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PRODUCT HOPPING: FEDERAL AND STATE APPROACHES

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INTRODUCTION

By any measure, the generic drug market is a success story of American health care policy. Largely spurred by the enactment of state drug substitution laws and an accelerated regulatory pathway for generics in the 1970s and '80s, generic drug competition saved American patients \$313 billion in 2019 alone.¹ In fact, a U.S. Food and Drug Administration study found that drugs with six or more competitors experienced price reductions of over 95 percent.² At a time when skyrocketing drug prices are a cause for national concern, the importance of competition in the pharmaceuticals market could not be greater.

Yet the brand-name drug companies that have profited handsomely from high-priced medicines have sought to take

1. "Securing Our Access & Savings: 2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report," Association for Accessible Medicines, 2020, p. 16. <https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generics-Biosimilars-Access-Savings-Report-US-Web.pdf>.

2. Ryan Conrad and Randall Lutter, "Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices," U.S. Food and Drug Administration, December 2019, p. 2. <https://www.fda.gov/media/133509/download>.

CONTENTS

Introduction	1
Product Hopping: Case Studies	2
Omeprazole (Prilosec) to Esomeprazole (Nexium)	2
Buprenorphine (Suboxone) Tablet to Sublingual Film	3
Albuterol (Ventolin) to Albuterol HFA	4
A Theory of Product Hopping	4
Patent Law	5
The Confluence of Patents and Regulation	6
Examples of Regulatory Costs	6
State Substitution Laws as Deregulation	7
Policy Alternatives to Curb Product Hopping	8
Evidence of Clinical Improvements	8
Modernizing Substitution Laws	9
Stricter Patent Requirements	10
Bridging the Patent-Regulation Divide	10
Conclusion	11
About the Author	11

advantage of legal and policy strategies to protect those profits. Chief among those strategies today is a technique called "product hopping," in which a company seeks to transition or 'hop' the market for a particular drug from one formulation over to another one. Generally, this is a two-step process wherein a manufacturer develops a new formulation of an existing, often best-selling drug and then convinces patients to switch to the new formulation, thereby disrupting generic competition over the old one.³ The practice is prevalent: one study estimates that new formulations are introduced for about half of all new small-molecule drugs.⁴ It is also costly, as one study indicates that five major examples of product hopping cost the U.S. health care system \$4.7 billion a year.⁵

The conventional response to product hopping has been antitrust enforcement, and while that avenue has been effective, it is also limited. And while patients, pharmacies and insurers who have charged pharmaceutical firms with anti-competitive product hopping have enjoyed successes, there have also been failures.⁶ Commentary on the matter has been

3. See, e.g., Kevin T. Richards et al., *Drug Pricing and Pharmaceutical Patenting Practices*, Congressional Research Service, Feb. 11, 2020, p. 20. <https://www.everycrsreport.com/reports/R46221.html>; Michael A. Carrier and Steve D. Shadowen, "Product Hopping: A New Framework," *Notre Dame Law Review* 92:1 (2016), p. 168. <https://scholarship.law.nd.edu/nldr/vol92/iss1/4>.

4. Reed F. Beall et al., "New Drug Formulations and Their Respective Generic Entry Dates," *Journal of Managed Care and Specialty Pharmacy* 25:2 (2019), p. 221. <https://www.jmcp.org/doi/pdf/10.18553/jmcp.2019.25.2.218>.

5. Alex Brill, "The Cost of Brand Drug Product Hopping," Matrix Global Advisors, September 2020, p. 6. <http://getmga.com/wp-content/uploads/2020/09/CostofProductHoppingSept2020.pdf>.

6. See, e.g., *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006); *Walgreen Co. v. AstraZeneca Pharm. LP*, 534 F. Supp. 2d 146 (D.D.C. 2008).

no less divided, all of which suggests a need to go beyond antitrust law as a response.⁷

Accordingly, this paper identifies several policy approaches that would limit the effects and prevalence of product hopping at both the federal and state levels. It posits that since it requires a combination of patent exclusivity on the new formulation of a drug and the imposition of a regulatory cost on the original one, solutions must target either the patent exclusivity arm or the regulatory cost arm. And moreover, the effectiveness of those solutions depends upon how well they are able to minimize the confluence of patents and regulation that enables product hopping. In particular, solutions worth consideration include improvements to FDA review of drugs, expansion of state generic substitution laws, strengthening of the patent examination processes and clarification of government patent licensing authority.

PRODUCT HOPPING: CASE STUDIES

Product hopping occurs when the manufacturer of an existing drug develops a slightly altered formulation and then convinces patients to switch over. Insofar as there is competition over the original formulation but not over the newer one, the effect is to enable the drug manufacturer to escape competition and thereby preserve inflated profits.

In a free market, product hopping should be doomed to fail. After all, if competitive prices on the older formulation are lower than monopoly prices on the new one, it stands to reason that patients would not want to switch unless the improvements were of substantial value. Nevertheless, in almost every case of product hopping, those improvements are minimal and insufficient to support a substantial price difference.

In light of this, as a first step to understanding how product hopping seems to defy this straightforward economic logic, this section presents several case studies of known product hops, which examine the actual changes made to each product, the drug companies' strategies for switching patients to the new formulation and the reactions of courts to those activities. These demonstrate the functioning of pharmaceutical markets and enable the development of the theory of product hopping that is presented in the following section.

7. See, e.g., Carrier and Shadowen (note that one coauthor was counsel for plaintiffs in several antitrust suits). <https://scholarship.law.nd.edu/ndlr/vol92/iss1/4>; Vikram Iyengar, "Should Pharmaceutical Product Hopping Be Subject to Antitrust Scrutiny?", *Journal of the Patent and Trademark Office Society* 97:4 (2015), p. 663. <https://assets.fenwick.com/legacy/FenwickDocuments/Pharmaceutical-Product-Hopping.pdf>; Timothy J. Muris and Jonathan E. Nuechterlein, "Generic Drugs, Used Textbooks, and the Limits of Liability for Product Improvements," *Criterion Journal on Innovation* 4 (2019), p. 207. <https://www.criterioninnovation.com/articles/muris-nuechterlein-generic-drugs-and-used-textbooks.pdf>.

