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CRYPTIC PATENT REFORM THROUGH THE INFLATION REDUCTION ACT

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ABSTRACT

If a statute substantially changes the way patents work in an industry where patents are central, but says almost nothing about patents, is it patent reform? We argue the answer is yes — and it's not a hypothetical question. The Inflation Reduction Act ("IRA") does not address patents, but its drug pricing provisions are likely to prompt major changes in how patents work in the pharmaceutical industry. For many years scholars have decried industry's ever-evolving strategies that use combinations of patents to block competition for as long as possible, widely known as "evergreening," but legislators have not been receptive to calls for reform. The IRA may just succeed in changing that pattern, at least to some extent, by imposing drug pricing reforms that alter the incentives for evergreening in the first place. In this Article, we lay out the case that the IRA contains implicit reforms to the pharmaceutical patent system. Its details are not straightforward, nor is its implementation, but its effects could nevertheless be major. Drug patent reform, a longtime priority for activists and scholars, may in fact have already happened.

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I. INTRODUCTION

For an alarming number of drugs, Americans clearly pay too much. Some drugs are priced too high relative to clinical benefit, while others are simply unaffordable to many patients, regardless of how much they might benefit.[1] More than one-quarter of survey respondents report

1. Questions regarding how to measure marginal clinical benefit, and how much society should pay for this medical value once it has been measured, are contested, but they are also the subject of a vast and sophisticated literature. *See, e.g.*, PETER J. NEUMANN, JOSHUA T. COHEN & DANIEL A. OLLENDORF, THE RIGHT PRICE: A VALUE-BASED PRESCRIPTION FOR DRUG COSTS (2021) (setting forth a comprehensive discussion of value-based pricing); Rebecca E. Wolitz, *States, Preemption, and Patented Drug Prices*, 52 SETON HALL L. REV. 385, 392 (2021) (discussing means of regulation to combat excessive pricing of pharmaceuticals); Govind Persad, *Pricing Drugs Fairly*, 62 WM. & MARY L. REV. 929, 956–58 (2021) (arguing drug prices should be based on social value); Daniel J. Hemel & Lisa Larrimore Ouellette, *Valuing Medical Innovation*, 75 STAN. L. REV. 517, 545–75 (2023) (describing complexities associated with measuring value).

difficulty affording their prescription drugs; the percentage figures are higher for those who are younger, have lower household incomes, or take more medications.[2] Costs are too high even for seniors with cancer: One recent study found that among patients who received insurance through Medicare, which provides health insurance coverage to Americans over sixty-five and to those with particular disabilities or diagnoses,[3] thirty percent of patients who do not receive additional financial support do not fill their initial prescriptions for cancer medications.[4] Too many Americans face tragic choices — to skip doses of their medications, cut pills in half, or avoid filling prescriptions entirely[5] — choices that can be fatal in some cases.[6] Indeed, Americans of all political views agree: prescription drug prices are "unreasonable," and they favor a range of reform efforts to decrease those prices.[7]

Why are prices so high? The answer is predictably complicated; scholars attribute high prices to a range of factors including legal limits on (and distortions of) purchaser bargaining,[8] moral hazard on the part of those choosing drugs,[9] international pricing dynamics,[10]

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2. *See* Ashley Kirzinger, Alex Montero, Grace Sparks, Isabelle Valdes & Liz Hamel, *Public Opinion on Prescription Drugs and Their Prices*, KAISER FAM. FOUND. (Aug. 21, 2023), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/ [https://perma.cc/6NXC-KEBF].

3. People who are age sixty-five or older, those who have certain disabilities, and patients with end-stage renal disease are eligible for Medicare. *See Medicare Program — General Information*, CTRS. FOR MEDICARE & MEDICAID SERVS., (Sept. 6, 2023), https://www.cms.gov/about-cms/what-we-do/medicare [https://perma.cc/MWU6-P4QY].

4. *See* Stacie B. Dusetzina, Haiden A. Huskamp, Russell L. Rothman, Laura C. Pinheiro, Andrew W. Roberts, Nilay D. Shah et al., *Many Medicare Beneficiaries Do Not Fill High-Price Specialty Drug Prescriptions*, 41 HEALTH AFFS. 487, 493 (2022).

