

A SURVEY OF THREE PATENT-BASED APPROACHES THAT MAY PLAY A ROLE IN DRUG PRICES

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I. AN INTRODUCTION TO THE INTERPLAY BETWEEN PATENTS AND DRUG PRICES

The Founders considered intellectual property (“IP”) rights so important toward the goal of producing technological advances to benefit society at large that they codified them in the U.S. Constitution.¹ Today, IP rights, including patent rights, can play an important role in the development and pricing of prescription drugs.² Patents are particularly important because the U.S. Patent and Trademark Office (“USPTO”) grants patent holders a temporary “monopoly” on their new inventions or products – a practice essential to the pharmaceutical industry due to the need to recoup the substantial amount of money that was invested in research and development.³ As a reward for their innovation, patent holders generally have exclusive rights “to make, use, sell, or import” their invention within the U.S. for a period that begins when the patent is issued by the USPTO and ends approximately twenty years from the date the applicant applied for the patent.⁴ During this time, the “monopoly” is in effect, and competition from generic companies is delayed.⁵

Upon expiration of a patent’s exclusivity,⁶ generic or biosimilar products can

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1. See U.S. CONST. art. I, § 8, cl. 8 (“The Congress shall have Power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”)

2. See KEVIN J. HICKEY ET AL., CONG. RESEARCH SERV., R45666, DRUG PRICING AND INTELLECTUAL PROPERTY LAW: A LEGAL OVERVIEW FOR THE 116TH CONGRESS 1 (2019), <https://crsreports.congress.gov/product/pdf/R/R45666> [<https://perma.cc/KBX4-KHJN>].

3. See Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20 (2016). Research showed that the average cost to develop and secure approval of a new medicine in 2013 was \$2.6 billion dollars, considering trial and error, the research failures along the way, and the cost of capital. See *id.* Also, note that the DiMasi-Grabowski approach to pricing is one, but not the only, approach to pricing in the U.S. In the U.S., value-based and cost-plus approaches are also used, among others.

4. 35 U.S.C. §§ 154(a)(2), 271(a) (2020); see also HICKEY ET AL., *supra* note 2, at 3.

5. HICKEY ET AL., *supra* note 2, at 4 (stating that “pharmaceutical products are frequently protected by IP rights, and some studies have shown that IP rights are the most important factors driving high drug prices. For example, [the] FDA has found that increased competition from generic drug manufacturers is associated with lower prices for pharmaceuticals”).

6. Kevin O’Connor, *How Patents Play a Role in Drug Pricing*, PHARMA LETTER (Jan. 19, 2018), <https://www.thepharmaletter.com/article/how-patents-play-a-role-in-drug-pricing>

enter the market, driving the price of the product down.⁷ This change can be significant: the first generic competitor's product is typically offered at a 20-30% discount, and subsequent generic entry can push the price down to 15%, or even less, of the product's original price.⁸

Notably, "many factors other than IP rights contribute to" pharmaceutical drug prices.⁹ Furthermore, while there are significant government interventions on pricing within government programs (*i.e.*, mandatory rebates, consumer price index penalties, or best price provisions in Medicaid), the U.S. currently has no direct price controls on pharmaceuticals.¹⁰

The complexities of drug pricing extend far beyond a single law review Note. However, this Note examines three patent law approaches that have recently made substantial impacts on drug prices and drug pricing legislation. First, this Note examines the doctrine of patent exhaustion and, subsequently, the patent practices of "patent thicketing" and "product hopping." It analyzes the impact of each on the price of pharmaceuticals in the U.S.

This Note begins with Section II, analyzing the doctrine of patent exhaustion, which has an important relationship to recently publicized legislation that proposes prescription drug re-importation from Canada. Further, Section II explains how a 2017 U.S. Supreme Court decision, coupled with proposed health law legislation by the U.S. Department of Health and Human Services ("HHS"), could potentially enable pharmaceutical drug re-importation into the U.S. from Canada as a means of lowering U.S. drug prices.¹¹ Section II is divided into four subsections: (A) an overview of the landscape of re-importation of pharmaceuticals into the U.S. from Canada; (B) the legal relationship between a recent U.S. Supreme Court decision and international patent exhaustion; (C) how the international exhaustion doctrine might affect the market prices of pharmaceuticals; and (D) how the current HHS has designed legislation to target pharmaceutical drug re-importation and U.S. price controls.

The next two sections of this Note describe practices by patentees (*e.g.*, pharmaceutical manufacturers) purportedly designed to extend or maintain the

[<https://perma.cc/UB4T-QTZU>] (discussing how regulatory exclusivity, in addition to patent exclusivity, plays a role in drug pricing).

7. *Id.*

8. *Id.*

9. HICKEY ET AL., *supra* note 2, at 4. Examples of some of these factors include "demand, manufacturing costs, R&D costs, the terms of private health insurance, and the involvement of a government insurance program such as Medicaid," to name a few. *Id.*

10. See *International Trade and Pharmaceuticals: Joint Hearing Before the Subcomm. on Int'l Trade & the Subcomm. on Health Care of the S. Comm. on Fin.*, 108th Cong. 1-3 (2004) (statement of Sen. Jon Kyl, Chairman, Subcomm. on Health Care).

11. See generally Graham O'Donnell, *The Next Step in the Battle Against High Pharmaceutical Prices: Lexmark & the DSCSA Have Paved the Way for Parallel*, 46 FLA. ST. U. L. REV. 197 (2018); see also *Safe Importation Action Plan*, U.S. FOOD & DRUG ADMIN. (July 31, 2019), <http://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf> [<https://perma.cc/Z4VS-DPGW>] [hereinafter *Safe Importation Action Plan*].

market exclusivity of a particular product. Section III details “patent thickening.” Patent thickening is a nickname for one of these practices, and it is a strategy purportedly employed by some pharmaceutical manufacturers that aim to extend the duration of the patent “monopoly” by protecting the product with as many additional patents as possible, thus creating a so-called “thicket” around the product.

Next, Section IV addresses the so-called practice of “product hopping,” in which the pharmaceutical company allegedly replaces its branded drugs with slightly modified versions. Product hopping could prevent generic pharmaceutical drug entry because the original pharmaceutical drugs must be on the market for regulatory purposes. Because product hopping is complex, Section IV is further divided into two subsections. Subsection A describes “Hard Switches” – the quintessential product hopping scenario in which a pharmaceutical company takes the original drug completely off the market. Subsection B discusses “Soft Switches” – the less forceful process in which a pharmaceutical company disparages the original form of the drug, making the generic version more difficult to obtain.

This Note concludes with a summary about the interplay between patent law and the cost of prescription drugs, as drug pricing remains “at the forefront of discussions among patients, advocacy groups, prescribers, payers, pharmaceutical companies, and policy makers.”¹² The number of people interested in this issue, coupled with current legislation targeting these practices, may result in near-term changes to drug prices in the U.S.