Omeprazole (Prilosec) to Esomeprazole (Nexium)

Omeprazole is used to treat acid reflux and other gastrointestinal conditions. Originally manufactured and patented by AstraZeneca and sold under the name Prilosec, it is on the World Health Organization's list of essential medicines, and has long been one of the most prescribed medications in the United States. In 2000, it had earned AstraZeneca an estimated \$6 billion.⁸ However, in 2001, the patent on omeprazole was due to expire, which AstraZeneca predicted would lead to a sharp decline in revenue.⁹ In response, the company initiated its "Shark Fin Project" (so named because without a strategy, the company's profits over time would resemble the gradually rising and then rapidly dropping contour of a shark's fin) to develop a replacement product to hop to.¹⁰

The reformulation that AstraZeneca chose, called esomeprazole, revealed near-zero innovation and near-zero benefit. Omeprazole is a mixture of two enantiomers; that is, two molecules that are identical in composition but mirror images of each other, as a left hand is to a right. Esomeprazole was just one of the two molecules.¹¹ While one isolated enantiomer can sometimes perform better than the mixture, the evidence of benefit simply was not there for esomeprazole.¹² In fact, study after study found no substantial difference.¹³ Indeed, AstraZeneca's own research only found a benefit when comparing 40 mg of esomeprazole to 20 mg of omeprazole, which led commentators to discount those studies as "stacked."¹⁴

Nevertheless, the minor change was sufficient to garner AstraZeneca a new patent, which it began selling under the

8. Mark Metzke, "Targeting Enantiomer Product Hopping with a New 'Obviousness' Standard," *UCLA Journal of Law and Technology* 14:1 (2010), p. 8. https://uclajolt.com/home/Articles/2010/01_100915_metzke.pdf; Model List of Essential Medicines World Health Organization, (21st edition, 2019). <https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf>.

9. Metzke, p. 8. https://uclajolt.com/home/Articles/2010/01_100915_metzke.pdf; "Purple Haze: How a Little Purple Pill Called Nexium Exposes Big Problems in the U.S. Drug Supply Chain," 3 Axis Advisors LLC, Nov. 7, 2019, p. 3. <https://www.3axisadvisors.com/projects/2019/12/10/purple-haze-how-a-little-purple-pill-called-nexium-exposes-big-problems-in-the-us-drug-supply-chain>.

10. "Purple Haze," p. 3. <https://www.3axisadvisors.com/projects/2019/12/10/purple-haze-how-a-little-purple-pill-called-nexium-exposes-big-problems-in-the-us-drug-supply-chain>.

11. Metzke, pp. 7-8. https://uclajolt.com/home/Articles/2010/01_100915_metzke.pdf.

12. Mark A. Lemley, "Expecting the Unexpected," *Notre Dame Law Review* 92:3 (2017), pp. 1377-79. <https://scholarship.law.nd.edu/ndlr/vol92/iss3/8>.

13. Waheed Asghar et al., "Comparative Efficacy of Esomeprazole and Omeprazole: Racemate to Single Enantiomer Switch," *DARU Journal of Pharmaceutical Sciences* 23 (2015), No. 50 (reviewing fourteen studies). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4647708>.

14. See, e.g., S. J. Edwards et al., "Systematic Review: Proton Pump Inhibitors (PPIs) for the Healing of Reflux Oesophagitis," *Alimentary Pharmacology and Therapeutics* 24:5 (2006), p. 745. <https://pubmed.ncbi.nlm.nih.gov/16918878>; Robert Langreth and Matthew Herper, "Pill Pushers," *Forbes*, Apr. 21, 2006. <https://www.forbes.com/forbes/2006/0508/094a.html>.

name Nexium.¹⁵ And, while generic omeprazole became available after the patent on that drug expired in 2001, AstraZeneca undertook aggressive efforts, through advertising to doctors and various regulatory delay tactics against generic competitors, to switch patients to its reformulated esomeprazole product.¹⁶ Such tactics were successful, as one study found that in 2006, generics accounted for a mere 7 percent of the omeprazole/esomeprazole market, and that AstraZeneca enjoyed over \$10 billion in profits from Nexium in 2003.¹⁷

In 2006 and 2007, several pharmacies brought suit against AstraZeneca, alleging that its product hopping from omeprazole to esomeprazole constituted an attempt at market monopolization in violation of antitrust law. A federal judge in the D.C. District Court rejected the suit on the grounds that the possible procompetitive benefits of adding the reformulated product to the market defeated any finding of anti-competitive conduct.¹⁸ In the judge's view, patients as market consumers were able to choose between omeprazole and esomeprazole since both remained on the market, such that the latter product would only have been profitable if patients perceived greater value in it.¹⁹

While the court's reasoning has superficial appeal, it is puzzling in view of the facts: Despite a near total lack of evidence of any benefit to esomeprazole, patients paid extraordinarily high prices for it rather than choosing available generics. That puzzle suggests that the market forces at play are more complex, enabling drug companies to engage in successful product hopping even where it ought not to work in a free market.

Buprenorphine (Suboxone) Tablet to Sublingual Film

The combination of buprenorphine with naloxone—sold under the brand name Suboxone—is prescribed in the treatment of opioid addiction. In 2008 alone, it reaped over \$540 billion in profits for its manufacturer, Reckitt Benckiser.²⁰ Suboxone was originally made available as a tablet, and Reckitt enjoyed regulatory exclusivity that prevented generic

competition over that formulation until it was due to expire in 2009. Faced with expiration, Reckitt devised a product hopping strategy. As with AstraZeneca and esomeprazole, Reckitt obtained patents on the new formulation, in this case a sublingual film strip designed to dissolve under the tongue, despite substantial evidence even known to the company that the newer product was not a substantial improvement and indeed potentially less child-resistant than the tablet.²¹

Reckitt's spinoff firm Indivior, which took over marketing for the sublingual film product, also pushed patients to switch to the new formulation. But its efforts were more striking in tactics and effect than AstraZeneca's, because they attempted to defraud government officials. Despite studies showing that children were more likely to open and consume the film formulation, Indivior represented to the Massachusetts Medicaid program, MassHealth, that children were less likely to eat it.²² As a result, MassHealth began reimbursing for the sublingual film, thereby enabling the product hop away from the tablet.²³ Although the Department of Justice uncovered the fraud and levied over \$1 billion in fines in 2019 and 2020, the product hopping strategy was nevertheless successful in that Reckitt continued to earn massive profits on the new formulation.²⁴ Indeed, they allegedly switched up to 85 percent of patients and earned over \$1 billion a year.²⁵

In 2013, a group of Suboxone patients and insurance companies brought suit against Reckitt, alleging unlawful monopolization.²⁶ Reckitt countered, citing the omeprazole decision as precedent, but the federal judge in the Eastern District of Pennsylvania disagreed.²⁷ Because Reckitt had actively worked to remove Suboxone tablets from the shelves under its false theory of child safety, the court concluded that Reckitt had engaged in "coercive measures" that denied patients any real choice between the formulations.²⁸ Accordingly, the court agreed that the theory of antitrust harm was plausible,

15. Method for the Treatment of Gastric Acid-Related Diseases and Production of Medication Using (-) Enantiomer of Omeprazole, U.S. Patent No. 5,877,192 (issued Mar. 2, 1999).

16. "Purple Haze," pp. 22–24. <https://www.3axisadvisors.com/projects/2019/12/10/purple-haze-how-a-little-purple-pill-called-nexium-exposes-big-problems-in-the-us-drug-supply-chain>.

17. *Ibid.*, pp. 30–31.