5. Kirzinger et al., *supra* note 2.

6. Antonio Olivo, *He Lost His Insurance and Turned to a Cheaper Form of Insulin. It Was a Fatal Decision.*, WASH. POST (Aug. 3, 2019), https://www.washingtonpost.com/local/he-lost-his-insurance-and-turned-to-cheaper-form-of-insulin-it-was-a-fatal-decision/2019/08/02/106ee79a-b24d-11e9-8f6c-7828e68cb15f_story.html [https://perma.cc/4Y7D-EW43].

7. Kirzinger et al., *supra* note 2 (noting that eighty-two percent of American adults believe drug costs are "unreasonable").

8. *See*, *e.g.*, Darius Lakdawalla & Wesley Yin, *Insurer's Negotiating Leverage and the External Effects of Medicare Part D*, 97 REV. ECON. STAT. 314, 314–17 (2015) (finding that larger insurers obtain better prices); Sara Fisher Ellison & Christopher M. Snyder, *Countervailing Power in Wholesale Pharmaceuticals*, 58 J. INDUS. ECON. 32, 35 (2010) (finding that larger drug purchasers receive discounts on off-patent antibiotics, but smaller purchasers do not); Robin Feldman, *Perverse Incentives: Why Everyone Prefers High Drug Prices — Except for Those Who Pay the Bills*, 57 HARV. J. ON LEGIS. 303, 320 (2020).

9. *See* Douglas Lundin, *Moral Hazard in Physician Prescription Behavior*, 19 J. HEALTH ECON. 639, 641 (2000) (finding that physicians select costlier, branded drugs for patients who have lower out-of-pocket costs).

10. *See* Michelle M. Mello, *What Makes Ensuring Access to Affordable Prescription Drugs the Hardest Problem in Health Policy*, 102 MINN. L. REV. 2273, 2286–87 (2018).

manufacturing woes,[11] various middlemen in the pharmaceutical supply chain,[12] and even the lack of a coherent ethical account of pharmaceutical innovation[13] — and of course, evaluations differ regarding what matters most.[14] But in any account of drug pricing, patents play a central role.[15] Drug manufacturers obtain patents on drug compounds, methods of treatment, formulations, manufacturing processes, and other related inventions,[16] and use those patents to keep competitors off the market and charge supracompetitive prices for as long as they can. A substantial scholarly literature considers how much patents matter for biopharmaceutical innovation,[17] how drug companies use them,[18]

11. *See* Erin R. Fox & Linda S. Tyler, *Potential Association between Drug Shortages and High-Cost Medications*, 37 PHARMACOTHERAPY: J. HUM. PHARMACOLOGY & DRUG THERAPY 36, 40 (2016).

12. Joanna Shepherd, *Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, 38 YALE L. & POL'Y REV. 360 (2020).

13. *See* Mello, *supra* note 10, at 2279–86.

14. *Cf.* Gerard F. Anderson, Uwe E. Reinhardt, Peter S. Hussey & Varduhi Petrosyan, *It's the Prices, Stupid: Why the United States Is So Different from Other Countries*, 22 HEALTH AFFS. 89, 90 (2003) (concluding that higher health care spending in the United States is "caused mostly by higher prices for health care goods and services in the United States").

15. *See*, *e.g.*, Margo A. Bagley, *The Morality of Compulsory Licensing as an Access to Medicines Tool*, 102 MINN. L. REV. 2463, 2463 (2018); Aaron S. Kesselheim, Jerry Avorn & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 861 (2016) ("The most important factor that allows manufacturers to set high drug prices for brand-name drugs is market exclusivity."). *But see* Daniel J. Hemel & Lisa Larrimore Ouellette, *The Generic Drug Trilemma*, 2 ENTREPRENEURSHIP & INNOVATION POL'Y & ECON. 41, 52–54 (2023) (describing pricing dynamics for post-patent generic drugs).

16. *See generally* Lisa Larrimore Ouellette, *How Many Patents Does It Take to Make a Drug? Follow-On Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMM. & TECH. L. REV. 299 (2010) (discussing types of patents obtained by pharmaceutical companies).

