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AN INDUSTRY-CONTEXTUAL APPROACH TO PREDATORY INNOVATION

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"Predatory innovation" claims allege that a monopolist has redesigned its product to exclude competition, in violation of antitrust law. This Article examines the messy jurisprudence on predatory innovation. It finds analytical paradigms that are almost as numerous as the decisions themselves, and persistent Circuit splits. While some courts worry that judicial scrutiny of product redesigns will chill future innovation, others are willing to examine the competitive effects of exclusionary redesigns.

The Article proposes a new, industry-contextual approach to untangle this predatory innovation jurisprudence. In existing law, antitrust courts often treat innovation as monolithic across industries. The Article draws on cross-disciplinary insights from patent and economic literature to show that, in fact, the characteristics of innovation are variable and deeply industry-specific. For example, patent literature observes a paradigmatic contrast between pharmaceutical innovation (which tends to be episodic, expensive and patent-driven) and software innovation (which tends to be cumulative, collaborative and less dependent on patent exclusivity). Since the processes and character of innovation vary widely by industry, the Article argues that antitrust analysis of innovation should vary as well. Courts should tailor their treatment of predatory innovation claims to account for the distinct processes and characteristics of innovation in the industry at stake.

The Article then applies this proposed industry-contextual approach to recent "product hopping" cases, which allege the predatory redesign of pharmaceutical drugs. It argues that industry context usefully informs two Circuit-splitting controversies: the appropriate

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level of judicial deference to product redesigns, and the use of consumer preference or choice to judge whether a redesign is innovative.

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I. INTRODUCTION

Judge Newman of the Federal Circuit warns that antitrust law is "self-defeating if it chills or stifles innovation."[1] But what if a redesigned product—arguably itself "innovation"—also blocks competition? Could a monopolist's new product then violate antitrust law? "Predatory innovation" claims raise these paradoxical questions, by alleging that a monopolist has modified its product to exclude competition, in violation of Section 2 of the Sherman Act.[2]

Judge Newman delivered her warning in a case that happened to involve the predatory redesign of a medical biopsy gun.[3] The redesign eliminated interoperability—and competition—with the replacement biopsy needles of rivals.[4] However, plaintiffs have brought predatory innovation claims across a wide variety of industries, from cameras[5] and coffee pods[6] to computer software,[7] pharmaceutical drugs and medical devices.[8] This Article uses "product hopping" cases, which allege the

1. C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1372 (Fed. Cir. 1998) (Newman J., dissenting on antitrust claims) ("[A]ntitrust jurisprudence has well understood that the enforcement of the antitrust laws is self-defeating if it chills or stifles innovation." (citing *In re* IBM Peripheral EDP Devices Antitrust Litig., 481 F. Supp. 965, 1002-05 (N.D. Cal. 1979), *aff'd sub nom.* Transamerica Comput. Co. v. Int'l Bus. Machs. Corp., 698 F.2d 1377 (9th Cir. 1983)); *see also* Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 414 (2004) (observing the chilling effect of false positives on the conduct antitrust law seeks to promote).

2. 15 U.S.C. § 2 (2018) (prohibiting monopolization, attempted monopolization, and conspiracy to monopolize trade or commerce). The Sherman Act is the principal federal antitrust law in the United States. Sherman Antitrust Act, 15 U.S.C. §§ 1–2 (the "Sherman Act"). Though typically labelled "predatory" innovation, it would often be more accurate to call this conduct "exclusionary" innovation since the conduct tends to exclude competition. *See* Alan Devlin & Michael Jacobs, *Anticompetitive Innovation and the Quality of Invention*, 27 BERKELEY TECH. L.J. 1, 5 (2012) (on terminology).

3. *C.R. Bard, Inc.*, 157 F.3d at 1369 (explaining the anticompetitive redesign allegation and affirming the District Court finding of antitrust law violation).

4. *Id.*

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

6. *In re* Keurig Green Mountain Single-Serve Coffee Antitrust Litig., 383 F. Supp. 3d 187 (S.D.N.Y. 2019).

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

8. Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP, 592 F.3d 991, 998-1000 (9th Cir. 2010) (pulse oximetry device redesign); C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340 (Fed. Cir. 1998) (tissue biopsy gun redesign).

predatory redesign of pharmaceutical drugs, as an analytical example throughout.[9] There have been a flurry of product hopping cases from 2006 to present, each claiming that a monopolist's redesign of a branded pharmaceutical drug unlawfully excludes competition from generic drugs.[10]

These and other predatory innovation claims present a dilemma for antitrust courts. The goal of modern antitrust law is to promote consumer welfare through competition.[11] Competition that spurs innovation—the development of new products and processes—is one of the most significant drivers of such welfare.[12] If a court condemns a redesign for its anticompetitive effects, does it risk chilling similar innovation in the future? If so, that judicial decision could harm consumers by denying the economic and social benefits of that future innovation. An antitrust regime that discourages innovation may therefore undermine itself, as Judge Newman warns. But if instead the court permits a predatory redesign, is it simply allowing a monopolist to foreclose competition? Such a decision would also harm consumers, because lessened competition leads to higher prices, lower quality products, and potentially also a drop in competition-driven innovation.

As Part II of this Article explains, this paradox has produced messy jurisprudence on predatory innovation claims. The case law is marked by varying and largely unreconciled analytical approaches, including multiple Circuit splits.

To untangle this jurisprudence, Part III of the Article proposes a new industry-contextual approach to predatory innovation claims. It draws on patent policy and economic research to develop cross-doctrinal arguments on the nature of innovation. This patent and economic research demonstrates that the characteristics of innovation are quite distinct across different industries. Since the processes and character of

9. Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Context*, 2007 MICH. ST. L. REV. 631, 657-58 (2007) (attributing the term "product hopping" to HERBERT HOVENKAMP ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPALS APPLIED TO INTELLECTUAL PROPERTY LAW (2002)).

10. *See infra* Part IV.A (discussing recent product hopping litigation).

11. *See, e.g.*, Reiter v. Sonotone Corp., 442 U.S. 330, 343 (1979) ("Congress designed the Sherman Act as a 'consumer welfare prescription.' "); *see also* Daniel A. Crane, *Optimizing Private Antitrust Enforcement*, 63 VAND. L. REV. 675, 678-702 (2010) (discussing the goals of competition law, which are themselves extensively debated in the literature).

12. JOSEPH A. SCHUMPETER, CAPITALISM, SOCIALISM AND DEMOCRACY 84-85 (Routledge 2006) (1942) (ebook) (describing "competition from the new commodity, the new technology, the new source of supply, the new type of organization" as "much more effective" and "so much more important" to economic advancement than price competition); J. Gregory Sidak & David J. Teece, *Dynamic Competition in Antitrust Law*, 5 J. COMPETITION L. & ECON. 581, 600 (2009) (describing the importance to consumer welfare of dynamic competition, which "relies on innovation").

innovation vary widely by industry, the Article argues that antitrust analysis of predatory innovation should vary as well, by tailoring assumptions and paradigms to the specific industry context at stake in cases.

In Part IV, the Article then applies the proposed industry-contextual approach to two dilemmas in the predatory innovation jurisprudence. It uses product hopping cases as the primary example for both arguments. First, the Article argues that judicial deference toward product redesigns should not be driven by generalized error-cost assumptions, as in existing law. Instead, such deference should be scaled based on whether innovation-chilling claims are consistent—or inconsistent—with the known characteristics of innovation in the industry at stake. Second, it contends that whether or not consumer preference (or "choice") is useful as a proxy for innovation depends heavily on industry context. It argues that product hopping cases have mis-applied a key precedent on consumer choice, *Berkey Photo, Inc. v. Eastman Kodak Co*. ("*Berkey Photo*"), by exporting it from a consumer product industry (where it applies) to the pharmaceutical drug industry (where the logic falls apart).

This proposal for industry contextualism is a new contribution to the literature, which has paid minimal attention the impact of industry-specific innovation characteristics on predatory innovation claims. At the same time, this proposal ought not be controversial. The Supreme Court has admonished that "[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue."[13] This wisdom has been oddly overlooked across much of the predatory innovation jurisprudence. This Article revives it. The proposed approach emphasizes the importance of deeper and more specific industry context to judicial understandings of innovation. It pushes courts and scholarship away from generalized error-cost assumptions in innovation analysis and toward more nuanced and modern views of the relationship between innovation and competition.

This work to untangle innovation theory is important not just for individual predatory innovation cases, but also for the broader modernization of antitrust law. Antitrust law has been built on static measures of competition, such as marginal impacts on price, quality and output.[14] Antitrust institutions still struggle to analyze dynamic

13. Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 411 (2004).

14. Sidak & Teece, *supra* note 12, at 602 (describing static competition, which manifests as "an unchanging menu of unimproved products at very good prices"); Douglas H. Ginsburg & Joshua D. Wright, *Dynamic Analysis and the Limits of Antitrust Institutions*, 78 ANTITRUST L.J. 1, 1 (2012) ("The static model of competition dominates modern antitrust analysis.").

competition, meaning competition "powered by the creation and commercialization of new products, new processes, and new business models"—in short, innovation competition.[15] The concept of innovation and its importance to competition, have only recently begun to appear in antitrust analytical frameworks.[16] Even with this growing recognition, courts and agencies have been slow to integrate dynamic competition into their traditional, price-focused antitrust analysis.[17]

This struggle with innovation-related analysis poses an existential problem for antitrust law. As early as the 1990's, Jorde and Teece influentially observed that, by focusing on the short term, static competition antitrust law may miss, or even negatively impact, the more economically significant consumer welfare gains from dynamic competition.[18] Dynamic competition is by far the most significant driver of consumer welfare from economic growth.[19] As scholar Mark Lemley quips, "ask yourself whether you would rather have a monopolistically-priced iPod or a perfectly competitive market for eight-track tapes."[20] Static competition works incrementally to lower tape prices; dynamic competition drives leaps and bounds of innovation such as the iPod—an invention already replaced by still-newer innovation.

The oft-cited goal of antitrust law is to improve consumer welfare. Dynamic competition is the most significant means by which to advance such welfare. To achieve its goal of consumer welfare, then, antitrust law needs to build and operationalize stronger theories of dynamic

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Conceptions of static competition permeate antitrust reasoning, from market definition through to assessment of anticompetitive effects, and tend to drive the decisions of antitrust courts and agencies. For example, a common basis for market definition relies on the analysis of "small but significant and non-transitory" price increases. *See* U.S. DEP'T OF JUST. & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES § 4.1.1 (2010) [hereinafter HORIZONTAL MERGER GUIDELINES].

15. Sidak & Teece, *supra* note 12, at 602.

16. For example, consider that as of 1992, the U.S. antitrust agency guidelines on merger review made no mention of innovation. The 2010 version of the guidelines now features a section titled "Innovation and Product Variety." *Compare* U.S. DEP'T OF JUST. & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES (1992), *with* HORIZONTAL MERGER GUIDELINES, *supra* note 14, § 6.4 (calling for analysis of "whether a merger is likely to diminish innovation competition").

17. Ginsburg & Wright, *supra* note 14, at 2 ("An increased focus upon dynamic competition has the potential to improve antitrust analysis and, thus, to benefit consumers. Realizing that potential, however, is challenging.").

18. Thomas M. Jorde & David J. Teece, *Innovation, Dynamic Competition, and Antitrust Policy*, 13 REG. 35, 36 (1990); Sidak & Teece, *supra* note 12, at 601 (emphasizing that the "superficial answers derived from implicitly held static notions about desirable forms of competition may well harm innovation and, in the long run, consumers").

19. *See* Mark A. Lemley, *Industry-Specific Antitrust Policy for Innovation*, 2011 COLUM. BUS. L. REV. 637, 638 (2011).

20. *Id.* at 639.

competition, in predatory innovation cases and beyond. Without such development, antitrust enforcement will continue to lean heavily toward static competition, and risk failing to maximize consumer welfare.[21] The theories of dynamic competition at stake in predatory innovation cases, including those addressed in this Article, thus go to the heart of antitrust law modernization and effectiveness.

II. BASELINE SKEPTICISM AND SCATTERED JURISPRUDENCE ON PREDATORY INNOVATION CLAIMS

This section describes the basic elements of a predatory innovation claim and the patchwork of judicial approaches being applied in the adjudication of such claims.

A. Elements of A Predatory Innovation Claim

Predatory innovation claims allege monopolization contrary to Section 2 of the Sherman Act. As with other Section 2 claims, the plaintiff must establish antitrust injury, and show that the defendant (i) possessed monopoly power in the relevant market and (ii) engaged in anticompetitive conduct to willfully acquire or maintain that power, as distinguished from "growth or development as a consequence of a superior product, business acumen, or historic accident."[22]

Although some predatory innovation claims are resolved based on a lack of monopoly power,[23] the second element—defendant misconduct—is often more contentious. There is no settled definition of what constitutes "anticompetitive conduct" in predatory innovation claims, although the allegations always center on the defendant monopolist introducing a redesigned product or service, which, in conjunction with other conduct, excludes competitors and reduces competition in the relevant antitrust market.

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21. Joshua D. Wright, *Antitrust, Multi-Dimensional Competition, and Innovation: Do We Have an Antitrust-Relevant Theory of Competition Now?*, *in* REGULATING INNOVATION: COMPETITION POLICY AND PATENT LAW UNDER UNCERTAINTY 228, 230 (Geoffrey A. Manne & Joshua D. Wright eds., 2011) ("An antitrust regime that ignores dynamic efficiencies and innovation and focuses solely on static product market competition is unlikely to improve consumer or total welfare.").

22. United States v. Grinnell Corp., 384 U.S. 563, 570-71 (1966).

23. *See, e.g.*, *In re* IBM Peripheral EDP Devices Antitrust Litig., 481 F. Supp. 965, 1021 (N.D. Cal. 1979), *aff'd sub nom.* Transamerica Comput. Co. v. Int'l Bus. Machs. Corp., 698 F.2d 1377 (9th Cir. 1983) (dismissing predatory innovation claim on grounds that IBM lacked monopoly power in the relevant market); Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co., 838 F.3d 421, 437-38 (3d Cir. 2016) (finding the defendant lacked monopoly power in the relevant market).

The specifics of the alleged anticompetitive conduct tend to vary by industry. In cases that involve computing hardware and medical devices, the allegation is often that the defendant has eliminated interoperability between the monopolist's product and a competing, complementary product, by modifying technical or physical interfaces to integrate two otherwise-separate products.[24] For example, in *United States v. Microsoft Corp.* ("*Microsoft*"), a leading predatory innovation case involving computer software, the defendant harmed competition by technologically tying its dominant Microsoft computer operating system to the company's web browser, which had the effect of excluding other browsers from competition.[25] Several cases against the newest generation of software-driven companies allege that the defendant engaged in the redesign of its algorithms[26] or its software[27] to exclude competition (though these claims are not necessarily presented in such terms of predatory innovation).

In predatory innovation cases that involve the pharmaceutical industry, the specific arguments differ, though the claims still center on exclusionary redesign. In recent product hopping cases, plaintiffs allege

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24. In these cases, the monopolist often sells both the complementary product and the main product with which the complement interoperates. *See, e.g.*, C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1367 (Fed. Cir. 1998); Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP, 592 F.3d 991, 998-1000 (9th Cir. 2010); *IBM Peripheral EDP Devices*, 481 F. Supp. at 976-77; *In re* Apple iPod iTunes Anti-Trust Litig., No. C 05-00037 JW, 2010 WL 2629907, at *4 (N.D. Cal. June 29, 2010); Cal. Comput. Prods., Inc. v. Int'l Bus. Machs. Corp., 613 F.2d 727, 744 (9th Cir. 1979) (defendant integrated disc drive controllers into its central processing units).

25. United States v. Microsoft Corp., 253 F.3d 34, 65 (D.C. Cir. 2001) (tying the code of the Microsoft Windows operating system with the company's own internet browser).

26. Press Release, European Comm'n, Antitrust: Commission Fines Google €2.42 Billion for Abusing Dominance as Search Engine by Giving Illegal Advantage to Own Comparison Shopping Service (June 27, 2017), https://ec.europa.eu/commission/presscorner/detail/en/IP_17_1784 (fining Google for abuse of dominance that involved preferring its own comparison shopping search results and demoting rivals position in the display of general search results). The FTC investigated but did not pursue a case against Google for similar practices. FTC, Statement Regarding Google's Search Practices In the Matter of Google Inc., FTC File No. 111-0163 (Jan. 3, 2013), https://www.ftc.gov/sites/default/files/documents/public_statements/statement-commission-regarding-googles-search-practices/130103brillgooglesearchstmt.pdf.

27. *See, e.g.*, Second Amended Complaint, Texas v. Google LLC, No. 4:20-CV-957-SDJ, 2021 WL 2043184, at 96-99 (E.D. Tex. Aug. 4, 2021) (alleging that search giant Google's plan to terminate third-party cookies access to its online browser (a product design change) is anticompetitive, because it "raise[s] barriers to entry and exclude[s] competition in the exchange and ad buying tool markets"); *In re* Apple iPod iTunes Antitrust Litig., Nos. C 05-00037 JW, C 07-06507 JW, 2010 WL 2629907, at *4-5 (N.D. Cal. June 29, 2010) (denying motion to dismiss claim that Apple violated Section 2 of the Sherman Act by updating Apple software to eliminate interoperability between competing audio file formats and the popular Apple iPod music player, which prevented the competing song formats from being played on iPods).

that a monopolist, typically a branded drug company, introduced minor tweaks to its drug formulation, then shifted market demand away from its old drug to its reformulated version (the "hop"). The defendant typically carries out the hop just before the patent terms expire for the original drug, by withdrawing its old drug from the market, and/or aggressively marketing the new drug formulation.[28] This practice of product hopping leverages the Food and Drug Administration ("FDA") regulatory regime,[29] and state laws that substitute generic drugs, [30] as a means to delay generic drug entry and competition.[31] The hop eliminates the installed base of patient demand for the original drug, for which the generic version would otherwise be substituted at the pharmacy level.[32] Generic drug competition is delayed, unless and until the generic company obtains FDA approval to sell an equivalent of the *new* drug design.[33] Although there is an abbreviated FDA approval process for

28. *See generally* Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 171-72 (2016) (describing the various attributes and forms of product hopping).

29. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in various sections of 15, 21, 28, 35 U.S.C.). Known as the Hatch-Waxman Act, this law created a new process for generic drugs to obtain FDA approval, in order to encourage generic drug competition. *See also* FTC v. Actavis, Inc., 570 U.S. 136, 152 (2013) (observing the "general procompetitive thrust" of the Hatch-Waxman Act).

30. Generic drugs rely almost entirely on pharmacy substitution to drive demand for their products. Once a generic drug obtains a biological equivalency rating from the FDA, *see* discussion *infra* note 31, most state laws either require or permit pharmacists to substitute the generic version of the drug for the branded equivalent at the pharmacy counter. New York v. Actavis, PLC, No. 14 Civ. 7473, 2014 WL 7015198, at *8 (S.D.N.Y. Dec. 11, 2014) (describing substitution laws most states that either permit or require pharmacists to dispense a therapeutically equivalent generic drug in place of a branded drug, unless the prescribing physician indicates otherwise).

31. Devlin, *supra* note 9, at 657 (explaining that product hopping often involves switching the drug formulation just as a potential generic competitor's Food and Drug Administration regulatory approval for the original formulation is issued (which would enable its pharmacy-level substitution for the branded product under many state laws), with the result that the generic "would either have to forego entering the market with a generic version of the incumbent's brand name drug, or restart the regulatory approval process all over again" to introduce a generic equivalent of the new product). An overview of the regulatory regime for branded and generic drugs, and pharmacy-level substitution is provided below. *See infra* note 34.

32. *See supra* note 30 (explaining the law on generic substitution).

33. Understanding why the product hop prevents generic drug competition requires some explanation of the complexities of both the FDA regulatory system for drug approval and state generic drug substitution laws. New potential drugs are required to go through a lengthy and expensive FDA approval process, including clinical studies, before the FDA may approve those drugs for sale. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399(f) (2012). The so-called New Drug Application, 21 U.S.C. § 355 (2018), must contain scientific evidence that demonstrates the drug is effective and safe, which requires "a long, comprehensive, and costly testing process." *Actavis, Inc.*, 570 U.S. at 142. Branded drug

generic equivalents to existing drugs, that process can take several years, during which time competition is delayed.[34]

Product hopping has attracted antitrust scrutiny because the newly redesigned drugs tend to be of limited therapeutic value for patients, and the new drug introduction is often timed to just precede the expiry of patent rights for the older drug design. Once the related patent or patents expire, generic versions can enter the market. Upon such entry, branded drugs typically face tough price competition from generic versions, driving down the branded price and market share.[35] The product hop forestalls these competitive effects on the branded firm.

B. A Patchwork of Judicial Approaches to Predatory Innovation Claims

Regardless of the specifics of a predatory innovation claim, the starting point for courts is to be "very skeptical . . . that competition has been harmed by a dominant firm's product design changes."[36] This foundational skepticism comes from an antitrust tenet: "any firm, even a monopolist, may . . . bring its products to market whenever and however

companies often conduct much of the research and development of new drugs, and so tend to be the parties that complete this onerous FDA process for new medicines. The federal Hatch-Waxman Act then allows equivalent generic drug formulations to "piggyback" on prior approvals of branded drugs with an abbreviated drug approval process or "ANDA." *See* Drug Price Competition and Patent Term Restoration Act of 1984, 35 U.S.C. § 156 (2012). To obtain FDA approval, called an "AB-rating," the generic drug manufacturer simply needs to show that its drug is the therapeutic and biological equivalent of the already-approved branded drug, and attest that no valid patent on the branded drug is infringed. *See generally* CTR. FOR DRUG EVALUATION & RESEARCH, FOOD & DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS § 1.7, at xii (2020) (discussing FDA therapeutic equivalency ratings). Generic drug companies tend not to conduct research and development on novel drug formulations, or at least conduct much less than branded companies. Instead, generic companies introduce copies of branded drugs after the related patents expire or are invalidated in patent infringement litigation. For this reason, generic drug companies' business strategies depend heavily on obtaining the therapeutic equivalency ratings that enable them to be substituted for, and thus compete with, branded versions of drugs. When the drug design changes, the generic must restart the FDA process to obtain an AB-rating for the new branded formulation. Until that is obtained, state laws prevent the substitution of the generic version of the original drug for the new (branded) formulation, leaving the branded drug with reduced or no competition during that time. Obtaining the AB-rating from the FDA is faster and easier than obtaining a new drug approval, but it can still take several years. *Actavis, Inc.*, 570 U.S. at 142.

34. *See* the explanation of the regulatory approval process for new drugs *supra* note 33.

35. New York v. Actavis, PLC, No. 14 Civ. 7473, 2014 WL 7015198, at *9 (S.D.N.Y. Dec. 11, 2014) (noting the dramatic impacts on price and share of branded drugs when a generic enters the market).

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

it chooses."[37] Monopolists are free to compete by introducing new products, even if doing so harms individual rivals.[38] Although less-competitive firms will suffer when their rivals introduce superior products into the marketplace, antitrust laws protect the overall process of competition, not individual firms.[39]

Since monopolists are free to introduce new products, courts have generally held that product redesigns, standing alone, are not unlawful. Instead, courts tend to require some form of "associated anticompetitive conduct" in conjunction with the disputed product design change to find an antitrust law violation.[40] Several cases treat the presence of such associated conduct as a threshold issue; if anticompetitive conduct appears present, these courts will proceed to consider other analytical paradigms, such as consumer choice (discussed below) to reach their final conclusion on whether there is an antitrust law violation.[41]

Despite this baseline skepticism, courts also acknowledge that design changes, and associated conduct, are not immune from antitrust scrutiny, and in "certain cases" may constitute an unlawful means of maintaining a monopoly under Section 2 of the Sherman Act.[42] The problem, however, is a lack of judicial consensus on how to determine

37. Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc., 171 F.3d 912, 925 n.7 (3d Cir. 1999) (quoting Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 286 (2d Cir. 1979)).

38. Cal. Comput. Prods., Inc. v. Int'l Bus. Machs. Corp., 613 F.2d 727, 744 (9th Cir. 1979) (holding that the monopolist defendant "had the right to redesign its products").

39. Brown Shoe Co. v. United States, 370 U.S. 294, 344 (1962) (noting that "[i]t is competition, not competitors" that antitrust law protects).

40. Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP, 592 F.3d 991, 999-1000 (9th Cir. 2010) (holding that product redesign is not anticompetitive unless there is other, associated anticompetitive conduct that occurs when introducing the product); Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 286 n.30 ("[I]t is not the product introduction itself, but some associated conduct, that supplies the violation."); New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 654 (2d Cir. 2015) ("But under *Berkey Photo*, 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." (citations omitted)); *In re* Keurig Green Mountain Single-Serve Coffee Antitrust Litig., 383 F. Supp. 3d 187, 230 (S.D.N.Y. 2019) ("[I]f [plaintiffs] had only alleged anticompetitive product design, such allegations would not withstand Keurig's motion to dismiss; however, the amended complaints are filled with allegations of 'associated conduct' . . . ."). It is less than clear in these cases why the *combination* of the design change and the other conduct amounts to a Section 2 Sherman Act violation. If the "associated conduct" of the monopolist is anticompetitive, then it ought to constitute a standalone violation regardless of any accompanying design change.

41. *Berkey Photo*, 603 F.2d at 286 n.30 (requiring associated anticompetitive conduct); *id.* at 287 (further analysis based on consumer choice or preference); *Namenda*, 787 F.3d at 654 (requiring "some other conduct" in addition to the new product introduction); *id.* at 652-53 (analysis finding coercion of consumers).

42. *See, e.g.*, *Allied Orthopedic Appliances Inc.*, 592 F.3d at 998.

these "certain cases." In the predatory innovation jurisprudence, courts have applied analytical paradigms almost as numerous as the decisions themselves.

As the following sections describe, courts have adjudicated predatory innovation claims by looking to whether the redesign is an objective improvement over the prior product, whether consumers are freely choosing the redesigned product in the market, the intent of the monopolist, and a variety of other analytical approaches.[43] Though discussed as separate analytical paradigms here, some predatory innovation cases consider more than one of these paradigms, without a clear indication of how each relates to the other, or which determines the case outcome.

1. The Question of Product Improvement in Predatory Innovation Claims

Leading antitrust scholar Herbert Hovenkamp suggests that predatory innovation jurisprudence can, at a minimum, be understood at its two extremes.[44] At one end, there are cases where the redesign is unquestionably and objectively a significant product improvement, and the design change is not accompanied by other misconduct.[45] Consistent with the principle that monopolists are free to introduce product design changes, courts have found that the introduction of such a product improvement does not violate Section 2 of the Sherman Act.[46] At the other extreme are cases where the disputed design change makes the product objectively worse—or at least offers no discernable improvement—with the only apparent purpose and effect of using monopoly power to gain a competitive advantage.[47] Such objective worsening of the product has influenced courts, and dissenting opinions, in which defendants were found to have violated antitrust law.[48]

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43. *See infra* Parts II.B.1-4 (discussing the various analytical paradigms applied in the predatory innovation jurisprudence).

44. HERBERT HOVENKAMP ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 12.03, at E.1, E.2 (2020), 2015 WL 9447726.

45. *See id.*

46. *Id.* at E.1 (citing Cal. Comput. Prods., Inc. v. Int'l Bus. Machs. Corp., 613 F.2d 727, 744 (9th Cir. 1979), which found the product redesign "certainly represents a superior product from the buyer's point of view," because it offered the same functionality as prior products at a lower price).

47. *Id.*

48. *Id.* at E.2 (citing *In re* IBM Peripheral EDP Devices Antitrust Litig., 481 F. Supp. 965, 1007-08 (N.D. Cal. 1979) (noting that the impugned product redesign degraded IBM's system performance "making its product less attractive to users. The only purpose served and the only effect of the degradation was the preclusion of competition"), *aff'd sub nom.*

However, Hovenkamp goes on to concede that few predatory innovation cases fall at either of these two extremes.[49] Instead, the defendant and plaintiff can typically both muster some evidence that suggests the redesign was, or was not, an improvement. This leaves the courts to evaluate the more difficult scenario of a product redesign with ambiguous merit over the prior version, where that redesign excludes some competition.[50]

Consider the leading case of *Berkey Photo*, in which the monopolist was accused of predatory redesign of its new film and camera system.[51] The plaintiff argued that the new film design was of poorer quality, because it had a shorter shelf life in storage than the prior designs.[52] The defendant emphasized that the film was an improvement, because it produced more finely-grained pictures than the previously available film.[53] The evidence on the merit of product redesigns often draws this type of mixed picture for the court.

Further, many courts are hesitant to opine at all on whether a product design change is an "improvement," viewing this question as beyond the appropriate role of the judiciary.[54] This difficult issue of judicial deference to product redesign is discussed separately below. It suggests that predatory innovation cases cannot be resolved simply by asking whether or not the redesign is an objective improvement over the older design.

2. Consumer Choice or Coercion Analysis of Predatory Innovation Claims

In the face of mixed evidence on a redesign's merits, seminal cases like *Berkey Photo* look to whether consumers prefer the monopolist's new product in the market.[55] When consumers freely choose to buy the redesigned product, courts have deferred to that preference as a proxy, taking it as an indication that the redesign is superior to the prior

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Transamerica Comput. Co. v. Int'l Bus. Machs. Corp., 698 F.2d 1377 (9th Cir. 1983); C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1382 (Fed. Cir. 1998) (Bryson, J., concurring in part and dissenting in part) (affirming that the jury could reasonably conclude that the product design changes to a biopsy gun that eliminated interoperability offered no improvement and the "real reasons" for modifying the resign was to exclude competitors).

49. HOVENKAMP, *supra* note 44, at E.3.

50. *Id.* at E.3.

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

52. *Id.* at 286.

53. *Id.* at 286-87.

54. *See id.*

55. *Id.* at 287; New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 654-55 (2d Cir. 2015).

version.[56] This view accepts consumer preferences as determinative rather than substituting the court's own opinion on the merits of the redesign, in some sense resolving the question of appropriate judicial deference to product changes.

Conversely, where the monopolist's actions coerce consumers into buying the redesigned product, eliminating choice in the market, that conduct is more likely to be viewed as anticompetitive.[57] This "consumer choice" paradigm was used to decide cases in the late 1970s,[58] and has re-emerged in a problematic way in recent pharmaceutical product hopping cases.[59]

3. Intent-Based Analysis of Predatory Innovation Claims

Other courts have considered the monopolist's intent or purpose in order to assess whether a product redesign is anticompetitive.[60] Where the defendant's purpose in introducing the design change is to exclude or disadvantage competitors, rather than to create a better product, such intent has influenced the conclusion that the conduct is anticompetitive.[61]

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

57. *See, e.g.*, *Namenda*, 787 F.3d at 652 ("Well-established case law makes clear that product redesign is anticompetitive when it coerces consumers and impedes competition."); *In re* Loestrin 24 FE Antitrust Litig., 261 F. Supp. 3d 307, 354 (D.R.I. 2017); *In re* Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., 64 F. Supp. 3d 665, 681-84 (E.D. Pa. 2014), *reconsideration in part*, 2015 WL 12910728 (E.D. Pa. Apr. 14, 2015) (denying motion to dismiss where the defendant allegedly coerced patients into switching from an old to new drug design); Abbott Labs. v. Teva Pharm. USA, Inc. (*TriCor*), 432 F. Supp. 2d 408, 424 (D. Del. 2006) (denying motion to dismiss where defendants conduct allegedly resulted in "consumer coercion").

58. *See, e.g.*, *Berkey Photo*, 603 F.2d at 287.

59. *See, e.g.*, product hopping cases cited at *supra*, note 57. This Article discusses the problems with using a consumer choice paradigm in product hopping cases in depth at *infra* Part IV.B.2.

60. *See* C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1372 (Fed. Cir. 1998) (considering evidence of defendant's predatory intent in making the design change, as well as whether the redesign was an improvement); Foremost Pro Color, Inc. v. Eastman Kodak Co., 703 F.2d 534, 543 (9th Cir. 1983) (holding that liability for a predatory redesign may be imposed when "the dominant purpose motivating Kodak's design and introduction . . . was to compel purchase of the entire system as a package, rather than to achieve the legitimate goal of marketing new, technologically superior products"), *overruled on other grounds by* Aerotec Int'l, Inc. v. Honeywell Int'l, Inc., 836 F.3d 1171 (9th Cir. 2016); Response of Carolina, Inc. v. Leasco Response, Inc., 537 F.2d 1307, 1330 (5th Cir. 1976) (noting in *obiter* that findings of technological tying "must be limited to those instances where the technological factor tying the [two products] has been designed for the purpose of tying the products, rather than to achieve some technologically beneficial result").

61. *See C.R. Bard, Inc.*, 157 F.3d at 1382.

Though intent may have some bearing on how courts interpret evidence,[62] antitrust law has long recognized that intent alone is not dispositive in distinguishing between robust competition and anticompetitive conduct.[63] The problem is that intent acts as a poor differentiator between the two. A monopolist's intent looks much the same when it engages in the robust competition (which antitrust law seeks to promote) as when it engages in unlawful anticompetitive conduct (which antitrust law seeks to prevent).[64] Both may have the purpose, and the effect, of harming individual rivals. The reality is that intent is often mixed—a monopolist may want to disadvantage a competitor with its redesign *and* it may also want to introduce an improved product to the market. Reflecting this wisdom, multiple predatory innovation cases have rejected an intent-based approach,[65] even where the predominant intent of the defendant was to harm competition.[66]

4. Disagreements Over Judicial Deference Influence the Analytical Paradigms for Predatory Innovation Claims

In the face of predatory innovation claims, a primary concern—and a frequent driver of disagreements over the correct analytical paradigm—is the appropriate level of judicial deference toward product redesigns and innovation. Consider a pair of predatory innovation cases brought against computer giant IBM in the Northern District of California.[67] The plaintiffs in both cases claimed that IBM had modified the design of its computer interfaces to eliminate interoperability with

62. Chi. Bd. of Trade v. United States, 246 U.S. 231, 238 (1918) ("[I]ntent may help the court to interpret facts and to predict consequences.").

63. *See* Caldera, Inc. v. Microsoft Corp., 72 F. Supp. 2d 1295, 1310-14 (D. Utah 1999) (demonstrating that intent is potentially useful but not dispositive); *see also* Xerox Corp. v. Media Scis. Int'l, Inc., 511 F. Supp. 2d 372, 387-89 (S.D.N.Y. 2007) (demonstrating that intent may inform analysis but is not determinative).

64. PHILLIP E. AREEDA, 7 ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 1506, at 389 (1986) ("Intention is often superfluous to the analysis of reasonableness, for it adds nothing to the conduct from which it is usually inferred.").

