

Making the Switch: How Little Is Too Little in a Competitive Market?

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ABSTRACT

The debate over whether competition or monopolies give rise to innovation is ongoing. Competition across industries provides firms with a “powerful motive” to innovate given that the most immediate beneficiaries are the firms themselves. Some have used this theory to contend that monopolists are bound to innovate as they are able to recoup investments into research and development, maintain market share, and exclude entrants. Alternatively, others have used the theory to argue that competition begets innovation, given that developing a new product grants monopoly profits to the first mover in a competitive market. The innovation standard in antitrust law has evolved as this debate has gone on, moving from a presumption of legality for any new innovation to a focus on the effects an innovation has on the consumer.

Most recently, in the product-hopping context, the Second Circuit has held that a “hard switch,” which removes the original product from the market forcing consumers to switch, is anticompetitive because it interferes with consumer choice. On the other hand, the court has left the door open for analysis of a “soft switch,” which allows a consumer to still obtain the original product or a modest reformulation. Looking to the legal standards applied in the most pivotal cases on attempted monopolization in the context of a new product, this article finds that a soft switch may be anticompetitive under certain standards. First, I propose that a soft switch would pass muster under the most permissible standard found in Kodak, which allows for the market to determine which product is better regardless of objective improvements. Second, I propose that a soft switch would not pass muster if it can be proven that advertising has been used as a coercive tool under the structured reasonableness standard proposed in Microsoft, which condemns a soft switch if the anticompetitive harm of the conduct outweighs the procompetitive benefit. Third, and finally, I propose that the manipulation of the patent system to obtain weak patents on the ancillary aspects of the drug is enough to constitute a Section 2 violation under the additional conduct standard put forth in Actavis, which requires a combination of conduct to condemn a soft switch.

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INTRODUCTION

Pharmaceutical companies are clever. To prevent competition, brand name pharmaceutical companies modestly reformulate their patented drugs.¹ This process, called “product-hopping,” often does not improve the drug therapeutically. Still, the process may allow a company to keep its “monopoly profits”: the slightly-altered drug may qualify for a new patent, and the brand name company might remove the old product from the market before generic companies can replicate and sell the older drug.² In May 2015, the Second Circuit became the first court to address whether product-hopping violates Section 2 of the Sherman Act.³ In its analysis, the court distinguished between a “soft switch” and a

1. FED. TRADE COMM’N, FTC FILES AMICUS BRIEF EXPLAINING THAT PHARMACEUTICAL “PRODUCT HOPPING” CAN BE THE BASIS FOR AN ANTITRUST LAWSUIT (2012), <https://www.ftc.gov/news-events/press-releases/2012/11/ftc-files-amicus-brief-explaining-pharmaceutical-product-hopping> [<https://perma.cc/2RXX-Z5N7>].

2. *Id.*

3. *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 659 (2d Cir. 2015), *cert. dismissed sub nom. Allergan PLC v. New York ex. rel. Schneiderman*, 136 S. Ct. 581 (2015).

“hard switch.” A “soft switch” allows a consumer to obtain either the original product or a modest reformulation, while a “hard switch” removes the original product from the market, forcing consumers to switch to the reformulation.⁴ The court thought the market could determine when one product is superior to another “so long as the free choice of consumers is preserved,” as it is when only a soft switch occurs.⁵ A “soft switch” allows a consumer to obtain either the original product or a modest reformulation, while a “hard switch” removes the original product from the market, forcing consumers to switch to the reformulation.⁶ Relying on this principle, the court held that:

[N]either product withdrawal nor product improvement alone is anticompetitive . . . [but] when a monopolist combines product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, and to impede competition, its actions are anticompetitive under the Sherman Act.⁷

The Second Circuit built upon the pivotal *United States v. Microsoft Corp.* case, in which the court addressed innovation in technologically dynamic markets.⁸ The court pointed out that firms routinely innovate in a competitive market in the hope of appealing to consumers. In certain instances, firms have made their products incompatible with those of rivals, but have not been subject to liability under the antitrust standard. The court insisted that there should be no difference in treatment for a monopolist engaging in such behavior, because imposing “liability when a monopolist does the same thing will inevitably deter a certain amount of innovation.”⁹ Such treatment of innovation is indicative of its value as a transcendental social good, nudging the scales toward presumptive legality. In fact, the court went out of its way to condemn a per se analysis of the tying arrangement because of the “undue risks of . . . deterring welfare enhancing innovation.”¹⁰ The court was quick to indicate that “[j]udicial deference to product innovation, however, does not mean that monopolist’s product design decisions are per se lawful.”¹¹

4. *Id.* at 648.

5. *Actavis*, 787 F.3d at 654–55 (quoting *Berkey Photo, Inc v. Eastman Kodak Co.*, 603 F.2d 263, 287(2d Cir. 1979)).

6. *Id.* at 648.

7. *Id.* at 653–54.

8. *United States v. Microsoft Corp.*, 253 F.3d 34, 49 (D.C. Cir. 2001).

9. *Id.* at 65.

10. *Id.* at 89–90. The tying arrangement in question was the bundling of the manufacturer’s internet browser with its personal computer operating system. The court found that there was not “enough empirical evidence regarding the effect of Microsoft’s practice on the amount of consumer surplus created or consumer choice foreclosed by the integration of added functionality into a platform software to exercise sensible judgment regarding that entire class of behavior.” *Id.* at 94. Thus, the court remanded the case for evaluation under the rule of reason so the lower court could further inquire into the actual impact of these arrangements on competition.

11. *Id.* at 65.

Although courts presume that innovation is procompetitive, the overarching question that I will address is: *How strong should this presumption be?* Allowing companies to continue to “product-hop” without punishment when a previous version of the product remains available fails to consider the effects that marginal innovation has on the consumer. In determining the legal standard, we must decide whether the goal of antitrust law is to protect the consumer from corporate greed or to reward business acumen. If the former, we would allow the government to regulate conduct that seeks to manipulate or coerce the consumer into purchasing a product, and we would employ the court system to police violations. If the latter, we would allow market forces to regulate and rectify bad behavior. This Note seeks to determine under what standard a court should analyze innovation, and to provide insight into which innovations allowable under the *Actavis* standard may be considered to be harmful to consumers. Within the analysis, this Note will touch on what anticompetitive conduct each standard may allow.

This article proceeds in four parts. Part I provides background, describing the statutory backdrop of product hopping and the Hatch-Waxman Act. Part II provides highlights from the debate over whether monopolies or competition better incentivize innovation. Part III describes the history of the innovation standard as scrutinized under the attempted monopolization prong of Section 2 of the Sherman Act. Part IV discusses the theories behind the legal standards for innovation in the antitrust context. Part V looks at innovation within the product-hopping context, analyzing whether a court could ever find a soft-switch anticompetitive.

II. THE HATCH-WAXMAN ACT

The Hatch-Waxman Act (the Act) regulates the marketing of drugs in the United States.¹² Under the Act, originator drug manufacturers must apply to the Food and Drug Administration (FDA) before marketing drugs. This application, known as a “new drug application” (NDA), includes evidence of the drug’s safety and efficacy, along with “a full statement of the [chemical] composition.”¹³ Once the FDA approves the drug, it is listed in a publicly available publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”).¹⁴ The Orange Book contains each patent’s number and expiration date. Importantly, the Orange Book also notes which drugs “a claim of patent infringement could reasonably be asserted [against] a

12. The Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc (2000), 35 U.S.C. §§ 156, 271, 282 (2000)), as amended by the Medicare, Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

13. Jennifer Sturiale, *Hatch-Waxman Patent Litigation and Inter Partes Review: A New Sort of Competition 8* (unpublished manuscript); 21 U.S.C. §§ 355 (a)–(b), (d) (2016).