17. *See, e.g.*, Eric Budish, Benjamin N. Roin & Heidi Williams, *Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials,* 105 AM. ECON. REV. 2044 (2015) (showing pharmaceutical firms' underinvestment in treatments that require longer clinical trials to show efficacy, and hence have shorter post-marketing patent life, relative to treatments that have longer post-marketing patent life); Stuart J.H. Graham, Robert P. Merges, Pam Samuelson & Ted Sichelman, *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH. L.J. 1255, 1286 (2009) (finding that biotechnology entrepreneurs value patents relatively more than entrepreneurs in other industries); Wesley M. Cohen, Richard R. Nelson & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* 2, 12 (Nat'l Bureau of Econ. Rsch., Working Paper No. 7552, 2000), http://www.nber.org/papers/w7552 [https://perma.cc/M8C5-LSCJ] (presenting survey data on the importance of patents to life science entrepreneurs and resource and development (R&D) managers).

18. Arti K. Rai & W. Nicholson Price II, *An Administrative Fix for Manufacturing Process Patent Thickets*, 39 NATURE BIOTECHNOLOGY 20 (2021) (discussing different types of patents that biologics firms assert in litigation against biosimilar competitors).

when and whether they are abused,[19] how they impact prices,[20] and how they interact with regimes of trade secrecy[21] and FDA-administered clinical trial data exclusivity. The data show that patents profoundly shape drug prices, drug innovation, and drug markets more generally.

It might come as a surprise, then, that when Democrats recently enacted major drug pricing reform as part of the August 2022 Inflation Reduction Act ("IRA"), after decades of trying, patent reform was not discussed in the law. Nonetheless, the pricing legislation may end up being one of the most significant biopharmaceutical patent reforms in recent history.[22]

The IRA significantly reformed existing drug pricing law within Medicare.[23] The law includes three primary elements: it authorizes Medicare to negotiate for prices on some high-cost drugs, it discourages pharmaceutical companies from raising their prices faster than inflation, and it restructures the way seniors and others pay for the prescription drug benefit.[24] But the IRA does not make substantive changes to existing patent law. Nothing in the IRA alters a patent owner's substantive or procedural rights to obtain patents or enforce them against potential competitors. The IRA does not change a patent holder's existing rights to exclude others from making, using, and selling their patented invention.[25] It does not force patent holders to permit competitors to enter the market.

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19. Scholars differ on this assessment. *Compare* Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 499 (2016) (arguing rampant abuse by pharmaceutical companies), *with* Erika Lietzan, *Paper Promises for Drug Innovation*, 26 GEO. MASON L. REV. 168, 168–69 (2018) (arguing that interacting practices destroy federal incentives for innovation); Erika Lietzan & Kristina M.L. Acri née Lybecker, *Distorted Drug Patents*, 95 WASH. L. REV. 1317, 1325 (2020) (arguing that drug company acquisition of later-expiring patents may be consonant with Congressional intentions).

20. *See, e.g.*, Kesselheim et al., *supra* note 15, at 861; Gerard T. Vondeling, Qi Cao, Maarten J. Postma & Mark H. Rozenbaum, *The Impact of Patent Expiry on Drug Prices: A Systematic Literature Review*, 16 APPLIED HEALTH ECON. & HEALTH POL'Y 653, 658 (2018).

21. *See, e.g.*, W. Nicholson Price II, *Expired Patents, Trade Secrets, and Stymied Competition*, 92 NOTRE DAME L. REV. 1611 (2017) (describing the interaction between patents, including expired patents, and trade secrecy).

22. For reasons discussed further below, *see infra* text accompanying notes 104–105 and 213–215, other potential contenders for that title, including the Biologics Price Competition and Innovation Act and the America Invents Act of 2011, do not appear to have had a huge impact on biopharmaceutical patent acquisition and enforcement.

23. Jim Tankersley, *Biden Signs Expansive Health, Climate and Tax Law*, N.Y. TIMES (Aug. 16, 2022), https://www.nytimes.com/2022/08/16/business/biden-climate-tax-inflation-reduction.html [https://perma.cc/U5W8-5QCT].

24. *See* Rachel Sachs, *Understanding the Democrats' Drug Pricing Package*, HEALTH AFFS. FOREFRONT (Aug. 10, 2022), https://www.healthaffairs.org/content/forefront/understanding-democrats-drug-pricing-package [https://perma.cc/L9YV-5867] for more details.

25. 35 U.S.C. § 271(a).

In this Article we argue that even though the IRA doesn't explicitly change patent law at all, it might nevertheless effect a substantial change to the patent system. Specifically, the IRA might have a substantial impact on biopharmaceutical patent *strategy*, even if it does not alter companies' substantive rights. This is because the IRA's changes impact firms' models for revenue maximization. And the IRA's impacts on revenue models may, in turn, alter firms' strategic choices about intellectual property enforcement and acquisition.