18. *Walgreen Co. v. AstraZeneca Pharm. LP*, 534 F. Supp. 2d 146, pp. 151–52 (D.D.C. 2008).

19. *Ibid.*

20. *Annual Report and Financial Statements 2008*, Reckitt Benckiser Group PLC, March 2009, p. 20. https://www.annualreports.com/HostedData/AnnualReportArchive/r/LSE_RB_2008.pdf. Note: these numbers apply a currency exchange rate of 1.6.

21. Rebecca L. Haffajee and Richard G. Frank, "Generic Drug Policy and Suboxone to Treat Opioid Use Disorder," *Journal of Law Medicine and Ethics* 47 (2019), pp. 44–45. <https://journals.sagepub.com/doi/abs/10.1177/1073110519898042>; Plea Agreement at Exh. B, paras. 18–26, pp. 5–8, *United States v. Indivior Sols., Inc.*, No. 1:19-cr-16 (W.D. Va. July 27, 2020) (Doc. No. 427-5). <https://www.justice.gov/usao-wdva/press-release/file/1300366/download>.

22. Plea Agreement at Exh. B, paras. 22–26, *Indivior Sols.*, No. 1:19-cr-16.

23. *Ibid.*, p. 27.

24. *Ibid.*, p. 3; See also: United States Department of Justice, "Justice Department Obtains \$1.4 Billion from Reckitt Benckiser Group in Largest Recovery in a Case Concerning an Opioid Drug in United States History," Press Release, July 11, 2019. <https://www.justice.gov/opa/pr/justice-department-obtains-14-billion-reckitt-benckiser-group-largest-recovery-case>.

25. *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, pp. 673–75 & n.3 (E.D. Pa. 2014).

26. *Ibid.*, p. 672.

27. *Ibid.*, p. 680.

28. *Ibid.*, p. 682.

and allowed the case to proceed.²⁹ The patents on the sublingual film formulation were also challenged in view of the fact that the formulation was an obvious change from the tablet; the USPTO and courts agreed, rendering the patents invalid and enabling generic firms to manufacture the film.³⁰

While the fraud conviction, initial antitrust suit success and patent invalidations are perhaps a satisfying outcome in this case, it should be concerning that Reckitt opted for this level of behavior in the first place. Presumably, the company could have developed a more child-resistant product if it had invested in research, and the fact that it did not do so suggests a serious misalignment in innovation incentives.

Albuterol (Ventolin) to Albuterol HFA

Albuterol is a drug commonly used for the treatment of asthma and is packaged in an inhaler. Through 2008, albuterol inhalers were widely available and relatively inexpensive due to the availability of generics. But, in 2008, the generic was effectively banned from sale, forcing patients to switch to a patented brand-name inhaler that cost up to twice as much even with insurance coverage.³¹ Although the albuterol switch is not often cited as an example of product hopping, it meets the definition and the events that enabled it are instructive as they demonstrate a less traditional, but nevertheless important way that product hopping can occur.

The albuterol inhaler contains two main components: the albuterol compound itself and a pressurized propellant that sprays the compound out of the inhaler's valve. Initial inhalers, developed in the mid-1900s, used chlorofluorocarbons (CFCs) as the propellant. By the 1970s, the environmental dangers of CFCs were becoming known and eventually led to the 1987 adoption of the Montreal Protocol that called for substantial reductions in the use of CFCs. A key exception in the Montreal Protocol was for essential-use medicines, which enabled the generic albuterol inhaler to remain on the market.³²

In 2005, the FDA began a proceeding to consider de-designating the inhaler as an essential-use medicine exempt under the Montreal Protocol by 2008, to be replaced with inhalers using a propellant of tetrafluoroethane (HFA-

134a).³³ Numerous patients criticized the change on the grounds that, because GlaxoSmithKline held patents on the HFA formulation, the prices of inhalers would increase substantially, potentially leaving some asthmatics unable to afford them.³⁴ Indeed, the FDA's own economic analysis suggested that Americans would spend about \$8 billion more for albuterol inhalers between the 2008 ban on generic inhalers and the 2017 anticipated expiration of GSK's patents.³⁵ It further anticipated that between 3 and 8 million fewer inhalers would be sold due to the increase in cost—even after “[t]aking into account GSK's commitment to provide free samples and coupons.”³⁶ Nevertheless, the FDA went forward with the de-designation, relying, in part, on the unquantifiable environmental benefits, in part on GSK's promises not to raise prices on the HFA inhalers and, in part, on a “general policy of encouraging innovation and protecting investment in research and development.”³⁷

This particular “product hop” reveals an unexpected dimension to the practice. Taking as a given that the more environmentally friendly inhaler was, in fact, a valuable improvement and that environmental regulation is publicly beneficial, then none of the events that occurred would seem amiss. Yet, the overall result—that some low-income asthma patients would be priced out of access to an essential medicine and others would be required to pay not just increased prices but monopoly prices on formerly generic inhalers—is problematic.³⁸ Indeed, a 2015 study of albuterol prices and usage found that, just among insured patients, out-of-pocket costs after insurance rose by 85 percent after the ban went into effect, and that use of inhalers declined by an estimated 5 percent due to the increase in cost.³⁹ The following sections will address the issues surrounding such a strategy and whether there is an alternative approach.

A THEORY OF PRODUCT HOPPING

The previous case studies reveal a pattern that suggests that product hopping requires the presence of two main impediments to competition: First, an easily obtained legal exclusivity (or, a patent) must exist that prevents competition over the new formulation. Second, there must exist a regulatory

29. *Ibid.*, p. 684.

30. *BioDelivery Scis. Int'l, Inc. v. RB Pharm. Ltd.*, No. IPR2014-00325, slip op. p. 2 (P.T.A.B. June 30, 2015) (final written decision), *aff'd* without opinion, 667 F. App'x 997 (Fed. Cir. 2016); *Indivior Inc. v. Dr. Reddy's Labs.*, SA, 930 F.3d 1325, pp. 1330–31 (Fed. Cir. 2019).

31. Anupam B. Jena et al., “The impact of the US Food and Drug Administration Chlorofluorocarbon ban on out-of-Pocket Costs and Use of Albuterol Inhalers Among Individuals with Asthma,” *JAMA Internal Medicine* 175:7 (2015), p. 1172. <https://pubmed.ncbi.nlm.nih.gov/25962128>.

32. Leslie Hendeles et al., “Withdrawal of Albuterol Inhalers Containing Chlorofluorocarbon Propellants,” *The New England Journal of Medicine* 356:13 (2007), p. 1345 & tbl.1. <https://pubmed.ncbi.nlm.nih.gov/17392304>.

33. *Ibid.*, p. 1345.

34. Use of Ozone-Depleting Substances; Removal of Essential-Use Designations, 70 Fed. Reg. 17167, p. 17175 (Food & Drug Admin. Apr. 4, 2005). <https://www.federalregister.gov/documents/2005/04/04/05-6599/use-of-ozone-depleting-substances-removal-of-essential-use-designations>.