It should be mentioned that many other patent practices exist in the context of drug pricing (*e.g.*, sham litigation, abuse of the Food and Drug Administration’s Risk Evaluation and Mitigation protocol, or abuse of the Food and Drug Administration’s Citizen Petition process), but these issues are beyond the scope of this Note.¹³

II. PATENT EXHAUSTION & DRUG RE-IMPORTATION

A. Re-importation of Lower Cost Pharmaceuticals into the U.S. from Canada

In 2003, legislators made changes to the Food, Drug, and Cosmetics Act (“FDCA”) that provided the Secretary of HHS with the legal authority to import prescription drugs from Canada.¹⁴ Despite this law being enacted over a decade ago, numerous hurdles prevented large-scale re-importation from Canada, one of which is the U.S. doctrine of patent exhaustion.¹⁵

12. O’Connor, *supra* note 6.

13. See generally Kerstin Noelle Vokinger et al., *Strategies that Delay Market Entry of Generic Drugs*, 177 JAMA INTERNAL MED. 1665 (2017).

14. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. This public law is better known as the law that created Medicare Part D.

15. *Patent Rights and Pharmaceutical Reimportation*, GEN (Nov. 1, 2005), <https://www.genengnews.com/magazine/38/patent-rights-and-pharmaceutical-reimportation/>

Under the doctrine of patent exhaustion, when a pharmaceutical manufacturer or licensee distributes patented medicines *within* the U.S., the patent rights with respect to these drugs are effectively terminated,¹⁶ and the purchaser and all subsequent owners are free to use or resell the product just like any other item of personal property without fear of an infringement lawsuit.¹⁷ However, the law has historically been unclear as to how this applies to international patent exhaustion. This means that, in the past, authorized sales and the corresponding distribution of patented medicines by pharmaceutical manufacturers to countries outside the U.S. (e.g., direct sales of a drug to Canada) would not terminate U.S. patent rights to that drug; or, at least, the law has historically been unclear on this point.¹⁸ Therefore, most people believed that re-importation of medicine initially sold or distributed to a foreign country, and then re-imported back into the U.S., would be considered an act of patent infringement.¹⁹

This rule is important to pharmaceutical re-importation because prices are lower in Canada and many other foreign countries than they are in the U.S.²⁰ One reason for this is that some governments (e.g., Canada) “are the primary or only payer of health care and in effect [can] dictate the prices of medicines as a condition of market access.”²¹ Therefore, pharmaceutical companies wanting to make their products available in Canada may be forced to sell their product at a lower price in Canada than in the U.S.²² In contrast, the U.S. does not participate in direct regulation of the prices that pharmaceutical manufacturers charge for their products, and the list price in the U.S. is often higher than in other industrialized nations, even though the actual price to the consumer often includes discounts, savings programs from the manufacturer, and negotiated out-of-pocket costs from the consumer’s insurer or pharmacy benefit manager.²³

[<https://perma.cc/8ESK-G6UL>].

16. *Id.*

17. *Impression Prods., Inc. v. Lexmark Int’l, Inc.*, 137 S. Ct. 1523, 1535 (2017).

18. *Patent Rights and Pharmaceutical Reimportation*, *supra* note 15; *see also* *Jazz Photo Corp. v. Int’l Trade Comm’n*, 264 F.3d 1094 (D.C. Cir. 2001) (holding that a patentee’s decision to sell a product abroad did not terminate its ability to bring an infringement suit against the buyer that imported the article and sold it in the U.S.); *Quanta Computer, Inc. v. LG Elecs., Inc.*, 128 S. Ct. 2109, 2122 (2008) (holding that the patentee could not bring an infringement suit because the “authorized sale . . . took its products outside of the patent monopoly”).

19. 35 U.S.C. § 271(a) (2020) (“Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the [U.S.] or imports into the [U.S.] any patented invention during the term of the patent therefor, infringes the patent.”).

20. *See* Panos Kanavos et al., *Higher US Branded Drug Prices and Spending Compared to Other Countries May Stem Partly from Quick Uptake of New Drugs*, 32 HEALTH AFF. 753 (2013).

21. Kevin Haninger, *Setting the Record Straight on International Reference Pricing*, CATALYST (July 16, 2019), <https://catalyst.phrma.org/setting-the-record-straight-on-international-reference-pricing> [<https://perma.cc/MLX7-GJBH>].

22. *Id.*

23. Topher Spiro et al., *Enough is Enough; The Time Has Come to Address Sky-High Drug Prices*, CTR. FOR AM. PROGRESS (Sept. 18, 2015), <https://www.americanprogress.org/issues/>

Canada sets its prices for patented medicines at the federal level through a quasi-judicial agency called the Patented Medicine Prices Review Board (“PMPRB”).²⁴ The PMPRB also places price caps after a prescription drug appears on the Canadian market. The price charged each successive year can rise only with the rate of inflation.²⁵ However, to paint a fair picture of this process, Canadians generally have less access to patented medicines.²⁶

In addition to patent exhaustion concerns, the passage of drug importation legislation in 2003 has been further hindered by complex legal, regulatory, and safety concerns.²⁷ Also, there have been numerous failed attempts to implement importation.²⁸ However, on July 31, 2019, HHS and U.S. Food and Drug Administration (“FDA”) issued a federal “Safe Importation Action Plan,” proposing two pathways to allow for the importation of drugs from Canada.²⁹ With the proper framework for drug safety assurances,³⁰ legislative support from individual states,³¹ and the recent U.S. Supreme Court decision regarding international patent exhaustion,³² the necessary logistics of parallel importation are increasing in probability.

healthcare/report/2015/09/18/121153/enough-is-enough/ [https://perma.cc/884M-YQWK].

24. *Patented Medicines Prices Review Board*, GOV’T CAN., <https://www.canada.ca/en/patented-medicine-prices-review.html> [https://perma.cc/R5QL-GKYA] (last visited Mar. 14, 2021).

25. PATENTED MEDS. PRICES REVIEW BD., GOV’T OF CAN., COMPENDIUM OF POLICIES, GUIDELINES AND PROCEDURES 45 (2017), <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=492#1645> [https://perma.cc/H6DP-6K9J#1645] (stating that the price of an existing patenting drug cannot increase by more than the Consumer Price Index).

26. BRAD MILLSON ET AL., INNOVATIVE MEDS. CAN., ACCESS TO NEW MEDICINES IN PUBLIC DRUG PLANS: CANADA AND COMPARABLE COUNTRIES 23 (2016), http://innovativemedicines.ca/wp-content/uploads/2016/05/20160524_Access_to_Medicines_Report_EN_Web.pdf [https://perma.cc/U6MV-Z9RQ]. In a 2016 report by Innovative Medicines Canada, comparing Canada to the twenty highest GDP nations, Canada ranked eighteen out of twenty, with only 37% of new medicines being reimbursed across the country. *Id.* at 5. Canada also ranked low for the length of time before reimbursement was granted in public drug plans, taking on average 449 days from new drug approval to reimbursement. *Id.* at 6.

27. *See, e.g.*, Monali Bhosle & Rajesh Balkrishnan, *Drug Reimportation Practices in the United States*, 3 THERAPEUTICS & CLINICAL RISK MGMT. 41 (2007).