To preview the argument: the IRA creates procedures whereby Medicare can negotiate prices for many of the drugs that cost the program the most money.[26] And those negotiation procedures have teeth — in some circumstances, failure to comply can result in extremely significant financial penalties.[27] When it takes effect,[28] negotiation can lead to substantial decreases in Medicare reimbursement. But negotiation is only available for drugs that lack a generic or biosimilar competitor. In the world before the IRA, it was to a drug company's advantage to forestall *all* competition for as long as possible. In the post-IRA world, that complete exclusion will sometimes make a product eligible for price negotiation. Will there be situations where companies prefer to avoid Medicare price negotiations by allowing a single, selected competitor into the market? We give examples of situations where this might occur. And if that's the case, the IRA will have changed the complicated dynamics of biopharmaceutical patents — affecting phenomena like evergreening and patent thickets coupled with trade secrecy indefinitely blocking all competition[29] — without touching patent law itself.

In conducting this examination, this Article joins a growing line of scholarship that recognizes and analyzes the interaction of legal changes in health law with other fields that affect innovation — here, patent law. In prior work, we have joined other scholars in exploring the ways in which a broad range of legal levers beyond patent law,

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26. In Part II, *infra*, we explore the IRA's provisions in more detail — there are certain exclusions and limitations on Medicare's power to engage in these negotiations.

27. *See* Inflation Reduction Act of 2022, Pub. L. No. 117-169, sec. 11003, § 5000D, 136 Stat. 1818, 1862. However, manufacturers can opt out of the negotiation program under additional conditions. *See, e.g.*, Celine Castronuovo & Nyah Phengsitthy, *How Drugmakers Can Dodge Medicare Price Negotiations: Explained*, BLOOMBERG L. (July 31, 2023), https://news.bloomberglaw.com/health-law-and-business/how-drugmakers-can-dodge-medicare-price-negotiations-explained [https://perma.cc/MNJ2-86TR].

28. For present purposes, we do not address various constitutional challenges to the IRA. These challenges, which have been filed in geographically diverse district courts by a host of biopharmaceutical industry and trade association plaintiffs, assert both rights-based (First Amendment compelled speech, Takings, Due Process, Eighth Amendment) and structural constitutional claims. For a summary of the challenges, see HANNAH-ALISE ROGERS, CONG. RSCH. SERV., R47682, CONSTITUTIONAL CHALLENGES TO THE MEDICARE DRUG PRICE NEGOTIATION PROGRAM (2023).

29. *See infra* Section IV.A.

including grants,[30] food and drug regulation,[31] trade secrets,[32] health law,[33] and other doctrines[34] can serve as innovation incentives or disincentives. The IRA is yet another example of legislation not focused on intellectual property that may nonetheless have a substantial influence on both innovation incentives and intellectual property practice.

In Part II, we briefly summarize the IRA and its drug pricing reform changes, primarily within Medicare. In Part III, we analyze the IRA's likely impacts on patent assertion. We argue that the IRA is quite likely to moderate patent assertion behavior, especially in the biologic drug context that represents forty-six percent of total U.S. invoice-level spending.[35] We dive into a case study involving one possible gaming strategy biologics manufacturers might seek to use to evade the brunt of the IRA's negotiation provisions. Part IV addresses patent acquisition, arguing that the IRA will probably not impact acquisition significantly. This is due to factors including the relative ease of obtaining patents and the timing of patent acquisition relative to market entry and negotiation under the IRA. Ultimately, our argument in these two Parts may be summarized as follows:

Table 1: Potentially Impacted Areas of Biopharmaceutical Patent Strategy

	Small Molecule Drugs	**Biologic Drugs**
Patent Assertion	Modest moderation	Major moderation
Patent Acquisition	Minor effect	Minor effect

The change in patent assertion strategies, if it occurs as we posit, would be remarkable. Competition against biologic drugs has long been anemic relative to competition against small molecule drugs;[36] more than a decade after Congress passed the Biologics Price Competition

30. W. Nicholson Price II, *Grants*, 34 BERKELEY TECH. L.J. 1 (2019).

31. Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345 (2006).

32. W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023 (2016).

33. Mark A. Lemley, Lisa Larrimore Ouellette & Rachel E. Sachs, *The Medicare Innovation Subsidy*, 95 N.Y.U. L. REV. 75 (2020).

34. Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 TEX. L. REV. 303 (2013) (discussing, and critiquing, innovation prizes).

35. IQVIA, *Biosimilars in the United States 2023–2027* (Jan. 2023), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027 [https://perma.cc/8FK5-LCPL].

36. Biologics are much larger than small molecule drugs and are more commonly used to treat diseases including cancer and autoimmune conditions. Small molecule drugs, such as aspirin, are produced through traditional medicinal chemistry techniques. *See* Price & Rai, *supra* note 32, at 1026.

and Innovation Act ("BPCIA")[37] to galvanize such competition, U.S. biosimilar entry remains relatively feeble, reflecting underlying technical challenges and impressively successful patent litigation strategies.[38] But the IRA may change these incentives, driving firms to actively facilitate competitive entry and to change their patent assertion strategy substantially. Given the volume of scholarly and policy critique that has been directed against the pharmaceutical industry's toolbox of strategies to preserve monopolies and delay competitive entry,[39] the IRA's potential to break the pattern and actually *promote* market entry represents a substantial shift in the way drug patents work. Ultimately, although the IRA is unlikely to operate as an ex ante reform that limits the industry's tactics in accumulating patents, it will likely have substantial effects as an ex post reform that brings down prices by clearing thickets that do accumulate. According to Congressional Budget Office projections,[40] Medicare should realize substantial savings.

Part V of this Article considers the policy implications of implementing patent reform indirectly. It begins by discussing actions the executive branch will need to take to implement the IRA in a manner that promotes biopharmaceutical competition and market entry, and the ways in which the federal government should be prepared regarding traditional patent gaming strategies and their applications to the IRA. It next considers, and evaluates normatively, how the passage of the IRA and the law's impacts on patent strategy may affect existing efforts to engage in patent reform more directly, both in Congress and within the U.S. Patent and Trademark Office ("USPTO"). The IRA may provide additional support for certain types of interventions, such as those addressed at product hopping.

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37. The BPCIA was included in the passage of the Patient Protection and Affordable Care Act. Biologics Price Competition and Innovation Act, Pub. L. No. 111-148, secs. 7001–03, 124 Stat. 119, 804–23 (2010).

38. *See* Bernard Chao & Rachel Goode, *Biological Patent Thickets and Delayed Access to Biosimilars: An American Problem*, 9 J.L. & BIOSCIENCES 1, 3 (2022).

39. *See, e.g.*, Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 39–40 (2009) (arguing for the illegality of monopoly-preserving reverse payment settlements); Dmitry Karshtedt, *The More Things Change: Improvement Patents, Drug Modifications, and the FDA*, 104 IOWA L. REV. 1129, 1141–42 (2019) (discussing the potential anticompetitive effects of product-hopping strategies); Feldman & Frondorf, *supra* note 19 (cataloging monopoly-extending strategies); Yaniv Heled, *Patents v. Statutory Exclusivities in Biological Pharmaceuticals: Do We Really Need Both*, 18 MICH. TELECOMM. & TECH. L. REV. 419, 461–64 (2012) (arguing that overlapping regulatory exclusivity and patent protection permits monopolistic gaming by biologics firms); Michael A. Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 AM. U. L. REV. 305 (2016) (describing anticompetitive behavior by pharmaceutical companies in filing citizen petitions at FDA to delay competition).

40. CONG. BUDGET OFF., ESTIMATED BUDGETARY EFFECTS OF PUBLIC LAW 117–169, at 1, 5 (2022), https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf [https://perma.cc/3YCP-CTSK].

A note on normative scope: in this Article, we focus not on a first-best system for incentivizing and allocating biomedical innovation, itself the subject of a substantial and contentious literature,[41] but instead on the IRA's implications for patents — including as compared to direct patent reform. That said, our discussion is informed by compelling evidence that, in the United States, the status quo is quite flawed: industry profits are often disconnected from clinical benefit,[42] and even drugs providing clinical benefits are often unaffordable to patients.[43]

II. THE INFLATION REDUCTION ACT'S CHANGES

The Inflation Reduction Act[44] enacts substantial drug pricing reforms, primarily within the Medicare context. This Part briefly describes the contours of those reforms, considering first what changes have been enacted with respect to Medicare itself, and second how much those changes may have an impact on the drug market as a whole.