14. See U.S. FOOD & DRUG ADMIN., *APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (ORANGE BOOK)* (2017), <http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm> [<https://perma.cc/B3QE-32KF>].

person not licensed by the owner engaged in the manufacture, use, or sale of the drug.”¹⁵ This published information “puts generic drug manufacturers on notice” of which patents listed in the Orange Book “would have to be successfully challenged in order for the generic drug manufacturer to enter the market [during the patent term] without risking liability.”¹⁶

The Hatch-Waxman Act was enacted “to streamline and make less costly the process by which generic drug manufacturers challenge patent claims covering pharmaceutical drugs and obtain approval by the FDA.”¹⁷ The Act also establishes an Abbreviated New Drug Application (ANDA), an expedited application that a generic drug manufacturer may submit to “show that the drug it seeks to market is effectively the same as an already-approved, brand-name drug” listed in the Orange Book.¹⁸ The generic manufacturer must show that “the active ingredients of the new drug are the same as those of the listed drug,” and provide “information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug.”¹⁹

Prior to passage of the Hatch-Waxman Act, generic drug manufacturers were required to submit clinical trial data supporting the drug’s safety and efficacy because clinical trial data covering “the brand-name version of the drug [was] considered propriety and protected by trade secret.”²⁰ This regulatory framework required generic drug manufacturers to duplicate efforts by brand name manufacturers to comply with the FDA’s requirements. Such efforts were incredibly costly and time consuming, such that only “35 percent of the best-selling off-patent drugs faced generic competition.”²¹ Thus, by not requiring generic drug manufacturers to submit clinical trial data, the Act opened the monopoly-dominated marketplace to competition.

III. MONOPOLIES V. COMPETITION: A REVIEW

Scholars continue to debate whether monopolies or competition, i.e., antitrust enforcement, better incentivizes innovation.²² Few would dispute that competition leads to better goods and lower prices, but it is less clear that competition encourages new and different products or improved production processes—that is, innovation.²³ Joseph Schumpeter argues that monopolists may be more innovative than other firms in competitive markets, because firms with strong

15. 21 U.S.C. § 355 (b)(1) (2016).

16. Sturiale, *supra* note 13, at 8–9.

17. *Id.* at 9.

18. *Id.*

19. 21 U.S.C. §§ 355 (j)(2)(ii)(II), (iii) (2016). *See* Sturiale, *supra* note 13, at 9.

20. Sturiale, *supra* note 13, at 10.

21. *Id.* (quoting Henry G. Grabowski et al., *Evolving Brand-Name and Generic Drug Competition May Warrant a Revision of the Hatch-Waxman Act*, 30 *Health Affs.* 2157, 2157 (2011), <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2010.0270> [<https://perma.cc/AG43-JWHQ>]).

22. *See* Jonathan B. Baker, *Beyond Schumpeter v. Arrow: How Antitrust Fosters Innovation*, 74 *ANTITRUST L.J.* 575, 575 (2007).

23. *Id.* at 576.

pre-existing market positions may be more willing to invest in research and development if there is a greater likelihood of recoupment.²⁴ Kenneth Arrow's competing theory notes that a monopolist will have less to gain through innovation, as the firm would already have "most of the business there is to get."²⁵ Arrow theorizes that competitive markets provide greater incentive to innovate, encouraging firms to "take away much of the business previously conducted by rival firms" or to gain market share.²⁶ Notably, neither theory can explain innovation in all markets, as innovation is greatest in oligopolistic market structures. Furthermore, an industry's conduciveness to innovation is dependent on many factors, including technological opportunities, room for improvement, and expectation of intellectual property protections.²⁷ Thus, the debate rages on.

The incentives that drive innovation in a competitive market versus a monopoly are not diametrically opposed. Competition with the prospect of monopolization promotes innovation, and the threat of competition incentivizes monopolists to invest in innovation to maintain monopolies and discourage new entrants.²⁸ In his analysis of competition and innovation, Jonathan Baker put forward four principles that attempt to reconcile the Schumpeter-Arrow debate. First, competition among firms seeking to develop the same new product or process encourages innovation. This principle embodies the race to patenting that exists in high-tech and other industries in the new economy.²⁹ Second, competition encourages firms to find ways to lower costs, improve quality, or develop better products to escape competition.³⁰ Third, competition promotes differentiated products, because firms that face more product market competition after innovation have less incentive to invest in research and development.³¹ Fourth, firms have extra incentive to innovate if doing so will discourage rivals from investing in research and development.³²

Where competition exists, there are enforcement actions that a governmental agency can take to promote innovation. In his analysis, Baker presents a series of enforcement policies that promote, rather than hinder, innovation. First, attacking agreements among innovation rivals not to conduct research and development, undertaken without any legitimate justification.³³ Second, challenging horizontal mergers that reduce the number of likely innovators when there are few (absent countervailing innovation efficiencies).³⁴ Third, challenging

24. *Id.* at 578.

25. *Id.*

26. *Id.*

27. *Id.* at 584.

28. *See id.* at 582.

29. *Id.* at 579.

30. *Id.*

31. *Id.* at 580.

32. *Id.* at 581.

33. *Id.* at 592.

34. *Id.*

conduct that raises transaction costs to firms participating in standard setting that would make new product development costlier for all.³⁵ Each of these enforcement policies attacks conduct that has no legitimate procompetitive justification while attempting to monopolize.

Baker's analysis and recommendations support the conclusion that targeting antitrust enforcement on industries and practices where it would enhance research and development incentives would result in greater innovation.³⁶ Further, Baker cites modern research that contradicts the idea that only oligopolistic industries are conducive to greater innovation.³⁷ Current research shows that a robust competition policy will likely have a positive overall effect on incentives to innovate.³⁸ On the whole, "structural queries are still essential in order to identify markets capable of being monopolized, dominant firms, the anticompetitive potential of vertical restraints, anticompetitive joint ventures of competitors, mergers that are likely to increase prices, and markets particularly susceptible to collusion."³⁹ However, competition across industries, regardless of structure, provides firms with a "powerful motive" to innovate given that the immediate beneficiaries are "the innovating firms themselves, which profit from product and process improvements, and their buyers who can purchase better or cheaper products."⁴⁰

IV. HISTORY OF THE INNOVATION AND ATTEMPTED MONOPOLIZATION STANDARD

Innovation can be distinguishing from its corresponding exclusionary restraints, such as a hard switch, incompatibility, or predatory pricing.⁴¹ The following cases consider whether the slightest innovation is permissible and whether it is enough to overcome a judicial attack on accompanying anticompetitive exclusionary restraints.

A. *Presumption of Legality*

Under the presumption of legality, any innovation, marginal or otherwise, is permissible. The standard was set forth in 1972, in a case where Kodak, the dominant firm in the "amateur conventional still camera" market, introduced a new photographic system: the Kodak 110. The 110 "Pocket Instamatic" and 126 "Instamatic" were small, light, instant-loading cameras that "employ[ed] film

35. *Id.* at 592–93.

36. *Id.* at 602.

37. *Id.* at 583–85. See also Stephen J. Nickell, *Competition and Corporate Performance*, 104 J. POL. ECON. 724 (1996) (providing preliminary evidence that increased numbers of competitors is associated with a significantly higher rate of total factor productivity growth).

38. Baker, *supra* note 22, at 585–86 (pointing to analyses of innovation within the same industry across nations with different competition policies).