28. *See, e.g., id.*

29. *Safe Importation Action Plan*, *supra* note 11.

30. *See* O’Donnell, *supra* note 11 (discussing the necessary safety frameworks for safe pharmaceutical drug importation).

31. Steven Findlay, *States Pass Record Number of Laws to Reel in Drug Prices*, KAISER HEALTH NEWS (Sept. 9, 2019), <https://khn.org/news/states-pass-record-number-of-laws-to-reel-in-drug-prices/> [https://perma.cc/Q7PS-T92E] (stating that four states – Colorado, Florida, Maine, and Vermont – established protocols in 2019 to begin the process of importing prescription drugs from Canada).

32. *See* *Impression Prods., Inc. v. Lexmark Int’l, Inc.*, 137 S. Ct. 1523 (2017).

B. International Patent Exhaustion & the Lexmark Decision

Prior to the *Lexmark* decision, even if the U.S. promulgated legislation that allowed for parallel drug importation, the doctrine of patent exhaustion would have precluded the sale of these imported pharmaceutical drugs in the U.S.³³ The facts and issues decided in *Lexmark* are thus instructive as to how re-importation questions may be resolved legally going forward.

Lexmark International, Inc. (“Lexmark International”) designed, manufactured, and sold toner cartridges to customers in the U.S. and globally.³⁴ Lexmark International owned several patents that covered components of their print cartridges and the manner in which they were used.³⁵ When toner cartridges ran out of toner, they could be refilled and reused again.³⁶ However, this created an opportunity for other companies – known as remanufacturers – to acquire empty Lexmark International cartridges from purchasers in the U.S. and abroad, refill them with toner, and then resell them at a lower price than the ones Lexmark International put on shelves.³⁷ In an attempt to combat this problem, Lexmark International structured its sales in a way that encouraged customers to return their empty cartridges back to them.³⁸ One means by which Lexmark International attempted to do this was to incentivize its customers to purchase a cartridge at a discount through a “Return Program.”³⁹ A customer who bought a cartridge through this program still owned the cartridge, but, “in exchange for the lower price, sign[ed] a contract agreeing to use it only once and to refrain from transferring the empty cartridge to anyone but Lexmark [International].”⁴⁰ Further, Lexmark International “install[ed] a microchip on each Return Program cartridge” that would further dissuade customers to reuse them.⁴¹ Despite these efforts, however, remanufacturers continued to successfully buy and refill Lexmark International cartridges, albeit more creatively.⁴² One issue was that the company’s “contractual single-use/no-resale agreements were with the initial customers, not with downstream purchasers like remanufacturers.”⁴³

The *Lexmark* decision thus presented one major question about the scope of the patent exhaustion doctrine that will become important to this Note’s discussion of the re-importation of pharmaceuticals later: whether patent rights

33. See generally *Jazz Photo Corp. v. Int’l Trade Comm’n*, 264 F.3d 1094 (D.C. Cir. 2001); see generally *Quanta Computer, Inc. v. LG Elecs., Inc.*, 128 S. Ct. 2109 (2008). Both seemed to imply that U.S. patent rights were not extinguished by an international sale.

34. *Impression Prods., Inc.*, 137 S. Ct. at 1529.

35. *Id.*

36. *Id.*

37. *Id.*

38. *Id.*

39. *Id.* at 1529-30.

40. *Id.* at 1530.

41. *Id.*

42. *Id.*

43. *Id.*

are exhausted when a patent owner sells its product outside of the U.S.⁴⁴ The U.S. Supreme Court concluded that a patentee's decision to sell a product "exhausts all of its patent rights in that item, regardless of any restrictions the patentee purports to impose" on the location of the sale, meaning that the patent owner may not use patent law to follow the product down the stream of commerce and sue subsequent purchasers for patent infringement.⁴⁵ Importantly, the U.S. Supreme Court noted that "even if the restrictions in [Lexmark International's] contracts with its customers were clear and enforceable under contract law, they do not entitle Lexmark [International] to retain patent rights in an item that it has elected to sell."⁴⁶

C. How Patent Exhaustion Can Affect the Market Prices of Prescription Drugs

To illustrate what could happen with the doctrine of patent exhaustion and pharmaceutical drug prices, it may be useful to study how a ruling by the U.S. Supreme Court on a similar intellectual property doctrine, the "first sale" doctrine of copyright law, influenced the prices of textbooks sold internationally. In 2013, a lawsuit between a major book publisher and a U.S. college student ensued after the student imported and resold textbooks in the U.S. that had been priced lower abroad.⁴⁷

When Kirtsaeng, the petitioner and a college student, moved from Thailand to the U.S. to study mathematics at Cornell University, "he asked friends and family to buy foreign edition English-language textbooks in Thai bookshops, where they [were] sold at low prices, and to mail them to him in the [U.S.]."⁴⁸ He then sold the books for a profit in the U.S. and reimbursed his family and friends.⁴⁹

Under the first sale doctrine of copyright law, when a copyright owner sells a lawfully made copy of its work, it loses the power to restrict the purchaser's freedom "to sell or otherwise dispose of . . . that copy."⁵⁰ However, like *Lexmark*, prior to *Kirtsaeng*, the Court had not ruled on whether this doctrine applied to the sale of works made and sold abroad.⁵¹

The U.S. Supreme Court granted Kirtsaeng's petition for certiorari and held that the first sale doctrine applies to copies of a copyrighted work lawfully made abroad.⁵² The U.S. Supreme Court in *Kirtsaeng* stated that what tipped the scales toward a global exhaustion policy was the fact that the first sale doctrine

44. *Id.* at 1529.

45. *Id.* at 1535.

46. *Id.* at 1526.

47. *See Kirtsaeng v. John Wiley & Sons, Inc.*, 133 S. Ct. 1351 (2013).

48. *Id.* at 1356.

49. *Id.*

50. 17 U.S.C. § 109(a) (2020).

51. *Impression Prods. v. Lexmark Int'l, Inc.*, 137 U.S. 1523, 1527 (2017).

52. *Kirtsaeng*, 133 S. Ct. at 1351.

originated in “the common law’s refusal to permit restraints on alienation of chattels.”⁵³

The Court expressly acknowledged that its decision was likely to impact prices, noting that “[a] publisher may find it more difficult to charge different prices for the same book in different geographic markets” but also that they could “find no basic principle of copyright law that suggests publishers are especially entitled to such rights.”⁵⁴

Notably, Justice Ruth Bader Ginsburg dissented in both the *Lexmark* and *Kirtsaeng* decisions. As the protections of the Patent Act have no extraterritorial effect, Justice Ginsburg argued that “it makes little sense to say that such a sale exhausts an inventor’s U.S. patent rights.”⁵⁵ This echoed the same position that Justice Ginsburg took when dissenting in *Kirtsaeng*, where she argued that a foreign sale should not exhaust U.S. copyright protections.⁵⁶

Regardless, most economists believe that parallel importation will result in more uniform pricing: namely, lower U.S. prices and higher prices abroad.⁵⁷ In its best-case scenario, the establishment of international exhaustion will align U.S. patent law with free trade principles, decreasing international price discrimination.⁵⁸

Notably, there is no uniform agreement on this point. The fact that mandatory exhaustion will benefit U.S. consumers’ pocketbooks does not mean that mandatory exhaustion will increase U.S. citizens’ welfare overall.⁵⁹ It is not yet clear whether the advantages to U.S. customers will outweigh the losses to U.S. patent holders and how that will affect the industry long-term.⁶⁰ In fact, a law school professor at the University of Pennsylvania argued against the U.S. Supreme Court’s patent exhaustion rule, calling it “draconian” and “indifferent to effects on innovation” because “[n]o further inquiry is made into the patentee’s market power, [anti-competitive] effects, or other types of harms, whether enforcement of the condition is socially costly or valuable, or has a positive or negative impact on innovation.”⁶¹

53. *Id.* at 1363.