A. The IRA's Three Reforms

The IRA aims to reform drug pricing in Medicare in three significant ways: establishing negotiation for certain costly drugs, imposing checks on price increases, and restructuring responsibility for drug payments. Each is likely to have a substantial impact, though they target different parts of the drug pricing equation — the first two principally target prices or reimbursement itself, and the third principally addresses those who pay the prices and incentives for those payers to control costs. Although we focus in this Article on drug price negotiation, the ultimate impact of this negotiation will (as we discuss below) depend to some extent on the other two reforms. Accordingly, we outline below each of the three major reforms.

First, the IRA authorizes Medicare to negotiate for the prices of a subset of high-cost drugs, potentially including high penalties for companies that do not agree to negotiate.[45] Permitting the government to negotiate for the prices of the prescription drugs it purchases for seniors is a significant change to existing law, and it is a policy goal Democrats

41. *See, e.g.*, Lietzan, *supra* note 19 (arguing that incentives are too weak); Feldman & Frondorf, *supra* note 19 (arguing that incentives are too complex and gameable); Daniel J. Hemel & Lisa Larrimore Ouellette, *Valuing Medical Innovation*, 75 STAN. L. REV. 517, 529–38 (arguing that prices and incentives are too weak for some drugs and too strong for others); Christopher Buccafusco & Jonathan S. Masur, *Drugs, Patents, and Well-Being,* 98 WASH. U. L. REV. 1403, 1405 (2021) (arguing that innovation incentives are misaligned with social welfare).

42. *See, e.g.*, Hemel & Ouellette, *supra* note 41, at 528–44.

43. *See, e.g.*, Dusetzina et al., *supra* note 4, at 492–93.

44. Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818 (codified as amended in scattered sections of 42 U.S.C.).

45. *Id.* sec. 11001.

have pursued for several decades.[46] However, this negotiation program is also quite targeted. Medicare may only select a small number of drugs for negotiation each year,[47] and a drug cannot be subject to a negotiated price until it has been approved by the Food and Drug Administration ("FDA") for several years: nine years for small molecule drugs and thirteen years for biologic drugs.[48] These drugs must also be among the most costly products to Medicare[49] and must lack competition from small molecule generic or biosimilar products.[50] Negotiated prices must fall at or below a statutory ceiling, which, in the most notable scenario, will be based on how long the drug has been approved or licensed at the time the negotiated price would take effect. In this scenario, the ceiling is defined as a percentage of the manufacturer's price for nonfederal buyers (the so-called nonfederal average manufacturer price)[51]: seventy-five percent for negotiation-eligible drugs with less than twelve years since approval (a twenty-five percent discount), sixty-five percent for those with twelve to fifteen years since approval (a thirty-

46. *See, e.g.*, Milt Freudenheim, *Clinton's Health Plan: Drug Companies Feeling Pressure of Clinton's Plan to Keep Their Prices Down*, N.Y. TIMES (Sept. 30, 1993), https://www.nytimes.com/1993/09/30/us/clinton-s-health-plan-drug-companies-feeling-pressure-clinton-s-plan-keep-their.html [https://perma.cc/TS9F-47LH]. The creation of Medicare Part D in 2003, under Republican President George W. Bush, formally prohibited Medicare itself from negotiating for the prices of the prescription drugs prescribed for beneficiaries under that program, although Democratic versions of a Medicare pharmacy benefit would have required Medicare to negotiate drug prices. *See* Rachel E. Sachs, *The Accidental Innovation Policymakers*, 72 DUKE L.J. 1431, 1449–50 (2023). The IRA creates an exception to this prohibition. *See* Inflation Reduction Act § 11001(b)(1)(C).

47. The negotiation provisions of the law phase in over time. Medicare will implement negotiated prices for ten drugs covered under Part D in 2026, an additional fifteen drugs covered under Part D in 2027, an additional fifteen drugs drawn from both Parts B and D in 2028, and an additional twenty drugs drawn from both Parts B and D in 2029 and each subsequent year. *See* Inflation Reduction Act § 11001(a) (amending Title XI of the Social Security Act § 1192(a)(1–4)).

48. *Id.* (amending Title XI of the Social Security Act §§ 1191(b)(3), 1192(e)(1)(A)(ii), 1192(e)(1)(B)(ii)).

49. *Id.* (amending Title XI of the Social Security Act § 1192(d)(1)).

