

ARTICLE

PRODUCT HOPPING: MONOPOLIZATION OR INNOVATION?

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ABSTRACT

The cost and availability of pharmaceutical drugs impact the daily lives of many Americans. Due in part to this relationship, the debate over the legality of “product hopping” has recently entered the antitrust spotlight. Product hopping is said to occur when a brand-name manufacturer—a company that innovates and produces new drugs—creates and markets a reformulated version of an already existing product. Generic manufacturers, in contrast, piggy-back on the innovative efforts and regulatory clearance of the brand-name drug to produce a bioequivalent version. They are able to do so because the Abbreviated New Drug Application (“ANDA”) process allows generics to rely on the brand-name drug’s regulatory application and because state switching laws allow the generic drug to be substituted for the brand-name drug at the pharmacy counter, removing the need for generic manufacturers to undertake independent marketing campaigns. A product hop undermines a generic drug’s bioequivalence and therefore the generic’s ability to utilize the ANDA process and state switching laws. Generics, therefore, have begun to argue that product hopping is exclusionary, and produces harmful, anticompetitive effects. A handful of product hopping cases have been heard in the federal District Courts, and the first Court of Appeals decision on the topic to date was issued in May 2015, and the second is currently pending. However, the courts are split on the correct answer to the antitrust question. This article seeks to decide the split, and answer the question whether product hopping is monopolization or innovation. Monopolization claims in innovation markets—such as the pharmaceutical drug market—are properly analyzed under a burden-shifting framework, which requires that the plaintiff prove anticompetitive effects and the defendant prove procompetitive justifications. If

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both are shown, the court must balance the two sides to determine the cumulative effect of the conduct. Utilizing this framework, courts should find that product hopping does not have an anticompetitive effect. Actual market entry is not impeded because generic manufacturers can still use the brand-name formulation that was removed from marketing as a basis for an ANDA application. Additionally, generic manufacturers' inability to utilize state switching laws after a product hop is not anticompetitive because it does not impede the generics' ability to compete on their own merits; to find otherwise would create for brand-name manufacturers an affirmative duty to deal, which antitrust law has long held does not exist. In contrast, product hopping has substantial procompetitive benefits. The most substantial benefit is that product hopping promotes innovation. Pharmaceutical innovation is an extremely complex and expensive process, and providing the necessary incentives to innovate requires that successful innovations that produce new and useful products be rewarded, rather than condemned as anticompetitive. Product hopping also provides additional consumer benefits in the form of increased product education and cost savings that may be passed on to consumers. Finally, if a balancing were to become necessary, courts should find that the procompetitive effects outweigh any anticompetitive effect. Neither the Supreme Court nor the leading courts of appeals decisions that utilize the balancing framework have provided guidance at this step. In light of this fact, this article argues that antitrust policy considerations become pertinent. Most notably, the heavily regulated nature of the pharmaceutical industry, the inappropriateness of antitrust law second-guessing legislative decisions, antitrust law's desire to avoid false positives and to promote innovation, and the Supreme Court's endorsement of aggressive competition by dominant firms all lend support to courts holding that, on balance, product hopping is innovation, not monopolization.

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I. INTRODUCTION

Due in part to the prominent role that pharmaceutical drugs—and healthcare generally—play in the daily lives of Americans, the competitive relationship between brand-name and generic pharmaceutical companies has entered the antitrust spotlight. In particular, “product hopping” by pharmaceutical companies has recently, and quickly, become a hot topic. Product hopping is the reformulation of a pharmaceutical drug by a brand-name pharmaceutical manufacturer prior to expiration of the relevant patent(s), and the subsequent marketing of a patented reformulation of that drug.¹ Antitrust critics of product hopping argue that the introduction of a new, patented product and the shift in marketing emphasis to that product impedes the ability of generic pharmaceutical manufacturers to enter the market for a particular drug and utilize state substitution laws to piggy-back on the brand-name company’s marketing efforts.² There have only been a handful of district court product hopping decisions,³ and the Court of Appeals for the Second Circuit issued the first appellate decision on product hopping in May 2015.⁴ Further, courts have

¹ See *infra* Part II.A for a more detailed discussion of this process. “Brand-name” and “generic” companies are defined *infra*, notes 20-24 and accompanying text (a brand-name manufacturer is an innovator company that creates and markets new products, while a generic manufacturer copies the formulation of the brand-name company to produce a bioequivalent product).

² See *infra* Part II.C for more detail on the antitrust concerns.

³ See, e.g., *infra* Part III.C (describing some of these district court cases).

⁴ See New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015); Melissa Lipman, *2nd Circ. Product-Hopping Ruling May Prompt More Suits*, LAW360 (Mar. 13, 2015, 4:44 PM), <http://www.law360.com/articles/630424/2nd-circ-product-hopping-ruling-may-prompt-more-suits> [<http://perma.cc/PB6C-98YR>]. The second case to reach the appellate level, *Mylan Pharmaceuticals Inc. v. Warner Chilcott Public Limited Co.*, is currently pending before the Court of Appeals for the Third Circuit. Dani Kass, *Warner Chilcott Defends Dismissal of Doryx Case in 3rd Circ.*, LAW360 (Dec. 17, 2015,

not consistently decided these cases; thus, this article seeks to address the split.

While obtaining a patent does not serve as a bar to antitrust scrutiny,⁵ “antitrust oversight of innovation is fraught with danger [because] [t]he pace and complexity of technological advancement in the new economy far exceed the capabilities of the judicial process to identify and assess bona fide invention accurately.”⁶ This complexity stems from the fact that innovation benefits cannot be easily quantified and that the consumer benefits that result from innovation are not immediately apparent.⁷ Analysis is further complicated by the reality that “there is no consensus as to the market conditions that best promote innovation.”⁸ As a result, antitrust law has been overly concerned with short-term price effects and insufficiently concerned with long-run innovation.⁹ Undoubtedly, complexity and difficulty of analysis is no reason for courts to shy away from applying the antitrust laws. But, it does call for courts to be especially mindful of the costs of applying the laws because “the social losses caused by innovation restraints are large, perhaps far larger than the social losses caused by monopolistic pricing.”¹⁰

The burden-shifting framework that was applied in *United States v. Microsoft Corp.*¹¹ is ideal for evaluating monopolization complaints in industries characterized by intense efforts to innovate, such as the market for pharmaceutical drugs. The advantage of this approach is that it allows a court to focus on the core purpose of any antitrust analysis, *i.e.*, whether there is harm to competition.¹² It also ensures that innovating parties have a full opportunity to justify their conduct based on its benefits, and that truly

9:46 PM), <http://www.law360.com/articles/739009/warner-chilcott-defends-dismissal-of-doryx-case-in-3rd-circ> [perma.cc/J3EN-TQZ6].

⁵ See William Kovacic, *From Microsoft to Google: Intellectual Property, High Technology, and the Reorientation of U.S. Competition Policy and Practice*, 23 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 645, 648 (2013).

⁶ Alan Devlin & Michael Jacobs, *Anticompetitive Innovation and the Quality of Invention*, 27 BERKELEY TECH L.J. 1, 22 (2012).

⁷ See *e.g.*, JAMES T. HALVERSON & BRIAN J. TELPNER, INNOVATION & POTENTIAL COMPETITION IN RAPIDLY-CHANGING HIGH-TECH INDUSTRIES 6 (2001), <http://www.steptoe.com/assets/attachments/23.pdf> [http://perma.cc/XK3N-K362]. Analysis of long-run innovation, in effect, requires courts to create a “but for” world, where the innovation under consideration never occurred, and predict the consequences of decreased innovation in that hypothetical world. *Cf.* Herbert Hovenkamp, *Restraints on Innovation*, 29 CARDOZO L. REV. 247, 260 (2007) (“[T]he impact of prospective innovations is impossible to predict, and quantifying the losses from any particular failure to innovate seems well nigh impossible.”).

⁸ HALVERSON & TELPNER, *supra* note 7, at 7.

⁹ See Hovenkamp, *supra* note 7, at 255.

¹⁰ See *id.* at 260.

¹¹ 253 F.3d 34 (D.C. Cir. 2001).

¹² See *id.* at 58.

beneficial activities are not wrongfully condemned.¹³

“[I]nnovation [in the pharmaceutical industry] has generated tremendous benefits for human health.”¹⁴ However, “[p]harmaceuticals are one of the most cost- and time-intensive areas of technological innovation as well as one of the industries most subject to regulatory intervention.”¹⁵ The cost of developing a new pharmaceutical drug is estimated to be approximately \$1 billion, and rising.¹⁶ Further, pharmaceutical companies that develop new drugs face additional costs marketing the new product and conducting post-marketing safety and efficacy studies.¹⁷ To recoup these costs, pharmaceutical development companies rely on patent protection and market exclusivity. However, the majority of developed drugs never earn sufficient profits to recoup their development costs.¹⁸ Moreover, pharmaceutical development is fraught with unsuccessful efforts.¹⁹ The ability to recoup sufficient profit from the few efforts that do succeed is what keeps innovating pharmaceutical companies afloat.

This article addresses the question: is product hopping monopolization or innovation? Part II defines the concept of product hopping, discusses the complex regulatory structure in which product hopping occurs, and frames the antitrust arguments on both sides of the debate. Part III sets forth the analysis using the *Microsoft* burden-shifting framework. After preliminarily discussing the concept of monopoly power and outlining the framework, this part discusses the anticompetitive arguments against product hopping and the procompetitive justifications for it. The analysis finds that product hopping does not create any anticompetitive harm; rather, the analysis finds that product hopping creates substantial innovation and other benefits that, on balance, the antitrust laws should seek to promote. Part IV concludes.

II. BACKGROUND

There are over 700 pharmaceutical manufacturing companies in the United States.²⁰ Pharmaceutical companies are generally classified into two broad

¹³ See *id.* at 59.

¹⁴ Paula Tironi, *Pharmaceutical Pricing: A Review of Proposals to Improve Access and Affordability of Prescription Drugs*, 19 ANNALS HEALTH L. 311, 311 (2010).

¹⁵ Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 245, 251 (2012).

¹⁶ *Id.* at 254.

¹⁷ *Id.* at 255.

