacturers can: (1) change some physical trait of the drug by switching from a capsule to a tablet or serrating the capsule itself for self-controlled dosing; (2) change the molecular components without having any bearing on the drug's activity itself; or (3) combine drugs that were once marketed individually.[43] From 1989 to 2000, for instance, only 35% of the 1,035 new drug applications approved by the FDA were for new molecular entities.[44] Moreover, 54% of all approvals were for drugs with new dosage forms, route of administration, or were combined with another active ingredient.[45]

---

37. Cheng, *supra* note 9, at 1494 ("Product hopping itself amounts to little more than a thinly disguised scheme to game the pharmaceutical industry's regulatory system.").

38. *See generally* M. Royall, *Antitrust Scrutiny of Pharmaceutical "Product Hopping",* 28 Antitrust (2013).

39. *See generally* Steven Tenn and Brett W. Wendling, *Entry Threats and Pricing in the Generic Drug Industry* (Oct. 2, 2012). US Federal Trade Commission Bureau of Economics Working Paper No. 301,https://ssrn.com/abstract=1622220 or http://dx.doi.org/10.2139/ssrn.1622220

40. Michael Carrier & Steve Shadowen, *Product Hopping: A New Framework*, 91 NOTRE DAME L. REV 167, 176 (2016).

41. *Id*. at 71.

42. Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, *IP & Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law § 15.3*, at 74.1(Supp. 2010). (lowercase title)

43. Steve Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L.J. 1, 24-25 (2009).

44. *Changing Patterns of Pharmaceutical Innovation*, The National Institute for Health Care Management Research and Educational Foundation, 7 (2002), http://www.nihcm.org/pdf/innovations.pdf (last visited Nov. 14, 2016) [Hereinafter *Changing Patterns*].

45. *Id.;* Shadowen, *supra* note 46.

While these changes may seem insignificant to consumers, they present unwarranted challenges to generic manufacturers and ultimately obstruct consumers' access to lower cost genetic drugs. This divergence between the interests of manufacturers and consumers occurs because prescription pharmaceutical markets are characterized by a "price disconnect" - a doctor, rather than the consumer, decides which product will be bought, but the product is ultimately paid for by the consumer.[46] Consequently, consumer choice is commandeered and true market competition is obstructed.

Resolving issues pertaining to product hopping requires a balancing act.[47] While courts are typically hesitant to question the judgment of the legislature, they also have a duty to preserve the integrity of the market by ensuring a balance between competition and innovation in these markets.[48]

A. The Sherman Act

The Sherman Act is a federal statute that prohibits certain business activities that federal government regulators deem to be anti-competitive, and requires the federal government to investigate and pursue trusts.[49]

Historically, parties have challenged product hopping as anticompetitive under Section 2 of the Sherman Act[50], and the judicial treatment thus far has hinged on the presence of consumer coercion.[51] Section 2 of the Sherman Act focuses on single-firm monopolization of a market. Under Section 2, it is a felony "to monopolize, attempt to monopolize, or combine or conspire with another person to monopolize trade."[52]

Attempted monopolization in violation of the Sherman Act has three elements: "(1) the defendant engaged in predatory or exclusionary conduct; (2) the defendant had a specific intent to monopolize; and (3) there was a dangerous probability that the defendant would successfully attain monopoly power."[53] A claim in a civil action for such a violation requires these elements plus an antitrust injury caused by the violation.[54] An antitrust injury is an injury "attributable to an anti-competitive aspect of

---

46. *Changing Patterns*, *supra* note 44.

47. Abbott Labs. v. Teva Pharm. USA, Inc., 432 F. Supp. 2d 408, 421 (D. Del. 2006); Walgreen Co. v. AstraZeneca Pharms. L.P., 534 F. Supp. 2d 149 (D.D.C. 2008).

48. Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 Tex. L. Rev. 685, 686 (2009).