50. *Id.* (amending Title XI of the Social Security Act §§ 1192(e)(1)(A)(iii), 1192(e)(1)(B)(iii)). As we discuss below, exactly what counts as a drug without competition may be a complex question. *See infra* notes 147–148 and accompanying text.

51. The nonfederal average manufacturer price ("non-FAMP") is the price that manufacturers charge wholesalers for drugs distributed to nonfederal purchasers. This price accounts for some discounts, although it does not include the typically larger rebates or discounts given to downstream payers. Unlike the so-called "list price," this price is not publicly available. *See* Lovisa Gustafsson, *Domestic Reference Pricing and Its Potential Role in Medicare Pharmaceutical Price Negotiations*, COMMONWEALTH FUND (Oct. 26, 2021), https://www.commonwealthfund.org/publications/explainer/2021/oct/domestic-reference-pricing-role-medicare-pharmaceutical-price [https://perma.cc/9ZQR-L6LD]. That said, because it does not include the large rebates sometimes paid to downstream payers like pharmacy benefit managers, it should be relatively close to list price.

five percent discount), and forty percent for those with sixteen or more years since approval (a sixty percent discount).[52]

Notably, the IRA's negotiation framework is designed to provide higher reimbursement for products that provide greater marginal clinical benefits for patients.[53] It thereby seeks to implement the sensible policy goal of measuring (and incentivizing) innovation according to health benefit rather than flawed proxies like numbers of new patents. Specifically, in determining its offer to a manufacturer under the negotiation framework, Medicare must consider the drug's "[c]omparative effectiveness," whether the drug "address[es] unmet medical needs," and the extent to which the drug is a "therapeutic advance as compared to existing therapeutic alternatives."[54]

Second, the IRA discourages pharmaceutical companies from substantially increasing the prices of their existing products. Manufacturers who increase their prices at rates outpacing inflation will be required to pay rebates back to Medicare when they do so.[55] This legal authority has long existed within the Medicaid program,[56] which covers lower-income Americans, and government estimates suggest that these inflation-based rebates are a significant contributor to the lower prices Medicaid is able to obtain.[57] Although the Medicaid data does not fully predict results for the Medicare program, it does suggest that manufacturers will not be able to retain the pre-IRA status quo simply by raising prices. Likely because both the Centers for Medicare & Medicaid Services ("CMS") and pharmaceutical manufacturers already have experience implementing and complying with a highly similar rebate structure in the Medicaid context, this element of the IRA is one of the first to go into effect, phasing in at the end of 2022 and the beginning of 2023.[58]

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52. Inflation Reduction Act § 11002 (amending Title XI of the Social Security Act § 1194(c)). If the federal government is, by virtue of prior negotiations, already paying less than the discounted amount, the ceiling is what it already pays. *Id.*

53. *See* Rachel Sachs, Loren Adler & Richard Frank, *A Holistic View of Innovation Incentives and Pharmaceutical Policy Reform*, 1 HEALTH AFFS. SCHOLAR 1, 2 (2023).

54. Inflation Reduction Act § 11002 (amending Title XI of the Social Security Act § 1194(e)(2)). These factors do not, however, necessarily allow Medicare to use the full suite of cost-effectiveness measures used in some European countries. *See* Nitzan Arad & Mark McClellan, *Drug Pricing Reform in the Inflation Reduction Act: What Are the Implications? Part 1*, HEALTH AFFS. FOREFRONT (Dec. 14, 2022) https://www.healthaffairs.org/content/forefront/drug-pricing-reform-inflation-reduction-act-implications-part-1 [https://perma.cc/KF9S-N296] (noting this point). But they do take a substantial step towards payment for health value, a proposition long advocated by many analysts.

55. Inflation Reduction Act §§ 11101–02.

56. *See* 42 U.S.C. § 1396r–8(c)(2)(A).

57. OFF. OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., MEDICAID REBATES FOR BRAND-NAME DRUGS EXCEEDED PART D REBATES BY A SUBSTANTIAL MARGIN 7 (2015).

58. *See* Inflation Reduction Act § 11101(a) (phasing in at the beginning of 2023 for Part B products); *id.* § 11102(a) (phasing in at the end of 2022 for Part D products).