¹⁸ See *id.* at 256–57, 259.

¹⁹ See M. Howard Morse, *Product Market Definition in the Pharmaceutical Industry*, 71 ANTITRUST L.J. 633, 636 (2003). One study “estimates the success rate for compounds entering clinical testing at only 22 percent, and few compounds that companies research ever even make it into clinical trials.” *Id.* at 637.

²⁰ *Id.* at 640.

categories—brand-name and generic. Brand-name pharmaceutical companies expend substantial resources to develop and market new drugs via their own innovation efforts.²¹ A brand-name manufacturer’s business model is, in effect, to create new pharmaceuticals, and to rely on patent protection to enable it to recoup its substantial investment; patent protection is necessary to incentivize the brand-name company’s innovation efforts.²²

In contrast stands the business model of generic pharmaceutical manufacturers. According to the Supreme Court, a generic drug is one “that contains the same active ingredients but not necessarily the same [inactive substances] as a so-called ‘pioneer drug’ that is marketed under a brand name.”²³ By relying on a brand-name manufacturer’s innovation efforts, a generic company is able to copy the brand-name product and avoid the extraordinary research and development (“R&D”) costs required to develop a pioneer drug, which allows the generic company to market its product at a price substantially below that of the brand-name company.²⁴ In addition to relying on the brand-name company for its safety and efficacy studies, generic manufacturers have also come to rely on brand-name companies for marketing and sales.²⁵ The generic manufacturers’ reliance on their brand-name counterparts is at the core of the antitrust debate over product hopping.

A. *Product Hopping Defined*

“Product hopping” is the process during which a brand-name manufacturer reformulates a pharmaceutical drug and, after receiving patent protection and successfully navigating the regulatory approval process, markets the reformulation to the public.²⁶ In some instances, the brand-name manufacturer will cease its marketing of the original drug in order to focus its commercial efforts on the reformulation.²⁷ If the brand-name manufacturer is unable to effectuate a product hop prior to expiration of its patent, and a generic manufacturer enters the market, market studies and case law have shown that the brand-name manufacturer will quickly lose the high level of sales it

²¹ See generally Tironi, *supra* note 14, at Part III.A.

²² See *id.* at 324 (“Innovator pharmaceutical manufacturers attempt to develop ‘blockbuster’ drugs with annual sales of at least \$1 billion in order to offset the high cost of R&D and to fund the development of subsequent products.”).

²³ United States v. Generix Drug Corp., 460 U.S. 453, 454–55 (1983).

²⁴ *Id.* at 455 n.1.

²⁵ See *infra* Part II.B.3 (discussing state substitution laws for pharmaceutical drugs).

²⁶ See Jessie Cheng, Note, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471, 1472 (2008). The patent system and the pharmaceutical approval process are discussed *infra*, in Part II.B.1 and Part.II.B.2, respectively.

²⁷ See *id.*

experienced during the period of patent protection.²⁸ Thus, product hopping raises the greatest antitrust suspicion when the brand-name drug is about to “go-off the patent cliff”²⁹—*i.e.*, when the brand-name manufacturer’s patent is about to expire.

B. The Regulatory Framework

The interaction between brand-name and generic pharmaceutical manufacturers is defined by a complex regulatory landscape involving patent law, federal drug law, state drug law, and antitrust law. This section of the article provides an overview of the relevant regulatory systems; the pertinent parts of these systems are discussed in more detail as they become relevant in the analysis section.

1. Patent Law

The Constitution empowers Congress to “promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right” to their works, and since 1790 Congress has from time to time passed such laws.³⁰ Ensuring that innovators receive a return on their investment is essential to promoting innovative activity.³¹ “[T]he pharmaceutical industry relies more than any other on the patent system as a means of ensuring returns for its substantial investments.”³²

The Patent and Trademark Office (“PTO”) is responsible for examining patent applications and determining whether a patent should be granted for a particular invention.³³ If the PTO decides to issue a patent, the inventor will receive the right to 20 years of exclusive use of the patent.³⁴ Most notably, during this period the patent holder has the ability to file lawsuits to exclude others from using the patent without permission or to charge licensees a fee for

²⁸ See Steve D. Shadowen, Keith B. Leffer & Joseph T. Lukens, *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L.J. 1, 50–51 (2009).

²⁹ *New York v. Actavis, PLC*, No. 14 Civ. 7473, 2014 WL 7015198, at *9 (S.D.N.Y. Dec. 11, 2014), *aff’d* 787 F.3d 638 (2d Cir. 2015).

³⁰ *General Information Concerning Patents*, U.S. PATENT & TRADEMARK OFFICE, <http://www.uspto.gov/patents-getting-started/general-information-concerning-patents> [<https://perma.cc/FJP2-SK8W>].

³¹ See Christopher R. Leslie, *Monopolization Through Patent Theft*, 103 GEO. L.J. 47, 55 (2014) (“Patent law’s suppression of competition is seen as necessary to encourage investment in innovation.”).

³² Amanda Fachler, Note, *The Need for Reform in Pharmaceutical Protection: The Inapplicability of the Patent System to the Pharmaceutical Industry and the Recommendation of a Shift Towards Regulatory Exclusivities*, 24 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1059, 1060 (2013).

³³ See U.S. PATENT & TRADEMARK OFFICE, *supra* note 30.

³⁴ See *id.*

its use.³⁵ Serving as a significant check on inappropriate patent protection, “[n]o pharmaceutical or other type of patent is ever declared definitively valid,” and thus courts have the obligation constantly to evaluate the validity of any challenged patent.³⁶

The main requirements for receiving (and defending) a patent are usefulness, novelty, and non-obviousness.³⁷ An invention satisfies the “usefulness” requirement so long as it works under experimental conditions; this requirement is easily met and does not garner much debate in the pharmaceutical context.³⁸ The “novelty” requirement dictates that a patent shall not be granted if the invention is previously known, used, patented, or described.³⁹ This requirement ensures that the item for which a patent is sought is actually new.⁴⁰

The third element, obviousness, “is regarded as the ultimate condition of patentability because it evaluates the technical merits of an invention . . . [and] considers whether an invention is a big enough technical advance to warrant patent protection.”⁴¹ In effect, it serves as a buffer against abuse of the patent system. Obviousness is determined from the perspective of a “person having ordinary skill in the art.”⁴² The term “art” refers to the “area or field of the invention” – for drug development this is “the art of pharmaceuticals, pharmacology, or biochemistry.”⁴³ The four factors that courts consider when determining obviousness are the “scope and content of the prior art, the level of ordinary skill in the art, *the differences between the claimed invention and the prior art*, and objective evidence of non-obviousness.”⁴⁴ In the context of product hopping, obviousness is potentially the most important and contentious

³⁵ See Eric Rogers & Young Jeon, *Inhibiting Patent Trolling: A New Approach for Applying Rule 11*, 12 NW. J. TECH. & INTELL. PROP. 291, 297 (2014).

³⁶ Morris, *supra* note 15, at 270 (citing *Blonder-Tongue Labs v. Univ. of Ill. Found.*, 402 U.S. 313, 330-31, 331 n.21 (1971)).

³⁷ See Jolie D. Lechner, Note, *Rebutting Obviousness in the Pharmaceutical Industry: Secondary Considerations of Analogs*, 11 CHI.-KENT J. INTELL. PROP. 146, 151 (2012).

³⁸ *Id.*

³⁹ See Alexander J. Kalter, Note, *Generic Drugs Post Novo Nordisk*, 7 OHIO ST. ENTREPRENEURIAL BUS. L.J. 193, 198 (2012). An item that has been previously known, used, patented, or described is known as “prior art.” *Id.* at 197.

⁴⁰ *See id.*

⁴¹ Lechner, *supra* note 37, at 151 (internal quotation omitted).

⁴² *See* 35 U.S.C. § 103 (2012).

⁴³ Kalter, *supra* note 39, at 198.

⁴⁴ *Id.* at 199 (emphasis added). Objective evidence of obviousness includes “considerations such as commercial success, the failure of others, long-felt but unmet needs, and unexpected results.” Lechner, *supra* note 37, at 152 (citing *Graham v. John Deere Co. of Kan.*, 383 U.S. 1 (1966)).

patentability requirement.⁴⁵

2. Federal Drug Law: The Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act,⁴⁶ was adopted with two goals in mind. The first goal—and the one that has proven to be more significant—is the promotion of generic drug entry and competition.⁴⁷ The second goal is to encourage investment in R&D activities, by increasing certain exclusivity incentives.⁴⁸ The portions of the Hatch-Waxman Act relevant to this article deal with the market entry process for both brand-name and generic companies and with market exclusivity for brand-name pharmaceuticals.

In order to be allowed to market a new drug, the innovator—*i.e.*, the brand-name company—must submit a New Drug Application (“NDA”) to the Federal Drug Administration (“FDA”).⁴⁹ The overall purpose of the NDA process is to ensure that the drug is effective and safe for consumer use.⁵⁰ “In total, the FDA approval process requires successfully completing twelve steps from the preclinical through post-marketing periods,” including animal testing, three phases of human testing, and an array of agency reviews.⁵¹ Simply gaining market entry may cost up to several billion dollars.⁵² The FDA also requires that branded manufacturers submit as part of an NDA a list of relevant patents.⁵³ Once the FDA approves a brand-name drug, it lists all patents involved in an FDA publication known as the “Orange Book.”⁵⁴

The Hatch-Waxman Act streamlined the approval process for generic drugs by creating the Abbreviated New Drug Application (“ANDA”).⁵⁵ The ANDA

⁴⁵ For example, if the new drug is too similar to the original version, the new drug will not receive a patent. *E.g.*, *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (holding that the claimed compound was rendered obvious by a structurally similar prior art compound with a similar utility).

⁴⁶ Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended primarily at 21 U.S.C. § 355 (2006), though also in scattered sections of Titles 15, 21, 35, and 42 of the U.S. Code.).

⁴⁷ *See Morris*, *supra* note 15, at 260.

⁴⁸ *See id.* at 260–61.

⁴⁹ Cheng, *supra* note 26, at 1475.

⁵⁰ *See id.*

⁵¹ Fachler, *supra* note 32, at 1070–71.