49. Sherman Act, 26 Stat. 209, 15 U.S.C. §§ 1–7 (2003).

50. Lyneger, *infra* note 43, at 672; *see also* Walgreen Co. v. AstraZeneca Pharm. L.P., 534 F. Supp. 2d 146, 150 (D.D.C. 2008) ("The antitrust injury requirement ensures that a plaintiff can recover only if the loss stems from a competition-*reducing* aspect or effect of the defendant's behavior.").

51. Cheng *supra note* 9, at 1473.

52. 15 U.S.C. § 2; *see also Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.,* 386 F.3d 485, 495 (2d Cir. 2004).

53. Taylor Pub. Co. v. Jostens, Inc., 216 F.3d 465 (5th Cir. 2000); *see also* Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 456, 113 S. Ct. 884, 891, 122 L.Ed. 247 (1993).

54. Pac. Express, Inc. v. United Airlines, Inc., 959 F.2d 814 (9th Cir. 1992).

the practice under scrutiny."[55] This means that the injury does not result from a competitor's superiority over an inferior generic product, but stems from a the competitor's successful "gaming" of the system by artificially extending their monopoly powers.

Courts have held that brand-name manufacturers are under no legal duty to help their generic competitors; however, they must refrain from activities that have no basis other than to thwart competition.[56] From an antitrust perspective, product hopping is within the class of behaviors and practices that the Sherman Act expressly condemns.[57]

The courts have attempted to create a workable rule to reconcile these undermining practices beginning with *Abbott Lab. v. Teva Pharm. USA, Inc.* (2006), the first case to allege an antitrust injury on the basis of product hopping, and *Walgreen Co. v. AstraZeneca Pharm. L.P.* (2008) [58]

B. Framing the Rule Against Product Hopping

Abbott Labs. v. Teva Pharm. USA was the first case to squarely frame an antitrust claim predicated on allegations of pharmaceutical product hopping.[59] In *Abbott Labs.,* Defendants Abbott and Fournier ("Defendants") were accused of making insignificant modifications to the brand-name drug TriCor in order to sabotage the entry of its generic equivalent in the pharmaceutical market.[60] Moreover, Defendants also removed the older versions of TriCor off the shelves and changed the code for TriCor in the National Drug Date File (NDDF)[61] to "obsolete," preventing pharmacies from filling both brand-name and generic prescriptions for TriCor's earlier formulations.[62]

The Court articulated that to violate Section 2 of Sherman Act, a monopolist's conduct "must harm competitive process and thereby harm consum-

55. Atlantic Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 334, 110 S.Ct. 1884, 495 U.S. 328 (1990).

56. *Id*. at 346; *see also* Walgreen Co. v. AstraZeneca Pharms. L.P., 534 F. Supp. 2d 146, 151 (D.D.C. 2008); United States v. Microsoft Corp., 253 F.3d 34, 65 (2001) ("Judicial deference to product innovation...does not mean that a monopolist's product design decisions are per se lawful.").

57. *See generally* United States v. Grinnell Corp., 384 U.S. 563, 570-71 (1966); *See also* Vikram Lyneger, *Should Pharmaceutical Product Hopping Be Subject to Antitrust Scrutiny?*, 7 J. Patent & Trademark Office Soc. 663 (2015) (discussing whether product hopping is within the realm of practices condemned under the Sherman Act).

58. Abbott Labs, 432 F. Supp. 2d 408, 416-17; AstraZeneca Pharms. L.P., 534 F. Supp. 2d 146.

59. Carrier, *supra* note 43, at 192.

60. Abbott Labs, 432 F. Supp. 2d 408, 416-17.

61. The NDDF, now called FDB MedKnowledge, is a private database that provides information about FDA-approved drugs. 2015AB UMLS FDB MedKnowledge Source Information, U.S. National Library of Medicine (2016), https://www.nlm.nih.gov/research/umls/sourcereleasedocs/current/NDDF/ (last visited Mar. 22, 2017).