65. *See* Berkey Photo, Inc. v. Eastman Kodak Co. , 603 F.2d 263, 288-90 (2d Cir. 1979) (reversing lower court finding of unlawful conduct based on intent); *see also In re* IBM Peripheral EDP Devices Antitrust Litig., 481 F. Supp. 965, 1003 (N.D. Cal. 1979) (holding a critical view of an intent-based approach, noting "the law against monopolization is much more concerned with the effect of conduct rather than with its purpose"), *aff'd sub nom.* Transamerica Computer Co. v. Int'l Bus. Machs. Corp., 698 F.2d 1377 (9th Cir. 1983).

66. *IBM Peripheral EDP Devices*, 481 F. Supp. at 1005 (finding the impugned product design was superior, and there was no liability for the redesign despite the defendant's "predominant intent . . . undoubtedly" being to "preclude or delay" competition).

67. ILC Peripherals Leasing Corp. v. Int'l Bus. Machs. Corp., 458 F. Supp. 423 (N.D. Cal. 1978), *aff'd sub nom.* Memorex Corp. v. Int'l Bus. Machs. Corp., 636 F.2d 1188 (9th Cir. 1980) (affirmed without analysis); *IBM Peripheral EDP Devices*, 481 F. Supp. 965.

the plaintiff's computer peripheral devices, excluding competition in violation of Section 2 of the Sherman Act.[68] IBM competed with the plaintiffs to sell its own peripherals, which, of course, remained compatible with the redesigned IBM computers.[69] Despite the similarity of the allegations against the same monopolist, and the adjudication of the lower court decisions just one year apart, the cases disagreed on the appropriate level of judicial deference toward IBM's product redesigns.[70]

The first decision, *ILC Peripherals Leasing Corp. v. Int'l Bus. Machines Corp.*, applied an analytical standard that inquired into whether there was a valid engineering dispute over the superiority of the redesigned product.[71] Since there was such an engineering dispute on the facts, the court refused to "allow itself to be enmeshed 'in a technical inquiry into the justifiability of product innovations.'"[72] The decision ultimately concludes that the plaintiff lacked evidence of the anticompetitive effects of IBM's actions.[73]

A year later, the second case against IBM, *In re IBM Peripheral EDP Devices*, rejected this analytical approach of looking for valid engineering disputes, finding it "overprotective" of innovation in the computer industry.[74] Instead, the decision adopts a standard that evaluates whether the exclusionary product design change was "unreasonably restrictive of competition,"[75] including consideration of

68. *ILC Peripherals Leasing Corp.*, 458 F. Supp. at 438-44 (describing IBM's various design changes to peripheral interfaces and claiming the conduct was exclusionary); *IBM Peripheral EDP Devices*, 481 F. Supp. at 1003 (alleging IBM attempted to monopolize through its "design conduct," eliminating competition by making the interfaces of new IBM central processing units incompatible with competing peripherals). *See also* the similar design change allegations in Cal. Comput. Prods., Inc. v. Int'l Bus. Machs. Corp., 613 F.2d 727 (9th Cir. 1979).

69. *IBM Peripheral EDP Devices*, 481 F. Supp. at 973 (discussing the evolution of IBM peripherals); *see ILC Peripherals Leasing Corp.*, 458 F. Supp. at 438-44 (describing IBM's interfaces design changes that benefited IBM itself).

70. *Compare IBM Peripheral EDP Devices*, 481 F. Supp. 965, *with ILC Peripherals Leasing Corp.*, 458 F. Supp. at 438-41.

71. *ILC Peripherals Leasing Corp.*, 458 F. Supp. at 438-44.

72. *Id.* at 439 (citing Response of Carolina, Inc. v. Leasco Response, Inc., 537 F.2d 1307, 1330 (5th Cir. 1976)). A later decision casts *ILC Peripherals Leasing Corp.* as requiring that the design change be "reasonable." GAF Corp. v. Eastman Kodak Co., 519 F. Supp. 1203, 1227-28 (S.D.N.Y. 1981) (describing *Cal. Comput. Prods., Inc.*, 613 F.2d at 727 and *ILC Peripherals Leasing Corp*., 458 F. Supp. at 438-41 as adopting a reasonableness standard for design changes).

73. *ILC Peripherals Leasing Corp.*, 458 F. Supp. at 444.

74. *IBM Peripheral EDP Devices*, 481 F. Supp. at 1003 (rejecting the analytical standard of *ILC Peripherals Leasing Corp.*, 458 F. Supp. 423 as inapplicable to the predatory innovation allegations).

75. *Id.* On the facts, the court found that the contested changes were improvements to the products and were not unreasonably restrictive of competition, therefore IBM did not violate

"the degree to which the design was the product of desirable technological creativity."[76] The two cases provide a powerful illustration of the disarray of predatory innovation jurisprudence; despite their many similarities, the decisions diverge in their view of the appropriate deference toward product redesigns, and also on the correct analytical standard for assessing predatory innovation claims.

In another deference-related split, predatory innovation cases disagree on whether courts should engage in weighing of the pro- and anticompetitive effects of a monopolist's redesigns. Under the standard analytical framework for Section 2 claims, once an antitrust court finds that i) a monopolist has engaged in conduct with effects shown to be *prima facie* anticompetitive, and ii) the monopolist has no procompetitive justification for that conduct, then the court is supposed to proceed to a third analytical step in which it weighs the anticompetitive harm of the conduct against its procompetitive benefits.[77] If the harm outweighs the benefits of the conduct, then a violation of Section 2 of the Sherman Act is established.[78] This third step is where the controversy lies in predatory innovation jurisprudence.

The D.C. Circuit in *Microsoft* proposed that this framework be applied to the predatory innovation allegations in the case, including the final weighing step.[79] The software giant Microsoft had engaged in technological tying, interconnecting its dominant Windows operating

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the Sherman Act. *IBM Peripheral EDP Devices*, 481 F. Supp. at 1003-05. Further, the court found the plaintiff had not suffered antitrust injury. *IBM Peripheral EDP Devices*, 481 F. Supp. at 1010. On appeal, the Ninth Circuit affirmed on the result, based only on the finding that there was no antitrust injury. Transamerica Comput. Co. v. Int'l Bus. Machs. Corp., 698 F.2d 1377, 1383 (9th Cir. 1983).

76. *IBM Peripheral EDP Devices*, 481 F. Supp. at 1003.

77. Section 2 Sherman Act claims subject to a "rule of reason" standard are typically analyzed based on this three-step burden shifting framework. First, the plaintiff must establish a *prima facie* anticompetitive effect from the alleged monopolization of a market. United States v. Microsoft Corp., 253 F.3d 34, at 58 (D.C. Cir. 2001). This typically involves a showing there was exclusionary conduct by the monopolist, which is "distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Id.* If established, the analysis proceeds to a second step, where the defendant is given an opportunity to prove there was a procompetitive justification for its conduct (that it was, in fact, competition on the merits). *Id.* at 59. If the defendant establishes such a justification, in theory the analysis proceeds to a third step, where the plaintiff may either rebut the justification, or prove that the anticompetitive harm of the conduct outweighs its procompetitive benefit. *Id.*

78. *Id.* at 59.

79. *Id.* at 64. However, *Microsoft* itself was decided at the earlier steps in the analysis, without the need to reach this proposed third step proposed (the same is true of most Section 2 Sherman Act cases). *See id.* at 60-64. For a more detailed explanation of the *Microsoft* and *Allied Orthopedic* cases, *see* Devlin & Jacobs, *supra* note 2, at 10-19.

system with its web browser.[80] The tying and other conduct at issue in the case blocked rival browsers from competing, at a time when those browsers threatened to displace Microsoft's operating system monopoly with their new functionality.[81] Although the Microsoft litigation nods to the concern of deference to innovation, noting that "[a]ntitrust scholars have long recognized the undesirability of having courts oversee product design," it ultimately takes the view that courts are capable of weighing the competitive effects of a product design change, and should do so.[82]

In contrast, the Ninth Circuit in *Allied Orthopedic Appliances v. Tyco Health Care Group* ("*Allied Orthopedic*") rejects *Microsoft*'s final weighing step as inapplicable to predatory innovation claims.[83] The defendant in *Allied Orthopedic* was accused of redesigning its medical device to exclude rival's complementary products, including the plaintiff's products, in violation of Section 2 of the Sherman Act.[84] There was undisputed evidence that the defendant's design change was an improvement, as it added new features and lowered the cost of compatibility with the defendant's other products.[85] The Ninth Circuit firmly refused to engage in any balancing of the competitive effects of the redesign, reasoning that:

> There is no room in this analysis for balancing the benefits or worth of a product improvement against its anticompetitive effects. If a monopolist's design change is an improvement, it is "necessarily tolerated by the antitrust laws," unless the monopolist abuses or leverages its monopoly power in some other way when introducing the product.[86]

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80. *Microsoft*, 253 F.3d at 45.

81. *Id.*

82. United States v. Microsoft Corp., 147 F.3d 935, 948 (D.C. Cir. 1998); *Microsoft Corp.*, 253 F.3d at 95. In practice, most Section 2 cases are determined earlier in the analysis without the need to continue to the balancing or weighing step. *See, e.g.*, Daniel A. Crane, *Rules Versus Standards in Antitrust Adjudication*, 64 WASH. & LEE L. REV. 49 (2007) (finding balancing analysis is often not determination of § 2 Sherman Act claims).

83. Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP, 592 F.3d 991, 999-1000 (9th Cir. 2010).

84. *Id.* at 994-96. The case involved sales by Tyco of patented pulse-oximetry devices used to measure blood oxygenation. The devices consisted of two main parts: sensors and monitors. Tyco faced the prospect of patent expiry, and the imminent generic competition for sales of sensors that would result. The company responded by developing a new type of sensor that moved the digital memory chip out of its monitor, integrating it directly into the sensor. This made generic sensors incompatible with all the new Tyco monitors. The plaintiff competitor alleged that, by introducing the new system, Tyco unlawfully maintained its monopoly over the sensor market in violation of Section 2 of the Sherman Act, among other arguments.

85. *See id.*

86. *Allied Orthopedic Appliances*, 592 F.3d at 1000 (quoting Foremost Pro Color, Inc. v. Eastman Kodak Co., 703 F.2d 534, 545 (9th Cir. 1983), *overruled on other grounds by*

The Ninth Circuit explains this rejection of the final "balancing" step as a matter of judicial competency and administrability, rooted in the unpredictability of future innovation:

> To weigh the benefits of an improved product design against the resulting injuries to competitors is not just unwise, it is unadministrable. There are 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. The balancing test proposed by plaintiffs would therefore require courts to weigh as-yet-unknown benefits against current competitive injuries.[87]

Under the *Allied Orthopedic* approach, no matter how small the benefit of the product redesign, once an improvement is shown, the analysis ends, and the defendant's product design changes are permitted. Even if the anticompetitive effects arising from the design change are significant, there is no cognizable antitrust violation.

More recently, a similar split arose between the Second Circuit in *New York ex rel. Schneiderman v. Actavis Plc* ("*Namenda*")[88] and the Third Circuit in *Mylan Pharmaceuticals, Inc. v. Warner Chilcott Public Limited Company* ("*Mylan*").[89] Both cases involve claims of product hopping—allegations that a branded drug company made minor design changes to its drug, then withdrew its old drug design from the market (or planned to) in order to block generic drug competition.[90] Despite these similarities, *Namenda* applies the *Microsoft* balancing analysis (albeit in the alternative)[91] and dismisses concerns over pharmaceutical innovation chilling,[92] while *Mylan* does not reach the balancing analysis,

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Aerotec Int'l, Inc. v. Honeywell Int'l, Inc., 836 F.3d 1171 (9th Cir. 2016)). This improvement-based standard is similar to the view taken by the D.C. Circuit in an earlier antitrust case against Microsoft, where the court was called on to determine whether the company had violated a 1994 consent decree prohibition on "integrated products" with design changes Microsoft made to link code for Windows 95 and Internet Explorer (pre-dating the more notorious Microsoft case that ended in 2001 and involved Windows 98). *Microsoft Corp.*, 147 F.3d at 950 (earlier consent decree dispute). The D.C. Circuit indicated that, at least in the context of interpreting whether a product redesign violated the consent decree, the question was whether "there is a plausible claim that it [the redesign] brings some advantage." *Id.*

87. *Allied Orthopedic*, 592 F.3d at 1000.

88. New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638 (2d Cir. 2015).

89. Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co., 838 F.3d 421 (3d Cir. 2016).

90. *Namenda*, 787 F.3d at 650; *Mylan*, 838 F.3d at 427. Both cases also include Section 1 Sherman Act allegations that are not discussed in further detail here.

91. *Namenda*, 787 F.3d at 652.

92. *Id.* at 659.

and is wary that judicial scrutiny of product hopping may slow or even stop pharmaceutical innovation.[93]

In *Namenda*, the plaintiff, New York Attorney General Eric Schneiderman, established that the product hop was a plausible Section 2 violation.[94] The defendants, drug company Actavis (now Allergan) and its subsidiary, were on the verge of withdrawing their old, twice-a-day Alzheimer's drug, Namenda IR, from the market as the related patent terms neared expiry. The company planned to "hop" patient demand to their new once-a-day drug called Namenda XR.[95] The defendants were found to have monopoly power, as Namenda IR was the only drug in the relevant market.[96]

Applying the analytical framework from *Microsoft*, the Second Circuit in *Namenda* found the product hop was likely anticompetitive, because the defendant was forcing patients to switch drugs through means "other than competition on the merits."[97] At the time of the hop, several generic equivalents of Namenda IR were poised to obtain FDA approval to begin competing with the branded drug.[98] This approval would have enabled pharmacy-level substitution—and competition—of these generic versions with Namenda IR.[99] By introducing its redesigned Namenda XR version, and withdrawing Namenda IR *before* the impending generic entry, the defendants compelled patients to switch

93. *Mylan*, 838 F.3d at 440 ("[C]ourts might need to balance the important public interest in encouraging innovation in the pharmaceutical industry with our obligations to protect consumers and to ensure fair competition under the antitrust laws."); *id.* at 432 ("Mylan's theory also risks slowing or even stopping pharmaceutical innovation." (quoting Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co., No. 12-3824, 2015 WL 1736957, at *16 (E.D. Pa. Apr. 16, 2015), *aff'd*, 838 F.3d 421 (3d Cir. 2016))).

94. *See Namenda*, 787 F.3d at 639.

95. *Id.* at 651-52. The defendant's old and new branded versions of the drug, both owned by Actavis, together comprised 100 percent of the relevant U.S. antitrust market. *Id.* at 652.

96. *Id.*

97. *Id.* at 655 (quoting United States v. Microsoft Corp., 253 F.3d 34, 65 (D.C. Cir. 2001).

98. *Id.* at 647 (noting five generic versions of IR had tentative FDA approval and seven others were pending approval). The Hatch-Waxman Act establishes an abbreviated FDA approval process for generic drugs that relies on a demonstration that the generic is equivalent to an already FDA-approved branded drug. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in various sections of 15, 21, 28, 35 U.S.C.); *see Mylan*, 838 F.3d at 427 (explaining that the abbreviated approval for the generic equivalent is quicker and less costly than for the initial FDA approval of the branded drug). Once an equivalency rating is obtained from the FDA through this process, many state laws allow or require the generic to be substituted for the branded version at the pharmacy level.

99. *See supra* text accompanying note 33 (describing the abbreviated new drug application process for generic created by Hatch-Waxman Act and its relevance to state laws on generic drug substitution).

to the new branded version to continue their treatment for Alzheimer's disease.[100]

In just one paragraph, the Second Circuit concluded that the defendants' proffered procompetitive justifications were "pretextual."[101] Though the analysis could have ended there, with a finding of a plausible antitrust violation, the court went on to the controversial final step of weighing the competitive effects of the conduct.[102] The Second Circuit concluded that the procompetitive benefits from the product hop, if any, were outweighed by the anticompetitive harms caused by the hop—including any negative effects on innovation.[103] The court upheld a preliminary injunction that required Actavis to keep the old drug formulation, Namenda IR, on the market until at least thirty days after the first availability of a generic version of the reformulation.[104]

Mylan, the second appellate decision on product hopping, was decided shortly after *Namenda*.[105] The plaintiff generic drug manufacturer, Mylan, alleged that the branded drug defendant, Warner Chilcott, had made a series of four design changes to its branded acne drug, Doryx.[106] The changes included a transition from capsule to tablet format, modifications of the tablet strength and changes to pill scoring (which enabled patients to split the pills into different dosages).[107] In some cases, Warner Chilcott removed the older formulation from the market, even buying capsules back and destroying inventory.[108] Mylan

100. *Namenda*, 787 F.3d at 654. Absent the litigation, this change would have left generic companies with no Namenda IR demand base for which to substitute their products at the pharmacy counter. The product hop would have forced those companies to restart the FDA approval process to show equivalency to the new XR formulation—delaying competition with the defendant's reformulated drug in the interim. The unique nature of the patient population exacerbated patient coercion, because the symptoms of Alzheimer's patients render them particularly sensitive and vulnerable to changes in their routine, making them unlikely to switch back when a generic of Namenda XR was eventually introduced to the market. *Id.* at 654-55.

101. *Id.* at 658.

102. *Id.* at 638, 658.

103. *Id.* at 658-59 (describing balancing of procompetitive effects and anticompetitive harms).