⁵² *Id.* at 1069.

⁵³ *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012).

⁵⁴ *See id.* The official name for this publication is the Approved Drug Products with Therapeutic Equivalence Evaluations. *See id.* The purpose of the Orange Book is to facilitate generic entry by putting generic manufacturers on notice for, *inter alia*, what patents they would potentially infringe and when those patents expire. *See id.*

⁵⁵ *See, e.g.*, M. Howard Morse, *Settlement of Intellectual Property Disputes in the Pharmaceutical and Medical Device Industries: Antitrust Rules*, 10 GEO. MASON L. REV.

process allows generics to “rely on the safety and effectiveness tests conducted by a [brand-name] drug manufacturer, so long as the generic applicant . . . demonstrate[s] that its drug is bio-equivalent to the approved [brand-name] drug.”⁵⁶ In addition, the ANDA filer must submit one of four certifications indicating the relationship between the generic drug and the brand-name company’s patents.⁵⁷ The four certifications are: “(I) that such patent information has not been filed, (II) that such patent has expired, (III) . . . the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug.”⁵⁸

The FDA approval process includes further complexity for the filers of both NDAs and ANDAs but, to simplify for this article, the critical point is that there is a long and expensive approval process for innovative products, while generic manufacturers may utilize a much shorter and less costly approval process that allows them “to piggy-back on the pioneer’s approval efforts.”⁵⁹ As evidence of the significance of this shortcut, since passage of the Hatch-Waxman Act, generic companies’ share of the U.S. prescription drug market has increased from approximately 20% to approximately 50%.⁶⁰

While the Hatch-Waxman Act has been quite successful in encouraging and expediting generic entry, it has been less successful in achieving its second goal—promoting innovation.⁶¹ The Hatch-Waxman Act sought to achieve this goal by extending the life of a brand-name drug’s patent for a time “equal to one-half of the time period from the start of human clinical trials to the start of the NDA approval process and all of the time spent during the NDA approval process.”⁶² However, the total patent life after any extension may not exceed 14 years from the beginning of marketing⁶³—*i.e.* the brand-name company receives *at most* 14 years of marketing exclusivity.

3. State Pharmaceutical Law: Drug Product Selection Law

“State drug product selection (DPS) laws, in effect in all fifty states today . . . allow—and in many states require—pharmacists . . . to substitute

359, 383 (2002).

⁵⁶ *Id.* at 383–84.

⁵⁷ *Id.* at 384.

⁵⁸ 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV) (2012).

⁵⁹ Brief for Intellectual Property and Antitrust Professors as Amici Curiae Supporting Plaintiff-Appellee, *New York v. Actavis, PLC*, 787 F.3d 638 (2d Cir. 2015) (No. 14-4624), at 11 (quoting *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013)).

⁶⁰ *See Morris*, *supra* note 15, at 265.

⁶¹ *See id.* at 247.

⁶² *Id.* at 260. The innovator company usually obtains the necessary patent(s) early in the development process and may have gone through multiple years of patent protection before any FDA-required testing even begins. *See Fachler*, *supra* note 32, at 1066–67.

⁶³ *See Morris*, *supra* note 15, at 260; *Fachler*, *supra* note 32, at 1067.

generic versions of brand-name prescriptions.”⁶⁴ The purpose of these laws is to lower the price paid by consumers for pharmaceutical drugs.⁶⁵ For a generic drug to be substituted for a brand-name version, the generic drug must be “AB-rated” by the FDA, meaning that the generic drug is both bioequivalent (as required for ANDA approval⁶⁶) and therapeutically equivalent to the brand-name version.⁶⁷ If a generic drug does not possess both characteristics, DPS laws do not apply.⁶⁸

In essence, when a physician writes a prescription for a brand-name drug and a consumer goes to a pharmacy to have that prescription filled, the pharmacy can or must (depending on the particular state’s law) fill the prescription with a generic drug that is bioequivalent and therapeutically equivalent to the brand-name drug that was prescribed. To determine whether any generic drug exists that can be substituted for the prescribed brand-name drug, pharmacies may reference private databases, such as the National Drug Data File (“NDDF”).⁶⁹ A consumer may avoid switching if the prescribing physician indicates that substitution should not occur for that particular prescription.⁷⁰ Substitution at the pharmacy is the primary means by which generic drugs compete with their brand-name equivalent.⁷¹

4. Antitrust Law: Monopolization Law Generally

The purpose of antitrust law is to ensure a competitive marketplace.⁷² In light of that goal, the Supreme Court has “rejected the notion that the existence of a patent precludes antitrust scrutiny of any conduct involving the patent.”⁷³ Antitrust scrutiny of intellectual property, including patents, is analyzed under the same general principles that are applied to conduct involving any other form of property.⁷⁴

⁶⁴ Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1017 (2010).

⁶⁵ *See id.*

⁶⁶ *See Morse, supra* note 55 at 383-84, and accompanying text.

⁶⁷ *See Carrier, supra* note 64, at 1018.

⁶⁸ *See Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 415 (D. Del. 2006).

⁶⁹ *See id.* at 416.

⁷⁰ *See Cheng, supra* note 26, at 1480.

⁷¹ *See New York v. Actavis, PLC*, No. 14 Civ. 7473, 2014 WL 7015198, at *8 (S.D.N.Y. Dec. 11, 2014).

⁷² *See, e.g.*, FED. TRADE COMM’N, COMPETITION GUIDANCE: GUIDE TO ANTITRUST LAWS, <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws> [<https://perma.cc/WV5V-FKWT>].

⁷³ Brief for Intellectual Property and Antitrust Professors, *supra* note 59, at 19.

⁷⁴ U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING INNOVATION AND COMPETITION 3-4 (2007)

Product hopping is a form of unilateral conduct, and is thus analyzed under monopolization law.⁷⁵ “[M]onopolization under § 2 of the Sherman Act⁷⁶ has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of superior product, business acumen, or historic accident.”⁷⁷ Monopoly power is defined generally as the ability of a competitor to raise the price of a product above a competitive level or to exclude a competitor from the market.⁷⁸ The antitrust laws do not presume the existence of monopoly power from the mere possession of a patent.⁷⁹

Possession of monopoly power, moreover, is not itself a violation of the antitrust laws.⁸⁰ Antitrust law is concerned with the way in which a competitor attains or maintains its monopoly power; the key consideration is the firm’s conduct.⁸¹ For a firm’s conduct to violate Section 2, that conduct must have an anticompetitive effect.⁸² The ways in which a firm can monopolize are myriad, and the resultant anticompetitive effects can take many forms.⁸³ Anticompetitive effects include price factors, such as higher prices and lower output, and non-price factors, such as “lower product quality, less consumer choice, and little product innovation.”⁸⁴ Antitrust laws are concerned with harm to the competitive process and thus to consumers, not with harm to any individual competitor.⁸⁵ If a firm’s conduct does not harm the competitive process or consumers, then the antitrust laws do not condemn that conduct.

[hereinafter PROMOTING INNOVATION].

⁷⁵ See *Walgreen Co. v. AstraZeneca Pharms., LP*, 534 F. Supp. 2d 146, 150 (D.D.C. 2008).

⁷⁶ 15 U.S.C. § 2 (2012). Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45 (2012), may also be used to prevent anticompetitive single-firm conduct. However, since only the FTC may enforce Section 5 and since product hopping decisions to date have been brought under the Sherman Act, this article will focus on the Sherman Act.

⁷⁷ *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966).

⁷⁸ *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956).

⁷⁹ See PROMOTING INNOVATION, *supra* note 74, at 2.

⁸⁰ See *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 274 (2d Cir. 1979) (“[Section] 2 does not condemn one ‘who merely by superior skill and intelligence . . . got the whole business because nobody could do it as well.’”) (quoting *United States v. United Shoe Mach. Corp.*, 110 F. Supp. 295, 341 (D. Mass. 1953)).

⁸¹ See *United States v. Microsoft Corp.*, 253 F.3d 34, 58 (D.C. Cir. 2001).

⁸² *Id.*

⁸³ *Id.*

⁸⁴ ANDREW I. GAVIL, WILLIAM E. KOVACIC & JONATHAN B. BAKER, ANTITRUST LAW IN PERSPECTIVE: CASES, CONCEPTS AND PROBLEMS IN COMPETITION POLICY 41 (2d ed. 2008).

⁸⁵ See *Microsoft*, 253 F.3d at 58. “Even an act of pure malice by one business competitor against another does not, without more, state a[n antitrust] claim” *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 225 (1993).

A corollary of antitrust law's role in deterring anticompetitive conduct is its role in promoting competitively beneficial conduct. Creating a competitive marketplace "encourages firms to increase output and lower prices, [and] also . . . to improve product quality and service, develop new products, and introduce new methods of production."⁸⁶ One key factor in determining whether a firm's conduct violates the antitrust laws is whether that conduct has any procompetitive justifications.⁸⁷ The Supreme Court has indicated that antitrust law should not be applied in a way that would destroy procompetitive or beneficial conduct.⁸⁸ Notably, "most business conduct involving innovation by high-technology firms is procompetitive or competitively benign."⁸⁹

C. The Antitrust Debate Over Product Hopping

The ultimate question for antitrust law is whether product hopping on balance harms the competitive process and consumers, or whether it benefits consumers. The effect on generic competition is at the core of this debate. Critics of product hopping claim that the ultimate effect of a hop is merely to extend the brand-name company's patent protection and to preserve the company's monopoly over a class of pharmaceutical drugs beyond the maximum statutory period.⁹⁰ This occurs because the hop causes the generic drugs to no longer be AB-rated with the next generation drug, which prevents generic manufacturers from taking advantage of state switching laws and requires them, if they want to be AB-rated, to restart the ANDA process.⁹¹ Critics claim that product hopping results in the generic manufacturers' exclusion from the product market, causing increased prices and decreased product choices for consumers.⁹²

"[B]rand-name pharma defends [product hopping] as enhancing patient outcomes, fostering competition within the marketplace, and generally expanding patient and physician choices"⁹³ One major argument in favor of product hopping is that it is legitimate innovation, which stimulates additional product development and increases consumer choice, and that this

⁸⁶ GAVIL ET AL., *supra* note 84, at 1158.