62. Abbott Labs, 432 F. Supp. 2d 408, 416.

ers, but harm to one or more competitors will not suffice."[63] As long as a manufacturer does not rob the consumer of choice, "[c]ourts should not condemn a product change . . . unless they are relatively confident that the conduct in question is anticompetitive." [64] Moreover, the Court found that the "rule-of-reason" test[65] should be applied, balancing the "merits of new product innovations against the arguable competitive obstacles such innovations may erect."[66]

In *Walgreen v. AstraZeneca*, the plaintiffs brought an action against AstraZeneca, alleging that the defendant violated the Sherman Act by introducing over-the-counter and prescription drug replacements for its prescription heartburn drug Prilosec as Prilosec's patent was about to expire.[67] The court found that the plaintiffs failed to state a claim for attempted market monopolization.[68] The court, relying on and distinguishing from the reasoning in *Abbott Lab* and *Microsoft*, found that there was no "eliminat[ion] [of] consumer choice[]"[69], adding that introduction of the new drug by AstraZeneca competed with both its own and others' drugs.[70] Extrapolating from both cases, a clear rule is articulated: a change in product design is per se legal, and courts will give deference to product innovation. However, the presumption is rebuttable if a plaintiff can articulate an anticompetitive injury. Upon showing an injury, the court will apply the rule-of-reason test to balance the benefits of innovation with the harms and obstructions those innovations might create in the competitive market.[71]

Although in *Abbott Lab* and *AstraZeneca* the courts arrived at two different decisions, the 'rule-of-reason' test was never applied in either case.[72]

---

63. Abbott Labs, *supra* note 50, at 420 (quoting United States v. Microsoft Corp., 253 F.3D 34,58 (D.C. Cir. 2001)).

64. *Id.* at 421 (quoting Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, *IP & Antitrust* § 12.1 (2006); *See* Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 63, 287 (2d Cir. 1979) ("If a monopolist's products gain acceptance in the market ... it is of no importance that a judge or jury may later regard them as inferior, so long as that success was not based on any form of coercion.").

65. This test was first articulated by the Supreme Court in *Standard Oil Co. v. United States,* 221 U.S. 1, 61–62, 31 S.Ct. 502, 516, 55 L.Ed. 619 (1911). The D.C. Circuit in the *Microsoft* case, 253 F.3d 34, used this test to balance the anticompetitive harm caused by Microsoft's design change to its website and its procompetitive benefit; *See also* Paycom Billing Servs., Inc. v. Mastercard Int'l, Inc., 467 F.3d 283, 289-90 (2d Cir. 2006) (explaining that courts analyze most antitrust claims under the rule-of-reason test).

66. Royall, *supra* note 38, at 73.

67. AstraZeneca Pharm. L.P., 534 F. Supp. 2d 146, 147-48.

68. *Id*. at 148.

69. *Id*. at 151.

70. *Id*.

71. *See generally* Standard Oil Co. v. United States, 221 U.S. 1, 31 S.Ct. 502, 55 L.Ed. 619 (1911); United States v. Microsoft Corp., 253 F.3D 34 (D.C. Cir. 2001); Paycom Billing Servs., Inc. v. Mastercard Int'l, Inc., 467 F.3d 283, 289-90 (2d Cir. 2006).

72. In 2009, Abbott Labs agreed to pay $184M to settle its antitrust claims arising out of litigation with competitors Teva and Impax laboratories; *See* Samuel Howard, *Abbott Settles TriCor Class Action*

Moreover, these cases fail to address the "grey area" between two polar-opposite scenarios.[73]

IV. 2015 SPLIT COURT DECISIONS

In 2015, the Second and Third Circuits rendered decisions for cases involving product hopping.