35. *Ibid.*, p. 17183.

36. *Ibid.*

37. *Ibid.*, p. 17176, pp. 17183–84, p. 17186.

38. See, e.g., Joseph S. Ross and Rita F. Redberg, “On Chlorofluorocarbon Bans and Inhaled Albuterol Prices,” *JAMA Internal Medicine* 175:7 (2015), p. 1179. <https://pubmed.ncbi.nlm.nih.gov/25962127>.

39. Jena et al., pp. 1174 and 1177. <https://pubmed.ncbi.nlm.nih.gov/25962128>.

regime that artificially increases the cost of the original formulation. Recognizing this relationship between patents and regulation in product hopping is important because, individually, both patents and regulation may seem benign. Patents are designed to encourage the development of new technologies and improvements to existing knowledge, and in the context of product hopping, they might appear to be serving that function well insofar as they do induce the development of new formulations that may offer consumer benefits. Regulations, too, are generally intended to promote the public interest and foster competition by correcting market failures, and the costs of regulatory compliance generally should be no more problematic than other costs of doing business. However, it is the unexpected interaction between these two seemingly unrelated legal regimes that becomes problematic.

Patent Law

As proposed above, half of the product hopping formula is an exclusivity right over the later product, and the most commonly used mechanism of exclusivity is the federal patent. Although there are other legal exclusivity rights available to drug makers that could support product hopping, patents feature most prominently because they are especially flexible, powerful and easy to obtain.⁴⁰ Accordingly, understanding the nature of patent protection is necessary to understand the mechanics of product hopping.

A patent is an exclusive right that the federal government grants over an invention that affords the holder the power to sue for damages or potentially to stop competitors who make, use or sell the same invention or similar ones.⁴¹ That exclusivity is temporary but relatively long-lived: 20 years from the date when an application for a patent is first filed. For a patent to be legally granted, the invention covered by the patent must, at the time of application, be new compared to existing technology and more than an obvious improvement of existing technology.⁴²

To apply for a patent, the inventor submits to the U.S. Patent and Trademark Office an application describing the invented technology and defining the “scope of the invention;” that is, the range of products and services that fall within the exclusivity protections of the desired patent. An agency examiner then searches the scientific literature and compares it against the defined scope of the invention as written in specialized

paragraphs of the patent application called “claims.”⁴³ If the examiner finds that the application’s claims meet the novelty and nonobviousness requirements, and that the application meets other requirements of format and content, the patent is granted.⁴⁴

A perhaps counterintuitive implication of this patent-granting process is that there is no simple correspondence between patents and invented technologies, since it is the inventors (and their attorneys) who define in the patent claims what the invention “is.” In practice, this means that what may seem like a single invention can, in fact, have numerous patents covering it. Consider the example (loosely based on the Wright Brothers’ patent lawsuit) of a patent on an airplane.⁴⁵ A first patent might claim a flying device having wings and a body; a second might claim a flying device further including a tail rudder. Even if this second patent is sought after the first one, it is nevertheless new and potentially nonobvious over the first patent if the earlier patent did not describe airplane tail rudders.

In the pharmaceutical context, analogues to the airplane-with-rudder patent are commonplace. These so-called “secondary patents” are applied for after the initial patent on the active ingredient of a drug, and they generally pertain to dosage regimes, reformulations, methods of administration, combinations with inactive ingredients, methods of manufacturing or other such tweaks to the original compound.⁴⁶ Secondary patents are prevalent across the pharmaceutical industry, and some blockbuster drugs are covered by “estates” of dozens or even hundreds.⁴⁷

Several features of patent law make secondary patents especially useful for product hopping strategies. First, because patent expiration is computed based on the date of filing, secondary patents last longer than the initial active-ingredient patent, effectively giving the patent holder months or years of additional exclusivity protection.⁴⁸

43. *Manual of Patent Examining Procedure*, United States Patent and Trademark Office (9th edition, rev. June 2020), § 2120. <https://www.uspto.gov/web/offices/pac/mpep/index.html>.

44. Menell et al., Sec. 14.1.1.3.1, pp. 14-7 to 14-9. https://www.fjc.gov/sites/default/files/2017/PCMJG3d_2016_final.pdf.

45. *Wright Co. v. Herring-Curtiss Co.*, 204 F. 597, pp. 598–99 (W.D.N.Y. 1913), aff’d, 211 F. 654 (2d Cir. 1914) (per curiam).

46. Richards et al., pp. 9 and 16–19. <https://www.everycrsreport.com/reports/R46221.html>.

47. See, e.g., Amy Kapczynski et al., “Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of ‘Secondary’ Pharmaceutical Patents,” *PLoS One* 7 (2012), p. 4. <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0049470>; Robin Feldman, “May Your Drug Price Be Evergreen,” *Journal of Law and the Biosciences* 5 (2018), p. 630 and Table 6. <https://academic.oup.com/jlb/article/5/3/590/5232981>; C. Scott Hemphill and Bhaven N. Sampat, “When Do Generics Challenge Drug Patents?,” *Journal of Empirical Legal Studies* 8 (2011), p. 644. <https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1740-1461.2011.01235.x>.

48. 35 U.S.C. § 154(a)(2).

40. Carrier and Shadowen, p. 221. <https://scholarship.law.nd.edu/ndlr/vol92/iss1/4>.

41. Peter S. Menell et al., *Patent Case Management Judicial Guide* (Federal Judicial Center, 3rd edition, 2016), Ch. 14. https://www.fjc.gov/sites/default/files/2017/PCMJG3d_2016_final.pdf.

42. 35 U.S.C. § 102; § 103.

Second, the tests of novelty and nonobviousness do not require the later-patented invention to be an improvement upon the first, but only different. This allows minor, inconsequential changes to a drug to be patented even if those changes have no benefit for the drug's safety or efficacy—indeed they may be patented even if the resulting treatment is worse than the original.⁴⁹

Third, even when the changes to a drug are indeed so minor that they fail to meet the thresholds of novelty and nonobviousness, they may nevertheless be patented due to the practical difficulties of patent examination. For example, patent examiners systematically lack funding and resources to examine patent applications thoroughly, which means that large numbers of issued patents—about a quarter, by one estimate—are likely erroneous even under current law.⁵⁰ Secondary patents on drugs, in particular, are reported in multiple studies to be vulnerable to challenge for failing to meet the statutory requirements for patents.⁵¹ Nevertheless, the issuance of just one invalid patent, let alone dozens or hundreds, can delay or deter competition due to the high costs of patent litigation.

Because of these features of current patent law, a drug company can develop a slightly altered formulation of a bestselling drug and obtain secondary patents on that formulation, setting the stage for a product hop. But the strategy would fail if competitors could sell the older formulation at cheap, competitive rates and consumers were able to buy it. Product hopping thus depends not only on secondary patents but also on a regulatory environment that pushes consumers toward reformulations at the drug maker's behest.