⁸⁷ *Single Firm Conduct*, FED. TRADE COMM'N, <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/single-firm-conduct> [<https://perma.cc/WV5V-FKWT>].

⁸⁸ *See* *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.'") (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986)).

⁸⁹ GAVIL ET AL., *supra* note 84, at 1161.

⁹⁰ *See* Cheng, *supra* note 26, at 1472.

⁹¹ *See* Brief for Intellectual Property and Antitrust Professors, *supra* note 59, at 13.

⁹² *See id.* at 28.

⁹³ Morris, *supra* note 15, at 259.

is a fundamental procompetitive end that antitrust law seeks to promote.⁹⁴ Additionally, in support of the brand-name manufacturer's shift in its manufacturing and marketing emphasis, proponents of product hopping cite to the longstanding antitrust principle that a monopolist does not have a general duty to help its competitors.⁹⁵

III. ANALYSIS: IS PRODUCT HOPPING MONOPOLIZATION OR INNOVATION?

A. Monopoly Power

The first inquiry in a Section 2 monopolization claim is whether the defendant possesses monopoly power.⁹⁶ Because the focus of this article is on the conduct aspect of product hopping, this section will only provide an overview of monopoly power. "A company has monopoly power if it can profitably raise prices without causing competing firms to expand output and drive down prices."⁹⁷ Monopoly power can be proven directly with evidence that a firm has the "power to control prices or exclude competition."⁹⁸ However, direct evidence is rarely available, and therefore a plaintiff must usually prove monopoly power via indirect evidence by defining a relevant market and establishing that the defendant has market power in the relevant market.⁹⁹

A "relevant product market" includes all products that are deemed "reasonably interchangeable by consumers for the same purpose."¹⁰⁰ In determining reasonable interchangeability, courts can consider any relevant evidence of consumer preference; in the pharmaceutical industry, that evidence has included physician and consumer testimony, economic price data, and

⁹⁴ See GAVIL ET AL., *supra* note 84, at 41.

⁹⁵ See, e.g., *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004).

⁹⁶ See *United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001); see also *supra* notes 77–81 and accompanying text.

⁹⁷ *Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd.*, Civ. No. 12-3824, 2015 WL 1736957, at *7 (E.D. Pa. Apr. 16, 2015) (citing *Harrison Aire, Inc. v. Aerostar Int'l, Inc.*, 423 F.2d 374, 380 (3d Cir. 2005)).

⁹⁸ *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956). Recall, however, that mere possession of a patent, and the market exclusivity it may confer, does not equate *per se* to a finding of monopoly power. See *supra* note 78 and accompanying text.

⁹⁹ See *Mylan Pharms.*, 2015 WL 1736957, at *7–*8. The purpose of defining a relevant market is to establish the context in which to analyze a defendant's conduct. See Anish Vaishnav, Note, *Product Market Definition in Pharmaceutical Antitrust Cases: Evaluating Cross-Price Elasticity of Demand*, 2011 COLUM. BUS. L. REV. 586, 592 (2011).

¹⁰⁰ *E.I. du Pont*, 351 U.S. at 395.

internal corporate documents and opinions.¹⁰¹

In the pharmaceutical industry, establishing a product market is not an easy undertaking and has not been achieved with consistency. An analysis of Federal Trade Commission (“FTC”) enforcement actions in the pharmaceutical industry finds that the FTC has used nine different considerations in defining a relevant market.¹⁰² The complexity of pharmaceutical drugs themselves—including the potential for different dosage amounts, different delivery methods, and different chemical formulations that treat the same condition—accounts for this variety of criteria.¹⁰³ The complexity of pharmaceutical drug distribution also impacts market definition. For instance, doctors and insurance companies augment the normal competitive process and impact consumer choices. Based on their role in making diagnoses and prescribing drugs, “the doctor is the most important [link] in the chain of those involved in the decision of which drug to prescribe.”¹⁰⁴ Insurance companies increasingly pressure pharmaceutical manufacturers to offer price discounts and other rebates.¹⁰⁵ These facts separate the ultimate consumer from the information-gathering, decision-making, and payment aspects of pharmaceutical drugs.¹⁰⁶

A plaintiff must also establish the geographic scope of the relevant market. This is “the area in which a hypothetical monopolist could impose an increase in the price of its products” without risking market entry by competitors that would force a decrease in prices.¹⁰⁷ Essentially, it is the physical area of product distribution. In the pharmaceutical industry, sales occur on a national (or even international) scale,¹⁰⁸ and product hopping courts have therefore defined the geographic market broadly to include at least the entire United States.¹⁰⁹

Once the relevant market has been defined, the plaintiff must show that the

¹⁰¹ See *Mylan Pharms.*, 2015 WL 1736957, at *8–*10.

¹⁰² See Morse, *supra* note 19, at 643–44. The FTC is one of two federal agencies charged with enforcing the antitrust laws in the United States. *The Enforcers*, FED. TRADE COMM’N, <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/enforcers> [https://perma.cc/DUW9-4WAY].

¹⁰³ See Morse, *supra* note 19, at 643–44.

¹⁰⁴ *Id.* at 661 (quoting *In re Schering-Plough Corp.*, No. 9297, 2002 WL 1488085, at *76 (F.T.C. 2002)).

¹⁰⁵ See *id.* at 639.

¹⁰⁶ See generally Jonathan J. Darrow, *Pharmaceutical Gatekeepers*, 47 IND. L. REV. 363 (2014).

¹⁰⁷ Tim McCarthy, *Refining Product Market Definition in the Antitrust Analysis of Bank Mergers*, 46 DUKE L.J. 865, 867 (1997).

¹⁰⁸ See Maryan M. Chirayath, Note, *Oh Canada!: Antitrust Geographic Market Definition and the Reimportation of Prescription Drugs*, 46 B.C. L. REV. 1027, 1030 (2005).

¹⁰⁹ See, e.g., *New York v. Actavis, PLC*, No. 14 Civ. 7473, 2014 WL 7015198, at *35 (S.D.N.Y. Dec. 11, 2014).

defendant possesses monopoly power in that market.¹¹⁰ Traditionally, a firm with a high market share in the relevant market is considered to have monopoly power.¹¹¹ Two additional considerations are also relevant to the market power analysis. First, in markets with a high degree of innovation, factors aside from market share—such as a “disproportionate investment in research and development or marketing”¹¹² and the disproportionate relationship between fixed and variable costs¹¹³—may be taken as evidence of monopoly power. Second, “existing firms that have the potential to provide new alternatives” and firms with products still in the development phase may be considered as “potential competitors” and assigned a market share.¹¹⁴ Market definition in the pharmaceutical industry is complex and uncertain, and is a topic best reserved for a separate article. This article analyzes the conduct prong of a product hopping complaint, and to that topic this article now turns.

B. The Analytical Framework for Monopolistic Conduct

The Court of Appeals for the District of Columbia’s *per curiam* decision in *United States v. Microsoft Corp.* set forth a four-step, burden-shifting framework for analyzing potentially monopolistic conduct.¹¹⁵ This framework provides the appropriate analysis for product hopping, and the Second Circuit adopted a balancing approach in its recent product hopping decision.¹¹⁶ After establishing a defendant’s monopoly power, the first step of the *Microsoft* framework requires the plaintiff to assert a cognizable theory of antitrust harm.¹¹⁷ This threshold inquiry looks at whether the alleged harm is to the competitive process and consumers, and not simply harm to any individual competitor.¹¹⁸ Only harm to the former is cognizable as a Section 2

¹¹⁰ In *Mylan Pharmaceuticals*, the district court granted summary judgment in favor of the defendant, brand-name manufacturer based on the plaintiff’s inability to prove that the defendant had market power, due to interchangeability with other tetracyclines and with generic versions of the brand-name. No. 12-3824, 2015 WL 1736957, at *9–11 (E.D. Pa. Apr. 16, 2015).

¹¹¹ See GAVIL ET AL., *supra* note 84, at 618 (“[A]ntitrust systems ordinarily equate monopoly or dominance with *substantial and durable* market power.”).

¹¹² John McGaraghan, Note, *A Modern Analytical Framework for Monopolization in Innovative Markets for Products with Network Effects*, 30 HASTINGS COMM. & ENT. L.J. 179, 197 (2007).

¹¹³ See Sunny Woan, *Antitrust in Wonderland: Regulating Markets of Innovation*, 27 TEMP. J. SCI. TECH. & ENVTL. L. 53, 60–61 (2008).

¹¹⁴ McGaraghan, *supra* note 112, at 196.

¹¹⁵ 253 F.3d 34, 58–59 (D.C. Cir. 2001).

¹¹⁶ See *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 652 (2d Cir. 2015).

¹¹⁷ See *Microsoft*, 253 F.3d at 58.

¹¹⁸ See *id.*

violation.¹¹⁹ Second, if the harm is cognizable, then the plaintiff has the burden to show “that the monopolist’s conduct indeed has the requisite anticompetitive effect.”¹²⁰ A successful showing at this step “establishes a *prima facie* case under § 2” and shifts the burden to the defendant for the third step, which is to offer any non-pretextual procompetitive justifications for its conduct.¹²¹ If the defendant presents such justifications, the plaintiff will have the opportunity to rebut them.¹²² The fourth and final step of the analysis is a balancing, whereby the “plaintiff must demonstrate that the anticompetitive harm outweighs the procompetitive benefit” of the conduct.¹²³

The fundamental benefit of *Microsoft’s* framework is that it looks past specific labels and tests, and instead focuses on the core of any antitrust analysis—is there harm to competition and consumers.¹²⁴ Recognizing that there are a “myriad” of ways in which a firm could exclude a competitor, or otherwise harm competition, the *Microsoft* framework “abandons the quest for a single definition” of monopolistic conduct.¹²⁵ By no longer being restricted to specific tests and labels, and the limited set of arguments they allow, both plaintiffs and defendants may offer a comprehensive explanation as to why particular conduct does or does not harm competition and consumers. Further, the burden-shifting framework enables courts to evaluate a monopoly claim free from institutional biases or presumptions; it does not create favoritism for one party or the other, but instead is “equally conducive to findings of legality and illegality.”¹²⁶

Requiring plaintiffs affirmatively to prove anticompetitive harm also helps to avoid false positives by ensuring that Section 2’s central focus on deterring anticompetitive conduct is not overlooked in the midst of the complexity of the case.¹²⁷ Burden-shifting provides defendants with an affirmative ability to explain why their conduct should be viewed as procompetitive.¹²⁸ This is

¹¹⁹ See *supra* notes 84–85 and accompanying text.