54. *Id.* at 1370.

55. *Impression Prods.*, 137 U.S. at 1539.

56. *Kirtsaeng*, 133 S. Ct. at 1373.

57. Daniel J. Hemel & Lisa Larrimore Ouellette, *Trade and Tradeoffs: The Case of International Patent Exhaustion*, 116 COLUM. L. REV. 17, 24-26 (2016).

58. Sarah R. Wasserman Rajec, *Impression Products, Inc. v. Lexmark Inc.: Will International Patent Exhaustion Bring Free Trade in Patented Goods*, PATENTLY-O (June 1, 2017), <https://patentlyo.com/patent/2017/06/impression-international-exhaustion.html> <https://perma.cc/B3JX-XDKX>].

59. Brief for Biotechnology Innovation Org. & CropLife Int’l as Amici Curiae in Support of Respondent at 17, *Impression Prods., Inc. v. Lexmark Int’l, Inc.*, 137 S. Ct. 1523 (2017) (stating that “[a]ny benefits to U.S. consumers would likely accrue at the expense of poorer consumers elsewhere”).

60. Hemel & Ouellette, *supra* note 57, at 25

61. Herbert Hovenkamp, *Reasonable Patent Exhaustion*, 35 YALE J. ON REG. 513, 515-16

Under a new definition of patent exhaustion, in a drug context, pharmaceutical companies may be left with few appealing options. In theory, U.S. manufacturers may need to raise prices in foreign markets and lower prices in U.S. markets under a rule of international exhaustion. In other words, the U.S. may need to move toward global prices. “Benefits should accrue to U.S. consumers who would pay something between the former U.S. ‘surplus’ price and the adjusted global price, assuming that the pre-international exhaustion price was higher.”⁶²

One possibility for pharmaceutical companies is to evaluate their contracts with distributors “to ensure that those contracts prohibit redistribution into the U.S.,” providing them with a contractual cause of action against the distributor if the distributor were to attempt to import its products back into the U.S.⁶³

Another creative approach is to restrict re-importation via license. As pointed out in one editorial by Daniel Hemel and Lisa Larrimore Ouellette, instead of selling medicines to foreign countries, the pharmaceutical company could “license” the pill to patients on the condition that they either “return the pill or ingest it,” utilizing a principle that is popular in many other industries with this issue.⁶⁴

Further, the U.S. patent exhaustion rule still starkly contrasts with the law in other areas of the world. For example, Canada’s Patent Act has no express provisions analogous to the exhaustion doctrine.⁶⁵ Additionally, the World Trade Organization’s Trade Related Aspects of Intellectual Property Rights allows member nations discretion regarding their own interpretations of the exhaustion doctrine “whether by statute, judicial opinion, or agency regulations.”⁶⁶

D. Legislation Addressing Drug Re-Importation & U.S. Price Controls

The post-*Lexmark* blogosphere was active in declaring that the patent exhaustion doctrine would not “throw open the gates for access to cheaper foreign

(2018).

62. Brief for Professor Frederick M. Abbot as Amicus Curiae in Support of Petitioner at 20, *Impression Prods., Inc. v. Lexmark Int’l, Inc.*, 137 S. Ct. 1523 (2017).

63. Doug Robinson, *Lexmark Case: Pharma Should Review Distribution Networks*, PHARMAPHORUM (Oct. 9, 2017), <https://pharmaphorum.com/views-and-analysis/pharma-distribution-channel-review/> [https://perma.cc/J7GR-TSVD].

64. Daniel Hemel & Lisa Larrimore Ouellette, *Licensing in the Shadow of Impression Products (with Lisa Larrimore Ouellette)*, MEDIUM (May 31, 2017), <https://medium.com/whatever-source-derived/licensing-in-the-shadow-of-impression-products-with-lisa-larrimore-ouellette-9bbf8c350c65> [https://perma.cc/J7TR-4RGG].

65. OLENA IVUS, CTR. FOR INT’L GOVERNANCE INNOVATION, PATENT EXHAUSTION IN THE UNITED STATES AND CANADA 2 (2018), <https://www.cigionline.org/sites/default/files/documents/Paper%20159web.pdf> [https://perma.cc/5ZPU-N9AC].

66. Lucas Brown, *Intellectual Property Rights Require a Balancing Act: The Exhaustion Doctrine and Patentee Rights vs. Consumer Protection*, WAKE FOREST J. BUS. & INTELL. PROP. L. 204, 207 (2019).

medicines” because Section 804 of the FDCA, which “directs [the] FDA to promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada,” had never been certified by the Secretary of HHS.⁶⁷

There are a few reasons for this. First, previous HHS guidance estimated that insurance companies, importers, and exporters would take a large portion of the savings that were intended for consumers. Also, sanctioning parallel trade could cripple the pharmaceutical industry’s ability to fund research and development (“R&D”) and innovation, which are “paramount to survival” and the costs of which have continued to rise over the past three decades.⁶⁸ Finally, the prospect of health risks seemed too high, meaning that many steps must be taken to ensure that drug re-importation would not increase the risk of harm to the American consumer.⁶⁹

Then, in July of 2019, former HHS Secretary Alex Azar II proposed a “Safe Importation Action Plan” that would begin to eliminate roadblocks to re-importing drugs from foreign countries, such as Canada, under two potential pathways, and attempted to address many of these concerns.⁷⁰

Under Pathway One, a Notice of Proposed Rulemaking (“NPRM”) would rely on Section 804 of the FDCA “to authorize demonstration projects to allow importation of drugs from Canada.”⁷¹ Section 804 can only be used if the Secretary of HHS certifies that importation would impose “no additional risk” to U.S. consumers and that it would “result in a significant reduction in the cost” of those prescription drugs.⁷² Of note, in the sixteen years since its enactment, no Secretary has ever given such approval.⁷³ Alex Azar was also initially opposed.⁷⁴

67. Dennis Crouch, *Demystifying Drug Importation After Impression v. Lexmark*, PATENTLY-O (June 6, 2017), <https://patentlyo.com/patent/2017/06/demystifying-importation-impression.html> [<https://perma.cc/LHL2-VNDQ>].