39. Herbert J. Hovenkamp, *Competition for Innovation*, 799 COLUMBIA BUS. L. REV. 799, 801 (2012).

40. Baker, *supra* note 22, at 587.

41. Predatory pricing is the act of setting prices low in an attempt to eliminate the competition. It is illegal because it makes markets vulnerable to a monopoly.

packaged in cartridges that can simply be dropped in the back of the camera, thus obviating the need to load and position a roll manually.”⁴² Kodak was also dominant in the film market and, with the introduction of the Kodak 110 camera, also introduced a new, faster, color print film in the 110 size. The sale of the Kodak color print film was tied-in with a photofinishing service, allowing Kodak to “parlay its film monopoly to achieve equivalent market power in photofinishing.”⁴³ Meanwhile, Berkey Keystone attempted to enter the “110 sweepstakes” but suffered paltry sales. Berkey contended that the introduction of the 110 system was an attempt to monopolize and actual monopolization of the camera market.⁴⁴ However, the court held that the “first firm, even a monopolist, to design a new [product] has a right to the lead time that follows from its success.”⁴⁵ The court showed little concern that Kodak “not only participated in but dominated” the market.⁴⁶ Here, the innovation itself was permissible because it was a genuinely new product upon which the firm had the right to capitalize as the early mover.⁴⁷

Courts construe broadly what counts as an innovative product when applying the presumption of legality. For example, a reduction in price for the same or a similar product constitutes an innovation and is entitled to the presumption of legality. This interpretation was set forth, in the 1980s, in a case involving central processing units (CPUs) and peripheral products, including disks, sold by IBM. At the time, California Computer Products, Inc. (CalComp) began manufacturing disk products that were “plug compatible”⁴⁸ with IBM’s and other suppliers’ CPUs. CalComp’s strategy was to “copy, and where possible, improve upon an IBM design, and undersell IBM to its own customers.”⁴⁹ CalComp was able to avoid the research and development expenditures incurred by IBM by reverse engineering IBM devices.⁵⁰ As a result, CalComp was able to pass savings on to customers through lower prices.⁵¹ The court “[g]ranted that [IBM’s] technological innovations resulted in ‘growth as a consequence of superior product.’”⁵² Still, the court held that CalComp “was entitled to maintain its consequent dominant position in the market” that it achieved through business acumen, because “[t]he Sherman Act does not draw a distinction between competition on the basis of price and of performance: the two are

42. *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 269 (2d Cir. 1979).

43. *Id.* at 269–70.

44. *Id.* at 278.

45. *Id.* at 283.

46. *Id.*

47. The court seems to overlook the tying of the photofinishing service with the purchase of the Kodak film because of the efficiencies tied to the new service.

48. The CalComp disks were compatible with IBM products.

49. *California Computer Products, Inc. v. Int’l Bus. Mach. Corp.*, 613 F.2d 727, 731 (9th Cir. 1979).

50. *Id.*

51. *Id.*

52. *Id.* at 742.

inseparable parts of any competitive offering.”⁵³ Here, though the actual design of the product piggy-backed on the designs of the originator, the court found “innovation” due to the lower price, indicating the presumption of legality for innovation encompasses even the same or similar product at a lower price.

Meanwhile, Transamerica was formed to supply the capital needed by plug-compatible manufacturers (PCMs), like CalComp.⁵⁴ IBM responded by engaging in a number of programs that allegedly violated the Sherman Act, including a leasing program, design changes, and pricing behavior. The leasing program allowed customers to “lease peripheral equipment for one year at an eight percent discount below the month-to-month rate, or for two years at a sixteen percent discount.”⁵⁵ IBM then redesigned the interface so that the PCM’s peripherals were no longer compatible with IBM’s CPUs.⁵⁶ Finally, IBM introduced several “new” products that were repackaged versions of prior peripherals at lower prices.⁵⁷ Following these actions, sixteen companies—including Transamerica—left the market after suffering huge losses.⁵⁸ The court found, relying on *CalComp* and *Memorex*, that the leasing program was legal and there was no antitrust injury to allow for recovery because Transamerica failed to prove that it “suffered . . . damages attributable to the redesign.”⁵⁹ On the issue of predatory pricing, the court rejected Transamerica’s evidence as insufficient because it only included price cuts, which were “hardly an unusual act in the computer industry or unusual in the face of competition.”⁶⁰ The court, even after criticizing each exclusionary restraint, allowed IBM to engage in redesign, a leasing program, and predatory pricing based on its presumption that the originator may take any steps necessary to recoup for its efforts.

B. Examination of Effects and Structured Reasonableness

Over time, the courts began to look at the effect of the innovation on the consumer in circumstances where an anticompetitive motivation was apparent. In 1998, *C.R. Bard* held patents on the original, second, and third generation biopsy needle guns. The first generation device was “designed to [inject] a commercially available biopsy needle assembly,” known as Tru-Cut.⁶¹ The second generation slightly modified how needles were loaded in the guns, but that modification rendered the Tru-Cut needles unusable. The third generation gun improved the external cocking mechanism, requiring less force to operate than the second-generation gun.⁶² *Bard* brought suit against M3 Systems,

53. *Id.*

54. *Transamerica Computer Co. v. Int’l Bus. Mach. Corp.*, 698 F.2d 1377, 1380 (9th Cir. 1983).

55. *Id.*

56. *Id.*

57. *Id.*

58. *Id.* at 1381.

59. *Id.*

60. *Id.* at 1389.

61. *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1347 (Fed. Cir. 1998).

62. *Id.* at 1348.

asserting that M3's ProMag biopsy gun and CAN/SACN biopsy "needle assembly infringed on the second and third generation patents."⁶³ M3 argued that the patents were invalid and charged Bard with an antitrust violation, proposing that "Bard had modified its biopsy gun and needles for the purpose of preventing use of Tru-Cut needles and [for] exclud[ing] M3's copies so that they did not fit the gun without an adapter."⁶⁴ The court ultimately affirmed Bard's liability on the antitrust counterclaim based on the harm that would befall customers, even with the marginal improvement in design. However, the court found that "Bard was under no duty to facilitate M3's competition by refraining from changing its products."⁶⁵ In fact, the court refused to find "antitrust liability premised on a theory that development of new products is illegally anticompetitive when a new product requires competing suppliers to adjust their product accordingly" because "the enforcement of antitrust laws is self-defeating if it chills or stifles innovation."⁶⁶ Here, for the first time, the Federal Circuit found that where the innovation was marginal, with underlying anticompetitive justifications, the inquiry should be whether the effects of the innovation would harm the consumer.

The courts again focused on the effects of innovation on consumers and the market in a pivotal Microsoft case. In 2001, after Microsoft had integrated its Internet Explorer browser into the Windows 95 operating system, the United States brought a complaint claiming that this technological integration was forcing purchasers of Windows to use Internet Explorer. The United States alleged that such conduct provided Microsoft an unfair advantage in the market for web browsers.⁶⁷ The D.C. Circuit applied a structured reasonableness method of analysis,⁶⁸ focusing on the effects of the innovation on the market and balancing that against procompetitive justifications of the innovation rather than asking whether the "commingling of code" was better characterized as an innovation or a restraint. The court held that the "commingling of code" had an anticompetitive effect as it deterred original equipment manufacturers from pre-installing rival browsers, reducing rivals' usage share, and led to less interest from developers in rivals' application programming interfaces.⁶⁹ It noted that imposing liability on a monopolist when it makes its products incompatible with rivals' products "will inevitably deter a certain amount of

63. *Id.* at 1346.