¹²⁰ *Microsoft*, 253 F.3d at 58–59.

¹²¹ *Id.* at 59.

¹²² *Id.*

¹²³ *Id.*

¹²⁴ See Jonathan Jacobson, Scott Sher & Edward Holman, *Predatory Innovation: An Analysis of Allied Orthopedic v. Tyco in the Context of Section 2 Jurisprudence*, 23 LOY. CONSUMER L. REV. 1, 21 (2010).

¹²⁵ Thomas A. Lambert, *Defining Unreasonably Exclusionary Conduct: The “Exclusion of A Competitive Rival” Approach*, 92 N.C. L. REV. 1175, 1199 (2014).

¹²⁶ Devlin & Jacobs, *supra* note 6, at 16.

¹²⁷ Cf. M. Sean Royall, Ashley E. Johnson & Jason C. McKenney, *Antitrust Scrutiny of Pharmaceutical “Product Hopping”*, 28 ANTITRUST 71, 76, n.6 (2013); PROMOTING INNOVATION, *supra* note 74, at 2–4.

¹²⁸ Cf. *Microsoft*, 253 F.3d at 59, 72 (“Of course, that *Microsoft’s* exclusive deals have the anticompetitive effect of preserving *Microsoft’s* monopoly does not, in itself, make them

critical to a defendant's success because innovation benefits frequently are not immediately apparent, especially when juxtaposed to price effects, which can be seen more quickly.¹²⁹ For instance, high prices experienced in the short-run may not represent monopolistic returns, but rather may represent the minimum amount of return needed to incentivize innovation.

C. The Framework Applied

1. The Theory of Harm

The first step of the *Microsoft* framework, establishing a cognizable theory of harm, provides a lens through which to analyze the monopolist's conduct and ensures that the focus of litigation is on harm to consumers and competition, and not any single competitor.¹³⁰ In essence, the question to be addressed is whether the complaint is truly dealing with a potential Section 2 violation, or merely a disgruntled competitor. Product hopping plaintiffs are concerned that (1) the introduction of a new product impedes market entry by undermining the ANDA process and (2) the shifting of marketing resources impedes the generics' ability to take advantage of state DPS laws.¹³¹ This conduct, plaintiffs allege, results in the exclusion of generic competitors and thus increased prices for consumers. This alleges a potential harm to consumers sufficient to proceed to the next step.

2. Anticompetitive Effects

The second step of the *Microsoft* framework requires that the plaintiff affirmatively prove that harms alleged in step one of the framework actually resulted from the monopolist's conduct.¹³² As the following analysis proves, brand-name manufacturers' introduction of a new drug and subsequent shift in marketing emphasis does not amount to monopolistic conduct.

a. Generic Entry is Unimpeded

A brand-name manufacturer's decision to bring a new product to market, either to replace or in addition to an existing product, is not monopolistic conduct because actual entry by generic manufacturers is not foreclosed.¹³³ A

unlawful.”).

¹²⁹ See Cheng, *supra* note 26, at 1504; see also *supra* notes 6–10 and accompanying text.

¹³⁰ See *Microsoft*, 253 F.3d at 58; see also *supra* notes 83–86 and accompanying text.

¹³¹ See, e.g., *Walgreen Co. v. AstraZeneca Pharms. L.P.*, 534 F. Supp. 2d 146, 150 (D.D.C. 2008).

¹³² See *Microsoft*, 253 F.3d at 58–59.

¹³³ See, e.g., *Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co.*, Civ. No. 12-3824, 2015 WL 1736957, at *12 (E.D. Pa. Apr. 16, 2015). See Cheng, *supra* note 26, at 1498 (“Because generic manufacturers remain free to enter the market with their equivalents and

generic manufacturer can still utilize the brand-name manufacturer's Orange Book listing to complete the ANDA process. When a brand-name manufacturer stops producing a pharmaceutical drug, the relevant Orange Book listing switches from an active marketing list to the discontinued marketing list.¹³⁴ When this occurs, the FDA evaluates whether the withdrawal from marketing was due to safety or effectiveness reasons. If the FDA determines this was the case, the brand-name product (and any approved ANDAs) are removed from the Orange Book; however, if the FDA determines that the removal was *not* due to safety or effectiveness reasons, the brand-name drug will continue to be listed in the discontinued section and remains available to support the ANDA process.¹³⁵

In the traditional product hopping scenario, withdrawal of the brand-name product is not for safety or effectiveness reasons. Thus, any approved generics may remain on the market, and any generics still undergoing the ANDA process may be approved for marketing.¹³⁶ Further, a brand-name product that is listed in the Orange Book's discontinued section may be used by future ANDAs to receive marketing approval.¹³⁷ Alternatively, the FDA may select one of the approved ANDAs to serve as the reference listed drug ("RLD"), the drug to which bioequivalence must be proven.¹³⁸ Thus, generic manufacturers are not excluded from entering the market when a brand-name manufacturer decides to stop production and distribution of a particular pharmaceutical drug and to introduce a new product. Courts should not condemn product innovation as monopolization when the entry of competition is not foreclosed.

to develop their own brand, product hopping neither prevents physicians from prescribing a generic manufacturer's product, nor threatens the availability of those drugs to consumers when a physician has prescribed them.").

¹³⁴ See U.S. FOOD & DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (34th ed. 2014), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm> [<http://perma.cc/E848-LBPL>].

¹³⁵ See 21 C.F.R. § 314.161 (2015).

¹³⁶ See Devlin & Jacobs, *supra* note 6, at 49; Notice, 80 Fed. Reg. 1424 (Jan. 9, 2015) (Determination That TAGAMET (Cimetidine) Tablets and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness).

¹³⁷ See Notice, 80 Fed. Reg. 1424, *supra* note 136.

¹³⁸ "FDA will designate all reference listed drugs. Generally, the reference listed drug will be the NDA drug product for a single source drug product. For multiple source NDA drug products or multiple source drug products without an NDA, the reference listed drug generally will be the market leader as determined by FDA on the basis of commercial data. . . . If an applicant believes that there are sound reasons for designating another drug as a reference listed drug, it should consult FDA." 57 Fed. Reg. 17,958 (Apr. 28, 1992). See Michelle Yeary, *What is an RLD and Why Does It Matter?*, DRUG & DEVICE L. BLOG (Feb. 3, 2012, 10:12 AM), <http://druganddevicelaw.blogspot.com/2012/02/what-is-rld-and-why-does-it-matter.html> (citing 57 Fed. Reg. 17,950, 17,958 (Apr. 28, 1992)).

b. Changing Product and Marketing Emphasis Does Not Exclude Generic Competition

Generic manufacturers' second exclusionary argument is that product hopping eliminates a generic drug's AB-rated equivalency, impeding the generic manufacturer's ability to take advantage of state switching laws. However, "[a]ll sorts of output-enhancing practices . . . tend to win business for the perpetrator and thereby reduce sales opportunities for its rivals."¹³⁹ Such conduct does not automatically raise the ire of antitrust law. Rather, it should only be viewed as an antitrust violation when that conduct is unreasonably exclusionary and is accomplished by means other than competition on the merits.¹⁴⁰

All that product hopping does is remove generic manufacturers' preferred channel of marketing; it does not eliminate the ability for generic manufacturers to compete by their own endeavors. "What [the generic] lost was not the ability to compete for [consumer] choice, but the ability to have sales automatically redirected to it by pharmacists . . ."¹⁴¹ Similar to brand-name manufacturers, generics retain the opportunity to undertake marketing activities of their own aimed at physicians or to encourage insurance companies to promote their version of a drug.¹⁴² In particular, studies have shown that direct-to-consumer ("DTC") advertising can result in a substantial increase in sales.¹⁴³ The hindrance suffered when a brand-name manufacturer withdraws its support for a product does not equate to unreasonably exclusionary conduct.¹⁴⁴

Generic companies, in response, argue that having to incur marketing costs to compete with brand-name companies will counteract the purpose and benefit of generic drugs—their low cost.¹⁴⁵ However, merely having to undertake their own advertising campaign does not impact generics' ability to utilize the ANDA process, whereby the generic manufacturer is still the beneficiary of substantial cost savings that approach \$1 billion, as compared to a brand-name manufacturer's investment.¹⁴⁶

In essence, what generic manufacturers are really asking for is that the brand-name manufacturer be required to continue promoting the original formulation, *i.e.*, that the brand-name manufacturer be found to have a

¹³⁹ Lambert, *supra* note 125, at 1177–78.

¹⁴⁰ *See id.* at 1178.

¹⁴¹ Guy V. Amoresano, *Branded Drug Reformulation: The Next Brand vs. Generic Antitrust Battleground*, 62 FOOD & DRUG L.J. 249, 254 (2007).

¹⁴² *See* Darrow, *supra* note 106, at 366, 374.

¹⁴³ *See id.* at 366.

¹⁴⁴ *See* Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Context*, 2007 MICH. ST. L. REV. 631, 665 (2007); Amoresano, *supra* note 141, at 255.

¹⁴⁵ *See* Cheng, *supra* note 26, at 1503.