68. JACOB ARFWEDSON, INST. FOR POL’Y INNOVATION, RE-IMPORTATION (PARALLEL TRADE) IN PHARMACEUTICALS 6 (2004), <https://www.ipi.org/docLib/PR182-ParallelTrade.pdf-OpenElement.pdf> [<https://perma.cc/TK3D-T3Y7>].

69. *Id.* at 25 (“Re-importation has been opposed by [ten] of the last [eleven] Food and Drug Administration Commissioners since 1969. All cited public safety concerns (including risks of mishandling, mislabeling, improper storage, ineffective product recalls, and expiration date violations). Some also expressed concern about the potential for opportunists to manufacture and sell counterfeit drugs.”).

70. *Safe Importation Action Plan*, *supra* note 11.

71. *Id.* at 1.

72. *Id.*

73. *Id.*

74. Alex M. Azar II, Secretary, U.S. Dep’t of Health & Hum. Servs., Remarks on Drug Pricing Blueprint in Washington, D.C. (May 14, 2018), <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html> [<https://perma.cc/UA9S-X6SG>] (“[T]he last four FDA commissioners have said there is no effective way to ensure drugs coming from Canada really are coming from Canada, rather than being routed from, say, a counterfeit factory in China. The [U.S.] has the safest regulatory system in the world. The last thing

Demonstration projects, which would “outlin[e] how they import Health-Canada approved drugs in compliance with [S]ection 505 of the [FDCA],” could be submitted by states, wholesalers, or pharmacists.⁷⁵ Further, there are a number of medications excluded under Pathway One: controlled substances, biological products, infused medications, intravenous injected medications, medications inhaled during surgery, certain parenteral medications, and medications associated with Risk Evaluation and Mitigation Strategies.⁷⁶

Under Pathway Two, the drug manufacturers themselves would re-import their own drugs after establishing with the FDA that the foreign version is the same as the U.S. version.⁷⁷ This would allow a pharmaceutical manufacturer to sell a foreign version of a drug product in the U.S. under a unique National Drug Code number compared to the U.S. version, which would allow the manufacturer, if they desired, to sell the product at a lower price.⁷⁸ Because the manufacturer would be able to import its drug through conventional supply channels, this pathway generally would rely on applicable existing safeguards to ensure supply chain integrity.⁷⁹

For supporters of importation, there are some potential challenges. Proposing a demonstration project, as required for Pathway One, that could allow these types of certifications will take extensive resources and time, potentially decreasing savings to the consumer.⁸⁰

Because Pathway One is also subject to the formal rulemaking process, which includes a required notice and comment period, this process could take several years before interested parties could begin submitting plans for demonstration projects.⁸¹ Further, there are restrictions on the types of medicines that may be imported through this pathway, and it excludes some of the more expensive categories of drugs (*e.g.*, biologics, such as insulin).⁸² Some of the groups eligible to use this pathway, such as pharmacy groups, oppose it because of concerns about patient safety and the desire to preserve their relationship with patients, “particularly for vulnerable patients with complex medication regimens.”⁸³

Next, Section 804 of the FDCA can only become effective if the Secretary of HHS certifies that its “implementation . . . will pose no additional risk to the

we need is to open borders for unsafe drugs in search of savings that cannot be safely achieved.”).

75. *Safe Importation Action Plan*, *supra* note 11.

76. *Id.* at 3.

77. *Id.*

78. *Id.*

79. *Id.*

80. Benjamin M. Zegarelli, *In Policy Reversal, HHS and FDA Propose Plan to Import Foreign Drugs*, MINTZ (Aug. 8, 2019), <https://www.mintz.com/insights-center/viewpoints/2791/2019-08-policy-reversal-hhs-and-fda-propose-plan-import-foreign> [<https://perma.cc/3CDC-EZLJ>].

81. *Id.*

82. *Id.*

83. *Issue Brief: Safe Importation Action Plan*, AM. SOC’Y HEALTH-SYSTEM PHARMACISTS, <https://www.ashp.org/Advocacy-and-Issues/Key-Issues/Drug-Pricing/Issue-Brief-Safe-Importation-Action-Plan> [<https://perma.cc/GEP6-ASLF>] (last visited Mar. 14, 2021).

public's health and safety and will result in a significant reduction in the cost of covered products to the American consumer."⁸⁴ However, since the passage of the Medicare Modernization Act in 2003, "no subsequent HHS secretary, Republican or Democrat," has been willing to certify that they are safe.⁸⁵ However, Secretary Azar is not planning to make that broad of a certification. Instead, he will "propose to condition certification on the ability to limit the program to demonstration projects under [S]ection 804(b)-(h) and would seek comments on that proposal."⁸⁶ "It is not clear that the Secretary has the legal authority to make a 'conditional' certification that is far short of the complete certification required by statute."⁸⁷

Second, HHS is proposing to include "States" as sponsors of demonstration projects.⁸⁸ Unfortunately, "States" are not authorized importers under the law. For example, "[t]he Secretary, after consultation with the [U.S.] Trade Representative and the Commissioner of U.S. Customs and Border Protection, shall promulgate regulations permitting *pharmacists and wholesalers* to import prescription drugs from Canada into the [U.S.]."⁸⁹ Thus, it is unclear whether HHS could authorize a demonstration project from any of the states.

Pathway Two has a significant advantage for U.S. consumers because "[i]t would apply to any 'versions of FDA-approved drug products' that a manufacturer sells abroad."⁹⁰ This includes, for example, generic versions that are sometimes produced, or authorized to be produced, by pharmaceutical manufacturers themselves.⁹¹

PhRMA and BIO, industry trade groups that often represent the voice of pharmaceutical manufacturers, have spoken in opposition to Pathway Two, making it "reasonable to expect that most manufacturers may choose to ignore [it]."⁹² Further, Canada tends to be generally opposed due to concerns about their own drug supply: "[a] recent study estimates that the entire Canadian drug supply would be exhausted in 183 days if only 20% of U.S. prescriptions were filled

84. *Safe Importation Action Plan*, *supra* note 11; *see generally* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

85. Merrill Matthews, *Vermont's Prescription for Failure*, INST. POL'Y INNOVATION (May 22, 2018), https://www.ipi.org/ipi_issues/detail/vermonts-prescription-for-failure [<https://perma.cc/BR4D-292T>] (providing the oppositions of Secretary Donna Shalala, Secretary Tommy Thompson, Commissioner Andrew C. von Eschenbach, and Commissioner Margaret Hamburg).

86. *Safe Importation Action Plan*, *supra* note 11.

87. *A Gimmick No More? HHS Moves to Authorize Prescription Drug Importation*, KING & SPAULDING (Aug. 6, 2019), https://www.kslaw.com/news-and-insights/a-gimmick-no-more-hhs-moves-to-authorize-prescription-drug-importation#_edn13 https://www.kslaw.com/news-and-insights/a-gimmick-no-more-hhs-moves-to-authorize-prescription-drug-importation#_edn13 [<https://perma.cc/FHM7-EKLZ>] [hereinafter KING & SPAULDING].

88. *Safe Importation Action Plan*, *supra* note 11.