64. *Id.* at 1346, 1369.

65. *Id.* at 1369, 1382.

66. *Id.* at 1372. The Federal Circuit noted, however, that in this case, "there was substantial evidence that Bard's real reasons for modifying the gun were to raise cost of entry to potential makers of replacement needles, to make doctors apprehensive about using non-Bard needles, and to preclude the use of 'copycat' needles." Thus, the court's overall decision rested on whether, on balance, Bard's conduct would harm customers, even though it was undisputed that there was marginal improvement. *Id.* at 1382.

67. *United States v. Microsoft Corp.*, 253 F.3d 34, 65 (D.C. Cir. 2001).

68. *Id.*

69. *Id.* at 66.

innovation,” especially in a high-tech market characterized by rapid change.⁷⁰ But “[j]udicial deference to product innovation . . . does not mean that a monopolist’s product design decisions are per se lawful.”⁷¹ Microsoft also took steps to exclude Java, another platform for software development by Sun Microsystems, from “developing as a viable cross-platform threat” by (1) designing a system incompatible with Java; (2) entering into contracts with independent software vendors to promote Microsoft’s product exclusively; (3) deceiving Java about the Windows specific nature of the tools it distributed to them; and (4) coercing Intel to stop aiding Java’s developers in improving the technology.⁷² Microsoft’s creation of a Java Virtual Machine (JVM) that “allow[ed] for Java applications to run faster on Windows than [on] Sun’s JVM,” did not allow a Java application designed to work on Sun’s JVM to work on Microsoft’s JVM.⁷³ The court rationalized that an incompatible product’s anticompetitive effect must outweigh its procompetitive justification to violate the antitrust laws, as “a monopolist does not violate the antitrust laws simply by developing a product that is incompatible with those of its rivals.”⁷⁴ Thus, the court reversed the imposition of liability for Microsoft’s development and promotion of the JVM.⁷⁵ Weighing the anticompetitive effects against the procompetitive justification, the court concluded that Microsoft’s exclusionary conduct was procompetitive.⁷⁶ By emphasizing the superiority of Microsoft’s design that allowed the applications to run faster on Windows, the court seemed to rely on the quality of the innovation in reaching its decision.

Aside from designing a system incompatible with Java, the court found each step that Microsoft took to exclude Java from the market as a restraint. First, Microsoft conditioned the independent software vendor’s (ISV) receipt of Windows technical information on an agreement that required ISVs to make their Java applications reliant on Windows-specific technologies.⁷⁷ This restraint was found to be anticompetitive because “the cumulative effect of the deals [was] anticompetitive and because Microsoft had no procompetitive justification for them.”⁷⁸ Second, Microsoft deceived Java developers with regard to the Windows-specific nature of the software development tools that included “certain ‘keywords’ and ‘compiler directives’ that could only be executed properly by Microsoft’s version of Java runtime environment for Windows.”⁷⁹ The court found this conduct “served to protect [Microsoft’s] monopoly of the operating system in a manner not attributable either to the

70. *Id.* at 65.

71. *Id.*

72. *Id.* at 74.

73. *Id.*

74. *Id.* at 75.

75. *Id.*

76. *Id.*

77. *Id.*

78. *Id.* at 76.

79. *Id.*

superiority of the operating system or to the acumen of its makers” because Java developers, relying on Microsoft’s public commitment to cooperate with Sun, believed that Microsoft’s tools developed cross-platform applications, and unwittingly developed applications that ran only on windows.⁸⁰ Finally, Microsoft leveraged its monopoly power to prevent Intel from aiding in the creation of cross-platform interfaces by threatening to “refuse to distribute Intel technologies bundled with Windows.”⁸¹ The court found this conduct exclusionary because Microsoft did not provide a procompetitive justification⁸² and the court characterized each of these efforts, external to the product itself, as an exclusionary restraint. Thus (unlike in *Berkey Photo*, *CalComp*, *Transamerica*, and *C.R. Bard*), the court scrutinized the effects of the conditioned agreement, deception, and leveraging of monopoly power more than the innovation itself.

C. Coercion and Additional Conduct

Coercion was a key consideration in cases where it could be inferred that consumers were pressured into purchasing an inferior or less sophisticated product by the innovating firm. In 2010, after Tyco developed a pulse oximetry sensor usable only with their pulse oximetry monitor system, hospitals claimed that offering the new monitor design was unreasonably restrictive under Section 2. However, the court held that because the new design was a “superior and more sophisticated offering” and Tyco “did nothing to force [these] monitors on its customers,” it was not a violation.⁸³ Relying on *Microsoft*, the court noted that “changes in product design are not immune from antitrust scrutiny and in certain cases may constitute an unlawful means of maintaining a monopoly under Section 2”—especially if the firm fails to provide a procompetitive justification.⁸⁴ Therefore, a monopolist’s discontinuation of its old technology may violate Section 2 if it effectively forces consumers to adopt its new technology.⁸⁵ Here, the court considered the quality of the innovation, as in *Microsoft*, and found that an inferior and less sophisticated product could be anticompetitive if the firm coerced customers into this reformulation.

Coercion in combination with the withdrawal of a predecessor product was also found to be anticompetitive in a subsequent case. In 2013, when Actavis’s twice-daily drug designed to treat Alzheimer’s disease—Namenda IR—was nearing the end of its patent exclusivity period, Actavis introduced a new once-daily version of the drug: Namenda XR.⁸⁶ The statutory landscape govern-

80. *Id.* at 76–77.

81. *Id.* at 377.

82. *Id.*

83. *Allied Orthopedic Appliance Inc. v. Tyco Health Care Group LP*, 592 F.3d 991, 995–96 (9th Cir. 2010).

84. *Id.* at 998.

85. *Id.* at 1002 (citing *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2d Cir. 1979)).

86. *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 642 (2d Cir. 2015), *cert. dismissed sub nom. Allergan PLC v. New York ex rel. Schneiderman*, 136 S. Ct. 581 (2015).

ing this “switch” included the Hatch-Waxman Act, which promoted competition from generic substitute drugs by permitting manufacturers to market a bioequivalent generic version of approved branded drugs.⁸⁷ Actavis withdrew virtually all Namenda IR products from the market in order to force Alzheimer’s patients to switch to the XR version of the drug before generic versions of the IR became available.⁸⁸ The district court granted New York a motion for preliminary injunction barring Actavis from restricting access to the IR version of the drug prior to generic entry.⁸⁹ The Second Circuit held that though “neither product withdrawal nor product improvement alone is anticompetitive,” when “a monopolist *combines* product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, and to impede competition, its actions are anticompetitive.”⁹⁰ The court said that Actavis’s “hard switch,” or the combination of introducing a new drug while effectively withdrawing its predecessor, “crosses the line from persuasion to coercion and is anticompetitive.”⁹¹ The court focused on the restraint of removing the predecessor product from the market, finding it anticompetitive even though the underlying change in the product from a twice-daily to once-daily drug was innovative.

V. LEGAL STANDARD FOR INNOVATION

The history of the innovation standard, discussed above, is grounded in competing legal theories advocating strict versus permissive enforcement standards under Section 2. The underlying dispute is whether a monopolist’s aggressive, competitive conduct is beneficial to consumers or whether a monopolist’s aggressive, exclusionary conduct is deleterious to consumers.⁹² Relying on any one theory is difficult because competitive and exclusionary conduct look alike—i.e., a firm may be cutting prices to compete with other firms on the merits or to engage in a predatory pricing strategy.⁹³

Courts have varying perspectives on this debate. In *Microsoft*, the D.C. Circuit found that “[i]nnovation can increase an already dominant market share and further delay the emergence of competition, [so] even monopolists have reason to invest in R&D.”⁹⁴ However, the court acknowledged the “undesirability of having courts oversee product design,” and the court worried about judicial oversight “dampening” innovation.⁹⁵ In *Tyco*, the Ninth Circuit went

87. *Id.* at 644.