A. New York v. Actavis PLC

In *New York v. Actavis PLC*, the United States Court of Appeals for the Second Circuit became the first appellate court to address product hopping.[74] This case raised a novel question of antitrust law: "under what circumstances does conduct by a monopolist to perpetuate patent exclusivity through successive products, commonly known as 'product hopping,' violate the Sherman Act?"[75]

The defendants manufacture the drug Namenda, a medication used to treat Alzheimer's disease[76]. The defendants have two formulations for the drug, *Namenda IR* (IR), an immediate-release drug, and *Namenda XR* (XR), an extended-release drug.[77] Both versions of Namenda are medically the same except that the IR version is taken twice a day while the XR version is only taken once a day, providing different dosing.[78] More importantly, they have different patent expiration dates; IR's patent was set to expire in July 2015, while XR's patent will expire in 2029.[79] Before this action, Actavis maintained a monopoly on the memantine-drug market.[80]

Upon expiration of IR's patent, several generic equivalents were poised to enter the market. Accordingly, the defendants removed their original formulation form the market. Namenda XR could not be substituted for Generic IR formulas because those drugs were not bioequivalent, which resulted in this litigation.

---

for $184M, Law 360, http://www.law360.com/articles/77718/abbott-settles-tricor-class-action-for-184m. (last visited Dec. 18, 2016).

73. Royall, *supra* note 38, at 74 (discussing how the combined holdings of *Abbott Labs* and *AstraZeneca* does not address varying scenarios including a manufacturer ceasing to market prior formulations but not entirely removing the formulation from the market).

74. Actavis PLC, 787 F. 3d 638.

75. *Id*. at 643.

76. *Id*. at 646.

77. *Id*.

78. *Id*. at 647

79. *Id*.

80. Memantine is an N-Methyl D-Aspartate ("NMDA") receptor antagonist that affects the glutamate pathway in the brain. Memantine-based drugs, like Namenda, partially block the brain's NMDA receptor in order to prevent "over-activation" of that receptor, which can cause toxicity to neurons in the brain; David Olivares et al., N-Methyl D-Aspartate (NMDA) Receptor Antagonists and Memantine Treatment for Alzheimer's Disease, Vascular Dementia and Parkinson's Disease, 9 Current Alzheimer Research 746–758, 746-758 (2012) (noting that while there were other FDA approved drugs on the market to treat Alzheimer's, such as Aricept, Exelon, and Razadyne, those drugs target different biochemical pathways, therefore, non-substitutable for Namenda).

In September 2014, New York State filed for a preliminary injunction against Actavis, alleging violations of antitrust laws.[81] The State alleges that in 2013, Actavis made a "soft switch" to the XR drug in response to IR's approaching patent expiration.[82] Despite its selling of both IR and XR formulas and vigorous promotion of XR to doctors, patients and pharmacies, Actavis ceased to promote its IR formulation..[83] Moreover, in 2014, the defendants attempted to make a hard-switch; they announced that they would discontinue IR and attempted to prevent medical providers from prescribing IR unless it was "medically necessary."[84]

The State argued that Actavis attempted to impede the entry of generic IR by removing Namenda IR from the market, and thus, coerces consumers into purchasing XR by depriving them of choice.[85] As a result, Actavis would maintain their monopoly over the memantine-drug market.[86]

The court analyzed whether Actavis attempted to maintain their monopoly under Section 2 of the Sherman Act[87]. Applying the rule-of-reason test articulated in *Microsoft*, [88] the court sought to extricate "conduct that defeats a competitor because of efficiency and consumer satisfaction"[89] from conduct that thwarts the competition by way of "gaming" the system.

The court found that the defendants' introduction of Namenda XR and subsequent withdrawal of IR to be coercive and would "likely impede generic completion by precluding generic substitution."[90] By Actavis removing IR from the market, leaving XR as the only available drug of choice, Actavis is limiting consumer choice to purchase XR[91]. Because XR has patent protection, no other bioequivalent drug can compete until its patent expires in 2029[92].