89. 21 U.S.C. § 384 (2020) (emphasis added).

90. KING & SPAULDING, *supra* note 87.

91. Zegarelli, *supra* note 80.

92. *Id.*

using Canadian prescription drug sources.”⁹³

In the past, plans to import drugs from Canada had been met with resistance from the U.S. over concerns about drug safety and the introduction of counterfeit drugs into the U.S. drug supply.⁹⁴ But, as drug prices in the U.S. have risen, the idea has gained support. States, including Florida, Maine, Colorado, and Vermont, have passed laws to allow imports, subject to the approval of HHS.⁹⁵ “This is going to exacerbate some of the drug shortages that [we are] already seeing in Canada,” said Joelle Walker, the vice president of public affairs for the Canadian Pharmacists Association. “We [are not] equipped to deal with a country that is ten times our size.”⁹⁶

Further, pharmaceutical companies, although they partner with government research and academia, are largely responsible for developing new medicines, which is an expensive process that can take many years.⁹⁷ Consequently, R&D expenditure is much greater than that of either government or academia. As an example, the R&D expenditure of pharmaceutical companies was nearly triple the National Institutes of Health’s R&D expenditure in 2017, the budget of which does not go entirely to drug development research.⁹⁸

If a pharmaceutical manufacturer’s profitability is reduced, they may choose to invest fewer dollars in R&D and could “shift their focus from very high-cost biological drugs for rare diseases back to more reasonably priced drugs for more common diseases.”⁹⁹ As with all things, “[t]he system will be better for some and worse for others.”¹⁰⁰

III. PATENT THICKETING

Patent thicketing is a patent strategy with origins outside of the

93. C. Michael White, *Cheaper Drugs from Canada Likely Won’t Cure What Ails US*, CT MIRROR (Oct. 4, 2019), <https://ctmirror.org/category/ct-viewpoints/why-cheaper-drugs-from-canada-likely-wont-cure-what-ails-us/> [<https://perma.cc/3J78-795N>]; see Allison Martell, *Exclusive: Canada Warns U.S. Against Drug Import Plans, Citing Shortage Concerns*, REUTERS (July 18, 2019), <https://www.reuters.com/article/us-canada-pharmaceuticals-exports-exclus/exclusive-canada-warns-us-against-drug-import-plans-citing-shortage-concerns-idUSKCN1UD2LN> [<https://perma.cc/X9H4-FL4B>]

94. White, *supra* note 93.

95. Findlay, *supra* note 31.

96. Amanda Coletta, *Trump and Sanders Want to Ease Imports of Drugs from Canada. Canada Says Not So Fast*, WASH. POST (Aug. 1, 2019), https://www.washingtonpost.com/world/the_americas/trump-and-sanders-want-to-ease-imports-of-drugs-from-canada-canada-says-not-so-fast/2019/08/01/1f0f91a6-b463-11e9-acc8-1d847bacca73_story.html [<https://perma.cc/84F3-9ZL3>].

97. Andrew Powaleny, *IP Explained: Understanding Biopharmaceutical Innovation*, CATALYST (July 30, 2019), <https://catalyst.phrma.org/ip-explained-understanding-biopharmaceutical-innovation> [<https://perma.cc/59TA-9Q7V>].

98. *Id.*

99. White, *supra* note 93.

100. *Id.*

pharmaceutical drug industry and is used to describe a practice allegedly intended to extend the patent life of a product by protecting said product with as many patents as possible.¹⁰¹ Despite the fact that thickening is prominent in crowded industries like computer software,¹⁰² examples are also present in the pharmaceutical industry.

This certainly is not intended to imply that pharmaceutical innovation is not happening – the Center for Drug Evaluation and Research approved forty-eight “novel drugs” in 2019, twenty of which were “first in class.”¹⁰³ In fact, cumulative innovation is often considered the essence of science.¹⁰⁴ “As Sir Isaac Newton put it, each scientist ‘stands on the shoulders of giants’ to reach new heights.”¹⁰⁵

However, while the practice of patenting incremental innovations is common, even necessary, it has gained notoriety in the public eye. Medications, like Humira (adalimumab), have received public scrutiny for the disproportionate numbers of patents that are obtained to retain market exclusivity decades beyond their original date of introduction.

Humira is currently the best-selling prescription drug in the world.¹⁰⁶ It is the single largest revenue source for AbbVie, with sales of over \$20 billion in 2018 alone.¹⁰⁷ In December 2016, Humira’s composition of matter patent expired.¹⁰⁸ However, companies with FDA-approved biosimilars (*e.g.*, Amgen, Boehringer Ingelheim, and Novartis) have not been able to enter the market and have instead reached deals with AbbVie to delay their products’ market entry until 2023.¹⁰⁹ This was done because the company now holds approximately 136 Humira patents.¹¹⁰ Of these, the USPTO

has granted the company more than [thirty] patents on the ways in which the drug is administered; more than [twenty-five] patents on various formulations of the drug; more than [fifty] patents related to Humira’s manufacturing processes; and about [twenty] patents on the delivery

101. Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, 1 INNOVATION POL’Y & ECON. 119, 119-21 (2001).

102. *Id.*

103. *Novel Drug Approvals for 2019*, FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2019> [<https://perma.cc/CTS9-FTFB>] (last updated Jan. 14, 2020).

104. Shapiro, *supra* note 101, at 119

105. *Id.* at 119-20.

106. Sy Mukherjee, *Protect at All Costs: How the Maker of the World’s Bestselling Drug Keeps Prices Sky-High*, FORTUNE (July 18, 2019), <https://fortune.com/longform/abbvie-humira-drug-costs-innovation/> [<https://perma.cc/AQ5F-WBHC>].

107. *Id.*

108. *Id.*

109. *Id.*

110. *Id.*

devices that customers use to take the medicine.¹¹¹

Notably, a discovery order from a case between Boehringer Ingelheim International GMBH (“BI”) and AbbVie shows a court acknowledging that it remains unclear whether there is anything improper about filing a large number of patents.¹¹² Further, “[m]any of AbbVie’s patents claim priority back to original patent applications filed in 2000 or 2001, before the drug went on sale.”¹¹³ Therefore, part of the reason that there was a large number of patents granted later is the result of a series of continuing applications that were filed at once, which is a common patent tactic.¹¹⁴ In May of 2019, AbbVie resolved its suit with BI.¹¹⁵ AbbVie fiercely defended its patent strategy, stating that the “allegations in the lawsuit [were] without merit.”¹¹⁶

Despite the fact that each patent is, in fact, received through legal means, the principle is quite unpopular in the public eye.¹¹⁷ In July 2018, FDA Commissioner Scott Gottlieb lamented that competition for biosimilars in the U.S. is “anemic,” and he specifically called out the case as being patent litigation due to patent thickets.¹¹⁸

Because these alleged patent thickets generally adhere to current patent laws, legislators have attempted to introduce legislation to define and address patent thicketing. Currently, there is one major piece of legislation addressing patent thicketing. The Affordable Prescriptions for Patients Act was introduced in the U.S. Senate on May 9, 2019, by U.S. Senators John Cornyn and Richard Blumenthal to prevent thicketing or risk of being sued by the Federal Trade Commission (“FTC”).¹¹⁹ This could happen to pharmaceutical manufacturers if they use tactics like obtaining duplicative patents in order to delay generic

111. *Id.*

112. *See* AbbVie Inc. v. Boehringer Ingelheim Int’l GMBH, No. 17-cv-01065-MSG-RL, 2019 U.S. Dist. LEXIS 28950, at *7-8 (D. Del. Feb. 25, 2019).