104. *Id.* at 650, 663. The defendant filed a petition for a writ of certiorari with the Supreme Court for review, but the parties settled in late 2015 before the petition was heard. Allergan PLC v. New York *ex. rel.* Schneiderman, 577 U.S. 1002 (2015); Press Release, N.Y. Office of the Att'y Gen., A.G. Schneiderman Announces Resolution of Lawsuit That Protected Alzheimer's Patients from Anticompetitive Tactic Aimed at Maintaining Higher Drug Prices (Nov. 25, 2015), https://ag.ny.gov/press-release/2015/ag-schneiderman-announces-resolution-lawsuit-protected-alzheimers-patients.

105. Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co., 838 F.3d 421 (3d Cir. 2016).

106. *Id.* at 429-30.

107. *Id.*

108. *Id.* at 429-31.

argued that the design changes were of "little or no therapeutic benefit" to patients, and the sole purpose of the redesigns and product hop was to block generic competitors from the market for acne antibiotics. [109]

The Third Circuit found that Warner Chilcott did not have monopoly power in the relevant market, as there were several rival oral acne drugs.[110] Although the court could have ended its analysis there, it continued on to find that the alleged product hopping was not anticompetitive,[111] and that the defendant had established a plausible business justification for its conduct.[112] Unlike *Namenda*, the Third Circuit did not proceed to any balancing step in its analysis.[113] Though procedural and factual difference account for some of the variation between *Mylan* and *Namenda*,[114] there remains an unreconciled tension. The two Circuits seem to have different views on the extent to which courts should inquire into effects on competition, and on how judicial deference impacts the appropriate analytical approach to predatory innovation claims.

These Circuit splits in predatory innovation cases reflect a pervasive judicial disagreement on the appropriate level of deference toward product design changes. Ultimately, decisions like *Allied Orthopedic* and *Mylan* are more deferential to the design choices of defendants, out of concern that judicial condemnation might chill innovation. Regardless of the presence or extent of any anticompetitive effects of a product redesign, those decisions would largely tolerate such effects in the name of innovation. The cases view antitrust courts as ill-equipped to judge whether a product constitutes "enough" of an

109. *Id.* at 429-31. Each time Warner Chilcott introduced a slightly modified version of Doryx, Mylan had to re-start the Hatch-Waxman Act approval process, effectively delaying FDA approval of a generic equivalent and blocking pharmacy-level substitution. *Id.*

110. *See id.* at 437-38.

111. *See Mylan*, 838 F.3d at 438-39. The Third Circuit largely adopts the reasoning of the Eastern District of Pennsylvania, which granted Warner Chilcott's motion for summary judgement.

112. *See id.* The justifications proffered by Warner Chilcott included product liability issues with one of the older designs and, with the later designs, responding to competitive pressures and consumer convenience considerations. *Id.* Mylan petitioned for rehearing of the case, which was denied. After filing for two extensions of time for appeal with the Supreme Court in 2017, Mylan did not ultimately file a petition for certiorari in the case.

113. Both decisions purport to apply the *Microsoft* analytical framework. *See* New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 652 (2d Cir. 2015); *Mylan*, 838 F.3d at 438. However, *Mylan* concludes its analysis before the contentious balancing of procompetitive benefits and anticompetitive effects.

114. *See Mylan*, 838 F.3d at 439-40 (finding *Namenda* "to be factually and procedurally distinguishable," as the defendant in Mylan did not have monopoly power while the defendant in *Namenda* did, the relevant patents were near-expiry patent on the original drug in *Namenda* but not in *Mylan*, and *Mylan* was a hearing on the merits while *Namenda* involved an appeal of a motion for a preliminary injunction).

improvement over the prior design to be permitted or condemned.[115] This reflects deeply-rooted antitrust concerns over false positives—mistakenly condemning procompetitive conduct—and the persistent costs that such judicial errors are assumed to have for consumers.[116] In contrast, cases like *Microsoft* and *Namenda* envision a more interventionist role for the courts. Both decisions subject exclusionary redesigns and associated conduct to antitrust scrutiny, and view the judiciary as capable of weighing costs and benefits to competition from predatory innovation.[117]

III. DEVELOPING AN INDUSTRY-CONTEXTUAL APPROACH TO PREDATORY INNOVATION

As this section describes, patent and economic literature richly demonstrate that innovation is industry-specific in its nature and processes. This section proposes that antitrust law adopt this cross-disciplinary insight, using it to tailor judicial analysis of predatory innovation claims to the industry context of each case.

A. Patent and Economic Theory Indicate That Innovation Models are Industry Specific

While the analysis of innovation is relatively new to antitrust law,[118] it is more familiar to patent policy and economic theory. Both demonstrate that the nature of innovation is highly industry-specific.

The *raison d'etre* of patent law is the promotion of innovation. The Constitution directs Congress "[t]o promote the [p]rogress of [s]cience and useful [a]rts by securing" exclusive rights for inventors and writers,[119] which Congress has sought to do by enacting copyright and patent law. The patent system seeks to promote innovation by rewarding patent holders with time-limited, exclusive rights over his or her new and useful invention, in exchange for disclosure of that invention to society.[120]

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115. *See, e.g.*, *Mylan*, 838 F.3d 421, 432 (3d Cir. 2016).

116. *See infra* Part IV.A for further discussion on error-cost assumptions.

117. *Namenda*, 787 F.3d at 658-59.

118. *See supra* notes 18-19 and accompanying text (observing the recency of innovation appearing within antitrust analysis, and antitrust law's challenges with analysis of dynamic competition).

119. U.S. CONST. art. I, § 8, cl. 8.

120. 35 U.S.C. § 101 (2018); FTC v. Actavis, Inc., 570 U.S. 136, 161 (2013) (Roberts, C.J., dissenting) ("The point of patent law is to grant limited monopolies as a way of encouraging innovation. Thus, a patent grants 'the right to exclude others from profiting by the patented invention.' ") (citing Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980)).

Patent literature indicates that there are striking differences across industries in how innovation occurs.[121] In particular, patent scholars draw a paradigmatic contrast between innovation in the pharmaceutical industry and innovation in the software industry, describing deep differences between their respective processes of invention, associated costs, dependencies on prior innovation and drivers of innovation risk and reward.[122] This classic patent comparison is helpful for antitrust law, as the pharmaceutical and software industries also frequently see predatory innovation claims.

Prescription drug innovation is cast as an expensive, long-term proposition that results in eventual and significant leaps in development. Though figures vary, by some estimates the average development cost per new prescription drug, including failures, has risen to nearly $2.6 billion.[123] This process is also time consuming, with industry estimates of an average of ten or more years to develop a new medicine.[124] First, the discovery of potential future drugs involves difficult and research-intensive screening of thousands of candidate compounds.[125] Then, once drug candidates are identified and developed, the FDA imposes extensive regulatory approval requirements on those new potential drugs, contributing to the long time frame and high cost of drug

121. *See* DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT 39 (2009); FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 1, 9-10, 46 (2003) [hereinafter FTC REPORT ON COMPETITION AND PATENT LAW], http://ftc.gov/os/2003/10/innovationrpt.pdf (drawing a contrast between consultation participants who describe patent protection as "essential" for pharmaceuticals and those who observe that, in computer software, "the patent system does not encourage innovation"); Gregory N. Mandel, *Proxy Signals: Capturing Private Information for Public Benefit*, 90 WASH. U. L. REV. 1, 5 (2012) (noting that it is "[w]ell recognized" that industries, particularly pharmaceuticals and software, interact with the patent system differently "due to differences in industry innovation characteristics").

122. *See* BURK & LEMLEY, *supra* note 121, at 37-48 (discussing the diversity of innovation across industries, with several contrasts drawn between software and pharmaceuticals); Mandel, *supra* note 121, at 5.

123. Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 26 (2016).

124. PHARM. RESEARCH & MFRS. OF AM., MODERNIZING DRUG DISCOVERY, DEVELOPMENT AND APPROVAL 1, 1 (2016), http://phrma-docs.phrma.org/sites/default/files/pdf/proactive-policy-drug-discovery.pdf.

125. PHARM. RESEARCH & MFRS. OF AM., BIOPHARMACEUTICAL RESEARCH & DEVELOPMENT: THE PROCESS BEHIND NEW MEDICINES, 1 (2015) http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf (noting the "thousands and sometimes millions of compounds" screened at the outset of new drug development) ; *see similarly* J P Hughes *et al*. *Principles of Early Drug Discovery*, 162 BRIT. J. OF PHARMACOLOGY 1239, 1248 (2011) (noting 200,000 compounds or more are often screened at the outset of each drug discovery project).

innovation.[126] Applications for FDA new drug approvals must contain scientific evidence that demonstrates the drug is effective and safe, which requires "a long, comprehensive, and costly testing process," including clinical studies, before the FDA will approve the drug for sale.[127] Industry estimates show that approximately ten to twelve percent of candidate drugs progress from the first phase of clinical trials to the final FDA approval required to introduce a drug onto the U.S. market.[128]

The number of new drugs invented over time reflects this difficult and long-term nature of pharmaceutical drug innovation. Throughout a fifteen-year period ending in 2012, the ten most productive pharmaceutical drug companies achieved FDA approval for only a collective total of approximately 130 new drugs.[129] This time consuming, costly development of prescription drugs is embodied in the term "blockbuster" drug, which evokes the episodic, singularly significant character of new medicine development.[130]

Patents are thought to play a major role in driving such pharmaceutical drug innovation.[131] Without the artificial, legislated appropriability provided by patent rights, competitors could fairly easily copy a drug after its introduction to the market, depriving the inventor of the chance to recoup its often significant investment.[132] Patent rights are an important mechanism to prevent such copying, endowing the patent owner with the exclusive authority to make, use, sell, offer for sale or import the patented drug for an approximately twenty-year patent term.[133] The theory is that, without this prospect of recoupment provided

126. *See generally* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399f (2012).

127. FTC v. Actavis, Inc., 570 U.S. 136, 142 (2013); *see* 21 U.S.C. § 355 (2018).

128. BIOTECHNOLOGY INNOVATION ORG., CLINICAL DEVELOPMENT SUCCESS RATES 2006-2015, at 7 (2016), https://www.bio.org/sites/default/files/legacy/bioorg/docs/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf (finding a 9.6 percent likelihood of drug candidate success from Phase I through to FDA approval); PHARM. RESEARCH & MFRS. OF AM., BIOPHARMACEUTICAL RESEARCH & DEVELOPMENT: THE PROCESS BEHIND NEW MEDICINES 1, 1 (2015), http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf (estimating an approval rate of less than twelve percent).

129. Matthew Herper, *The Best Drug Companies Of The Past 15 Years*, FORBES (Feb. 9, 2012, 1:19 PM), https://www.forbes.com/sites/matthewherper/2012/02/09/the-best-drug-companies-of-the-past-15-years/#660edb3413b1 (listing total number of drug inventions of top ten companies).

130. *See generally* JIE JACK LI, *Beginning of an Era: The First Blockbuster Drug, Tagamet*, *in* BLOCKBUSTER DRUGS: THE RISE AND DECLINE OF THE PHARMACEUTICAL INDUSTRY 5-40 (2014) (tracing the rise of the phenomenon of "blockbuster" drugs).

131. BURK & LEMLEY, *supra* note 121, at 50 ("[P]atents play a major role in supporting innovation in only a few industries, most notably in chemistry and pharmaceuticals.").

132. *Id.* at 42-43 (discussing the ratio of inventor cost to imitator cost).

133. 35 U.S.C. § 271(a) (2018) (exclusive rights conferred by a patent); 35 U.S.C. §154(a)(2) (2018) (twenty-year patent term from patent issuance); *see* BURK & LEMLEY,

by patent rights, investment in drug development would become less likely in the future, impairing pharmaceutical innovation over the long term.[134]

Patent literature contrasts this model of pharmaceutical innovation with the software industry, where the nature and processes of invention look quite different.[135] Unlike episodic blockbuster drug discoveries, new software development is typically cumulative from prior invention,[136] incrementally building on, and benefitting from, other innovation over time.[137] Prior technology or code is improved with new versions, or different applications, and the earlier developments play an essential role in later software innovation.[138]

The writing of new software code also tends to be fast and cheap relative to the development of new pharmaceutical drugs.[139] There are no pharma-like regulatory approvals that add time and expense to bringing software to market. Unlike drug development pipelines with their low rates of ultimate success, once software development is undertaken, there is generally much less uncertainty as to whether the software program can be completed.

In a reflection of these differences, exclusive patent rights are thought to play a less important role in driving and rewarding new software innovation than in industries like pharmaceuticals.[140] In fact, the software industry itself has a long history of opposing software patentability.[141] Up until the late 1990s, the law was uncertain as to

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supra note 121, at 5-7 (discussing the role of patents in pharmaceutical innovation, given the high ratio of inventor cost to imitator cost the pharmaceutical industry).

134. BURK & LEMLEY, *supra* note 121, at 43.

135. *See* Mandel, *supra* note 121, at 5; BURK & LEMLEY, *id*. at 37-48 (discussing the diversity of innovation across industries with several contrasts drawn between software and pharmaceuticals).

136. *See, e.g.*, Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CAL. L. REV. 1, 41 (2001).

137. James Bessen & Eric Maskin, *Sequential Innovation, Patents, and Imitation* 3 (Mass. Inst. of Tech. Dep't of Econ., Working Paper No. 00-01, 2000), https://dspace.mit.edu/bitstream/handle/1721.1/64176/sequentialinnova00bess.pdf?sequence=1.

138. BURK & LEMLEY, *supra* note 121, at 47 ("[I]n computer software cumulative innovation is extraordinarily important.").

139. *Id.* at 39-40, 156-57 (contrasting the cost and regulatory burden of pharmaceuticals development with that of software).

140. Jonathan M. Barnett, *Private Protection of Patentable Goods*, 25 CARDOZO L. REV. 1251, 1251-52 (2004) (discussing the importance of alternatives to patents as appropriability mechanisms in some technology sectors); JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 106-09 (2008) (finding large differences in patent value for pharmaceuticals compared to complex technology patents primarily in the computing and electronics industry).

141. BESSEN & MEURER, *supra* note 140 at 189 (discussing industry opposition to software patenting from the 1960s through the 1990s).

whether software *could* even be patentable.[142] As a result, the incentives to invest in software research and development came from sources other than patent rights.[143] Rapid market growth, scale economies, and network effects more often reward successful software firms in the race to innovate.[144]

For many software-driven firms, patent rights lack the same centrality of importance those rights hold for pharmaceutical companies. In a simple illustration of this, consider the 2020 annual reports from leading U.S. pharmaceutical companies Pfizer and Merck.[145] These reports use the term "patent" approximately 212 and 143 times, respectively, to describe their businesses.[146] Contrast this to references to "patent" in the annual reports of leading software-driven companies for the same period: the word appears just twenty-one times in social media company Facebook's annual report,[147] and only sixteen times for search giant Google.[148] In its short section on intellectual property, Facebook observes that "[w]e do not believe that our proprietary technology is dependent on any single patent or copyright or groups of

142. State St. Bank & Tr. Co. v. Signature Fin. Grp., Inc., 149 F.3d 1368, 1373 (Fed. Cir. 1998), *abrogated by In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008); AT&T Corp. v. Excel Commc'ns, Inc., 172 F.3d 1352 (Fed. Cir. 1999) (confirming that software is patentable subject matter), *abrogated by In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008). *See* Cohen & Lemley, *supra* note 136, at 10-11 (tracing the law on whether software is patentable).

143. *See generally* BURK & LEMLEY, *supra* note 121, at 42 (citing Barnett, *supra* note 140) (observing that in complex technology sectors, alternatives to patents can be more important appropriability mechanisms, including for some software).

144. *See* Jonathan B. Baker, *Evaluating Appropriability Defenses for the Exclusionary Conduct of Dominant Firms in Innovative Industries*, 80 ANTITRUST L.J. 431, 437 (2016).

145. Pfizer Inc., Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2020 (Form 10-K)(Feb. 25, 2021) [hereinafter Pfizer Annual Report]; Merck & Co., Inc., Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2020 (Form 10-K) (Feb. 25, 2021) [hereinafter Merck Annual Report].

146. *See* Pfizer Annual Report, *supra* note 145; Merck Annual Report, *supra* note 145.

147. *See* Facebook, Inc., Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2020 (Form 10-K) (Jan. 27, 2021) [hereinafter Facebook Annual Report].

148. *See* Alphabet Inc., Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2020 (Form 10-K) (Feb. 2, 2021). Alphabet Inc. is the parent company of Google. *Id.* at 5. At the time of writing, Google was by far the leading provider of online search and Facebook the leading provider of social media networking services. *Search Engine Market Share Worldwide - January 2021*, STATCOUNTER GLOBALSTATS, https://gs.statcounter.com/search-engine-market-share (last visited Apr. 9, 2021) (identifying Google as having the highest search engine market share worldwide by number of page views); *Most popular social networks worldwide as of January 2022, ranked by number of monthly active users*, STATISTA, https://www.statista.com/statistics/272014/global-social-networks-ranked-by-number-of-users/ (last visited Mar. 9, 2022) (identifying Facebook as the most popular social network worldwide as of January 2022).

related patents or copyrights."[149] The value of these software companies is not primarily driven by patent rights. It depends to a much greater extent on factors like carefully honed algorithms, software design and network effects that drive end-user engagement. In contrast, by one estimate, "[o]ver one-half of the value of worldwide patents accrues to a small number of large pharmaceutical firms."[150] This is not to imply that patents are irrelevant to the software industry, but rather to illustrate that patents play an observably less important role in the value of software businesses. These patent differences strongly suggest that innovation is created, and its benefits reaped, in very distinct ways across these two industries.