Moreover, it is likely that once generic IR is introduced, its marketability would be severely impaired by XR's status as the drug of choice, ridding consumers of incentive to switch back.[93] In this scenario, XR's popularity is not generated by consumer choice but by an artificial monopolization of the

81. Complaint at 1, New York v. Actavis PLC, 2014 WL 4627802 (S.D.N.Y. Sept. 15, 2014) (14 CV 7473).

82. Actavis PLC, 787 F.3d at 648.

83. *Id.* at 647-68.

84. *Id.* at 648 (attempting to show "medical necessity" would prove futile since both Namenda IR and XR were only distinguished by their dosing).

85. *Id*. at 654.

86. *Id.* at 649.

87. *Id*. at 651-60.

88. Microsoft, *supra* note 68.

89. *Id.* at 652 (quoting *U.S. Football League v. Nat'l Football League*, 842 F.2d 1335, 1359 (2d Cir. 1988)).

90. *Id*. at 654.

91. *Id*. at 654-55.

92. *Id*. at 642.

93. *Id.* at 656.

memantine-drug market. Additionally, the court found Actavis' procompetitive defense to be "pretextual"[94], reasoning that the defendants' conduct "makes sense only because it eliminates competition."[95]

The court concluded that the "combination of withdrawing a successful drug from the market and introducing a reformulated version of that drug… without a legitimate business justification" violated Section 2 of the Sherman Act.[96]

B. Mylan v. Warner Chilcott

In *Mylan v. Warner Chilcott*, the plaintiff alleged that Warner Chilcott, the manufacturer of an unpatented acne medication, violated antitrust laws by engaging in a "product-hoping scheme" designed to impede generic competition.[97] Mylan brought several claims under the Sherman Act;[98] relevant to this discussion is Mylan's allegation that in anticipation of generic entry, the defendant executed three product switches[99] and then subsequently removed their original formulation off the shelves.[100] The plaintiff argued that "these switches," provided "little or no therapeutic benefit to consumers," but "devastated the market for the prior versions of Doryx". [101]

The defendant rebutted that branded drug companies were under no duty to assist generic drug companies by waiting to phase out older branded formulations until a generic substitute was available to the public,[102] suggesting that this type of "free riding" is "'the antithesis of competition.'"[103] The plaintiff, on the other hand, contended that this case was indistinguishable from *New York v. Actavis*, and that Warner Chilcott's act of removing

---

94. *Id.* at 658.

95. *Id.* at 659 (quoting *In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 133 (2d Cir. 2014)).

96. *Id.*

97. Brief for FTC as Amicus Curiae at 18, *Mylan Pharm., Inc. v. Warner Chilcott*, Pub. Co., No. 12-3824 (E.D. Pa. Nov. 21, 2012) [hereinafter FTC Mylan Brief], https://www.ftc.gov/system/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.warner-chilcott-plc-et-al./151001mylanamicusbrief.pdf.

98. *See* Appellate Court Opinion at 8, *Mylan Pharm., Inc. v. Warner Chilcott,* Pub. Co., No 15-2236 (3d Cir. Sep. 28 2016) [hereinafter Mylan Opinion], www2.ca3.uscourts.gov/opinarch/152236p.pdf.

99. *Id.* Wilcott introduced three new variations of their existing formula, first from a capsule to a tablet, then from 75mg and 100mg tablets to a single 150mg dosage strength, and finally from a single-scored version of the 150mg tablet to a dual-scored version.

100. Complaint*,* Mylan Pharm., Inc. v. Warner Chilcott Pub. Co., No. 12-3824, 2-5 (E.D. Pa. July 6, 2012) [hereinafter Mylan Complaint].

101. Royall, *supra* note 38, at 74-75 (citing Mylan Complaint, at 2, 9). Doryx, an oral tetracycline, is used to treat a wide variety of bacterial infections, including those that cause acne.