The Confluence of Patents and Regulation

Consider a situation involving a lifesaving drug, such that demand is perfectly inelastic (since patients cannot choose not to take it). The drug's original formulation is off-patent and subject to generic competition, and a patented improvement is also available. In the absence of external regulation, patients would choose between the products based on the value that they assign to the improvement. For example, if the improvement is from an injectable drug to a tablet, some patients might care greatly about the change while others may be more indifferent. The patent-holding drug maker may then raise the price of the improvement drug to maxi-

49. W. Nicholson Price II, "The Cost of Novelty," *Columbia Law Review* 120 (2020), p. 794. <https://columbialawreview.org/content/the-cost-of-novelty>.

50. See, e.g., Michael D. Frakes and Melissa F. Wasserman, "Irrational Ignorance at the Patent Office," *Vanderbilt Law Review* 72 (2019), p. 975. <https://vanderbiltlawreview.org/lawreview/2019/04/irrational-ignorance-at-the-patent-office>; Shawn P. Miller, "Where's the Innovation: An Analysis of the Quantity and Qualities of Anticipated and Obvious Patents," *Virginia Journal of Law and Technology* 18 (2013), p. 1. <https://www.vjolt.org/volume-18>.

51. See, e.g., Hemphill and Sampat. <https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1740-1461.2011.01235.x>.

mize profits based on those consumer preferences. Because the patent holder possesses a monopoly, the chosen price will be based on that monopoly position and not maximize social welfare. Nevertheless, the market disciplines the set price, and the drug maker stands to profit more if the improvement brings more value to consumers.

Introducing just a small degree of regulation on the off-patent product, however, changes incentives dramatically. The regulation may be thought of as an added cost atop the price of the off-patent formulation, insofar as either the generic manufacturer must outlay costs of compliance or the consumer must make extra effort to procure the regulated generic.⁵² In this case, if the patent-holding drug maker charges marginally less than the competitive price of the off-patent drug plus the cost of the regulation, then it captures the entire market. The magnitude of the improvement is irrelevant, since patients will choose the patented "improvement" over the generic purely for cost reasons. Indeed, the cost imposed by the regulation is the driving force behind the pricing of the drug, and if the regulation makes the off-patent formulation unobtainable (effectively giving it infinite cost), then the patent-holding drug maker is free to charge as much as it wants for the improvement—even if the improvement offers no consumer benefit.

Notably, this result occurs only in the presence of both a patent exclusivity over the improvement product and a regulatory cost on the original formulation. Without the patent, competitors would be free to sell the improvement product as well, overcoming the regulatory cost and driving down the price of the improvement to competitive levels. Without the regulation, pricing of the improvement product would simply fall to ordinary market dynamics as described above. It is only in the presence of both that a valueless improvement can capture a market and restrain competition over the original formulation.

Examples of Regulatory Costs

The cases of product hopping discussed so far, as well as others, closely fit this pattern of product hopping as a confluence of patents and regulation. That said, it is sometimes not obvious what constitutes a "regulation" or how that regulation imposes costs on competitors. This section therefore considers several forms of regulatory barriers that drug companies have taken advantage of in executing their product hopping strategies.

The most striking regulatory strategy would be to ban the pre-improvement formulation outright. The albuterol HFA inhaler example above fits this pattern, as GlaxoSmithKline

52. Richard A. Posner, "Taxation by Regulation," *Bell Journal of Economics and Management Science* 2:1 (1971), p. 22. https://econpapers.repec.org/article/rjebellj/v_3a2_3ay_3a1971_3ai_3aspring_3ap_3a22-50.htm.

was able to have the FDA withdraw approval of the older generic formulation. Similar tactics have been used for other drugs. Purdue Pharma, the manufacturer of oxycodone (OxyContin) developed a patented abuse-resistant formulation called OxyContin OP and persuaded the FDA to withdraw approval for the older formulation just as generics were preparing to come to market.⁵³ While the rationale for the withdrawal was to prevent illegitimate use of oxycodone, the ultimate effect was to prevent generic competition, guaranteeing Purdue additional years of monopoly protection.⁵⁴

A partial ban can be achieved at different levels of the health insurance system. For example, with Suboxone, the patent-holding manufacturer lobbied the Massachusetts Medicaid program to stop reimbursing for the tablet form of the drug, favoring the newer sublingual film product instead. Had the lobbying effort been successful, Massachusetts Medicaid patients at least would have been unable to take advantage of generic competition, instead being forced to pay Indivior's patent-backed monopoly prices on the sublingual film. These examples are known as "hard switches," where the patent holder removes the older product from the market, leaving only the patent-protected newer formulation available.⁵⁵

A second product hopping strategy is the "soft switch," where the patent holder leaves the older product available and even continues to sell it, but promotes the newer product through advertisements and marketing.⁵⁶ Superficially, the soft switch might appear to be ordinary competition between the older and newer products, which has led some commentators and judges to view soft-switch product hopping as not economically problematic.⁵⁷ Yet soft-switch product hopping takes advantage of regulation as well: namely, the requirement that patients obtain a prescription or other medical provider authorization in order to obtain certain drugs.⁵⁸ The prescriber, not being responsible for the costs of the drug, lacks incentives to weigh the costs and benefits of different formulations, which gives rise to a misalignment between the patient and the prescriber known as the "price disconnect."⁵⁹ (A second price disconnect is between an insured patient

and the insurer, but insurers can close that disconnect by higher shared-responsibility payments for costlier brand-name drugs.⁶⁰) In order to overcome the price disconnect, a patient could research the available options and discuss them with the prescriber, but that imposes costs on both parties in the form of time consumed to conduct that research.⁶¹ As a result, the price disconnect is, in effect, a regulatory cost imposed on the older, unadvertised formulation, and that cost explains the success of soft-switch product hops.

State Substitution Laws as Deregulation

If the requirement for a prescription acts as a regulatory cost on consumer choice, then laws that restore consumer choice in appropriate situations are essentially deregulatory measures, which may help to alleviate that cost and restore competitive drug pricing. Such measures are found in every state in the nation, and are commonly known as generic substitution laws.⁶² While these laws vary from state to state, they generally allow or require a pharmacist filling a prescription for a brand-name drug to substitute a generic equivalent, subject to the patient's approval.⁶³ Substitution laws thus give the patient a greater opportunity to intervene in the choice among a brand-name drug and lower-cost generics.