88. *Id.* at 642.

89. *Id.*

90. *Id.* at 653–54.

91. *Id.* at 654.

92. Frank H. Easterbrook, *On Identifying Exclusionary Conduct*, 61 NOTRE DAME L. REV. 972, 972 (1986).

93. *Id.*

94. *United States v. Microsoft Corp.*, 253 F.3d 34, 57 (D.C. Cir. 2001).

95. *United States v. Microsoft Corp.*, 147 F.3d 935, 948 (D.C. Cir. 1998).

further: “weigh[ing] the benefits of an improved product design against the resulting injuries to competitors is not just *unwise*, it is *unadministrable*.”⁹⁶ The court explained:

[There is] no criteria that courts can use to calculate the ‘right’ amount of innovation, which would maximize social gains and minimize competitive injury. A seemingly minor technological improvement today can lead to much greater advances in the future. [A] balancing test . . . would therefore require courts to weigh as-yet-unknown benefits against current competitive injuries.⁹⁷

Notably, the court also placed weight on the fact that the Patent and Trademark Office granted a patent, stating that “the existence of a patent on a new product design is some evidence that the change is an improvement over previous designs” because “the proper amount of gains to innovation are left to Congress, who has the authority to vary the terms of patent protections, the point in time from which protections run, or the scope of patentable innovations.”⁹⁸

The choice of either a strict or permissive view depends on the type of error the system can tolerate without disincentivizing innovation. Two types of errors could result from scrutinizing innovation in antitrust cases: false convictions and false acquittals. “[F]alse convictions are outcomes in which the court erroneously finds the defendant liable and thereby enjoins procompetitive conduct. False acquittals are outcomes in which the court erroneously allows the defendant to escape liability and thereby permits anticompetitive conduct.”⁹⁹

A. *The Unnecessarily Restrictive Conduct Test*

The “unnecessarily restrictive conduct” test holds the monopolist liable “when the exclusionary effects of his conduct outweigh the associated consumer benefits.”¹⁰⁰ Under-enforcement leads to a greater number of false acquittals than false convictions,¹⁰¹ a result justified under this theory by the fact that false convictions “encourage firms to avoid aggressive competition and engage in implicitly or explicitly collusive conduct.”¹⁰² For example, a conviction for predatory pricing would “punish firms for cutting their prices” and

96. *Allied Orthopedic Appliance Inc. v. Tyco Health Care Group LP*, 592 F.3d 991, 1000 (9th Cir. 2010) (emphasis added).

97. *Id.*

98. *Id.* at 1000–01; see also PHILIP E. AREEDA & HERBERT HOVENKAMP, *ANTITRUST LAW* (2d ed. 2000).

99. Steven C. Salop & R. Craig Romaine, *Preserving Monopoly: Economic Analysis, Legal Standards, and Microsoft*, 7 *GEO. MASON L. REV.* 617, 653–54 (1999).

100. Ronald A. Cass & Keith N. Hylton, *Preserving Competition: Economic Analysis, Legal Standards and Microsoft*, 8 *GEO. MASON L. REV.* 1, 25 (1999).

101. Alan Devlin & Michael Jacobs, *Anticompetitive Innovation and the Quality of Invention*, 27 *BERKLEY TECH. L.J.* 1, 6 (2012).

102. Cass & Hylton, *supra* note 100, at 31.

result in “firms increasingly avoid[ing] price competition.”¹⁰³ Further, this theory posits that the price of false convictions is likely to be severe because it would erroneously find that a social welfare increasing act of invention was in fact welfare decreasing, depriving the consumer of the benefits of the innovation and society of any efficiencies derived therefrom.¹⁰⁴

A critique of this view is that a nonexistent or insignificant “improvement” can delay or eliminate the onset of competition, reducing levels of static efficiency without a concomitant and offsetting dynamic-efficiency gain.¹⁰⁵ When consumers are incapable of effectively distinguishing between various technologies, or when a regulatory mechanism lends itself to manipulation, strategic product development may frustrate rivals’ efforts to enter the market with substitute products or introduce superior technologies.¹⁰⁶ Additionally, false convictions would open the floodgates of litigation, encouraging firms to “seek compensation in the courts for actions by competitors that harm them”—resulting in a “market in which no firm has an incentive to compete aggressively, for fear that any competitive act may give rise to a suit for treble damages.”¹⁰⁷

B. *The Sole Purpose Test*

The “sole purpose test” holds the monopolist liable “only when the creation of competition barriers is the sole purpose of the conduct.”¹⁰⁸ The test asks whether “the monopolist’s conduct would have been unprofitable in the absence of competition barriers imposed by the monopolist.”¹⁰⁹ The theory rests on the view that condemning socially valuable innovation generates perverse incentives, such as the incentive to not compete on price, as price-cutting may be viewed as predation.¹¹⁰ A permissive test allows inventions with some other potential purpose to pass muster. Cass and Hylton argue that the “cost of false acquittal . . . will be small whenever entry is easy. A firm that excludes a competitor in a market with easy entry will not be able to enjoy the fruits of its exclusionary efforts; consequently, consumers will not be harmed.”¹¹¹ The duo points out that “[m]onopoly profits attract entrants and entry leads to an

103. *Id.*

104. Geoffrey A. Manne & Joshua D. Wright, *Google and the Limits of Antitrust: The Case Against the Case Against God*, 34 HARV. J.L. & PUB. POL’Y 171, 182–84 (2011) (arguing that innovation “by definition, generally involves new business practices or products,” which have not been treated kindly by antitrust law, with anticompetitive explanations prematurely ascribed to new forms of conduct that are not well understood).

105. Devlin & Jacobs, *supra* note 101, at 10.

106. Nicholas Economides & William N. Hebert, *Patents and Antitrust: Application to Adjacent Markets*, 6 J. TELECOMM & HIGH TECH. L. 455, 480 (2008).

107. Cass & Hylton, *supra* note 100, at 31.

108. *Id.* at 25.

109. *Id.*

110. Devlin & Jacobs, *supra* note 101, at 4.

111. Cass & Hylton, *supra* note 100, at 30.

equilibrium in which consumer welfare is at a maximum.”¹¹²

Critics of this view contend that the permissive test would allow innovations that would produce long-run social costs and, on net, reduce consumer welfare to escape antitrust condemnation.¹¹³ This test could result in consumers paying a “premium” entirely due to marketing and advertising rather than from a technologically cognizable improvement.¹¹⁴ Total deference to the marketing of dominant firms’ self-proclaimed improvements, with no antitrust enforcement, could conceivably foreclose channels for follow-on innovation—thus denying competing sources of technological development and commercialization to consumers.¹¹⁵ Furthermore, the theory “shields all redesign under the guise of ‘innovation,’ no matter how minimal its benefits may be, no matter whether it is predatory in design and effect, and no matter its ultimate impact on market prices, output, or quality.”¹¹⁶

Critics argue that, regardless of the intent or “sole purpose” of the firm’s conduct, “[i]f a firm engages in exclusionary conduct that permits it to achieve, enhance, or maintain monopoly power, with insufficient offsetting efficiency benefits, then consumer welfare is reduced and the goals of the antitrust laws are violated.”¹¹⁷ Though the sole purpose test is easier to administer, that comes with a “high incidence of erroneous outcomes and adverse effects on consumer welfare and optimal deterrence.”¹¹⁸ Furthermore, false acquittals are more serious than false convictions because exclusion “decreases innovation competition by reducing the incentives of new entrants to attempt to compete on the basis of better products,” “deters future entry attempts that might have succeeded and benefitted consumers,” and “limits the ability of enforcers to detect and improve anticompetitive conduct to the satisfaction of skeptical courts who set high burdens of proof on plaintiffs.”¹¹⁹

C. *Balancing Test: Structured Reasonableness*

One solution to this dichotomy is the balancing test applied in *Microsoft*, which engages in a cost-benefit calculus to determine competitive effect, and thus legality. A balancing test can accommodate different policy preferences, determining which type of error would be most harmful to innovation in context:

112. *Id.* at 30.