Economic research reinforces this finding that innovation varies widely by industry. In his influential writing, Joseph Schumpeter theorized that the "perennial gale of creative destruction" stimulates competition, and that large firms and concentrated market structures encourage investment that leads to such innovation.[151] Though the relationship between competition, market structure and innovation is not yet definitively understood,[152] theories of this relationship have continued to develop since Schumpeter's seminal work. In particular, a critical insight from the recent "second wave" economic research on Joseph Schumpeter's innovation theory is that "incentives for R&D [research and development] . . . can differ greatly across industries."[153]

Richard Gilbert, in his extensive review of post-Schumpeter economic literature on the relationship between innovation and competition, concludes that there are fundamental distinctions between the economic models applicable to industries where exclusive property rights (exemplified by patents) are at stake in the race to innovate, and those industries in which exclusive rights play a less important role in the incentives to create.[154] His literature review reaches the meta-

149. Facebook Annual Report, *supra* note 147, at 8.

150. BESSEN & MEURER, *supra* note 140, at 109.

151. *See* SCHUMPETER, *supra* note 12, at 81-90; *see generally* JOSEPH A. SCHUMPETER, THE THEORY OF ECONOMIC DEVELOPMENT (Redvers Opie trans., Harvard University Press) (1934).

152. Schumpeter's thinking was famously challenged by Kenneth Arrow, who theorized that market competition rather than monopoly drives innovation. This debate continues today. *See, e.g.*, Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, *in* THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS 609, 622 (1962).

153. Richard Gilbert, *Looking for Mr. Schumpeter: Where Are We in the Competition—Innovation Debate?*, 6 INNOVATION POL'Y & ECON. 159, 194 (2006).

154. *See id.* at 175-76.

conclusion that "it is important to know which model is appropriate for each market context."[155]

As Gilbert explains, competition without exclusive rights is likely to result in redundant research and development expenditures by multiple firms, such that "[i]t would be better for one firm to invest in R&D and to share the results of that knowledge with others, . . . avoid[ing] [repeated] R&D costs."[156] This is anecdotally observable in the "hacker culture" of computer scientists in Silicon Valley, which emphasizes free-flowing information and collaborative code-sharing.[157] To avoid duplicative writing of basic software, essential software code is often made available to all.[158] This sharing ethos enables computer programmers to focus their efforts on the point of novelty, improving shared basics with later innovations, rather than re-inventing the same software wheel.[159] Patents were, and to some extent still are, a philosophical anathema to the communities of open-source software developers who created our online world.[160] It makes sense to share basic knowledge to avoid repeated costs in the development of software code—just as economic theory predicts for industries in which exclusive rights are not at stake in the race to innovate.

B. Proposal: An Industry-Contextual Approach to Predatory Innovation

Patent policy and economic research both recognize the importance of industry context to innovation, deeply distinguishing between industries in their discussion of innovation models. Antitrust law should reflect this same insight—that innovation varies by industry. This means tailoring the adjudication of predatory innovation claims to better reflect the industry-specific innovation context in which those claims occur.

This industry-contextual approach would improve the logic and clarity of judicial reasoning on predatory innovation. As the following sections of this Article argue, courts are too wary of "innovation"

155. *Id.* at 165.

156. *Id.* at 177.

157. *See* STEVEN LEVY, HACKERS: HEROES OF THE COMPUTER REVOLUTION 24 (Mike Hendrickson ed., 2010).

158. *Id.* (noting that among early hackers, emphasis that "information should be free" led to sharing of program code to "prevent[] the dreaded, time-wasting ritual of reinventing the wheel: instead of everybody writing his own version of the same program, the best version would be available to everyone, and everyone would be free to delve into the code and improve on *that*").

159. *Id.*

160. *See, e.g.*, Eric von Hippel & Georg von Krogh, *Open Source Software and the "Private-Collective" Innovation Model: Issues for Organization Science*, 14 ORG. SCI. 209, 209-12 (2003) (describing the history of open source software development).

chilling in predatory innovation cases, beyond what is dictated by the industry innovation context and evidence.[161] Analytical paradigms for predatory innovation tend to be exported from industries where the logic applies, to industries where it does not.[162] In place of this overly cautious and monolithic treatment of innovation, the proposed approach would infuse the analysis of predatory innovation claims with insights from patent law and economics on the processes and characteristics of innovation in the particular industry at stake.

This proposal for deeper emphasis on industry context offers a new way to approach predatory innovation claims, but it ought not be controversial. Modern antitrust law is often premised on economic theory, and the analysis of predatory innovation should be no exception. Further, antitrust typically places a heavy emphasis on industry context, recognizing that competition varies widely by specific industry and by relevant market. The Supreme Court has admonished that "[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue."[163]

This wisdom is oddly overlooked in many predatory innovation cases. Innovation is treated as unitary, despite systematic industry differences. This proposal for industry contextualism simply re-focuses the analysis of predatory innovation on the Supreme Court's guidance. The specific context and circumstances of the industry are of no less importance in understanding innovation-based competition than in analysis of traditional, price-based competition. In fact, the innovation characteristics catalogued by patent and economic literature may reflect even greater industry-based differences than those seen in price effects.

This borrowing of patent insight on innovation should be particularly uncontroversial in predatory innovation cases, where the relationship between patents and innovation has been recognized, albeit on more general terms than proposed in this Article. Cases like *Allied Orthopedic* acknowledge the potential relevance of patent rights to their conclusions on innovation, reasoning that "the existence of a patent on a new product design is some evidence that the change is an improvement over previous designs."[164] The expiry of patent terms also plays a role in product hopping cases; the imminent expiry of a patent on an existing

161. *See infra* Part IV.A (discussing disagreement on the effects on innovation arising from antitrust scrutiny of product hopping).

162. *See infra* Part IV.B.2 (arguing that product hopping cases over-extend the consumer choice/coercion paradigm to an industry where it is ill-fitting).

163. Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 411 (2004).

164. Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP, 592 F.3d 991, 1000-01 (9th Cir. 2010).

drug may indicate that the monopolist's product hop was timed to delay generic competition.[165] Patent thinking on innovation thus already plays some role in predatory innovation cases. The proposal here extends this wisdom. It draws even more fundamentally upon patent insights, as a way to understand how industry-specific innovation traits affect the analysis of predatory innovation claims.

IV. APPLYING AN INDUSTRY-CONTEXTUAL APPROACH TO INNOVATION CONTROVERSIES

How could an industry-contextual approach bring order to the messy judicial analysis of predatory innovation? The remainder of this Article explores two areas in which industry context would clarify and improve the logic of predatory innovation jurisprudence.[166]

First, this Part applies an industry-contextual approach to reconcile a split between the Second and Third Circuits on the likely innovation impacts of judicial scrutiny of product hopping. Second, this Part argues that product hopping cases are mis-applying consumer choice as a proxy to judge innovation, and examines how industry context can be used to correct this error.

A. Easterbrook's Legacy in Transition: Disagreement on Judicial Deference Toward Product Hopping and the Innovation Effects of Antitrust Scrutiny

In product hopping cases, appellate courts have disagreed on the appropriate level of judicial deference to afford pharmaceutical drug innovation. The roots of this disagreement trace back to Frank Easterbrook's influential error-cost framework. This section argues that

165. New York *ex rel*. Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 647-48 (2d Cir. 2015) (explaining the concept of a patent expiry "cliff" where branded drug exclusivity in the market ends); *id.* at 653-54 n.25 (observing there was no genuine dispute that defendants intended to avoid the patent expiry cliff with their product redesign); *cf.* Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co., 838 F.3d 421, 439-40 (3d Cir. 2016) (distinguishing *Namenda* on the basis that the case involved a " 'patent cliff'—the end of patent exclusivity" at which time generic drugs enter the market, while *Mylan* did not).

166. Among the variety of analytical paradigms for predatory innovation described above, there are some—such as intent and questions of product improvement—that inform judicial reasoning, but that are often insufficient to determine the case outcome. *See supra* Part II.B.1 (discussing product improvement analysis of predatory innovation claims, and its limitations) and Part II.B.3 (discussing intent-based analysis of predatory innovation claims and its challenges). Others, like consumer choice and judicial deference, hold greater power to drive decisions, and lie at the heart of many challenges posed by predatory innovation cases. *See supra* Part II.B.2 (discussing analysis of predatory innovation claims based on consumer choice or coercion) and Part II.B.4 (discussing the role of judicial deference to innovation in predatory innovation claims adjudication). Given their importance, the latter two topics are the focus of the discussion in the remainder of this Article.

these generalized error cost assumptions should be replaced with industry-specific understanding of how innovation occurs, varying deference in a manner informed by patent and economic insights.

The first two appellate decisions on product hopping, *Mylan* and *Namenda*, look similar in their facts and allegations.[167] Both involved a branded drug company that introduced, or planned to introduce, minor changes to its drug design, allegedly to prevent generic competition.[168] Despite these similarities, the cases take strikingly different views of how antitrust scrutiny is likely to impact pharmaceutical drug innovation. The *Namenda* court is quick to dismiss the defendants' arguments that future pharmaceutical innovation will be chilled by antitrust attention to product hopping, finding a lack of supporting evidence.[169] The court then goes further, to find that a *failure* of antitrust law to scrutinize such conduct could itself harm innovation:

> [I]mmunizing product hopping from antitrust scrutiny may deter significant innovation by encouraging manufacturers to focus on switching the market to trivial or minor product reformulations rather than investing in the research and development necessary to develop riskier, but medically significant innovations.[170]

In other words, allowing product hopping gamesmanship to go unchecked by antitrust courts may reduce innovation, because it encourages companies to spend research and development resources on incremental product hops, rather than on the next blockbuster drug.[171]

The Third Circuit in *Mylan* reflects a different view of how judicial deference is likely to impact innovation in pharmaceutical drugs. This is despite scrutinizing the same industry and similar conduct to that in *Namenda*. The *Mylan* court repeatedly expresses concern that antitrust scrutiny could chill future pharmaceutical innovation.[172] The court is wary of "turning courts into tribunals over innovation sufficiency."[173] The decision quotes an entire page of the district court reasoning that expresses deep skepticism over the judicial competency to adjudicate predatory innovation claims, and worry over effects on innovation:

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167. *See supra* Part II.B.4 for a discussion of the case facts in *Namenda* and *Mylan*.

168. *Namenda*, 787 F.3d at 642; *Mylan*, 838 F.3d at 426.

169. *Namenda*, 787 F.3d at 659.

170. *Id.*

171. *Id.*

172. *Id.* ("[C]ourts might need to balance the important public interest in encouraging innovation in the pharmaceutical industry with our obligations to protect consumers and to ensure fair competition under the antitrust laws."); *id.* at 432 ("Mylan's theory also risks slowing or even stopping pharmaceutical innovation." (quoting Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co., No. 12-3824, 2015 WL 1736957, at *16 (E.D. Pa. Apr. 16, 2015), *aff'd*, 838 F.3d 421 (3d Cir. 2016)).

173. *Id.* at 440.

> Adoption of Mylan's theory of "anticompetitive product redesign" could well have adverse, unintended consequences . . . . Mylan has failed to offer an intelligible test of innovation "sufficiency," and I doubt that courts could ever fashion one. Mylan's theory also risks slowing or even stopping pharmaceutical innovation. The prospect of costly and uncertain litigation every time a company reformulates a brand-name drug would likely increase costs and discourage manufacturers from seeking to improve existing drugs. [174]

Later in the decision, the *Mylan* court again invokes caution in condemning drug redesigns, noting the important "public interest in encouraging innovation in the pharmaceutical industry," although the court observes that interest may need to be weighed against the benefits of fair competition.[175]

Though procedural and factual distinctions between *Mylan* and *Namenda* explain some of their differences,[176] those distinctions cannot explain the divergent views expressed on the likely impacts of pharmaceutical innovation. The cases, after all, involve the same prescription drug industry and similar alleged misconduct—how could the likely innovation impacts of judicial intervention differ so significantly?

Antitrust scholarship has developed into a similar split, divided on how judicial scrutiny of product hopping affects innovation. On one hand, scholars such as Joshua D. Wright and Judge Douglas H. Ginsburg argue that by creating the risk of antitrust litigation for minor drug redesigns, product hopping cases will deter innovation that could be a critical stepping stone to later life-saving inventions.[177] Given this innovation-chilling risk, they insist product hopping should not be subject to antitrust scrutiny, unless the conduct is a complete sham for the exclusion of rivals, with no consumer welfare benefits.[178]

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174. *Id.* at 432 (citations omitted) (quoting *Mylan Pharm., Inc.*, 2015 WL 1736957, at *15-16).

175. *Id.* at 440. This comes amid a long list of factors the Mylan court mentions as potentially relevant to future cases, but does not explain, including: the role of Congress in governing conduct that delays generic entry, the unique characteristics of the pharmaceutical market, physician coercion or misrepresentations and patent cliffs. *Id.* at 428, 439-41.

176. *See Mylan*, 838 F.3d at 439-40 (finding *Namenda* "to be factually and procedurally distinguishable," as the defendant in Mylan did not have monopoly power while the defendant in *Namenda* did, there was a near-expiry patent on the original drug design in *Namenda* but not in *Mylan*, and *Mylan* was a hearing on the merits while *Namenda* involved an appeal of a motion for a preliminary injunction).

177. Former Fed. Trade Comm'r Joshua D. Wright & Judge Douglas H. Ginsburg, Comment on the Canadian Competition Bureau's Draft Updated Intellectual Property Enforcement Guidelines, at 2 (Aug. 10, 2015), https://www.ftc.gov/system/files/documents/public_statements/734661/150810canadacomment.pdf.

178. *Id.* at 4.

Scholars such as Michael A. Carrier and Steve D. Shadowen insist the opposite—that immunizing product hopping from antitrust scrutiny will harm innovation.[179] In particular, they argue that by shielding product hopping from antitrust inquiry, courts will encourage branded firms to withhold incremental product changes from the market.[180] Even after obtaining regulatory approval, firms may delay the release of a drug design change, choosing to introduce it later, at a competitively strategic time when generic entry becomes imminent.[181] They are critical of Wright and Ginsburg, noting the lack of "empirical or even theoretical basis for believing that *in this industry* [of prescription pharmaceuticals], where the gains from price competition are so enormous, that any supposed positive innovation effects would outweigh the documented negative price effects."[182] This Article expands upon this acknowledgement by Carrier and Shadowen that industry context is important to any assessment (or assumption) of innovation effects, in product hopping cases and beyond.

These scholarly and judicial divides represent antitrust thinking in a state of transition. Cases like *Mylan*, and scholars like Wright and Ginsburg, re-emphasize Frank Easterbrook's long-standing assumptions around judicial error costs in antitrust decision-making. Cases like *Namenda*, and scholars like Carrier and Shadowen (and this Article) push for an evolution that brings greater nuance to Easterbrook's assumptions.

In his influential writing during the 1980's, Frank Easterbrook reasoned that courts are likely to make errors in antitrust case adjudication, because it is exceedingly difficult to distinguish between efficient, procompetitive business conduct and anticompetitive behavior—despite this being the basic distinction required by antitrust law.[183] Both categories of action aggressively target and harm

179. Carrier & Shadowen, *supra* note 28, at 202.

180. *Id.*

181. *Id.* (citing *Namenda* and an earlier lower court case, Abbott Labs. v. Teva Pharm. USA, Inc. (*TriCor*), 432 F. Supp. 2d 408 (D. Del. 2006), as examples wherein branded companies waited until generic competition was imminent to introduce their respective product changes, to bring the redesign to market sooner). Shadowen also co-authored the American Antitrust Institute amicus brief in *Namenda* advancing the same argument. Brief for American Antitrust Institute as Amicus Curiae Supporting Appellees, New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015) (No. 14-4624).

182. Carrier & Shadowen, *supra* note 28, at 203.

183. Frank H. Easterbrook, *The Limits of Antitrust*, 63 TEX. L. REV. 1, 3-4 (1984) (describing the difficulty for courts in distinguishing between business practices that are successful competition and those that are anticompetitive, and likely error costs that will result from this difficulty); *see also* United States v. Microsoft Corp., 253 F.3d 34, 58 (D.C. Cir. 2001) ("The challenge for an antitrust court lies in stating a general rule for distinguishing

competitors. In trying to differentiate between the two, courts must often parse complex economic theories and evidence, which exacerbates the likelihood of error.[184]

Given that both types of errors are to be expected, Easterbrook called for antitrust law to favor false negatives over false positives, as a way to minimize the costs to consumers of such errors.[185] When a court mistakenly condemns procompetitive conduct, Easterbrook reasoned that mistake has a high cost, because judicial errors are slow to be overturned.[186] The benefits consumers would have received from that procompetitive conduct are lost for the length of time it takes for the judicial error to be overturned. In contrast, when a court mistakenly fails to punish anticompetitive conduct, Easterbrook argued that the error costs are less, because the misconduct is likely to be corrected, at least in part, by market forces.[187] The lure of monopoly profits tends to attract new competitive entry into a market over time, eroding those profits and the harms permitted by the judicial error.[188] Easterbrook's error-cost framing has been deeply influential in modern antitrust jurisprudence, often orienting antitrust courts and scholars toward a preference for false negatives over false positives.[189]

This influence is at the root of concern over innovation chilling in decisions like *Mylan*, and certain antitrust scholarship. Scholars like Geoffrey Manne and Joshua Wright double down on Easterbrook's warning about the harm from false positives in the context of predatory innovation, arguing that those error costs are exacerbated where

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between exclusionary acts, which reduce social welfare, and competitive acts, which increase it.").