In their current form, however, state substitution laws do not address product hopping because of current limits on the substitutions that may be made. States generally require a substituted generic to be "therapeutically equivalent" to the prescribed drug, meaning that the generic is identical in dosage, route of administration, quantity of active ingredient, clinical effect and safety profile.⁶⁴ The FDA evaluates therapeutic equivalence in approving drugs, and most states rely on the FDA's determinations in approving substitutions under individual state laws.⁶⁵ While these substitution laws apply to the general class of small-molecule drugs, even more stringent state laws apply to the increasingly common class of large-molecule therapeutics known as biologics. States permit substitution of brand-name biologics only with competitor compounds that the FDA deems "interchangeable"

53. Lars Noah, "Product Hopping 2.0: Getting the FDA To Yank Your Original License Beats Stacking Patents," *Marquette Intellectual Property Law Review* 19:2 (2015), pp. 172-75. <https://scholarship.law.marquette.edu/cgi/viewcontent.cgi?article=1276&context=iplr>.

54. *Ibid.*, pp. 176-77.

55. Richards et al., pp. 20-21. <https://www.everycrsreport.com/reports/R46221.html>.

56. *Ibid.*

57. See, e.g., *Walgreen Co. v. AstraZeneca Pharm. LP*, 534 F. Supp. 2d 146, p. 151 (D.D.C. 2008); Benjamin M. Miller, "Product Hopping: Monopolization or Innovation?," *Boston University Journal of Science and Technology Law* 22 (2016), pp. 133-34. http://www.bu.edu/jostl/files/2016/05/MILLER_ART_MACROD_FINALWEB.pdf.

58. Federal Food, Drug, and Cosmetic Act p. 503/b, 21 U.S.C. § 353, <https://www.law.cornell.edu/uscode/text/21/353>.

59. Carrier and Shadowen, pp. 179-80. <https://scholarship.law.nd.edu/ndlr/vol92/iss1/4>. See also: *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, p. 684 (E.D. Pa. 2014).

60. Jennifer N. Howard et al., "Influencers of Generic Drug Utilization: A Systematic Review," *Research in Social and Administrative Pharmacy* 14:7 (2018), p. 619. <https://pubmed.ncbi.nlm.nih.gov/28814375>.

61. Alison Masson and Robert L. Steiner, "Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws," Federal Trade Commission, 1985, pp. 46-47. <https://www.ftc.gov/sites/default/files/documents/reports/generic-substitution-prescription-drug-prices-economic-effects-state-drug-product-selection-laws/massonsteiner.pdf>.

62. Jesse C. Vivian, "Generic-Substitution Laws," *US Pharmacist* 33:6 (2008), p. 30. <https://www.uspharmacist.com/article/generic-substitution-laws>.

63. *Ibid.*; Masson and Steiner, pp. 1-2. <https://www.ftc.gov/sites/default/files/documents/reports/generic-substitution-prescription-drug-prices-economic-effects-state-drug-product-selection-laws/massonsteiner.pdf>.

64. *Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book)* (U.S. Food and Drug Administration, 41st edition, 2021), p. vii [hereinafter *Orange Book*]. <https://www.fda.gov/media/71474/download>.

65. Vivian, Table 2. <https://www.uspharmacist.com/article/generic-substitution-laws>.

under a recently enacted federal biologics law.⁶⁶ While the FDA has approved several biologics as “biosimilar” to brand-name products, none has been approved as interchangeable to date.⁶⁷

Since product hopping involves introducing a reformulated product that is different from the generically available one, substitution laws will generally not overcome the price disconnect or enable consumer choice. If a prescription is written for the new formulation, the pharmacist cannot invoke substitution laws to dispense a generic of the original formulation since the two formulations are not therapeutically equivalent. A small number of states permit “therapeutic substitution,” which permits the pharmacist to select from a wider range of equivalents, but those laws are more cumbersome to use as they require the prescriber to actively approve such substitution.⁶⁸ With respect to product hopping, then, state substitution laws are a helpful starting point for policy but not a solution in themselves.

POLICY ALTERNATIVES TO CURB PRODUCT HOPPING

If product hopping depends on both patent exclusivity on a new drug formulation and a regulatory cost on the older, unpatented formulation, then policy that limits product hopping should target at least one of those two dependencies. The wrinkle in identifying appropriate policy reform, however, is that both the patent system and regulatory law serve important purposes standing alone. The goal of the proposals below, then, is to overcome the patent–regulation confluence while minimally disrupting the individual benefits of each legal system.

Evidence of Clinical Improvements

The price disconnect of soft-switch product hopping depends on an information asymmetry: The prescriber may have better information about available treatments but diminished incentives to care about cost; the patient is cost-sensitive but must expend time and effort to learn about available alternatives. A straightforward approach to reducing the effectiveness of product hopping then is to reduce this asymmetry by better informing patients. Patients who are aware of lower-cost alternatives to the drugs that their providers prescribe are at least in a position to have a conver-

sation with their provider about the best course of treatment in view of their financial interests.

Dmitry Karshtedt proposes alleviating the prescriber–patient information asymmetry through a new form of FDA labeling. The FDA is tasked with evaluating—based on a drug manufacturer’s input and studies— whether a new formulation exhibits any improvements over existing available treatments.⁶⁹ If the manufacturer declines or is unable to prove such improvements, Karshtedt proposes that the drug label should contain a warning that no comparative data has been provided; otherwise the label would summarize the improvements found.⁷⁰ Being able to review this information, patients would be aware of options available to them and potentially opt for lower-cost treatments in consultation with their medical providers.

While Karshtedt’s proposed “general authority” to evaluate drug improvements would be a novel addition to the FDA’s purview, the agency is already familiar with assessing whether new drugs are improvements upon older ones in multiple contexts. For example, the FDA grants priority review status to a drug application, which reduces the pendency of agency review, for drugs that “would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious or life-threatening condition compared to available therapies.”⁷¹ The FDA may also grant accelerated approval status for drugs that “provide meaningful therapeutic benefit to patients over existing treatments.”⁷² The FDA also permits drug companies to request inclusion of comparative remarks on the drug label, provided that they can show clinical data to the FDA’s satisfaction supporting those comparative remarks. Indeed, many companies actively seek to include such remarks since they are advantageous for marketing the approved drug.⁷³ Notably, the improvements need not be to safety or efficacy: Benefits such as patient convenience can be noted on the label, so long as the drug company can show study evidence of those benefits.⁷⁴ These examples

66. Richard Cauchi, “State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars,” *National Conference of State Legislatures*, May 3, 2019. <https://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx>.

67. Ana Santos Rutschman, “Regulatory Malfunctions in the Drug Patent Ecosystem,” *Emory Law Journal* 70:2 (2020), pp. 374–75. <https://scholarlycommons.law.emory.edu/eli/vol70/iss2/3>.

68. Jonathan J. Darrow et al., “Reconsidering the Scope of US State Laws Allowing Pharmacist Substitution of Generic Drugs,” *BMJ* 369 (2020), p. 4 and Table 2. <https://www.bmj.com/content/369/bmj.m2236>.