113. Zachary Silbersher, *Did AbbVie Create a Wrongful “Patent Thicket” Around Humira®?*, MARKMAN ADVISORS (Aug. 27, 2018), <https://www.markmanadvisors.com/blog/2018/8/27/did-abbvie-create-a-wrongful-patent-thicket-around-humira> [<https://perma.cc/MH7A-27T3>].

114. *Id.*

115. Press Release, AbbVie Inc., AbbVie Resolves HUMIRA® (adalimumab) U.S. Patent Litigation with Boehringer Ingelheim (May 14, 2019), <https://news.abbvie.com/news/press-releases/abbvie-resolves-humira-adalimumab-us-patent-litigation-with-boehringer-ingelheim.htm> [<https://perma.cc/R4XN-VXCS>].

116. Mukherjee, *supra* note 106.

117. *Id.* (describing how New York Law School professor Jacob Sherkow believes that AbbVie is “just taking advantage of existing law”).

118. Silbersher, *supra* note 113.

119. Susannah Luthi & Sarah Oweremohle, ‘Patent Thicket’ Bill Caught in Tug-of-War Over Drug Pricing Reforms, POLITICO (Oct. 25, 2019), <https://www.politico.com/news/2019/10/25/patent-thicket-bill-caught-in-tug-of-war-over-drug-pricing-reforms-056858> [<https://perma.cc/9N7R-JLDF>].

versions of the medication from market entry.¹²⁰ On the other hand, industry group PhRMA disagrees with the presumption of guilt that the bill places on the manufacturer, saying it would create “a presumption of anti-trust violation for almost any post-approval innovation.”¹²¹

VI. PRODUCT HOPPING

Product hopping refers to an alleged practice in which a pharmaceutical company purportedly replaces prescription drugs that are already on the market with slightly modified versions that have the same active pharmaceutical ingredient. The FDCA requires FDA approval before any drug may be marketed.¹²² Generic manufacturers must submit an “Abbreviated New Drug Application” to show only that their generic product is the bioequivalent to an already approved “reference” drug.¹²³ If the generic product is the branded medication’s bioequivalent and the two are the same dosage, strength, and form, the FDA identifies the generic product as the branded version’s “AB-rated” equivalent.¹²⁴ At the pharmacy, the generic product can then be substituted for the branded medication, which is usually less expensive than the branded version.¹²⁵

There are two ways a pharmaceutical manufacturer can use the AB-rating necessity to their advantage. The first is through a practice called a “hard switch,” in which a pharmaceutical company purportedly takes a prescription drug completely off the market.¹²⁶ This would allegedly create a forced-switch because generic substitution is not possible if the branded medication is no longer available.¹²⁷ The second so-called product hopping scenario is called a “soft switch,” in which the pharmaceutical company allegedly leaves the original drug on the market, though a similar outcome results.¹²⁸

A. Hard Switches

A famous example of a so-called hard switch is the case of *New York ex rel. Schneiderman v. Actavis PLC*, in which the branded company Actavis sought to replace its twice-daily dosage of the memantine molecule (Namenda IR) with an extended-release, once-daily version (Namenda XR).¹²⁹ Actavis allegedly began

120. *Id.*

121. *Id.*

122. *See* 21 U.S.C. § 355 (2020).

123. Jessie Chang, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471, 1479 (2008).

124. 21 U.S.C. § 355.

125. Chang, *supra* note 123, at 1479.

126. *See, e.g., New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 647-49 (2d Cir. 2015).

127. *Id.* at 642.

128. Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 N.D.L. REV. 167, 168 (2016).

129. *See, e.g., Actavis*, 787 F.3d. at 638.

marketing Namenda XR to its patients and made use of rebates to offer it at a low price, a process believed to be a “soft switch.”¹³⁰ The purported reason for this was that Namenda XR was covered by multiple patents that would expire almost fifteen years after the patents that covered Namenda IR.¹³¹ Then, nine months before patents for Namenda IR expired, Actavis sought to remove it from the market.¹³² This was purportedly the “hard switch.”¹³³ The New York State Attorney General sued Actavis under antitrust laws, and the trial court granted its request for a preliminary injunction.¹³⁴ The Court of Appeals for the Second Circuit affirmed, ruling that Actavis had to keep Namenda IR on the market for thirty days after the generic would first be available.¹³⁵

Interestingly, the holding in *Actavis* contrasts with the outcome in *Mylan Pharmaceuticals Inc. v. Warner Chilcott Public Limited Company*.¹³⁶ Mylan, the generic company, sued Warner Chilcott, the drug manufacturer, alleging a number of product-hopping complaints about its product Doryx.¹³⁷ The court found that Warner Chilcott “made four critical changes to Doryx, all of which required generics to apply for AB-rating if they wanted to continue to benefit from state substitution laws.”¹³⁸ However, the court “held that Mylan failed to muster sufficient evidence of Defendant’s monopoly power.”¹³⁹ Warner Chilcott Public Limited Company’s (“Warner Chilcott”) market share “was – at most – only about 18%, an amount insufficient to show that [it] exercised monopoly power.”¹⁴⁰ Thus, Warner Chilcott was said not to be engaging in a hard switch product hopping.

B. Soft Switches

A so-called soft switch is when the old drug is kept on the market, and it can also allegedly have significant drug price implications. In a soft-switch situation, the original drug stays on the market, allowing the consumer a choice, but the process imparts what is known as a “price disconnect,” meaning the general market balance between price and quality is disrupted because the doctor

130. See *Pharmaceutical Antitrust Update: Courts Address How and When Product Hopping May Violate the Antitrust Laws*, HAUG PARTNERS (Mar. 29, 2017), <https://www.haugpartners.com/article/pharmaceutical-antitrust-update-courts-address-how-and-when-product-hopping-may-violate-the-antitrust-laws/> [https://perma.cc/W4ZV-GCMJ].

131. *Id.*

132. *Id.*

133. *Id.*

134. *Actavis*, 787 F.3d. at 649.

135. *Id.*

136. See *Mylan Pharm. Inc. v. Warner Chilcott Pub. Co.*, 838 F.3d 421 (3d Cir. 2016).

137. See *id.*

138. *Id.* at 430.

139. *Id.* at 431.