184. Easterbrook, *supra* note 183, at 9 (discussing likelihood that judges will prefer established models of atomistic competition to more complex theories of why practices may be procompetitive).

185. *See id.* at 14-16.

186. *Id.* at 2.

187. *Id.* at 3 ("[J]udicial errors that tolerate baleful practices are self-correcting, while erroneous condemnations are not.").

188. *See id.* at 21.

189. *See, e.g.*, Geoffrey A. Manne & Joshua D. Wright, *Innovation and the Limits of Antitrust*, 6 J. COMPETITION L. & ECON. 153, 156 (2009) (describing Easterbrook's error-cost framework as "one of the most influential contributions to antitrust law and economics"); Fred S. McChesney, *Easterbrook on Errors*, 6 J. COMPETITION L. & ECON. 11, 11-13 (2010) (discussing the influence of Easterbrook's error cost approach); Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 414 (2004) ("Mistaken inferences and the resulting false condemnations 'are especially costly, because they chill the very conduct the antitrust laws are designed to protect.' The cost of false positives counsels against an undue expansion of § 2 liability." (quoting Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 594 (1986)); Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 458 (1993) ("[T]his Court and other courts have been careful to avoid constructions of § 2 which might chill competition, rather than foster it.").

anticompetitive conduct involves product redesigns.[190] They argue that false positives in predatory innovation cases cost consumers in both the immediate benefit of the new product in the litigation, and the chilling of future innovation.[191]

Similarly, the *Mylan* court errs on the side of non-intervention, or even non-scrutiny, of product hopping to avoid chilling future innovation. The innovation chilling concerns in *Mylan* echo earlier cases like *Allied Orthopedic*, which emphasized judicial restraint out of concern for impeding "as-yet-unknown benefits" of innovation.[192] The central concern is that "[a] seemingly minor technological improvement today can lead to much greater advances in the future."[193]

Cases like *Mylan* seem to take Easterbrook's caution to the extreme, accepting at face value that the judicial scrutiny of minor product design changes is likely to harm innovation. The *Mylan* court does not inquire into the plausibility of the defendant's warning over innovation chilling. Instead, in *Mylan*, and all too often in other predatory innovation jurisprudence, the concept of "innovation" is invoked in general terms *because* it prompts an "Easterbrookean" reaction of judicial deference—one that plays on antitrust's deeply-rooted aversions to error costs, innovation chilling, and warnings against courts becoming arbiters of "innovation sufficiency."[194] Defendants are able to invoke the risk of innovation chilling or the "danger" of courts becoming innovation arbiters—whether established on the specific facts or not. This becomes a blunt and immediate shield to antitrust scrutiny.

1. Applying an Industry-Contextual Approach: Judicial Deference in Product Hopping Claims

Instead of this blunt judicial aversion to all things "innovation" related, error-cost assumptions about innovation should instead be tailored to the specific industry, drawing on patent and economic insights about how innovation occurs. The degree of judicial deference should vary based on whether the defendant's innovation chilling arguments are plausibly consistent—or inconsistent—with the established characteristics of innovation in the industry at stake.

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190. *See* Manne & Wright, *supra* note 189, at 164-72 (arguing that error costs are higher where innovation is at stake).

191. *See id.*

192. Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP, 592 F.3d 991, 1000 (9th Cir. 2010).

193. *Id.*

194. Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co., 838 F.3d 421, 440 (3d Cir. 2016).

First, economic and patent research suggest that the characteristics of innovation are specific to each industry.[195] It is fair to assume that, whether patent policy or antitrust claims are being considered in an industry, the innovation traits are inherent to the industry itself and so would remain the same across various types of litigation. The processes and characteristics of new drug development, for example, transcend any specific litigation related to that drug and would not suddenly shift with the doctrinal context of contemporaneous litigation in patent law and antitrust law.[196]

Second, the innovation chilling claims a defendant makes in any given case may or may not be consistent with the nature and processes of innovation within a given industry. Where a party claims a risk of innovation harm that is consistent with industry innovation dynamics, courts should lend greater credence to the risk of such innovation impacts. The product redesign should be afforded a higher degree of judicial deference, because false positive error costs are likely greater where the very nature or characteristics of innovation driving that industry are at stake. There is a plausible risk that judicial intervention could harm innovation, as it is understood within that specific industry.

But conversely, where there is a mismatch between the claim of innovation chilling and the nature of innovation within the industry, courts should be more skeptical of generalized assertions that judicial scrutiny of product redesign (and associated conduct) will chill innovation. If judicial deference is driven by the perceived risk of chilling future innovation (as it often seems to be), this concern is lessened in this scenario of mismatch between defendant arguments and innovation characteristics. The degree of deference should be reduced accordingly. The likely costs to consumers of a false positive decision are less where any such costs are unrelated to the nature, process, or form of innovation that drives a particular industry. This approach roots judicial deference in the economic and patent-informed reality of industry-specific innovation, rather than employing sweeping error cost assumptions, which have less force when situated within specific industries.

This approach could be developed further into industry-specific presumptions over time, as antitrust law accumulates precedent around

195. *See supra* Part III.A (discussing patent and economic literature on industry-specific innovation traits).

196. Over the long term, it is possible that the manner in which innovation occurs in an industry may change. It is not clear that this would be an issue, on the assumption full-scale, revolutionary changes in innovation models would likely occur over time, and these changes could be reflected in the common law.

the various traits and characteristics of innovation in particular industries. When a party claims that judicial scrutiny will chill innovation, but its arguments rely on conceptions of innovation that are inconsistent with the industry innovation dynamics, the starting presumption would be one of lessened judicial deference. This would place the court in an orientation akin to the approach in *Microsoft* or *Namenda*. In contrast, when a party makes innovation chilling arguments that are consistent with the industry innovation dynamics, the starting presumption would be one of heightened judicial deference, closer to that afforded in cases like *Mylan* or *Allied Orthopedic*.

Though courts may be ill-equipped to predict the future path of innovation, such foresight is not required by this proposed approach. Instead, courts would focus on a more modest inquiry—the plausibility of the innovation impacts claimed within the particular industry innovation context.

How might this industry-contextual approach be applied to reconcile *Mylan* and *Namenda*'s divergent views on innovation effects? The patent literature describes characteristics of pharmaceutical drug innovation that are much closer to the innovation picture painted by *Namenda* than that of *Mylan*.[197] That literature indicates that prescription drug innovation centers on long-term, expensive, blockbuster drug development.[198] The minuscule design changes at stake in product hopping claims—a change in pill scoring, or a move from capsule to tablet—are far removed from that established picture of pharmaceutical innovation models and processes. In fact, the incremental nature of the redesign is at the core of product hopping allegations—it is the insignificant nature of the design change that lends credence to the plaintiff's arguments that the design was introduced to exclude competition, rather than to improve the product.

Further, in cases like *Mylan*, the innovation-chilling arguments invoked to shield product hopping from antitrust scrutiny are inconsistent with the pharmaceutical drug industry's own characterization of innovation processes in patent policy.[199] As Gregory N. Mandel observes, pharmaceutical and biotechnology industries "have argued . . . strenuously that strong patent protection is critical to the

197. *See supra* Part III.A (describing patent literature on pharmaceutical drug innovation).

198. *Id.*

199. *See* FTC REPORT ON COMPETITION AND PATENT LAW, *supra* note 121, at 9 ("Participants in the Hearings [including the Pharmaceutical Research and Manufacturers of America] overwhelmingly expressed the view that patent rights for pharmaceuticals are essential for brand-name companies to prevent free riding and recoup their significant investments . . . .").

survival of their industries and to continued technological innovation."[200] The exceptionally long and expensive nature of prescription drug development is invoked by branded pharmaceutical makers to justify strong patent protection, as an incentive driving drug innovation. Yet the minor tweaks or minimal design changes being challenged in product hopping cases seem unrelated to this vision of pharmaceutical drug innovation. If minor redesigns are so all-important to innovation, as branded companies claim in product hopping litigation, those changes could be accomplished more quickly and cheaply than the average of $2.6 billion over ten years for drug development, which the pharmaceutical industry cites in defense of strong patent protection.[201] In other words, there is a mismatch between the concern in *Mylan* over judicial scrutiny of minor drug redesigns (at the end of a related patent term) and the better-established patent understanding of the long term, capital, and regulation-heavy paths of pharmaceutical drug innovation.

Could it be that both are true—that the chilling of minor drug redesigns will also affect blockbuster drug innovation? In short, could incremental, small changes lead to later, major inventions? Scholars calling for heightened deference toward product hopping argue it is "well-established" that drug innovation, even when it involves small changes in product designs, can generate significant but unpredictable consumer benefits.[202]

Here, again, it proves helpful to consider industry innovation context, which refutes this purported connection between incremental and significant innovation. In a study of 1,500 FDA drug approvals, innovation researchers found that a company's prior experience in breakthrough innovations—defined as new active ingredients never before marketed in the United States—increases the likelihood that the

200. Mandel, *supra* note 121, at 23.

201. DiMasi et al., *supra* note 123, at 26.

202. Wright & Ginsburg, *supra* note 177, at 2. Wright and Ginsburg point to one study indicating medical and economic benefits from incremental innovation in biopharmaceuticals, including new indications, new dosages, new combinations, new formulations, and labeling for expanded populations (Ernst R. Berndt, Iain M. Cockburn & Karen A. Grépin, *The Impact of Incremental Innovation in Biopharmaceuticals: Drug Utilisation in Original and Supplemental Indications*, 24 PHARMACOECONOMICS 69-86 (2006)). The Berndt et. al. study includes drug variations, like new indications and combinations, distinct from those at issue in product hopping cases, and the study is based on three types of biopharmaceuticals. Biopharmaceuticals comprise only an estimated twenty percent of pharmaceuticals. *See, e.g.*, Ralf Otto et al., *Rapid growth in biopharma: Challenges and opportunities*, MCKINSEY & COMPANY (Dec. 1, 2014), http://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/rapid-growth-in-biopharma.

company's current innovations will also be breakthroughs.[203] In contrast, prior experience in incremental innovation did not impact the likelihood of breakthrough innovation for branded companies.[204] Incremental innovation was defined to include new drug applications for previously-marketed chemical types (among other developments),[205] a definition that would encompass the product redesigns at issue in many of the product hopping cases. This research is consistent with the patent literature, which concludes that "the pharmaceutical industry is not driven by either cumulative or complementary innovation."[206] Applied to product hopping, this research suggests the minor drug improvements at stake in such litigation are unlikely to amount to consequential later breakthroughs in prescription drugs, regardless of antitrust law scrutiny.

Informed by this industry innovation context, the costs to consumers of a false positive product hopping decision appear to be lessened. If a judicial decision condemns a minor drug redesign (whether mistakenly or because it is anticompetitive) and the effect is to chill minor modifications to existing drugs, the industry innovation context suggests that dynamic, long-term drug discovery will continue largely unabated. Though the next tablet-to-pill conversion may not occur, the next blockbuster drug will.

In fact, the narratives of the *Mylan* defendant (and scholars) claiming that small, incremental changes that lead to later, significant innovation sound much more like the software industry's cumulative innovation model.[207] Computer programs improve with each version, as previous code evolves bit-by-bit into something novel. It is difficult to imagine that the minor redesigns in product hopping cases transcend the deeply-rooted and systematic differences between pharmaceutical and software innovation to render minor changes of major importance to future innovation. *Mylan*'s concern over shielding trivial drug changes from antitrust scrutiny is at odds with this broader understanding of how innovation occurs in the pharmaceutical drug industry.

In contrast, *Namenda* simply adopts the industry-realist view—argued by the industry itself in the patent policy context—that

203. Denise Dunlap-Hinkler et al., *A Story of Breakthrough Versus Incremental Innovation: Corporate Entrepreneurship in the Global Pharmaceutical Industry*, 4 STRATEGIC ENTREPRENEURSHIP J. 106, 121 (2010).

204. *Id.* (defining incremental innovation to include ANDAs (abbreviated new drug applications), generic drugs equivalent to existing drugs, new drug applications for chemical types that had been marketed before in the United States, and new efficacy supplemental applications for existing drugs).

205. *Id.* at 115.

206. Lemley, *supra* note 19, at 644.

207. *See* Part III.A (discussing the characteristics commonly seen in software innovation).

pharmaceutical markets are driven by long-term, episodic innovation. The Second Circuit rejected the defendant's arguments about pharmaceutical innovation chilling, because the defendant provided no evidence to support the claimed effects.[208] The court then adopted the view argued by *amici*—that meaningful innovation is unlikely to be impacted by antitrust scrutiny of the conduct.[209] In a case like *Namenda*, the presumptions proposed above on innovation-context would stand unrebutted.

Finally, it is possible that the relevant market in an antitrust case innovates in a manner distinct from the industry as a whole. If the defendant makes such an argument, then courts should demand proof from the defendant of this distinction.[210] This is also consistent with the approach of *Namenda*, where the court required evidence to establish innovation claims.

As this section demonstrates, industry context is valuable. It informs the judicial divide on the appropriate level of deference to innovation. In place of a monolithic, generalized aversion to the risk of innovation chilling, this Article calls for an industry-specific approach in which innovation context (based on industry traits and evidence) informs the appropriate level of judicial deference to redesigns and is used to scale that deference to the likely risk that antitrust law will "chill[] or stifle[] innovation."[211]

2. Applying an Industry-Contextual Approach: Judicial Deference to Redesign in Other Industries

This Article focuses on the pharmaceutical and software industries because (i) the innovation models of those industries are often contrasted as extremes of one another, making them useful to illustrate how industry context could influence judicial logic and (ii) several leading predatory innovation cases take place in the pharmaceutical and software industries. However, the proposed industry-contextual approach to

208. New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 659 (2d Cir. 2015).

209. *Id.*

210. For example, there are early indications that the sub-specialty of biologics in pharmaceuticals may have different timelines and development approaches than the classical blockbuster drug model of the pharmaceutical companies described here. *See, e.g.*, Ajay Gautam & Xiaogang Pan, *The Changing Model of Big Pharma: Impact of Key Trends*, 21 DRUG DISCOVERY TODAY 379, 379 (2016).

211. C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1372 (Fed. Cir. 1998); *see similarly* Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 414 (2004) (observing the chilling effect of false positives on the conduct antitrust law seeks to promote).

judicial deference could also be usefully extended to predatory innovation analysis in other industries.

Patent scholars, economists, and the Federal Trade Commission have investigated, modeled, and categorized rich understandings of the ways in which innovation occurs in many industries, from medical devices and biotechnology to semiconductors, computer hardware, and beyond.[212] Those insights are useful for bringing industry context to predatory innovation claims within these other industries.

For example, consider two leading predatory innovation cases, both of which involve medical devices: *Allied Orthopedic* (challenging a redesigned pulse oximetry sensor)[213] and *C.R. Bard* (challenging a redesigned tissue biopsy gun).[214] In both, the plaintiff competitors alleged that the defendant's redesign rendered their complementary products incompatible, excluding competition in violation of Section 2 of the Sherman Act.[215] The decisions seem to diverge in their views of the appropriate level of judicial deference toward product redesigns (though this is explained in part by the more substantial nature of the design improvement in *Allied Orthopedic*).

The *Allied Orthopedic* court found that the disputed redesign was an improvement, and therefore refused to inquire into its costs and benefits, explaining that "[a] seemingly minor technological improvement today can lead to much greater advances in the future. The balancing test proposed by the plaintiffs would therefore require the court to weigh as-yet-unknown benefits against current competitive

212. *See, e.g.*, FTC REPORT ON COMPETITION AND PATENT LAW, *supra* note 121 (considering competition and the promotion of innovation through patent rights in biotechnology, pharmaceuticals, computer hardware and computer software); Mandel, *supra* note 121, at 33 (categorizing innovation characteristics of the biotechnology, pharmaceutical, software, semiconductor, medical device, telecommunication, mechanical, financial, and information technology industries); *see generally* Ashish Arora et. al., *R&D and the Patent Premium*, 26 INT'L J. INDUS. ORG. 1153 (2008) (discussing value to innovation of patenting for biotechnology, pharmaceutical, and medical device companies and finding it varies by industry); David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, 85 TEX. L. REV. 1677, 1687 (2007); Bronwyn H. Hall & Rosemarie Ham Ziedonis, *The Patent Paradox Revisited: An Empirical Study of Patenting in the U.S. Semiconductor Industry, 1979–1995*, 32 RAND J. ECON. 101, 102 (2001).

213. Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP, 592 F.3d 991, 993-94 (9th Cir. 2010) (alleging unlawful monopoly maintenance in violation of Section 2 of the Sherman Act based on the introduction of a new pulse oximetry monitor/sensor system, which rendered the defendant's monitors incompatible with competing, generic sensors).

214. C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1347 (Fed. Cir. 1998) (noting that redesign of a biopsy gun excluded competitor needles previously compatible with the gun design).