113. *See* Salop & Romaine, *supra* note 99, at 660.

114. Devlin & Jacobs, *supra* note 101, at 6.

115. *Id.* at 24.

116. Jonathan Jacobson, et al., *Predatory Innovation: An Analysis of Allied Orthopedic v. Tyco in the Context of Section 2 Jurisprudence*, 23 LOY. CONSUMER L. REV. 7 (2010).

117. Salop & Romaine, *supra* note 99, at 652.

118. *Id.* at 71.

119. *Id.* at 655.

If the court were to conclude that the likelihood and cost of each type of error were equal for a particular class of conduct, then it could use a pure consumer welfare effects test. Exclusionary conduct that reduces consumer welfare would be condemned as unnecessarily restrictive. If the courts or legislature were to conclude that erroneous convictions were the more serious type of error for a particular class of conduct, however, and that it was relatively more important to maintain incentives to innovate, then they could marginally tip the scales of the standard in order to accommodate this concern.¹²⁰

Critics of the balancing tests argue that it reduces legal certainty.¹²¹ Although courts are increasingly shifting to use of a balancing test that accounts for the consumer welfare effects of conduct, no test has yet won out to the exclusion of the others.

VI. APPLICATION TO PRODUCT HOPPING OF EXISTING LEGAL STANDARDS ON INNOVATION

Product hopping occurs when brand name pharmaceutical companies “try to obstruct generic competitors and preserve monopoly profits on a patented drug by making modest reformulations that offer little or no therapeutic advantages.”¹²² Competition from lower-priced therapeutically identical generic drugs saves American consumers billions of dollars a year while resulting in a “rapid and steep decline in sales and profits” for brand drug companies.¹²³ Thus, the threat of generic competition creates a “powerful incentive” for brand drug companies to protect their revenue stream either by creating innovative products that provide medical benefits or obstructing generic competition through product hopping.¹²⁴

Despite widespread belief to the contrary, generic entry is not fully impeded if a product is withdrawn from the market to replace an existing product. Applicants can rely on the Orange Book’s “Discontinued Drug Product List” when seeking approval of an ANDA as long as the drug in question was not withdrawn for safety or efficacy reasons.¹²⁵ A determination of whether a listed drug voluntarily withdrawn from sale was withdrawn for safety or efficacy reasons may be made by the agency at any time after the drug has been voluntarily withdrawn.¹²⁶ However, such a determination must be made (1) prior to approving an abbreviated new drug application that refers to the listed drugs;

120. *Id.* at 661.

121. Devlin & Jacobs, *supra* note 101, at 6.

122. FED. TRADE COMM’N, *supra* note 1.

123. Brief for Federal Trade Commission as Amicus Curiae, *Mylan Pharm., Inc. v. Warner Chilcott Pub. Co.* (No. 12-3824), 2012 WL 7649225.

124. *Id.*

125. U.S. FOOD & DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (2017), <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm> [<https://perma.cc/JBX5-QRY4>].

126. 21 C.F.R. § 314.161 (2015).

(2) whenever a listed drug is voluntarily withdrawn from sale and an abbreviated new drug application that referred to the listed drug has been approved; and (3) when a person petitions for such a determination.¹²⁷ Once the FDA determines that a listed drug in the Discontinued Section was not withdrawn for safety or efficacy reasons and publishes their conclusion in the Federal Register, the following notation accompanies the product listing in the Orange Book: “**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**.” A generic company may then rely on it for purposes of the ANDA.¹²⁸

It takes considerable time for the FDA to determine that a product was not withdrawn from sale for reasons of safety or efficacy, and during that time, generic companies cannot compete effectively.¹²⁹ Though the FDA may independently choose to make a determination on the safety or efficacy of a particular withdrawn drug, more often than not the FDA waits until a citizen petitions for this determination before acting.¹³⁰ This process extends the time it takes for a generic product reliant on the FDA’s findings to enter the market, effectively excluding generic competition from the market for up to a few years. Meanwhile, branded pharmaceutical companies can use this additional time to engage in product hopping by marketing an reformulated product and switching the demand for their old, withdrawn product to the new product.

Generic pharmaceutical manufacturers also must overcome state substitution laws, which “prohibit pharmacists from substituting generic drugs that are not therapeutically equivalent to brand drug[s]” still on the market.¹³¹ In many cases, a “therapeutically equivalent” drug must be both bio- and pharmaceutically equivalent to a brand drug, meaning the active ingredient, dosage form, strength, and administration route are the same.¹³² This requirement has allowed “brand manufacturers to ‘game’ the system” by simply changing the strength or dosage in the reformulation to prevent generic competition.¹³³

An example of how product hopping can occur in practice is the following. First, the brand manufacturer:

127. *Id.*

128. U.S. FOOD & DRUG ADMIN., REFERENCING APPROVED DRUG PRODUCTS IN ANDA SUBMISSIONS (2017), <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM536962.pdf> [<https://perma.cc/AX4H-A4NT>].

129. *See* REGULATIONS.GOV (2017), <https://www.regulations.gov/searchResults?rpp=25&po=0&s=Not%2BWithdrawn%2BFrom%2BSale%2Bfor%2BReasons%2Bof%2BSafety%2Bor%2BEffectiveness&fp=true&ns=true> [<https://perma.cc/P4VN-36VF>] (querying for “Not Withdrawn From Sale for Reasons of Safety or Effectiveness”) (providing a showing of the number of products that are withdrawn from sale and the extensive notice and comment process involved in doing so).

130. *Id.*

131. *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 645 (2d Cir.), *cert. dismissed sub nom. Allergan PLC v. New York ex rel. Schneiderman*, 136 S. Ct. 581 (2015).

132. *Id.*

133. *Id.*

makes minor non-therapeutic changes to the brand product, such as a dosage or form change. Next, it removes the original product from the marketplace, or accomplishes this indirectly, such as by recalling supply of the original product or raising the price of the original product by a meaningful amount above the reformulated one.¹³⁴

Brand manufacturers can “convert the existing market demand for its original product to its reformulated product” by pushing physicians and patients to purchase the new product, not due to preference but “simply because the original product is no longer available or is more costly.”¹³⁵ In *Actavis*, the court found that the line between lawful and unlawful conduct is the distinction between the “hard switch” and the “soft switch.” A manufacturer makes a “hard switch” when it withdraws a branded incumbent product prior to generic entry, inducing patients to switch to a follow-on product. A “soft switch” is conduct seen as encouraging a switch, but without withdrawal of the incumbent product.¹³⁶

A. Presumption of Legality

A Section 2 monopolization offense has two basic elements: “(1) the possession of monopoly power in the relevant market, and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen or historic accident.”¹³⁷ “A monopolist willfully acquires or maintains monopoly power when it competes on some basis other than the merits.”¹³⁸ That said, the advertising or price manipulation associated with a soft switch may not meet the threshold for lawful innovation described above (i.e., a soft switch could violate Section 2).