69. Dmitry Karshtedt, “The More Things Change: Improvement Patents, Drug Modifications, and the FDA,” *Iowa Law Review* 104:3 (2019), pp. 1194–98. <https://ilr.law.uiowa.edu/print/volume-104-issue-3/the-more-things-change-improvement-patents-drug-modifications-and-the-fda>.

70. *Ibid.*, p. 1195.

71. Center for Drug Evaluation and Research, “Manual of Policies and Procedures 6020.3: Review Designation Policy: Priority (P) and Standard (S),” Food and Drug Administration, June 25, 2013, p. 6. <https://www.fda.gov/media/72723/download>.

72. 21 C.F.R. § 314.500.

73. “Guidance for Industry: Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products—Content and Format,” U.S. Food and Drug Administration, January 2006, pp. 5–6. <https://www.fda.gov/media/72140/download>.

74. See, e.g., “Patient Preference Information – Voluntary Submission, Review in Pre-market Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling,” U.S. Food and Drug Administration, May 18, 2015, pp. 18–20. <https://www.fda.gov/media/92593/download>; F. Reed Johnson and Mo Zhou, “Patient Preferences in Regulatory Benefit-Risk Assessments: A US Perspective,” *Value in Health* 19:6 (2016), p. 741. <https://pubmed.ncbi.nlm.nih.gov/2712700>.

show that the FDA has the capacity to evaluate comparative improvements between drug formulations, and that capacity could easily be leveraged to overcome information asymmetries that underlie many instances of product hopping.

Modernizing Substitution Laws

One may wonder whether improved information about a product-hopped drug's benefits would be sufficient to inform patients about their available alternatives and initiate a conversation with their providers. After all, generic alternatives to brand-name drugs are published in the FDA's *Orange Book*, and yet the existence and use of generic substitution laws suggest that patients may be insufficiently aware of those generic alternatives or reluctant to ask physicians about them.⁷⁵ This observation suggests a second reform for product hopping: Expanding state substitution laws in ways that further improve patient informedness and decrease the regulatory barrier to choosing lower-cost options.

A first cut would be to allow for a wider range of substitutions. Jonathan Darrow and colleagues propose broadening substitution laws to give state health agencies greater discretion to deem particular drug formulations substitutable, and also note several states that permit, with physician approval, "therapeutic substitution" of non-equivalent drugs within the same therapeutic class.⁷⁶ Since product hopping generally involves minor reformulations of existing drugs, Darrow and colleagues contend that broader substitution authority will forestall some degree of product hopping at the point of dispensation.⁷⁷

Commentators have raised two main concerns with therapeutic substitution. The first is that there may be uncertainty in substituting a well-tested drug with a newer one of less-established safety or efficacy.⁷⁸ But this concern is irrelevant to substitution in the context of product hopping, since the substituted drug is older and likely better evaluated than the new formulation. Second, several medical professionals have argued that the prescriber rather than the pharmacist is in the best position to select among alternative treatments for a particular patient.⁷⁹ Darrow and colleagues counter that pharmacists are often in a better position to evaluate these

questions, since they have greater training in drug chemistry than physicians.⁸⁰ Yet, even taking this concern as true, it is unclear how prescribing physicians can make these evaluations of differences between drug formulations without scientific comparisons.⁸¹ This would merely bolster the case for FDA-approved comparative studies of drug improvements as described above.⁸²

Indeed, the combination of expanded substitution laws with a requirement for comparative studies appears especially powerful. FDA-approved comparative information on a drug reformulation's label would give a scientific basis for state health agencies to determine whether a non-equivalent reformulation is substitutable with a different generic. In effect, the FDA serves an information-forcing role to determine what improvements a new formulation exhibits, and broadened substitution enables pharmacists to ensure that patients can take advantage of that information at the time of purchase. Taken together, these two reforms lower informational costs to patients, thereby reducing the regulatory cost gap that arises from the patient-prescriber price disconnect and decreasing the effectiveness of product hopping.

Expanding substitution laws would likely also require making the procedures of substitution more flexible. Currently, each state applies a largely uniform approach to substitution: If a prescribed brand-name drug has a generic equivalent, then the pharmacy generally follows the same rules of patient consent and provider notification regardless of the nature of the drug.⁸³ This one-size-fits-all approach is reasonable where the substituted drug is therapeutically equivalent, but where non-equivalent drugs are substitutable, variations in procedure may be required. Where a new formulation is shown to be safer or more efficacious than its predecessor, for example, it may be appropriate to deny substitution altogether; where no clinical difference is shown, on the other hand, substitution may be permitted with minimal patient approval. An important case is when the new formulation is clinically indistinguishable but shown to be more convenient for patients, for example a reformulation to make a pill smaller and easier to swallow. Patient choice should be paramount here, as the patient is the only person in a position to weigh the benefits of convenience over any additional costs of the reformulated drug. A greater range of substitutability thus requires a greater range of substitution procedures.

75. Masson and Steiner, pp. 42 and 45. <https://www.ftc.gov/sites/default/files/documents/reports/generic-substitution-prescription-drug-prices-economic-effects-state-drug-product-selection-laws/massonsteiner.pdf>.

76. Darrow et al., pp. 3–4. <https://www.bmi.com/content/369/bmi.m2236>.

77. *Ibid.*, p. 3.

78. See, e.g., Curt D. Furberg et al., "Are Drugs Within a Class Interchangeable?", *Lancet* 354:9185 (1999), p. 1203. <https://pubmed.ncbi.nlm.nih.gov/10513728>.

79. Elliott M. Antman and James J. Ferguson, "Should evidence-based proof of efficacy as defined for specific therapeutic agent be extrapolated to encompass a therapeutic class of agents?", *Circulation* 108:21 (2003), p. 2606. <https://pubmed.ncbi.nlm.nih.gov/14638523>; Dean J. Kereiakes and James T. Willerson, "Therapeutic Substitution: Guilty Until Proven Innocent," *Circulation* 108:21 (2003), p. 2612. <https://pubmed.ncbi.nlm.nih.gov/14638525>.

80. Darrow et al., p. 4. <https://www.bmi.com/content/369/bmi.m2236>.

81. Furberg et al., p. 1203. <https://pubmed.ncbi.nlm.nih.gov/10513728>.

82. *Ibid.*, pp. 1203–04.

83. See, e.g., Vivian. <https://www.uspharmacist.com/article/generic-substitution-laws>; Yan Song and Douglas Barthold, "The Effects of State-Level Pharmacist Regulations on Generic Substitution of Prescription Drugs," *Health Economics* 27:11 (2018), p. 1717. <https://pubmed.ncbi.nlm.nih.gov/29992674>.

Stricter Patent Requirements

While the above two policy recommendations focus on the regulatory cost arm of product hopping, approaches that target the patent exclusivity arm are viable as well. As discussed above, patents are the preferred form of exclusivity for product hopping because they are easily obtained without a required showing of improvement, and because they are powerfully enforceable even when erroneously granted. Requiring a greater showing of improvement as a condition for patentability would therefore limit the effectiveness of patents as a tool for product hopping.