140. *Id.*

prescribing the medication is not the same person or entity paying for it.¹⁴¹

Therefore, as one court explained in an ongoing antitrust product hopping case, “the ordinary market forces that would allow consumers to consider price when selecting a product are derailed.”¹⁴² Therefore, a pharmaceutical company that removes or disparages its original product for the alleged sole purpose of transitioning patients to a newer and higher-priced product may be viewed as anti-competitive.¹⁴³

Numerous pieces of legislation are currently attempting to address product hopping. The Affordable Prescriptions for Patients Act would address product hopping in addition to its sections regarding patent thickening.¹⁴⁴ The bill would define product hopping as anti-competitive behavior, thereby allowing the FTC to “bring antitrust suits against bad actors who deliberately game the system, and would give them injunctive authority to make the system fairer and operate as Congress intended.”¹⁴⁵

The Affordable Prescriptions for Patients Through Promoting Competition Act of 2019 was introduced in the House on September 19, 2019, by Congressman Cicilline.¹⁴⁶ The bill was designed to “prohibit [anti-competitive] behaviors by drug product manufacturers, and for other purposes.”¹⁴⁷ Also, it specifically prohibits product hopping.¹⁴⁸

The most common tool to combat product hopping has been to sue pharmaceutical manufacturers under antitrust laws.¹⁴⁹ On the other hand, because product hopping nearly always involves medication improvements with benefits to patients, some argue that it should be generally viewed as lawful because anything else would chill innovation.¹⁵⁰ Whether and how this trade-off should be managed as a matter of regulatory or competition policy is an important question that has yet to be adequately resolved.

141. Carrier & Shadowen, *supra* note 128, at 179.

142. *In re* Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig., 64 F. Supp. 3d 665, 684 (E.D. Pa. 2014).

143. *Id.*

144. *Affordable Prescriptions for Patients Act Introduced in the Senate*, GOODWIN L. (May 15, 2019), <https://www.goodwinlaw.com/publications/2019/05/affordable-prescriptions-for-patients-act-introduc> [<https://perma.cc/ZM4A-WGJF>].

145. *Id.*

146. *Cicilline Introduces Bill to Drive Down Costs of Prescription Drugs*, CONGRESSMAN DAVID CICILLINE (Sept. 19, 2019), <https://cicilline.house.gov/press-release/cicilline-introduces-bill-drive-down-costs-prescription-drugs> [<https://perma/H7NH-LWTA>].

147. *See* H.R. 4398, 116th Cong. (2019).

148. *Id.*

149. Arti K. Rai & Barak D. Richman, *A Preferable Path for Thwarting Pharmaceutical Product Hopping*, HEALTH AFF. (May 22, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20180522.408497/full/> [<https://perma.cc/3VPU-4XEH>].

150. Carrier & Shadowen, *supra* note 128, at 200.

V. CONCLUSION

There are several proposed Congressional reforms to address drug prices that would modify the existing legal structure of IP rights in the context of pharmaceutical drugs.¹⁵¹ Because patents provide incentives for innovation, IP reforms are a matter of public policy that must find a “balance between providing incentives to create innovative new medicines versus the costs those incentives may impose on the public.”¹⁵²

The costs associated with developing a new prescription drug are enormous, with conservative estimates of the cost to develop a new medicine estimated to be somewhere between \$500 million to \$1 billion.¹⁵³ Therefore, the patent exclusivity that the pharmaceutical manufacturer receives, which is twenty years from the date on which the application for the patent was filed, is a valuable incentive.¹⁵⁴ However, that sounds better than it is. In actuality, by the time most new drugs are approved, the patents covering the medicine often have less than twelve years remaining of the patent term “due to the years required for development, clinical studies, and regulatory review.”¹⁵⁵ Despite this, many people feel that their prescription drug prices are too high, with one survey finding that nearly 23% of Americans have been unable to afford their medications in the past year.¹⁵⁶

A. Patent Exhaustion

The development of an exhaustion doctrine forces policymakers to seek a balance between protecting consumer well-being and providing economic incentives for innovators. While a strong exhaustion doctrine, as proposed in *Lexmark*, empowers consumers and limits the ability of patent owners to control the post-sale conduct of purchasers, it also can have the effect of deterring innovation, as a patent owner may not “reap the expected fruits of his or her labor.”¹⁵⁷ While blogs, scholars, and courts have weighed in on the doctrine, the reality is that, at the current time, “the impact of re-importation is not clear cut enough to confidently make policy recommendations on economic grounds.”¹⁵⁸ Therefore, only time will tell how the impact of the *Lexmark* decision, coupled with the “Safe Importation Action Plan” and the behaviors of motivated actors, may affect drug prices.

151. HICKEY ET AL., *supra* note 2, at 4.

152. *Id.* at 51.

153. O’Connor, *supra* note 6.

154. *Id.*

155. *Id.*

156. Dan Witters, *Millions in U.S. Lost Someone Who Couldn’t Afford Treatment*, GALLUP (Nov. 12, 2019), <https://www.csrpxp.org/icymi-gallup-finds-nearly-58-million-americans-unable-to-afford-their-prescription-drugs-up-four-percent-from-January/> [<https://perma.cc/QUQ8-S5FU>].

157. Brown, *supra* note 66, at 208.

158. ARFWEDSON, *supra* note 68, at 20.

B. Patent Thicketing

Proposed legislation like the Affordable Prescriptions for Patients Act would attempt to prevent patent thickening by allowing the FTC to challenge the practice as anti-competitive and to enable the FTC to bring antitrust suits against pharmaceutical manufacturers.¹⁵⁹ While the proposed legislation states that manufacturers will be allowed to argue that their actions are not anti-competitive by submitting rebuttal evidence,¹⁶⁰ the situation remains that, even in the most extreme cases of alleged thickening, the patents were obtained lawfully by the USPTO. Therefore, while this legislation may lower drug prices, it also may have a more significant impact on how patents are granted generally by the USPTO or how innovators approach bringing these new ideas to the market generally.

C. Product Hopping

While the practice of so-called “product hopping” may not be easy to recognize, this practice can result in “monopoly pricing, burdening patients, the government, and the health care system as a whole.”¹⁶¹ Product hopping raises issues that intersect with multiple areas of the law: patent, antitrust, and state drug product substitution laws, for example.¹⁶² It is particularly complicated due to the unique market forces and pricing disconnect surrounding pharmaceuticals. Bills such as the Affordable Prescriptions for Patients Act and the Affordable Prescriptions for Patients Through Promoting Price Competition Act of 2019 aim to curb anti-competitive product hops but must do so cautiously as these efforts could easily prevent legitimate product advances.¹⁶³

159. *Senate Bill Seeks to Give FTC Authority to Fight Patent Thickets, Product Hopping*, CTR. FOR BIOSIMILARS (May 15, 2019), <https://www.centerforbiosimilars.com/news/senate-bill-seeks-to-give-ftc-authority-to-fight-patent-thickets-product-hopping> [<https://perma.cc/K8KM-GX9A>].

160. *Id.*

161. Michael Carrier & Steve Shadowen, *Pharmaceutical Product Hopping: A Proposed Framework for Antitrust Analysis*, HEALTH AFF. (June 1, 2017), <https://www.healthaffairs.org/doi/10.1377/hblog20170601.060360/full/> [<https://perma.cc/Y4F7-AHPY>].

162. *Id.*

163. *Id.*