The standard under *Kodak* and *IBM* allows for nearly any new invention to pass muster, effectively resulting in a presumption of legality. *Kodak* did not involve product hopping, as *Kodak* attempted to use its dominant status in the camera and film markets to gain dominant status in the photofinishing market. However, the rationale behind *Kodak* is equally applicable to product hopping: if consumers like and purchase a new product—regardless of the product’s technical merits—then there is no predation. *Kodak* found it “of no importance that a judge or jury may later” regard products as “inferior”; rather, the legal question turns on whether the products success was based on any form of coercion.¹³⁹ *Kodak* emphasizes that courts could not question a product’s

134. Brief for Federal Trade Commission as Amicus Curiae at 8, *Mylan Pharmaceuticals, Inc. v. Warner Chilcott Pub. Co. Public*, (Nos. 12-3824, 13-4542), 2013 WL 5433528.

135. *Id.*

136. 8 *Product-Hopping Takeaways from Namenda Ruling*, LAW 360 (June 11, 2011, 9:01 PM), <https://www.law360.com/articles/665837/8-product-hopping-takeaways-from-namenda-ruling> [<https://perma.cc/9YXF-9AXF>].

137. *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966).

138. *LePage’s Inc. v. 3M*, 324 F.3d 141, 147 (3d Cir. 2003).

139. *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 287 (2d Cir. 1979).

quality because quality is highly subjective: “A product that commends itself to many users because it is superior in certain respects may be rendered unsatisfactory to others by flaws they consider fatal.”¹⁴⁰ Consider that in *Kodak*, certain users enjoyed the original camera’s “pocketability” while others “found the original models unsatisfactory because of the high incidence of ‘red eye.’”¹⁴¹ In the drug context, customers might find a particular dosage to be more convenient, such as the once-a-day dosage in the *Actavis* case, even though there was no significant innovation involved in the new dose’s creation.¹⁴²

Consumer preferences, then, are evidence that “in such circumstances no one can determine with any reasonable assurance whether one product is ‘superior’ to another. Preference is a matter of individual taste.”¹⁴³ The only metric available is “whether there is sufficient demand for a particular product to make its production worthwhile, and the response, so long as the free choice of consumers is preserved, can only be inferred from the reaction of the market.”¹⁴⁴ Analysts must also consider that producers may “emphasize[] a product’s strengths and minimize[] its weakness[es].” Generally, such advertising does not “constitute anticompetitive conduct violative” of Section 2.¹⁴⁵ Thus, in the context of pharmaceuticals, a consumer may prefer the newer, reformulated version of a drug even though there is no cognizable therapeutic value added. Under *Kodak* and the *IBM* cases, consumer preference for such a reformulation is enough to render the innovation legal under Section 2, even if the preference is due to significant persuasion through manufacturer advertising.

CalComp’s strategy to copy, improve upon IBM’s design, and undersell IBM¹⁴⁶ can be likened to the strategy employed by generic drug manufacturers, and supports the branded pharmaceutical companies’ rationale for why product-hopping should be presumptively competitive. The argument for legality is that product-hopping is an action by which a firm maintains its dominant position through business acumen.¹⁴⁷ The counterargument is that often incremental changes do not increase the efficacy of the product, as CalComp claimed of IBM’s “technological manipulation.”¹⁴⁸ However, under the *CalComp* standard, a monopolistic firm has “the right to redesign its products to make them more attractive to buyers—whether by reason of lowering manufacturing cost and price or improved performance.”¹⁴⁹

Applying this standard to the pharmaceutical and other high-tech markets, a soft switch would still be permissible when a brand name company introduces a

140. *Id.* at 286.

141. *Id.* at 287.

142. *8 Product-Hopping Takeaways from Namenda Ruling*, *supra* note 136.

143. *Berkey Photo*, 603 F.2d at 287.

144. *Id.*

145. *Id.* at 287–88.

146. *Cal. Comput. Products, Inc. v. Int’l Bus. Mach. Corp.*, 613 F.2d 727, 731 (9th Cir. 1979).

147. *See id.*

148. *Id.* at 744.

149. *Id.*

new product into the market. Even if the producer spends significant resources to “push” the product, this would still amount to “competition on the merits” as “a producer is ordinarily permitted . . . to bathe his cause in the best light possible.”¹⁵⁰ An argument—as in *IBM*—that the firm is simply maintaining its dominant position through business acumen, capitalizing on the research and development of originators, reverse engineering new products, and passing along the savings to consumers through lower prices would pass muster under the *CalComp* standard.¹⁵¹ Companies could rationalize a soft switch as an effort to remain ahead of the curve through incremental changes not yet adopted by lower-cost imitators.

Even still, a hard switch under the *IBM/Kodak* theory would remain impermissible because the “free choice of consumers” would not be preserved.¹⁵² Unlike in *Kodak*, in which a new product was introduced while the old product remained on the market, consumers would be “compelled” to purchase the follow-on product in the hard switch context where the older product was removed from the market. This would be especially true in pharmaceutical and high-tech markets, where the follow-on product would garner another 20 years of patent protection—preventing generic or lower-cost competition from providing the consumers with “free choice.”¹⁵³

B. *Balancing Test: Structured Reasonableness*

The *Microsoft* standard is a structured reasonableness test that considers the effects of conduct on consumer welfare. The standard imposes a rebuttable presumption of competitiveness centered on consumer welfare. Under the structured reasonableness inquiry, a court must analyze the short-term harms and long-term benefits of the conduct at issue. The structured inquiry considers a four-step test. First, “a monopolist’s act must have an ‘anticompetitive effect.’”¹⁵⁴ Second, the plaintiff “must demonstrate that a monopolist’s conduct indeed has the requisite anticompetitive effect.”¹⁵⁵ Third, a monopolist may then proffer a procompetitive justification.¹⁵⁶ Finally, the “plaintiff must demonstrate that the anticompetitive harm of the conduct outweighs the procompetitive benefit.”¹⁵⁷ The inquiry’s focus is the effect of the conduct, not the intent behind it.¹⁵⁸

150. *Berkey Photo*, 603 F.2d at 287–88.

151. *CalComp*, 613 F.2d at 731, 742.

152. *Berkey Photo*, 603 F.2d at 287.

153. *Id.*

154. *United States v. Microsoft Corp.*, 253 F.3d 34, 58 (D.C. Cir. 2001) (to be condemned as exclusionary, a monopolist’s act “must harm the competitive process and thereby harm consumers).

155. *Id.* (“[I]n a case brought by the Government, [the plaintiff] must demonstrate that the monopolist’s conduct harmed competition, not just a competitor.”).

156. *Id.* at 59.