102. Memorandum of Law in Support of Defendant Warner Chilcott's Motion to Dismiss at 16–19, Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co., No. 12-3824 (E.D. Pa. Oct. 1, 2012).

103. *Id*. at 24 (quoting *Olympia Equip. Leasing Co. v. W. Union Tel. Co*., 797 F.2d 370, 376–79 (7th Cir. 1986) (Posner, J.)).

its branded medication off the market combined with the introduction of three substitute formulations violated Section 2 of the Sherman Act. [104]

The Court articulated that the Sherman Act "directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself."[105] Here, the court distinguished from *Actavis*, finding that the defendant had not established a monopoly over tetracycline-drug market,[106] and holding that Mylan was not "foreclosed" from the market. [107] The plaintiff could introduce generic Doryx at any time after 1985, as Doryx has been on the market for more than 20 years with no patent protection. However, Mylan failed to begin its own production until 2003.[108]

Mylan eventually obtained FDA approval for several of its formulations that would be allowed to compete against other tetracycline drugs. Thus, any argument that the defendant's subsequent formulations obstructed the generic market failed. Ultimately, the court found that Mylan failed to state an anticompetitive injury.[109] Reconciling other claims, the court addressed the second prong of the *Microsoft* test. The court found that even if an anti-competitive injury was present, the defendant presented legitimate business justifications.[110] Accordingly, the Third Circuit held that the plaintiff's did not meet its burden under Section 2 of the Sherman Act.

V. RECONCILING THE SPLIT

A. Product Shifting

Articulated in *AstraZeneca* and *Microsoft*, courts will give deference to innovation.[111] Perceivably frivolous changes made to an existing product formulation are legal per se. In both *Actavis* and *Mylan*, brand-name manufacturers made changes to their drug formulations related to either dosing or

104. Mylan Opinion, *supra* note 102, at 34.

105. *Id.* at 35 (quoting Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 458 (1993)).

106. *Id.* 28-32 (discussing how several other tetracycline drugs were on the market and Doryx's market share never exceeded 18%). Tetracyline drugs are antibiotic drugs used to treat bacterial infections. Tetracyclines are used to treat various infections including acne, sexually transmitted diseases such as syphilis, and pneumonia.

107. *Id.* at 36. ("[*Actavis*] involved the defendants' attempts to avoid a "patent cliff" – the end of patent exclusivity, corresponding to the brand drug's loss of market share – by stringing together new periods of patent exclusivity in order to completely bar generics from entering the market. It was alleged that the defendants did so by introducing changes to their product to delay the expiration of their patent. Here, there were no patent cliffs on the horizon, and the evidence demonstrates that there were plenty of other competitors already in the oral tetracycline market."). *Id*. at 38.

108. *Id.* at 16-17.

109. *Id.* at 37.

110. *Id.* Warner Chilcott's formulation changes were in response to doxycycline capsules being linked with esophageal problems, poor shelf-life, and competitive manufacturers' introduction of "self-dosing" tablets.

111. *See* AstraZeneca Pharms.,534 F. Supp. 2d 146, 151; Microsoft Corp., 253 F.3d 34, 65.

switching from capsule to tablet form.[112] As expressed in *Berkley*, courts do not investigate the significance of these innovations; the purview of their inquiry deals with whether those innovations create an injury to the competitive market.[113]

B. Anticompetitive Injury

Injury to the competitor alone is not sufficient to raise an antitrust claim[114]. The injury must cause harm to the consumer by way of coercion[115]. In both cases, generic manufacturers accused brand-name manufacturers of strategically timing the release of their derivative products in order to interfere with generic competition. In *Actavis*, the court held that the introduction of patented Namenda XR followed by the removal of Namenda IR from the market in response to impending generic IR entry rose to the level of coercion[116]. Thus, the defendants' acts were violative of the Sherman Act.[117] Conversely, *Mylan* arrived at a different conclusion, finding that Cilcott's introduction of three varied Doryx formulas and removal of its capsulated Doryx formula did not violate the Sherman Act. [118]