215. *Allied Orthopedic Appliances Inc.*, 592 F.3d at 991; *C.R. Bard, Inc.*, 157 F.3d at 1340.

injuries."[216] The court emphasized "the undesirability of having courts oversee product design" and the "dampening of technological innovation" that could result.[217]

C.R. Bard includes a dissent that parallels *Allied Orthopedic*. It would refuse to inquire into design changes that are an "improvement" by some measure.[218] The dissent then sets forth the judicial warning where this Article began—that antitrust intervention in product design choices may chill or stifle innovation.[219]

The majority in *C.R. Bard*, however, affirmed the jury finding that the redesign was exclusionary and anticompetitive.[220] As one concurring opinion explains, the dissent's concern over ambiguous "chilling" of innovation should be dismissed in favor of specific evidence, which indicates that the redesign may not have been an improvement, and that the defendant modified its biopsy gun to exclude competition.[221]

Given these differences between *Allied Orthopedic* and *C.R. Bard*, how could industry context inform the appropriate degree of judicial deference toward medical device redesigns? It would suggest that *Allied Orthopedic*'s concern over innovation chilling is overestimated, given the nature of innovation within the medical device industry. Patent scholars observe that the medical device industry shares a number of innovation characteristics with the pharmaceutical drug industry.[222] Medical device invention is research and development intensive, although slightly less so than pharmaceutical invention.[223] Like pharmaceuticals, medical devices can be easy to reverse engineer once released onto the market, meaning the industry depends on patent protection to appropriate returns from innovation.[224] Perhaps most importantly, the patent literature suggests that medical device invention

216. *Allied Orthopedic Appliances Inc.*, 592 F.3d at 1000.

217. *Id.*

218. *C.R. Bard*, 157 F.3d at 1372 (Newman J., dissenting on antitrust claims).

219. *Id.* ("[A]ntitrust jurisprudence has well understood that the enforcement of the antitrust laws is self-defeating if it chills or stifles innovation." (citing *In re* IBM Peripheral EDP Devices Antitrust Litig., 481 F. Supp. 965, 1002-05 (N.D. Cal. 1979), *aff'd sub nom.* Transamerica Comput. Co. v. Int'l Bus. Machs. Corp., 698 F.2d 1377 (9th Cir. 1983)).

220. *C.R. Bard, Inc.*, 157 F.3d at 1374 (Mayer, C.J., concurring in part and dissenting in part) (agreeing to sustain the jury verdict on the antitrust counterclaim in part and form the majority).

221. *Id.* at 1382-83 (Bryson, J., concurring in part and dissenting in part) (agreeing to affirm the jury finding that Bard had monopoly power and acquired or maintained that power through restrictive or exclusionary conduct).

222. *See* Mandel, *supra* note 121, at 33 tabl.1 (comparing research and development intensity of medical devices, pharmaceuticals and other industries).

223. *Id.*

224. *Id.* at 29-30.

tends to be episodic or "stand-alone" in its development, rather than cumulative or incremental from prior inventions.[225]

With this added context, *Allied Orthopedic*'s worry that "[a] seemingly minor technological improvement today can lead to much greater advances in the future,"[226] appears largely unfounded. First, as in *Mylan*, there is inconsistency between the claimed innovation-chilling risk for small design changes and the episodic nature of innovation in the industry. The court worried that innovation would be harmed by antitrust scrutiny of minor design tweaks in medical devices, yet *Allied Orthopedic* took place in an industry where medical device innovation is episodic, occurring in major design leaps. Because of this mismatch, the likely costs to consumers of false positive decisions are lessened—the design changes being challenged are largely unrelated to the type of innovation that drives the industry (unless the defendant can prove a connection between such minor changes and later innovative leaps in medical devices). Even if a judicial decision condemns the minor redesign of an existing medical device—whether mistakenly or because it is part of anticompetitive conduct—the next new device remains likely to be invented.

Second, none of the defendants in *C.R. Bard* or *Allied Orthopedic* provided evidence that, in their specific market for medical devices, innovation occurs in a manner that is distinguishable from the industry as a whole, wherein minor design changes affect innovation. Such evidence, if it existed, could have substantiated the concerns over innovation chilling. This initial look suggests a mismatch between the asserted risk and the industry context, though other characteristics of innovation in the medical device industry may well inform this analysis in more depth.

Overall, this industry context helps to inform and tailor predatory innovation analysis to the medical device industry. *Allied Orthopedic*'s deep concern over future innovation chilling looks over-stated when viewed through an industry-specific lens.[227] Though the reasoning in

225. *Id.* at 33 tbl.1 (finding that both pharmaceutical and medical device industries engage primarily in stand-alone, rather than cumulative, innovation).

226. Allied Orthopedic Appliances, Inc. v. Tyco Health Care Grp. LP, 592 F.3d 991, 1000 (9th Cir. 2010).

227. Despite its strong opinions on innovation chilling risk, as noted above, *Allied Orthopedic* was ultimately decided on other grounds—the redesign was found to be a significant improvement, and there was no "associated anticompetitive conduct" through which the defendant exerted its market power. *Id.* at 1002.

C.R. Bard is limited, and less than perfect,[228] the majority appears correct in its willingness to defer to jury views on evidence specific to the device redesign, emphasizing this evidence over generalized assertions of future innovation harms.

B. Applying an Industry-Contextual Approach to the Consumer Choice Paradigm

This section applies an industry-contextual approach to another important dimension of predatory innovation reasoning: the use of consumer choice (or coercion) as a proxy to determine whether a redesign is anticompetitive. It argues that product-hopping cases have over-extended the logic of the leading precedent on consumer choice, *Berkey Photo, Inc. v. Eastman Kodak Co*., by exporting it from an industry where consumer choice is a plausible proxy for innovation (cameras and film), to an industry where it is not (prescription drugs). The result is an unprincipled approach to deciding product hopping claims that may be both over and under-inclusive of anticompetitive conduct.

1. Tracing the Origin of Consumer Choice Theory in Predatory Innovation Claims

The use of consumer preference or "choice" to decide predatory innovation claims is often premised on the leading decision of *Berkey Photo, Inc. v. Eastman Kodak Co*.[229] At the time of this 1979 case, Kodak was the dominant seller of film and cameras.[230] The company had just introduced a new camera and film system to the market.[231] The new film design was, at least initially, only compatible with Kodak's own redesigned cameras.[232] Kodak's product design changes caused the plaintiff competitor, Berkey Photo, to lose camera sales, because Berkey could not offer consumers a camera that was compatible with the popular new Kodak film format.[233] Berkey brought a predatory innovation claim, alleging that Kodak's introduction of the new film/camera system

228. The concurrence in *C.R. Bard* emphasizes intent evidence, which can be problematic. *See supra* Part II.B.3 (discussing the flaws of intent-based analysis of predatory innovation claims).

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

230. *Id.* at 269.

231. *Id.* at 270.

232. *See id.*

233. *Id.* at 269-70.

was an unlawful monopolization of the camera market, and, further, that Kodak was leveraging its film monopoly into the camera market.[234]

The Second Circuit found that Kodak's introduction of the camera/film redesign was not anticompetitive,[235] and based its reasoning on the role of consumer preference in the relevant market. It was unclear on the evidence whether Kodak's new products constituted "improvements" over the old designs.[236] In some respects the new camera/film combination was more desirable than the older design—the camera was smaller and more portable, with new red-eye reduction features, while the associated film produced more finely-grained pictures than the previously available film.[237] However, evidence also showed that the new film was less desirable to consumers in other respects—in particular, it had a shorter shelf life in storage than the prior designs.[238]

Given these varying dimensions of quality, the court viewed any preference between the old and new versions as a matter of individual consumer taste.[239] Kodak had left its older film design available on the market, yet consumers were freely choosing Kodak's new products, with no evidence of coercion by the company.[240] If the new film spurred sales of the new camera, "it did so because some consumers regarded it as superior" upon weighing the various different features and qualities.[241] The court explained this view as a matter of judicial deference: "[i]f 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."[242] Thus in *Berkey Photo*, consumer preference for the redesign was the "major logical underpinning" for the court's refusal to inquire further into the alleged anticompetitive effects of Kodak's new products.[243] The court deferred to the market popularity of Kodak's new system as a means to find that the redesign was not anticompetitive—in effect, it used a consumer referendum in the marketplace to judge innovation. Since consumers were freely choosing the product redesign, the court deferred

234. *Id.* at 278. The case involved both Section 2 Sherman Act claims, discussed here, and Section 1 Sherman Act claims which are not discussed.

235. *Berkey Photo*, 603 F.2d at 268.

236. *Id.* at 286.

237. *Id.* at 286-87.

238. *Id.* at 286.

239. *Id.* at 287.

240. *Id.*

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

242. *Id.*

243. Abbott Labs. v. Teva Pharm. USA, Inc. (*TriCor*), 432 F. Supp. 2d 408, 421 (D. Del. 2006) (describing *Berkey Photo*, 603 F.2d at 263).

to that choice rather than substitute its own opinion on the merits of the product changes.[244]

Berkey Photo went on to explain, in *obiter dicta*, how its analysis would be impacted if, instead, the monopolist had denied consumers the opportunity to choose between the old and new product designs.[245] In a footnote, the court indicates "the situation might be completely different" if Kodak had stopped producing the film used in its old cameras, thereby coercing consumers to purchase the redesigned product.[246] In that hypothetical situation, *Berkey Photo* would not have relied upon consumer preference to answer whether the redesign was procompetitive.[247] Instead, where there is no consumer choice, the court explained that "the technological desirability of the product change" might influence the outcome of the case.[248] The judge or jury may need to inquire into whether the redesign was technologically desirable—its merits—to adjudicate the predatory innovation claim.

2. Product Hopping Cases Over-Extend the Consumer Choice/Coercion Paradigm

In *Namenda*, the Second Circuit picked up this *dicta* on consumer choice from *Berkey Photo*, and crystallized it into a new analytical standard for product hopping claims.[249] The *Namenda* court reasoned that, when a monopolist withdraws its old drug design from the market, this action coerces consumers into accepting its redesigned version.[250] It views this consumer compulsion as the "completely different" situation contemplated by *Berkey Photo* in a footnote.[251] In a footnote of its own, *Namenda* then recasts judicial history somewhat, describing the approaches to predatory innovation in *Allied Orthopedic*, *Microsoft* and other cases as premised on consumer coercion—despite limited emphasis on choice analysis in these cases.[252] The court concludes that product hopping is plausibly anticompetitive under Section 2 of the

244. *Berkey Photo*, 603 F.2d at 287.
245. *Id.* at 287 n.39.
246. *Id.*
247. *See id.*
248. *Id.*
249. New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 652-53 (2d Cir. 2015). *Namenda* was the first Circuit Court decision to endorse this consumer choice analysis, but see also lower court decisions before *Namenda* that took this approach, such as Abbott Labs. v. Teva Pharm. USA, Inc. (*TriCor*), 432 F. Supp. 2d 408, 421 (D. Del. 2006).
250. *Namenda*, 787 F.3d at 652-53.
251. *Id.* at 653.
252. *Id.* at 652-53 n.23 (referencing the *Mylan* district court decision).

Sherman Act when a monopolist "coerce[s] consumers rather than persuade[s] them on the merits" to use its new product design.[253]

Applying this law to the facts, the *Namenda* court found that the defendants had "coerced" consumers into using their redesigned drug with its impending withdrawal of the old product from the market.[254] Since the withdrawal was expected to occur before any generic equivalent entered the market, there would be no competing drugs in the relevant market.[255] The defendants' planned withdrawal of Namenda IR from the market meant that patients would be forced to switch to the company's Namenda XR reformulation to continue uninterrupted treatment of their Alzheimer's disease.[256] Though *Namenda* itself involved a hard switch only, the court observes that if the defendant had allowed the old drug design to remain on the market, "doctors and Alzheimer's patients could have decided" freely whether to switch to the redesigned drug, or to use the generic version of the old design instead.[257] Given this coercion, the *Namenda* court found the defendants' product redesign was plausibly anticompetitive.[258]

This consumer coercion reasoning in *Namenda* has become the touchstone for motions to dismiss in product hopping claims.[259] Courts are permitting claims to proceed when the defendant has allegedly engaged in a so-called "hard switch," meaning the defendant removed its old drug design from the market so that consumers were not afforded a choice between the old and new drugs.[260] When the defendant has instead engaged in a "soft switch," meaning both the old and new drug formulation continue to be sold at the same time, product hopping claims

253. *Id.* at 654.

254. *Id.* at 652 ("Well-established case law makes clear that product redesign is anticompetitive when it coerces consumers and impedes competition.").

255. *Id.* at 654.

256. *Id.*

257. *Id.* at 655.

258. *Id.* at 662.

259. *See, e.g.*, *In re* Loestrin 24 FE Antitrust Litig., 261 F. Supp. 3d 307, 353 (D.R.I. 2017); *In re* Asacol Antitrust Litig., 233 F. Supp. 3d 247, 269-70 (D. Mass. 2017).

260. *In re* Loestrin 24 FE Antitrust Litig., 261 F. Supp. 3d at 354 (finding the alleged conduct constituted a "hard" switch); *In re* Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., 64 F. Supp. 3d 665, 681-84 (E.D. Pa. 2014) *reconsideration in part*, 2015 WL 12910728 (E.D. Pa. Apr. 14, 2015) (denying motion to dismiss where the defendant allegedly coerced patients into switching from the tablet form of a drug—for which their patent was set to expire—to a new film version of the drug, by raising false safety concerns about the tablet and announcing that it would soon be withdrawn from the market); Abbott Labs. v. Teva Pharm. USA, Inc. (*TriCor*), 432 F. Supp. 2d 408, 415 (D. Del. 2006) (denying motion to dismiss where defendants conduct allegedly resulted in "consumer coercion").

are being dismissed at the preliminary motion stage, with a finding of no cognizable antitrust law violation.[261]

The hard switch cases have found consumer coercion where the monopolist actively removes the old product design from the market through various means.[262] This includes the monopolist buying back inventory of its old drug design to remove it from the market,[263] marking the original drug formulation as obsolete in Medicare formularies or other databases (which prevents substitution of a generic version of the original drug),[264] raising false safety concerns about the generic version of the original drug[265] and various combinations of similar conduct.[266]

In contrast, soft switches involve actions such as aggressive marketing by the defendant to shift patient demand over to the company's new branded drug design.[267] The major distinction being drawn between this conduct and the hard switch cases is that consumer choice between the old and new branded formulation is thought to persist, despite the defendant's actions. Applying *Berkey Photo*, as adopted in *Namenda*, courts reason that the judiciary should not substitute its opinions on the merit of the redesigned product where consumers remain free to choose between the new or old design in the market.[268]

Unfortunately, the application of this consumer choice paradigm to "soft switch" cases over-extends the logic of *Berkey Photo*. It disregards the very premise for deference to consumer choice that drives the

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261. *Compare* "hard switch" cases *supra* note 260, *with* "soft switch" cases such as *In re Asacol Antitrust Litig.*, 233 F. Supp. 3d at 269-70 (refusing to consider whether conduct was anticompetitive after finding it constituted a "soft" switch, dismissing soft switch claims); Walgreen Co. v. AstraZeneca Pharm. L.P., 534 F. Supp. 2d 146, 150-52 (D.D.C. 2008) (dismissing claims for alleging attempted market monopolization because, in contrast to *TriCor*, 432 F. Supp. 2d at 408, "there is no allegation that AstraZeneca eliminated any consumer choices. Rather, AstraZeneca . . . introduced a new drug to compete with already-established drugs—both its own and others'—and with the generic substitutes for at least one of the established drugs").

262. *See* cases cited *supra* note 261.

263. *See, e.g.*, *TriCor*, 432 F. Supp. 2d at 416 (denying motion to dismiss where brand manufacturer bought back existing supply of old formulation of drug from pharmacies).

264. *Namenda*, 787 F.3d at 648 (defendant's strategy for the product switch included efforts to have the old, branded drug removed from the formulary list, to end its coverage by Medicare).

265. *In re* Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., 64 F. Supp. 3d 665, 681-84 (E.D. Pa. 2014), *reconsideration in part*, 2015 WL 12910728 (E.D. Pa. Apr. 14, 2015).

266. *See, e.g.*, *TriCor*, 432 F. Supp. 2d at 416 (buying back the old drug formulation and marking the formulation "obsolete" in database indicating FDA-approved drugs).

267. *See, e.g.*, *In re* Asacol Antitrust Litig, 233 F.3d 247, 269-70 (D. Mass. 2017).

268. *See, e.g.*, *id.* at 269; *In re* Loestrin 24 FE Antitrust Litig., 261 F. Supp. 3d 307, 354 (D.R.I. 2017) (citing *Namenda*, 787 F.3d at 659 to find a "hard switch" is alleged).

reasoning in *Berkey Photo*: consumer preference—in fact—for the new product.[269] This preference for the newly redesigned camera operated as a proxy, indicating that the new camera was an improvement over the prior design. Product hopping cases have exported this logic of deference to consumer choice from markets where consumer choice is occurring in fact (cameras and film) to markets where choice is deeply distorted, even in the absence of the monopolist's misconduct (prescription drugs).