157. *Id.*

158. *Id.*

In the product-hopping context, the effect of a hard switch would be to coerce consumers into purchasing the new version of the drug by withdrawing the original version from the market. Such a move causes anticompetitive harm by restricting consumer choice, which outweighs the procompetitive benefits of (at best) a marginally better drug. In *Actavis*, the drug manufacturer argued that the purpose of removing an original product from the market “is to reduce its competitors’ ability to free-ride on prescriptions for an older version” of the drug.¹⁵⁹ The drug manufacturer admitted that it sought “to limit distribution of its older product so that consumers buy its new product” but argued that “competition within the same firm raises no antitrust concern,” because “implementing a single, unitary firm’s policies does not deprive the marketplace of the independent centers of decisionmaking that competition assumes and demands.”¹⁶⁰ However, this argument ignores the fact that patent protection was the reason the firm was the only seller of these particular drugs. Limiting consumer choices was found to be exclusionary in *Microsoft*, where the firm coerced consumers into purchasing the browser with the operating system by integrating Internet Explorer with the Windows 95 system. This provided Microsoft with an unfair advantage in the market for browsers.¹⁶¹ Thus, under the *Microsoft* standard, restricting access to the original drug would result in condemnation under Section 2 because such restrictions “offered no benefits to patients, physicians or caregivers” and “would hurt some patients tremendously,” because the disruption caused by the restriction could cause some patients to cease the treatment entirely.¹⁶²

Under this analysis, a soft switch could also be condemned under a structured analysis if the anticompetitive harm of the conduct outweighs the procompetitive benefit. Studies show that the majority of doctors demonstrate either a lack of or limited price sensitivity; however, personal selling with free samples can affect prescription practices.¹⁶³ Despite an “upward and accelerating trend in spending on direct-to-consumer advertising for prescription drugs in recent years,” pharmaceutical companies still spend eighty percent of their advertising dollars on promotion to health care professionals.¹⁶⁴ Many patients (about twenty-five percent) have initiated conversations with their physicians about a drug they saw on television—though only a fraction of those actually received

159. Final Form Brief of Defendants-Appellants (Redacted) at 40, *New York v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015) (No. 14-4624).

160. *Id.*

161. *Id.* at 64.

162. Final Brief for Appellee at 32, *New York v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015) (No. 14-4624).

163. Füsün F. Gönül et al., *Promotion of Prescription Drugs and Its Impact on Physicians’ Choice Behavior*, 65 J. OF MKTG. 79, 89 (2001).

164. Meredith B. Rosenthal et al., *Promotion of Prescription Drugs to Consumers*, 346 N. ENGL. J. MED. 498, 499 (2002), <http://www.nejm.org/doi/full/10.1056/nejmsa012075#t=article> [https://perma.cc/J9N5-RJWL].

the advertised prescription after inquiring about it.¹⁶⁵ Pharmaceutical marketing research shows that a “concerted marketing effort” targeting physicians through personal selling and “synchronizing” that effort with direct-to-consumer advertisement can create “promotional synergy and lead to enhanced [advertising] effectiveness.”¹⁶⁶ This concerted conduct, if found to have no procompetitive effect—such as educating the consumer—and to have the anticompetitive effect of coercing the consumer to purchase the incorrect drug, could be an instance of a soft switch violating Section 2.

C. Coercion and Additional Conduct

Neither product withdrawal nor product reformulation alone is anticompetitive, but “when a monopolist *combines* product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits and to impede competition, its actions are anticompetitive under the Sherman Act.”¹⁶⁷ In *C.R. Bard*, the court emphasized the “basic premise of patent law . . . that the commercial advantage gained by new technology, and its statutory protection by patent, do not convert the possessor thereof into a prohibited monopolist.”¹⁶⁸ The court explained that an antitrust violation requires both the improper use of a patent right as well as a Section 2 violation “[w]hen the market for a new technology is protected by patent.”¹⁶⁹

Thus, though a soft switch would not automatically violate Section 2 under the traditional interpretation put forward in *Actavis*, it could be an automatic violation under the “additional conduct” standard put forth in *C.R. Bard*.¹⁷⁰ If manipulation of the patent system—by pushing through a barely novel and non-useful incremental change as novel and worthy of patent protection—is improper, any use of the right garnered from such fraud would be an improper use of the right. Observers have noted the “increasing acquisition of additional patents” of “doubtful validity or applicability” by brand-name drug makers to delay generic competition.¹⁷¹ Follow-on patents often cover merely “ancillary aspects of the drug,” rather than the drug’s active ingredient, and thus are less likely to be found valid by courts.¹⁷² Such patenting tactics are part of a larger strategy to extend market exclusivity for therapies facing generic entry.

In *Actavis*, the brand drug manufacturer brought the follow-on drug to market as part of a “product extension strategy[y] to convert patients from [the original

165. *Id.* at 504.

166. Gönül et al., *supra* note 163, at 89.

167. *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 654 (2d Cir. 2015) *cert. dismissed sub nom. Allergan PLC v. New York ex rel. Schneiderman*, 136 S. Ct. 581 (2015).

168. *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1371 (Fed. Cir. 1998).

169. *Id.* (citing *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965)).

170. *Id.* at 1371.

171. C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 327 (2012).

172. *Id.* at 328.

drug] to [the reformulation] and, thus, to avoid the patent cliff.”¹⁷³ The brand drug manufacturer stopped actively marketing the original drug and spent resources promoting the reformulation to doctors, patients, and pharmacists.¹⁷⁴ Furthermore, the firm sold the reformulation at a significant discount compared to the original drug, and “issued rebates to health plans to ensure that patients did not have to pay higher co-payments” for the reformulation than for the original drug.¹⁷⁵ The court deemed such conduct a soft switch and did not explicitly find it anticompetitive.¹⁷⁶ Had the court instead relied on *Tyco* and examined the “product-extension” strategy through an innovation lens, the steps taken to promote adoption of the drug could be seen as coercive additional conduct if the reformulation was found to be inferior and less sophisticated than the previous generation. If the *Activis* court also found malicious intent in the firm’s acquisition of the follow-on patent and weak support for its validity, then the conduct promoting the reformulated drug’s use would not have a procompetitive justification. The promotion of an inferior product coupled with an intentionally weak patent could be exclusionary conduct under the additional conduct/coercion standard under Section 2. But such an analysis would require courts to assess the design of a product, which courts have traditionally rejected doing on principle. Notably, courts have engaged in such analysis of product design in practice, as evidenced by the *C.R. Bard* court’s scrutiny of marginal improvements in needle designs and the *Microsoft* court’s consideration of Java Virtual Machine quality. Given the precedent’s value in the promotion of consumer welfare through the prevention of false acquittals,¹⁷⁷ the court should continue to analyze the quality of an innovation for the purposes of Section 2 actions.

CONCLUSION

Innovation is considered presumptively procompetitive. But innovation is often coupled with anticompetitive restraints, such as the removal of an earlier version of the product from the market (“hard switch”), incompatibility with other products on the market, or predatory pricing. In setting the legal standard for innovation, Courts have struggled to decide whether the presumption of legality encompasses the restraints as well as the innovation itself. Though courts have shied away from assessing the design of a product, they have chipped away at the presumption of legality that blanketed innovations and the restraints that made them profitable. In the pharmaceutical context, the Second Circuit recently held that where a monopolist removes a product from the market in an effort to “switch” the demand from this original product to a

173. *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 648 (2d Cir.), *cert. dismissed sub nom. Allergan PLC v. New York ex rel. Schneiderman*, 136 S. Ct. 581 (2015).

174. *Id.*

175. *Id.*

176. *Id.* at 653–54.

177. *See supra* Part V.

reformulated product, that the innovation must be more than marginal to avoid condemnation under Section 2. The court left open whether producers could escape condemnation by allowing consumers to obtain the original product or a modest reformulation. In this Note, I analyzed whether such a “fix” was enough to pass muster under each of the legal standards in modern case law. I showed that a “soft switch” should not be presumed legal or treated as a preferable alternative to a “hard switch”, but rather should be considered a new issue to be analyzed for legality. I further proposed that courts have considered the quality of innovations in the past and should continue to do so in the future for the sake of consumer welfare.