¹⁴⁶ *See* Morris, *supra* note 15, at 254.

continuing duty to deal.¹⁴⁷ However, antitrust law does not require a firm to produce and market any particular product, and it does not require a firm that has decided to market a product to continue marketing that product indefinitely.¹⁴⁸ Instead, “[t]he competition-favoring rule is that an innovator has no duty to help its competitors.”¹⁴⁹ Requiring firms to “share the source of their advantage is in some tension with the underlying purpose of antitrust law, since it may lessen the incentive for the monopolist, its rival, or both to invest in those economically beneficial activities.”¹⁵⁰ This core tenet of antitrust law is particularly true in the patent realm; due to the large amount of investment and innovation required, there is a greater “risk that liability for refusal to deal in that product will deter procompetitive economic activity.”¹⁵¹

The Supreme Court has recognized that a monopolist can be liable for refusing to deal with a competitor in only one very narrow circumstance—when there is a “unilateral termination of a voluntary (*and thus presumably profitable*) course of dealing” which “suggest[s] a willingness to forsake short-term profits to achieve an anticompetitive end.”¹⁵² However, a brand-name manufacturer’s development and marketing of a pharmaceutical drug subject to state DPS laws does not satisfy this narrow exception. Rather, the situation faced by brand-name manufacturers is similar to that faced by the monopolist in *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP* (“*Trinko*”).¹⁵³ In *Trinko*, the Supreme Court found that the monopolist, Verizon, did not violate Section 2 by taking steps to restrain its competitors’ use of Verizon’s own infrastructure, where the federal and state regulatory regime required that Verizon share its source of advantage with its competitors.¹⁵⁴ The Court held that when a regulatory scheme is designed to directly address competition concerns, additional antitrust scrutiny should be applied with great caution.¹⁵⁵

¹⁴⁷ Cf. Cheng, *supra* note 26, at 1494 (“[B]rand name manufacturers are under no legal duty to help their generic competitors by curtailing formulation changes . . .”).

¹⁴⁸ See e.g., *Christy Sports, LLC v. Deer Valley Resort Co.*, 555 F.3d 1188, 1194–96 (10th Cir. 2009).

¹⁴⁹ *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1370 (Fed. Cir. 1998).

¹⁵⁰ John DeQ. Briggs & Daniel J. Matheson, *The Supreme Court’s 21st Century Section 2 Jurisprudence: Penelope of Thermopylae?*, 11 SEDONA CONF. J. 137, 140 (2010).

¹⁵¹ Howard A. Shelanski, *Unilateral Refusals to Deal in Intellectual and Other Property*, 76 ANTITRUST L.J. 369, 375 (2009).

¹⁵² *Verizon Commc’ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 409 (2004).

¹⁵³ 540 U.S. 398 (2004).

¹⁵⁴ *Id.* at 409–10.

¹⁵⁵ *Id.* at 411–12. *Trinko* established “an inverse relationship between the regulatory scheme’s effectiveness at protecting competition and the need for antitrust intervention.” Brief for Intellectual Property and Antitrust Professors, *supra* note 59, at 17.

The Hatch-Waxman Act and state DPS laws provide a regulatory structure analogous to that in *Trinko*. In both the product hopping context and in *Trinko*, the monopolist's obligation to cooperate would not exist but for the regulatory scheme.¹⁵⁶ It is only the ability for easier market entry created by the Hatch-Waxman Act and the ability for pharmacy substitution created by state DPS laws that allows generic manufacturers the opportunity to conduct their business the way they currently do—*i.e.*, without conducting their own R&D and their own advertising. This indicates that brand-name manufacturers have not voluntarily entered into a course of dealing with generic manufacturers. Indeed, any such agreement would be unprofitable for a brand-name manufacturer, based on the history of low-cost generic competition taking substantial sales and market share away from brand-name drugs.¹⁵⁷

Further, and contrary to the Second Circuit's decision in *New York v. Actavis*,¹⁵⁸ a brand-name manufacturer's decision to market a reformulated product, as a replacement for an older version, is not equivalent to the brand-name manufacturer forsaking short-term profits. Instead, product hopping is the replacement of one product for another, and this theoretically has no impact on the overall demand for a brand-name drug, and thus no impact on the brand-name manufacturer's profit. Thus, pharmaceutical competition under the Hatch-Waxman Act and state DPS laws does not fit within the extremely narrow exception for refusal to deal liability; rather, brand-name manufacturers are reducing their exposure to an involuntary and unprofitable regulatory structure.

Lastly, this is not an instance where the courts should create an additional exception to this longstanding antitrust rule against forced dealings. When industry regulation is designed specifically to address competition in that industry, it is not the role of antitrust law to supplant legislative judgment.¹⁵⁹ Here, as discussed above, the combination of the Hatch-Waxman Act and state DPS laws creates a pervasive framework to address the specific issue of generic competition in the pharmaceutical industry.¹⁶⁰ This regime explicitly attempts to balance two competing competition concerns—protecting brand-name innovation and promoting generic competition.¹⁶¹ Moreover, recent amendments to the Hatch-Waxman Act show a continuing concern with

¹⁵⁶ See *Trinko*, 540 U.S. at 409.

¹⁵⁷ See *In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 135 (2d Cir. 2014).

¹⁵⁸ See *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 659 (2d Cir. 2015).

¹⁵⁹ See Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 14 (2004). “[T]he greater the degree to which practices challenged under the antitrust laws have been explicitly mandated or approved by a regulatory enterprise, the less room there is for antitrust in that particular market.” *Id.*

¹⁶⁰ See, e.g., Cheng, *supra* note 26, at 1509.

¹⁶¹ See Kalter, *supra* note 39, at 212.

ensuring the proper competitive balance in the pharmaceutical marketplace. The legislative framework at issue in this article has been amended in recent years in response to perceived anticompetitive abuses.¹⁶² In particular, one amendment in 2010 dealt specifically with market exclusivity for new products that contained only “minor changes . . . such as a new indication, route of administration, dosing schedule, dosage form, delivery stem, delivery device, or strength.”¹⁶³ In that case, Congress limited the relevant provisions of this amendment to biologic drugs only, as opposed to all forms of pharmaceutical drugs.¹⁶⁴ In essence, Congress enacted pharmaceutical regulatory legislation with specific knowledge of product hopping, and chose not to alter the existing balance between brand-name innovation and generic competition. Asking antitrust law to intervene is the equivalent of asking antitrust law to legislate where federal and state legislatures have not.¹⁶⁵

As the above analysis has shown, product hopping does not impede generic manufacturers’ ability to enter into a particular pharmaceutical drug market and it does not impede their ability to compete in that market on the basis of their products’ merits. Where a monopolist’s conduct does not interfere with open market competition, its conduct is not anticompetitive.

3. Procompetitive Justifications

“When a legitimate business justification supports a monopolist’s exclusionary conduct, that conduct does not violate § 2”¹⁶⁶ In the third step of the *Microsoft* framework, the defendant assumes the burden of proving procompetitive justifications for its conduct.¹⁶⁷ There are multiple justifications for product hopping. The most substantial justification is the role of antitrust law to promote innovation. Product hopping also incentivizes

¹⁶² See *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1678 (2012).

¹⁶³ Darren S. Tucker & Gregory F. Wells, *Emerging Competition Issues Involving Follow-On Biologics*, 29 ANTITRUST 100, 104 (2014).

¹⁶⁴ See *id.* Biologics differ from other pharmaceuticals in that they are “derived from living organisms.” *Id.* at 100.

¹⁶⁵ Lipman, *supra* note 4.

¹⁶⁶ *Image Technical Servs., Inc. v. Eastman Kodak Co.*, 125 F.3d 1195, 1212 (9th Cir. 1997). Proffered justifications may be rebutted as illegitimate if the plaintiff can prove “either that the justification does not legitimately promote competition or that the justification is pretextual.” *Id.*

¹⁶⁷ See *United States v. Microsoft Corp.*, 253 F.3d 34, 59 (D.C. Cir. 2001). Where a product hopping plaintiff has not satisfied its burden in step two, it is unnecessary to proceed to this stage of the analysis. See *Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co.*, Civ. No. 12-3824, 2015 WL 1736957, at *12 (E.D. Pa. Apr. 16, 2015). Similar to the most recent court decision, *see id.*, this paper’s analysis found that product hopping is not anticompetitive, and thus it is unnecessary to address procompetitive justifications. In the interest of providing a complete analysis, this article will nonetheless discuss product hopping’s procompetitive justifications in the *Microsoft* framework’s third step.

consumer education programs and decreases costs faced by manufacturers that are passed on to consumers.

a. Antitrust Law Should Promote Product Innovation

Product innovation is one of the cornerstones of competition in the current economy.¹⁶⁸ Because innovation “stimulates long-term economic growth,”¹⁶⁹ it is inimical to the purpose of antitrust law to condemn a brand-name manufacturer’s innovation efforts as anticompetitive.¹⁷⁰ Given the substantial costs and high level of uncertainty involved, the promotion of innovation in the pharmaceutical industry is paramount. “[O]nly 30% of marketed drugs ever earn enough profit to cover their average developmental costs”¹⁷¹ of roughly \$1 billion.¹⁷² That figure does not even take into account pharmaceuticals that do not make it past the development phase and into the marketing phase.¹⁷³ Additionally, drug development is becoming increasingly complex, lengthy, and more expensive.¹⁷⁴ As a result, this already low success rate may become even lower.

A decreased success rate creates a need to increase the reward for successful innovations in order to continue promoting innovation.¹⁷⁵ However, the amount of patent-granted market exclusivity that innovator firms currently receive in the pharmaceutical industry is insufficient to allow recoupment and to encourage investments in innovation. While the typical patent receives 20 years of marketing exclusivity,¹⁷⁶ the Hatch-Waxman Act limits the amount of marketing protection that an innovator pharmaceutical company can receive to 14 years *at most*.¹⁷⁷ This is far too little time to allow recoupment, especially considering the high costs and low success rates of pharmaceutical innovation.¹⁷⁸ Moreover, this 14-year period is the *maximum* attainable.¹⁷⁹ Given the extensive and complex NDA process that new drugs face, it is

¹⁶⁸ See GAVIL ET AL., *supra* note 84, at 1162.

¹⁶⁹ McGaraghan, *supra* note 112, at 186.

¹⁷⁰ See John M. Newman, *Anticompetitive Product Design in the New Economy*, 39 FLA. ST. U. L. REV. 681, 725 (2012) (“As a baseline principle, all courts have recognized that product improvement without more is protected and beyond antitrust challenge.”) (citing 3B PHILLIP E. AREEDA & HERBERT HOVENKAMP, *ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION* ¶ 776a, at 286 (3d ed. 2006)).