In arriving at the holding in these cases, both courts addressed whether respondent has a pre-existing monopoly or attempted to create a monopoly over their perspective drugs markets[119]. Under this analysis, *Actavis* is distinguished from *Mylan*. In *Actavis*, Namenda IR and XR were the only memantine drugs on the market[120]. However, in *Mylan*, there were several bioequivalent generic drugs on the market prior to Chilcott's new formulation releases[121]. Under Section 2 of the Sherman Act, Actavis had an existing monopoly and their attempts at product hopping would have likely resulted in them extending that monopoly. However, in *Mylan*, it was unlikely for Chilcott to obtain a monopoly, as their drug competed with many others in the market and their market share had never exceeded 18%.[122]

These cases are further distinguished by the protections granted to the brand-name manufacturers' subsequent formulations. In *Actavis*, Namenda XR was patent protected. In *Mylan*, Doryx's new formulations were not patented.[123] Namenda XR provided the defendant with an advantage by

112. Actavis PLC, 787 F. 3d 638, 647-49; Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co., 838 F.3d 421, 428-31 (3d Cir. 2016).
113. Berkey Photo, *supra* note 67.
114. *See* Mylan Pharm., 838 F.3d 421, 438.
115. Actavis PLC, 787 F. 3d 638, 654-55; Mylan Pharm., 838 F.3d 421, 441.
116. Actavis PLC, 787 F. 3d 638, 655.
117. *Id*. at 663.
118. Mylan Pharm., 838 F.3d 421, 441-42.
119. *Id.*, at 433-38; Actavis PLC, 787 F. 3d 638, 651-52.
120. Actavis PLC, 787 F. 3d 638, 652.
121. Mylan Pharm., 838, F. 3d 421, 437-38.
122. *Id.* at 438.
123. *Id*. at 440.

artificially extending Actavis' absolute monopoly for another 15 years[124]. In *Mylan*, however, neither the original nor derivative formulations were patented. Doryx's popularity in its market was merit-based while Namenda became a leading brand through exclusivity.[125]

C. Legitimate Business Justifications

Microsoft provided that the defendants may rebut a claim that they engaged in anticompetitive practices by providing procompetitive justifications.[126] Under this prong, the cases were further distinguished. In *Actavis*, the court found that the defendant's purpose was flagrant;[127] the defendants wanted to fend off generic competition. In *Mylan*, on the other hand, the defendant provided substantial justifications. [128]

VI. CONCLUSION

While the Second and Third Circuits have appeared to reach unequivocal decisions in two factually similar cases, both courts have followed the doctrine of *stare decisis*, rendering decisions consistent with the standards articulated in of *Abbott Lab* and *AstraZeneca*[129]. Where the precedent cases remained silent,[130] the Second and Third Circuits have filled in the gaps. Accordingly, courts should defer to the rule-of-reason test, initially weighing procompetitive benefits and anticompetitive harms, disregarding whether an intent to establish a monopoly was present. If a product on its merits results in a monopoly, it reflects the choices of consumers. Thus, further inquiry would frustrate the purpose of antitrust laws.

---

124. Actavis PLC, 787 F. 3d 638, 660.

125. *See* Mylan Pharm., 838, F. 3d 421, 438-39; *See* Actavis PLC, 787 F. 3d 638, 660-61.

126. Microsoft, *supra* note 92, at 59.

127. Actavis PLC, 787 F.3d 638, 658 ("We need to transition volume to XR to protect our Namenda revenue from generic penetration in 2015 when we lose IR patent exclusivity.").

128. Mylan, *supra* note 15, at 37.

129. Abbott Labs., 432 F. Supp. 2d 408, 421–23; AstraZeneca Pharm. L.P., 534 F. Supp. 2d 146, 150.

130. Royall, *supra* note 38, at 74.