The most direct reform would be to change the substantive patent law requirements to demand this showing of improvement. Senator Lindsey Graham drafted (but did not introduce) legislation that would have created a presumption of obviousness for certain drug combinations or reformulations, and other commentators have proposed declaring specific improvements of drugs unpatentable.⁸⁴ While tightening of patentability requirements would likely have a strong effect on product hopping, such reform faces at least two practical difficulties. First, recent experience with efforts to reform a different aspect of substantive patentability law shows that doing so would be politically complicated and difficult.⁸⁵ Second, the courts have historically played a vigorous role in interpreting patentability rules, so any legislation changing rules would have potentially indeterminate effect for years until the courts decide enough cases to develop a body of law around that legislation.⁸⁶

Accordingly, a more promising avenue is procedural reform to ensure that patents are granted correctly at the USPTO.⁸⁷ As observed above with respect to Suboxone and other product-hopped drugs, the patents that enable product hopping often fail the tests of validity even under current law, so preventing those patents from erroneously issuing in the first place would reduce at least some of the worst cases of product hopping. Research by Michael Frakes and Melissa Wassermann shows that giving patent examiners more time to review patent applications could cut down on errors sub-

stantially and cost-effectively.⁸⁸ Furthermore, accurate patent examination depends on relevant expertise in science and drug development, and the FDA houses much of that expertise.⁸⁹ Increased collaboration between the USPTO and the FDA could thus enable knowledge transfers that would lead to improved examination of secondary drug patents, limiting issuance of erroneous patents that can become the basis of product hopping.

Bridging the Patent–Regulation Divide

The policy recommendations thus far have focused on product hopping in general or soft-switch product hopping, rather than hard-switch examples. Indeed, the recommendations on consumer choice and drug substitutions would be ineffective for hard switches where the older formulation is prohibited from sale entirely. It is arguably reasonable to focus more on soft-switch product hopping because antitrust law appears to be largely effective in remedying hard switches. Several courts have drawn a line between hard and soft switches with respect to antitrust suits against the firm engaging in product hopping.⁹⁰ Although commentators such as Carrier and Shadowen disagree with how courts have applied antitrust law to soft switches, they agree that hard-switch product hopping is anticompetitive in most cases.⁹¹

Still, a non-antitrust approach to product hopping may be desirable in cases like the albuterol inhaler where the regulatory arm of the product hopping scheme involves a public interest rulemaking. One particularly clever approach may be drawn from fields such as telecommunications. As Tejas Narechania observes, Federal Communications Commission projects such as the digital television transition and modernization of the 911 system have run into roadblocks when the relevant technologies for the projects were patented.⁹² To overcome these, the FCC has occasionally adopted regulations requiring use of particular technologies on the condition that holders of patents on those technologies make commitments to license their patents to competitors on fair, reasonable and non-discriminatory terms.⁹³ Indeed, it is longstanding executive policy that federal agencies may only adopt technology standards into regulations where pat-

84. Steve Brachmann, "Congress Adds TERM Act and No Combination Drug Patents Act to List of Drug Patent Bills Being Considered," *IPWatchdog*, June 20, 2019, <https://www.ipwatchdog.com/2019/06/20/congress-term-act-no-combination-drug-patents-act-added-list-drug-patent-bills-considered/id=110525>. See also: Metzke, https://uclajoiit.com/home/Articles/2010/01_100915_metzke.pdf.

85. See, e.g., Barry J. Herman and William R. Hubbard, "The Uncertain Future of Patent Eligibility," *The National Law Review*, Aug. 1, 2019, <https://www.natlawreview.com/article/uncertain-future-patent-eligibility>.

86. Jonas Anderson, "Congress as a Catalyst of Patent Reform at the Federal Circuit," *American University Law Review* 63:4 (2014), pp. 1010–12. <https://digitalcommons.wcl.american.edu/aulr/vol63/iss4/2>.

87. C. Scott Hemphill and Bhaven Sampat, "Drug Patents at the Supreme Court," *Science* 339 (2013), p. 1387. http://awa2014.concurrences.com/IMG/pdf/drug_patents_at_the_supreme_court_science.pdf; *Pharmaceutical Sector Inquiry: Final Report*, Competition Directorate-General, European Commission, July 8, 2009, p. 191. https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

88. Frakes and Wasserman, <https://vanderbiltlawreview.org/lawreview/2019/04/irrational-ignorance-at-the-patent-office>.

89. Karshtedt, pp. 1143–44. <https://ilr.law.uiowa.edu/print/volume-104-issue-3/the-more-things-change-improvement-patents-drug-modifications-and-the-fda>.

90. See, e.g., *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, pp. 681–82 (E.D. Pa. 2014); *Walgreen Co. v. AstraZeneca Pharm. LP*, 534 F. Supp. 2d 146, p. 151 (D.D.C. 2008).

91. Carrier and Shadowen, pp. 218–19. <https://scholarship.law.nd.edu/ndlr/vol92/iss1/4>.

92. Tejas N. Narechania, "Patent Conflicts," *Georgetown Law Journal* 103 (2015), pp. 1498–1501 and 1533–34. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2520698.

93. *Ibid.*, p. 1534; Conversion to Digital Television, 67 Fed. Reg. 63290, p. 63294 (Federal Communications Commission Oct. 11, 2002).

ent holders have committed to license any patents covering those technology standards.⁹⁴

Patent licensing requirements could similarly prevent hard-switch product hopping. If the FDA had included patent licensing as a component of its inhaler propellant regulation or its withdrawal of the oxycodone license, the increases in cost resulting from the unavailability of generics would have been greatly mitigated, since the generic manufacturers would also have been able to manufacture competing reformulations at the cost of a patent royalty—likely no more than 10 percent. Whether the inclusion of a patent licensing requirement would require congressional authorization is up for debate, although Narechania takes the view that existing ancillary authority under administrative law may be sufficient.⁹⁵ In any event, no legislative authorization is necessary for an agency such as the FDA to investigate the existence and potential effect of patents relevant to a proposed regulatory measure, and to consider that effect as part of its decision-making process.

CONCLUSION

The costs of product hopping to American patients and the economy suggest that reforms will have immense public value, but they also suggest that the industries that have enjoyed the benefits of product hopping will have strong incentives to maintain the status quo. Policymakers will therefore need a multifaceted approach to deal with the many different forms that product hopping can take. Nevertheless, the many possible policy solutions to product hopping ultimately share the common thread of enhancing competition among generic drugs, enabling consumer choice and lowering drug prices. Any progress toward that goal would be a valuable continuation of the success of the American health care system.

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94. OMB Circular A-119, Final Revision, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, Jan. 27, 2016, p. 9. <https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-119-1.pdf>.

95. Narechania, pp. 1518–21. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2520698.