¹⁷¹ See Morris, *supra* note 15, at 259.

¹⁷² See *id.* at 254.

¹⁷³ See *id.* at 259.

¹⁷⁴ See *id.* at 252.

¹⁷⁵ See Fachler, *supra* note 32, at 1071.

¹⁷⁶ See *id.* at 1066.

¹⁷⁷ See Kalter, *supra* note 39, at 211.

¹⁷⁸ Morris, *supra* note 15, at 248.

¹⁷⁹ Kalter, *supra* note 39, at 211.

common for a newly approved drug to receive marketing exclusivity for a much shorter period of time.¹⁸⁰ As the FDA increases the length and complexity of its approval process, the amount of patent protection that pharmaceutical drugs receive will only decrease further.¹⁸¹

It is in light of these market and regulatory realities that antitrust law must be applied.¹⁸² One of the key goals of antitrust law is “to bring new and better technologies, products, and services to consumers.”¹⁸³ Because “the social losses caused by innovation restraints are large,” courts should be especially mindful of the costs when applying antitrust law.¹⁸⁴ Further, the “treble damage provision of the antitrust laws tends to occasion overdeterrence in the Section 2 context” and results in even greater impairment to beneficial innovation.¹⁸⁵

When applying antitrust law to innovative industries, courts and agencies must be highly cognizant of the “unique characteristics of R&D activity.”¹⁸⁶ The unique cost structure of innovation activities and innovative industries, discussed in Part I, *supra*, is one such characteristic. Another key characteristic, and one that is potentially even more central to understanding innovation benefits, is how new innovative efforts and discoveries come to fruition. A vast amount of innovation results from previous efforts or comes from fortuitous and unintended discovery.

As Isaac Newton famously remarked, “if I have seen further than others, it is by standing upon the shoulders of giants.”¹⁸⁷ The result of a firm’s innovation efforts is much more than just an isolated new technology or product; innovation creates a broader knowledge base, and as more R&D is encouraged and performed the stockpile of knowledge available to other innovators becomes larger.¹⁸⁸ The resulting benefits for consumers and society are substantial. This “stockpile” reduces the amount of time and the costs required

¹⁸⁰ See Morris, *supra* note 15, at 248 (citing an empirical analysis by Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 *MANAGERIAL & DECISION ECON.* 491, 501 (2007)).

¹⁸¹ See Fachler, *supra* note 32, at 1087.

¹⁸² See *Verizon Commc’ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004) (“[A]ntitrust analysis must sensitively recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies.” (internal citation omitted)).

¹⁸³ PROMOTING INNOVATION, *supra* note 74, at 1.

¹⁸⁴ See Hovenkamp, *supra* note 7, at 260.

¹⁸⁵ Lambert, *supra* note 125, at 1236–37 (citing to Herbert Hovenkamp and Richard Posner).

¹⁸⁶ Woan, *supra* note 113, at 55.

¹⁸⁷ THE YALE BOOK OF QUOTATIONS 550 (Fred R. Shapiro ed., 2006).

¹⁸⁸ See Thomas K. Cheng, *A Developmental Approach to the Patent-Antitrust Interface*, 33 *NW. J. INT’L L. & BUS.* 1, 13 (2012); Woan, *supra* note 113, at 63.

for additional innovation and enables innovators to focus their efforts on achieving the next level of development and advancement.¹⁸⁹

Many times, innovation results from unexpected events—an innovative firm may be looking to develop a drug for one use, but ultimately discovers something entirely unexpected and equally, or possibly more, beneficial. For instance, certain hair loss supplements were developed from research into glaucoma treatment.¹⁹⁰ Viagra[®], the popular erectile dysfunction drug, was discovered during research efforts aimed at curing angina and other heart pains.¹⁹¹ Moreover, even during the development phase, scientists “will make minor modifications to a lead compound’s structure with the goal of optimizing its efficacy and safety.”¹⁹² While the tweak made by the innovator may be minor, the impact it can have on consumers may be substantial. For instance, in *New York v. Actavis* the difference between the original and improved formulations was between a twice-daily dosage and a once-daily dosage with extended release.¹⁹³ While a seemingly minor alteration, the court recognized that it had several substantial benefits for Alzheimer’s patients. First, taking one dosage per day is much simpler for Alzheimer’s patients, who have memory problems.¹⁹⁴ Second, once-daily, extended release drugs have proven to be “associated with improved tolerability” for Alzheimer’s patients, who typically become more confused, anxious, and agitated later in the day, making it more difficult to administer the medication.¹⁹⁵ Significantly, the Hatch-Waxman Act itself acknowledges the reality and benefit of incremental pharmaceutical innovation by stating that an approved drug may “include an active ingredient . . . that has been approved in another application”¹⁹⁶ and by providing market exclusivity based on the level of added efficacy of the new drug.¹⁹⁷

Some critics argue that promoting innovation has its limits, and that a product hop should be considered anticompetitive when a new drug does not contain substantial changes or provide substantial added benefits to consumers.¹⁹⁸ These critics fail to appreciate both the realities of innovation previously discussed and the safeguards against abuse provided by the patent

¹⁸⁹ See Cheng, *supra* note 188, at 13.

¹⁹⁰ See Allergan, Inc. v. Apotex, Inc., 754 F.3d 952, 956 (Fed. Cir. 2014).

¹⁹¹ See Hovenkamp, *supra* note 7, at 256.

¹⁹² Lechner, *supra* note 37, at 149.

¹⁹³ No. 14 Civ. 7473, 2014 WL 7015198, at *10–12 (S.D.N.Y. Dec 11, 2014).

¹⁹⁴ See *id.* at *12.

¹⁹⁵ *Id.*

¹⁹⁶ 21 U.S.C. § 355(j)(5)(F)(iii) (2012).

¹⁹⁷ See Darrow, *supra* note 106, at 404. For instance, compared to the three years of guaranteed exclusivity “new indications of existing medicines” receive, drugs that contain a “new molecular entity” will receive five years. *Id.*

¹⁹⁸ See *Actavis*, 2014 WL 7015198, at *10.

and pharmaceutical regulatory systems. The patent system's obviousness requirement, discussed in Part II.B.1, *supra*, requires that a new product embody a technical or scientific advancement of the relevant art before conferring the benefits of patent protection.¹⁹⁹ Notably, the Supreme Court has recently made it more difficult to satisfy the obviousness requirement and receive a patent.²⁰⁰ Any pharmaceutical drug that has received patent protection has therefore satisfied this standard. The relevance of obviousness to product hopping is due to the essential function that patents play in allowing an innovator pharmaceutical company to recoup its investment, thus incentivizing its innovative efforts.²⁰¹ A pharmaceutical drug that does not receive patent protection will not be further developed or marketed, and therefore the abuse identified by product hopping critics is unlikely to occur.²⁰² The fact that patents are never considered definitively valid and are constantly vulnerable to validity challenges serves as an additional barrier against anticompetitive abuses.²⁰³

The expense and time associated with the FDA approval process impedes the ability of an innovator company to suddenly product hop in order to suppress incipient generic competition. In addition to the multi-year R&D process, NDA approval takes an average of 18 months²⁰⁴ and the total cost is close to \$1 billion.²⁰⁵ For a brand-name company to complete a hop before the window for generic entry opens, it must commit to producing the new formulation long before the threat of generic entry materializes, due to the large disparity between approval timelines for brand-name and generic products.²⁰⁶ Further, given the substantial costs, it is unlikely that an innovator firm would be able to experiment continuously on ways to alter a single drug

¹⁹⁹ See *supra* note 41 and accompanying text.

²⁰⁰ See Shelanski, *supra* note 151, at 388 (discussing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007)).

²⁰¹ See, e.g., Fachler, *supra* note 32, at 1066.

²⁰² See *id.* at 1066-1067. "[P]atents are issued very early on in a product's development; for pharmaceutical innovations, they are issued before the clinical trial testing required for FDA approval has occurred." *Id.* Thus, if a patent were not issued, the innovator would be able to cease its efforts early in the development process and avoid expending substantial resources.

²⁰³ See *supra* note 36 and accompanying text. The creation of inter partes review in 2012, a new procedure for challenging patent validity, will make challenges to patent validity quicker and less burdensome for the challenger. See Lorelei Laird, *Reverse Trolling*, A.B.A. J. 17, 18 (Dec. 2015). The increased ease of challenge acts as a further buffer against abuse of the patent system by innovator companies.

²⁰⁴ See Shadowen et al., *supra* note 28, at 5.

²⁰⁵ See Morris, *supra* note 15, at 254.

²⁰⁶ Accord *id.* at 257-58.

for the sole purpose of excluding competition.²⁰⁷ The company must focus, instead, on securing legitimate innovation; simply because the result is an alteration of an existing compound does not mean the antitrust laws should suddenly condemn that innovation.

The innovation associated with product hopping provides substantial benefits to consumers, both in the short-term and in the long-term. When a pharmaceutical company has developed a new product that is sufficiently innovative to receive patent protection, the antitrust law should not condemn that innovative effort.²⁰⁸ Such over-enforcement will only discourage the very conduct that antitrust law seeks to promote.

b. Consumers Benefit From More Information and Lower Costs

Product hopping also benefits consumers by allowing increased product education and by decreasing certain pharmaceutical company costs. New pharmaceutical product releases are accompanied by “large marketing and education investments in order to introduce physicians, hospital formularies, pharmacies, and insurers to the new drug and to educate them about the drug’s benefits and risks, [and] how to use it safely.”²⁰⁹ Without these services, responsibility for determining which drugs are safest for particular patient classes and which drugs have the best outcomes would fall squarely on the shoulders of patients and physicians.²¹⁰ This would result in increased safety risks for consumers and increased costs and time for consumers and physicians.

Only brand-name manufacturers provide these services; generic manufacturers do not.²¹¹ However, after generic entry, these services become economically unfeasible for brand-name manufacturers, and the brand-name manufacturer will typically cease to provide them.²¹² The reason for this is

²⁰⁷ See *supra* notes 15–19 and accompanying text (discussing the significant number of failed pharmaceutical development attempts and the costs associated with pharmaceutical development).