When it comes to consumer choice, prescription drug markets are fundamentally distinct from the market for cameras and film in *Berkey Photo*. In markets like those for film and cameras, absent misconduct, it is reasonable to expect that consumers will weigh the various characteristics of the old and new product designs—the price, features, quality and innovation. In this type of well-functioning market, courts can fairly assume that the success of a redesigned product is evidence that the redesign is innovative or otherwise valuable to consumers.[270]

In contrast, the FTC warns that such an inference of innovation is "not always warranted in the pharmaceutical marketplace," because of the unique separation between drug payor and drug user.[271] In many prescription drug markets, consumers exercise little direct choice over the drugs that are prescribed to them. These markets are characterized by an unusual disconnect between the doctor or pharmacist, who chooses the drug, and the patient, or, more often, the third-party insurer who pays for the drug. In this complex decision-making process, no single party weighs the bundle of attributes of a new drug design, such as price, innovativeness, and quality. Since the physicians who choose the prescription drugs "do not internalize the economic costs" of anticompetitive product redesigns, popularity in the market may not signal that end consumers value the new design.[272]

Instead of the bundle of overall attributes driving product choice, as *Berkey Photo* assumed, drug decisions are influenced by factors like insurance coverage and pharmacy-level substitutability, which may have little to do with product merit.[273] The result is that the popularity of a

269. *See* Berkey Photo, Inc. v. Eastman Kodak Co. 603 F.2d 263, 286-87 (2d Cir. 1979).

270. *See, e.g.*, *Berkey Photo*, 603 F.2d at 287.

271. Brief for Federal Trade Commission as Amicus Curiae Supporting Plaintiff-Appellant at 14, Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co., 838 F.3d 421 (3d Cir. 2016) (No. 15-2236), https://www.ftc.gov/system/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.warner-chilcott-plc-et-al./151001mylanamicusbrief.pdf.

272. *Id.* at 14; *see also id.* at 4 ("Empirical studies confirm that physicians are often poorly informed about drug prices and the availability of cheaper alternatives.").

273. *Id.* at 4 (discussing market distortions in prescription pharmaceuticals, explaining the role of insurance and "[p]atients have little influence in determining which products they will

prescription drug redesign will not necessarily indicate its superiority over the prior design. There may simply be other market forces driving drug selection. This is particularly true in product hopping cases, where the disputed changes are minor,[274] meaning the change may not have the therapeutic advantages that would be expected to influence a physician's selection of drug for a patient. The reality of these industry distinctions means that courts cannot simply export the rationale from *Berkey Photo* to justify judicial deference toward prescription drug redesigns. By allowing product hopping in prescription drug markets on the premise of "choice," courts ignore these unique pharmaceutical industry distortions.

Economic literature dating back to the 1960s recognizes these distortions in prescription drug markets.[275] However, as Carrier and Shadowen point out, the idea began to appear only much later in the legal literature, beginning around 2000.[276] Still today, the implications of the price/choice disconnect in prescription drug markets have not fully permeated judicial reasoning on product hopping. Though *Mylan* and *Namenda* pay lip service to the unusual separation between buyer and patient in pharmaceutical markets,[277] neither recognizes how this difference limits the utility of consumer choice in deciding product hopping claims.

A careful look back at the predatory innovation jurisprudence reveals that this limit on the *Berkey Photo* reasoning was recognized just two years after the decision itself, in a case called *Northeastern Telephone Company v. American Telephone & Telegraph Company*

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buy and what prices they must pay for prescriptions" (quoting FTC, DRUG PRODUCT SELECTION, STAFF REPORT, BUREAU OF CONSUMER PROTECTION 2, 3 (1979)); *id.* at 5 ("[R]etail pharmacies have financial incentives to make efficient generic substitutions because they compete with other pharmacies on price and because they earn greater profits on generics than brand-name drugs.").

274. Carrier & Shadowen, *supra* note 28, at 181 (describing the minor nature of product hopping design changes).

275. *Id.* at 180 n.62 (tracing economic literature on the price/choice disconnect in pharmaceutical markets).

276. *Id.*

277. New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 645-46 (2d Cir. 2015) ("[T]he pharmaceutical market is not a well-functioning market. . . . The doctor selects the drug, but the patient, or in most cases a third-party payor such as a public or private health insurer, pays for the drug. As a result, the doctor may not know or even care about the price and generally has no incentive to take the price into account."); Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co., 838 F.3d 421, 440-41 (3d Cir. 2016) ("[C]ourts may need to be cognizant of the unique separation between consumers and drug manufacturers in the pharmaceutical market, especially in cases where there is evidence of extreme coercion . . . .").

(*Northeastern*).[278] The case involved a product redesign, as well as telecommunications regulation which eliminated consumer choice. The plaintiff in *Northeastern* alleged that AT&T had purposefully mis-designed a piece of its interconnection equipment, called protective couplers, to impair compatibility with competitor's telecommunications equipment and to reduce the quality of competing services that interconnected with AT&T's network.[279]

In earlier proceedings, the Federal Communications Commission (FCC) had ordered AT&T to allow third-party interconnection.[280] However, AT&T had won a related concession from the agency: a tariff that required all third parties who interconnected with the AT&T network to use only AT&T-supplied protective couplers.[281] The couplers were meant to guard AT&T's network from electrical problems that could be caused by interconnection with faulty third-party equipment.[282] The plaintiff, Northeastern, supplied third-party interconnection equipment that was used in conjunction with AT&T's tariff-mandated couplers.[283]

Northeastern complained that AT&T had intentionally mis-designed the couplers, "making them unnecessarily expensive and subject to break down," as a way to continue to exclude competition from AT&T's network, despite the FCC mandate to provide third-party access.[284] Northeastern argued that the couplers were designed to work poorly with the technical standards of competing equipment, and to rely unnecessarily on an external power source.[285] The disputed design flaws meant that, during a power failure, Northeastern's customers would lose telecommunications services, while customers using AT&T affiliated equipment would continue to receive phone service.[286] Northeastern claimed its own couplers were technologically superior, and that, but for the FCC tariff, it could have supplied those couplers for use by its customers.[287]

278. *See* Ne. Tel. Co. v. Am. Tel. & Tel. Co., 651 F.2d 76, 79 (2d Cir. 1981). The decision colorfully casts Northeastern as the "mosquito challenging an elephant" of AT&T and related entities. *Id.* at 80.

279. *Id.* at 81.

280. *Id.* at 79-80.

281. *Id.* at 80-81 (explaining tariffs for protective couplers following the FCC decision to require interconnection, *In re* Use of Carterfone Device, 13 F.C.C.2d 420, *reconsideration denied*, 14 F.C.C.2d 571 (1968)).

282. *Id.* at 81.

283. *See id.* at 80-81.

284. *Northeastern*, 651 F.2d at 81.

285. *Id.*

286. *Id.* at 81 n.5.

287. *See id.* at 81.

The Second Circuit found that *Berkey Photo's* choice-based rationale did not apply to this predatory innovation claim in the telecommunications industry.[288] Remanding the claim for a new trial on other grounds, the court explained that:

> In other circumstances, we might be reluctant to allow a jury to second-guess engineers' decisions as to the proper construction of a sophisticated piece of equipment [the couplers]. But in this case *we cannot look to the reaction of the competitive market to determine whether one design is superior to another* [because the FCC tariff gave AT&T the exclusive right to supply the couplers]. . . . *Market forces cannot operate under such circumstances.* Thus, we see no alternative to entrusting the matter of coupler design to the judgment of the jury.[289]

The consumer preference paradigm of *Berkey Photo* could not be logically applied to evaluate the merits of AT&T's coupler design in *Northeastern*, because of the telecommunications industry characteristics. The FCC had granted AT&T the exclusive right to supply the couplers subject to the predatory innovation claim, which meant that buyers of the couplers had no opportunity to weigh the merits of various designs, or to express a preference that could later be a proxy for the judicial assessment of AT&T's product design. Instead, the question of whether the design was built to exclude competition had to be remanded for consideration by a jury.[290] This interpretation of *Berkey Photo* is faithful to the decision itself, which indicates that in the absence of consumer choice, courts may need to inquire into "the technological desirability of the product change."[291]

This understanding of *Berkey Photo*—and the limits of its logic—has been lost over time in the application of consumer choice to product hopping claims. Not unlike the telecommunications industry in *Northeastern*, heavy regulation of prescription pharmaceuticals, along with other unique industry characteristics (such as the disconnect

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288. *Id.* at 79 ("This case presents us with the opportunity to elucidate and to apply the rationale of *Berkey* in the context of the American telecommunications industry," but then finding that the rationale does not apply).

289. *Id.* at 95 n.29 (emphasis added) (citation omitted). The Court found some evidence supporting Northeastern's claim that AT&T had intentionally designed the couplers to impede competition. *See id.* at 94. The case was remanded for a new trial on whether this constituted a Sherman Act violation, due to ambiguity in the jury verdict form for this specific claim. *See id.* at 94-95.

290. *Northeastern*, 651 F.2d at 94-95; *see also* GAF Corp. v. Eastman Kodak Co., 519 F. Supp. 1203, 1228 (S.D.N.Y. 1981) (describing *Berkey* as requiring judicial scrutiny of product redesigns in situations where "market forces cannot operate" (quoting *Northeastern*, 651 F.2d at 95 n.29)).

291. Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 287 n.39 (2d Cir. 1979).

between payor and user) have largely eliminated the opportunity for consumers to assess the bundle of attributes offered by a slightly redesigned drug. The popularity of a redesigned prescription drug does not necessarily signal its superiority over an older drug formulation.

The short hand of consumer choice, embodied in the hard switch/soft switch dichotomy of *Namenda*, is potentially both under and over inclusive in determining whether product hopping is anticompetitive. As Carrier and Shadowen point out, requiring that the defendant coerce consumers may be under inclusive, as it could lead courts to allow "soft" switches that are in fact anticompetitive.[292] The competitive effects, they argue, may occur regardless of the specific means by which the swap occurs, because those effects come from the branded company cannibalizing its own prescription drug base to swap in its redesign, in a price-disconnected prescription drug market.[293] When decisions permit the conduct simply because consumer choice persists, there is no effort to analyze the pro- or anticompetitive effects of that conduct. This leaves unclear whether such switches are harming consumers and competition.

Judicial deference to "choice" therefore becomes problematic in soft switch cases, where courts use it as a shortcut to dismiss cases without assessing anti-competitive effects. For example, in 2017, the Massachusetts District Court in *In re Asacol Antitrust Litigation* quickly and categorically concluded that there could be no antitrust law violation, because the defendant left its old generic drug formulation available on the market.[294] The court reasoned that, in the absence of facts indicating a hard switch, it could not "take into account . . . factors that inform whether" the conduct was anticompetitive, such as "the unique separation between consumers and drug manufacturers in the pharmaceutical market," whether the defendant's patent expiry was imminent at the time the product hop occurred, or weak or inconsistent evidence of procompetitive justifications.[295] Citing *Namenda* and *Berkey Photo*, the court found instead that soft switches do not have an

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292. Carrier & Shadowen, *supra* note 28, at 200 (criticizing *Namenda* for its "coercion-based framework [which] does not make room for potential soft-switch harms that arise from the unique nature of drug markets and that might not make economic sense").

293. *Id.* at 219 (proposing instead a "no-economic-sense" test that would condemn product hopping conduct where it does not make economic sense unless generic competition is impaired).

294. *In re* Asacol Antitrust Litig., 233 F. Supp. 3d 247, 268-70 (D. Mass. 2017).

295. *Id.* at 269-70 ("[T]hose considerations better inform whether a hard switch occurred to assess whether the switch was anticompetitive in nature. Here, where no hard switch occurred from Asacol to Asacol HD, the Court cannot take into account these factors that inform whether a hard switch was monopolistic.").

anticompetitive result because "the market can determine whether one product is superior to another."[296] This blinkered reasoning ignores the unique characteristics of prescription drug markets in favor of an overly-simplified "choice/no choice" paradigm.

It makes little sense to emphasize consumer choice in markets where such choice is distorted for reasons unrelated to the alleged misconduct. It is far beyond the power of antitrust law to create *Berkey Photo*-style "choice in fact" within prescription drug markets. Enabling consumers to choose between prescription drugs directly, as they do for consumer goods, would require fundamental regulatory, political, and structural changes that are far outside the domain of antitrust law, and likely not feasible or desirable. The fiction of "choice" has become a problematic legal gloss, substituting for the analysis of how the impugned conduct affects competition in the market.

The consumer choice paradigm risk overinclusion as well, leading courts to condemn hard switches that are not, in fact, anticompetitive. So far, courts have relied upon the finding of a hard switch only to deny preliminary motions to dismiss.[297] This means the case may proceed to a determination on the merits, where courts could further evaluate the competitive effects of the redesign (unlike the soft switch dismissals, discussed above, which may end the litigation). However, if the consumer choice paradigm were expanded to adjudication of the merits in hard-switch cases, this would be problematic. Conduct could be condemned based on an unprincipled fiction of eliminating "choice" for prescription drugs, rather than on an inquiry into anticompetitive and procompetitive effects.

Courts may be beginning to acknowledge this oversimplification problem in consumer choice analysis. A recent product hopping case, *In re Loestrin 24 Fe Antitrust Litigation*, seems to soften the dichotomy of hard versus soft switches, finding that there can be a hard switch "'in effect' where the branded product remains on the market in some limited fashion," and generic competitors entered the market but are denied the cost-efficient means of increasing competition through generic substitution.[298] The plaintiffs argued that a mere showing of a hard switch was adequate for the case to proceed, but the court found instead that there must be "evidence of conduct *beyond* the hard switch that could support a jury finding that [the defendant] employed

296. *Id.* at 269 (quoting New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 654-55 (2d Cir. 2015)).

297. *See* cases cited *supra* note 260.

298. *In re* Loestrin 24 FE Antitrust Litig., 433 F. Supp. 3d 274, 330 (D.R.I. 2019).

anticompetitive conduct."[299] Since the plaintiff had, in fact, provided such evidence to the jury the court denied the defendant's motion for summary judgment.[300] The case refocuses somewhat on the anticompetitive nature of the defendant's conduct, rather than the formalistic distinction between hard and soft switches.

The lesson from the product hopping jurisprudence is to take careful account of industry context before applying the consumer choice paradigm to predatory innovation claims. Courts should consider the specific characteristics of the industry at issue, and whether consumers have the power and ability to exercise choice over products in a manner wherein such choice is likely to indicate the merit of a product redesign. If so, then as in *Berkey Photo*, consumer preference may be a helpful proxy to signal that a redesign is innovative and, by inference, not anticompetitive.[301] It may be reasonable for courts to defer to such preference in adjudicating the merits of a product redesign. In this type of predatory innovation case, the logic of *Berkey Photo* can continue to be usefully applied. For example, past predatory innovation cases have involved products like single-serve coffee makers[302] or printer cartridges,[303] where it is reasonable to expect that consumers will evaluate the bundle of product attributes. Based on their assessment of innovation, price and quality, consumers will exercise choice between the redesign and older products based on their preferred bundle of characteristics. If consumers freely prefer the new design, courts can logically defer to that choice to find there is likely no predatory innovation.

If instead the industry (or specific market) has characteristics that deeply distort or even eliminate consumers' choice of products—whether by regulation, or any means other than the defendant's own misconduct—then consumer "preference" is unlikely to act as a meaningful proxy for the innovativeness of a product redesign. In such

299. *Id.* at 331 (emphasis added).

300. *Id.* at 331-333 (observing plaintiff's evidence that the defendant had implemented pharmacy pop-up notifications to swap to its new drug design, sent promotional materials to doctors, patients, and pharmacies urging a switch because the old formulation would no longer be manufactured, among other conduct).

301. In cases where the old product was removed by the monopolist, then, as in *Namenda*, consumer choice could continue to act as an initial screen, indicating the court will need to inquire further to determine whether there is anticompetitive conduct occurring.

302. *In re* Keurig Green Mountain Single-Serve Coffee Antitrust Litig., 383 F. Supp. 3d 187, 227-28 (S.D.N.Y. 2019) (plausibly alleging markets for single-serve brewers and compatible or portion pack markets).

303. Xerox Corp. v. Media Sciences Int'l, Inc., 511 F. Supp. 2d 372, 387-85 (S.D.N.Y. 2007) (making the reasonable allegation alleging that the relevant market was replacement solid ink sticks compatible with Xerox printers).

cases, courts should instead adopt an analytical paradigm that reflects the reality of that industry.

V. CONCLUSION

Innovation is not a unitary phenomenon. Yet antitrust courts often overlook the industry-specific nature of innovation in their adjudication of predatory innovation claims. This lack of attention to industry context is responsible, at least in part, for the messy state of predatory innovation jurisprudence. As this Article describes, the law on predatory innovation is marked by numerous analytical standards, persistent Circuit splits and divided scholarly perspectives.

The Article proposes a new, industry-contextual approach to bring order to this predatory innovation jurisprudence. It draws on patent policy and economic literature to demonstrate that innovation varies significantly by industry. For example, this literature describes a paradigmatic contrast between innovation in pharmaceutical drugs, which tends to be episodic, expensive and patent-driven, and innovation in software, which tends to be cumulative, collaborative and less dependent on patent exclusivity. The Article argues that, in the adjudication of predatory innovation claims, antitrust law should tailor its paradigms and assumptions to better account for these industry-specific innovation processes, incentives, and characteristics.

The Article then applies the proposed industry-contextual approach to inform two controversies in the predatory innovation jurisprudence: the appropriate level of judicial deference to product redesigns, and the use of consumer preference to determine whether a redesign is innovative. It argues that industry innovation context should influence both the degree of judicial deference that is afforded to product redesigns, and whether consumer choice is applicable as a proxy for innovation. The Article uses product hopping cases to illustrate each of these arguments, then extends the logic to other industry contexts.

In an area of intensely divided cases and literature, this industry-contextual approach offers a new way to understand the jurisprudence on predatory innovation. More broadly, it also contributes to theories of dynamic competition, which are essential to the modernization of antitrust law.