²⁰⁸ See, e.g., *Allied Orthopedic Appliances, Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 1000 (9th Cir. 2010); J. Thomas Rosch, Comm’r, Fed. Trade Comm’n, Remarks Before the World Generic Medicine Congress, *The Antitrust/Intellectual Property Interface: Thoughts on How to Best Wade Through the Thicket in the Pharmaceutical Context 2* (Nov. 17, 2010).

²⁰⁹ Morris, *supra* note 15, at 255.

²¹⁰ See *id.* at 282–83 (“[T]hese outlays in distributing information also save consumers and health-care providers from having to make as great an investment on their own in identifying and understanding which new drugs are on the market . . . [and] may be a much more effective and cost-efficient way than physician research in providing important information . . .”).

²¹¹ See Shadowen et al., *supra* note 28, at 46.

²¹² See *id.* at 15.

state DPS laws and generic free-riding. The effect of a state DPS law is that brand-name manufacturer marketing efforts will result in generic sales, eliminating brand-name manufacturers' incentives to conduct education and marketing programs.²¹³ As a result of pharmacy switching, the brand-name manufacturer loses the benefit it derives from the education programs— "[g]oodwill, name recognition and brand loyalty," which "are all features of open market competition."²¹⁴ The period of market exclusivity that brand-name manufacturers receive after launching a new formulation and before generic entry provides the return necessary to incentivize the provision of beneficial consumer and physician education and advertising programs.²¹⁵

Product hopping can result in cost savings for pharmaceutical companies, which would ultimately be passed on to consumers. Given the complex R&D and approval process, there are multiple areas where reformulations could result in cost savings for manufacturers. For example, a change to the molecular structure or release mechanism of a compound might lead to lower manufacturing costs.²¹⁶ One common change to pharmaceutical formulations is to increase the dosage amount contained within one unit of the drug.²¹⁷ Such change has also been coupled with scoring, which is "a groove that runs across the [drug's] surface [that] allows the user to split" the single unit into multiple doses.²¹⁸ Combining a larger amount of the drug into one unit and allowing a customer to divide that unit as their needs require reduces the total quantity the consumer must purchase, potentially lowering the total cost for the consumer.

Another area where product hopping may result in substantial cost savings is paragraph IV litigation. As noted in Part II.B.2, *supra*, when submitting an ANDA, a generic manufacturer must submit one of four patent certifications, the fourth possible certification being that any relevant "patent is invalid or

²¹³ See Henry N. Butler & Jeffrey Paul Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 IOWA L. REV. 57, 99–100 (2010) ("Because brand-name drug manufacturers face lower prices and lose a significant portion of their market share upon generic entry, they also lose much of their incentive to market the drug."). Additionally, "[v]igorous marketing may increase consumption of the drug more than any increases in consumption due to cheaper prices when a generic drug enters the market." *Id.* at 99.

²¹⁴ Amoresano, *supra* note 141, at 255.

²¹⁵ See Ashley Doty, *Leegin v. PSKS: New Standard, New Challenges*, 23 BERKELEY TECH. L.J. 655, 657–58 (2008) (discussing how guaranteed profits induce retailers to provide customer services).

²¹⁶ See Shadowen et al., *supra* note 28, at 4.

²¹⁷ See, e.g., *Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co.*, Civ. No. 12-3824, 2015 WL 1736957, at *3 (E.D. Pa. Apr. 16, 2015); *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 418 (D. Del. 2006).

²¹⁸ *Mylan Pharms.*, 2015 WL 1736957, at *3.

will not be infringed by the manufacture, use, or sale of the new drug.”²¹⁹ Such certification—known as a paragraph IV certification—”automatically counts as patent infringement . . . and often means provoking litigation.”²²⁰ This patent litigation can cost over \$10 million,²²¹ and its initiation triggers an automatic 30-month stay against the generic manufacturer marketing its product.²²² The mere risk of paragraph IV litigation and the associated uncertainties has a detrimental effect on the value of pharmaceutical R&D investments and incentives to innovate.²²³ However, after a product hop, a brand-name manufacturer may be less interested in fighting a long, expensive lawsuit over the original formulation it no longer markets, and may choose to forego initiating the lawsuit. By avoiding the 30-month stay and the litigation expenses, product hopping can accelerate market entry by generics and decrease the cost for the generic manufacturer and, ultimately, for consumers.

Where conduct results in legitimate procompetitive benefits, antitrust law should not condemn that activity; product hopping is such an activity. Product hopping is innovation, not monopolization, and should not be condemned by antitrust law.

4. Balancing the Competitive Effects

In the last step of the *Microsoft* framework, the burden shifts back to the plaintiff to “demonstrate that the anticompetitive harm of the conduct outweighs the procompetitive benefit.”²²⁴ The courts’ focus during the balancing “is upon the effect of [the] conduct.”²²⁵ Therefore, balancing revives a theme touched upon throughout this article—the difficulty in valuing long-term innovation benefits.²²⁶ For decades, both courts and leading antitrust

²¹⁹ 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012).

²²⁰ *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013) (internal quotation marks omitted). These patent lawsuits commonly result in reverse payment settlements, whereby the brand-name-plaintiff pays the generic-defendant to delay marketing of the relevant generic drug. These settlements have recently received significant antitrust scrutiny.

²²¹ See C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 952 (2011).

²²² See 21 U.S.C. § 355(j)(5)(B)(iii).

²²³ See *Morris*, *supra* note 15, at 276.

²²⁴ *United States v. Microsoft Corp.*, 253 F.3d 34, 59 (D.C. Cir. 2001). Balancing becomes necessary only when anticompetitive harm has been proven and procompetitive justifications have not been rebutted. Given the lack of anticompetitive harm and the finding of procompetitive benefit, balancing in a product hopping case will ultimately be unnecessary; however, in order to provide a complete analysis, this article examines the balancing step.

²²⁵ *Id.*

²²⁶ The complexity of such analysis is discussed *supra*, notes 4–9 and accompanying text.

scholars have realized “that courts are ill suited to distinguish between helpful and harmful innovation, a task better left to the marketplace.”²²⁷ In contrast to the difficulty in evaluating long-term innovation effects, short-term effects such as increased prices and decreased output can be easily quantified. Unfortunately, the *Microsoft* decision did not provide any guidance on how to balance competing long-term and short-term effects, and the Supreme Court has never ruled on a predatory innovation case.²²⁸ Without direct guidance, an analysis of pertinent antitrust policy considerations is necessary to help formulate a balancing test.

The first pertinent consideration, based on the heavily regulated nature of the pharmaceutical industry, is that antitrust law should not second-guess industry-specific regulatory regimes when those regimes were created to address the specific competition issue at hand.²²⁹ As previously discussed, the Hatch-Waxman Act and state DPS laws form a pervasive framework created specifically to regulate pharmaceutical competition and innovation.²³⁰

The second policy concern is the substantial harm to beneficial competition that can result from “mistaken inferences and the resulting false condemnations.”²³¹ In the product hopping context, the fear of wrongly impeding the substantial benefits that accrue from innovation strongly counsels against antitrust condemnation. Opponents of this view contend that high prices are an anticompetitive evil as well, and that this effect should weigh against product hopping and in favor of increased generic competition. While the premise of the argument is valid, the reality is “th[at] social losses caused by innovation restraints are . . . far larger than the social losses caused by monopolistic pricing.”²³² The deterrent effect that condemning product hopping will have on innovation is magnified by the treble damages awarded under the Sherman Act.²³³ Innovation itself is a “substantial source of competitive vigor,”²³⁴ which includes price competition. Thus, promoting innovation can kill two birds with one stone: promoting innovation and ultimately lowering prices.

²²⁷ Amoresano, *supra* note 141, at 252.

²²⁸ See Devlin & Jacobs, *supra* note 6, at 7.

²²⁹ See Hovenkamp, *supra* note 159, at 14.

²³⁰ See *supra* notes 159–164 and accompanying text.

²³¹ *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 414 (2004).

²³² Hovenkamp, *supra* note 7, at 260. Another prominent antitrust scholar has remarked, “[w]hen enforcing the antitrust laws [in the pharmaceutical] industries, such [price] savings must of course be balanced against maintaining incentives for firms to invest in innovation as societal benefits from technological progress quickly swamp short-term price effects.” Morse, *supra* note 55, at 367.

²³³ Lambert, *supra* note 125, at 1236–37.

²³⁴ GAVIL ET AL., *supra* note 84, at 1162.

The third policy consideration is the Supreme Court's current tone toward dominant firm competition. For the past twenty years, the Supreme Court has continually "endors[ed] aggressive competition by dominant firms."²³⁵ This has created an "overall trend" in antitrust law, whereby courts have increasingly realized the benefits that result by allowing innovator firms greater freedom to choose their product design and distribution strategies.²³⁶

A synthesis of these considerations indicates a general consensus as to the importance of promoting innovation and the associated benefits. In the product hopping context, courts should be reluctant to find that violates Section 2 of the Sherman Act.

IV. CONCLUSION

The competitive value of product hopping by brand-name pharmaceutical manufacturers is an increasingly common question being faced by courts. Yet the outcomes reached by courts facing this issue have not been consistent. No court decision has proceeded through trial on the merits: a handful have been decided at the motion to dismiss stage, and the most recent trial court decision was on summary judgment. Further, these decisions have all been by trial courts. The first case to reach the courts of appeal was decided in mid-May 2015, and it was not a decision on the merits but merely affirmed the district court's grant of a preliminary injunction. The only other case to reach the courts of appeals, *Mylan Pharmaceuticals Inc. v. Warner Chilcott Public Limited Co.*, is still pending before the Third Circuit.

In view of this uncertainty and in light of the importance of innovation in the pharmaceutical industry, this article has undertaken an in-depth look at product hopping from the antitrust perspective to analyze how courts should consider product hopping on the merits. By utilizing the burden-shifting *Microsoft* framework for analyzing monopolistic conduct, this article has found that product hopping results in procompetitive outcomes and does not produce anticompetitive effects. Product hopping is pharmaceutical innovation, not monopolization.

²³⁵ Briggs & Matheson, *supra* note 150, at 141.

²³⁶ Kovacic, *supra* note 5, at 647.