Third, the IRA restructures Medicare Part D,[59] the portion of Medicare that provides a stand-alone pharmacy benefit to seniors,[60] in two ways. The IRA both provides seniors with greater financial protections in Part D by capping their out-of-pocket costs[61] and gives Part D plans substantially greater financial incentives to control costs over time,[62] encouraging plans to identify opportunities to provide lower-priced products as compared with higher-priced ones.[63]

A significant amount of public commentary and analysis has considered how the IRA might impact Medicare's and patients' finances. The Congressional Budget Office ("CBO") has projected that the negotiation provisions of the law alone are likely to save Medicare nearly $100 billion between 2022 and 2031, even though the negotiation provisions do not phase in until 2026.[64] Benjamin Rome and colleagues recently concluded that applying the negotiation framework from 2018 to 2020 would have saved $26.5 billion.[65] And policy experts at the Kaiser Family Foundation have concluded that seniors are likely to benefit directly from the law's new limits on their out-of-pocket costs.[66]

B. Impacts Outside Medicare

Though the IRA's drug pricing reforms are significant, they are almost entirely limited to Medicare.[67] In particular, the IRA squarely

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59. 42 U.S.C. §§ 1395w-101 to -54.

60. *Id.*

61. Inflation Reduction Act § 11201(a)(3).

62. *Id.* § 11201(b); *see also* Arad & McClellan, *supra* note 54 ("While removing financial barriers for beneficiaries that limit drug use, the redesign creates much greater incentives for plans to negotiate aggressively . . . .").

63. *See* MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY 411, 416, 419 (2021).

64. CONG. BUDGET OFF., *supra* note 40, at 5.

65. Benjamin N. Rome, Sarosh Nagar, Alexander C. Egilman, Junyi Wang, William B. Feldman & Aaron S. Kesselheim, *Simulated Medicare Drug Price Negotiation Under the Inflation Reduction Act of 2022*, JAMA HEALTH F., Jan. 2023, at 1.

66. *See, e.g.*, Juliette Cubanski, Tricia Neuman & Anthony Damico, *Millions of Medicare Part D Enrollees Have Had Out-of-Pocket Drug Spending Above the Catastrophic Threshold over Time*, KAISER FAM. FOUND. (July 23, 2021), https://www.kff.org/medicare/issue-brief/millions-of-medicare-part-d-enrollees-have-had-out-of-pocket-drug-spending-above-the-catastrophic-threshold-over-time/ [https://perma.cc/H8HY-BWSF].

67. This is primarily because the IRA passed through the reconciliation process, which permits Congress to enact legislation that impacts taxes and spending with a bare majority in the Senate of fifty-one votes (including the Vice President, if necessary) rather than the sixty votes needed to break a filibuster. *See* David Wessel, *What Is Reconciliation In Congress?*, BROOKINGS (Feb. 5, 2021), https://www.brookings.edu/blog/up-front/2021/02/05/what-is-reconciliation-in-congress/ [https://perma.cc/YD68-GB64] (explaining the reconciliation process and its major limitations). As a result, Congress could pass reforms to Medicare drug payment policy through the IRA, as those reforms substantially impact government spending policy, but could not as substantially impact the private insurance market. To be sure, though, at least some policy experts have argued that the IRA's inflationary rebates are likely to

changes only Medicare's negotiating authority, not that of Medicaid or private payers. Medicare is the single largest payer for healthcare in the United States — but it only covers about one in five Americans.[68] As a result, patients who have difficulty affording their medications but are not yet eligible for Medicare are less likely to see benefits from the law's changes, and politicians have already recognized that other reforms will be necessary to help other populations.[69]

Nevertheless, the law is likely to have industry-wide implications. How much a program of Medicare drug price negotiations will matter to industry as a whole is complicated and highly context dependent. In general, however, Medicare negotiations will be of greater financial importance for those drugs that are primarily used in its covered populations.[70] A very expensive treatment indicated primarily for pregnant people, for instance, would be very unlikely to be subject to Medicare negotiations.[71] Similarly, treatments focused on pediatric illnesses are

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discourage manufacturers from raising private market prices as well as prices to Medicare, because private market prices are relevant to the calculation of the inflationary rebates that manufacturers would owe Medicare. *See, e.g.*, Sachs, *supra* note 24 (citing a policy expert articulating this claim). These private market prices would presumably include the non-FAMP against which negotiated prices are calculated (thereby avoiding gaming in which manufacturers attempted to avoid price cuts by raising non-FAMP).

68. *See, e.g.*, *CMS Releases Latest Enrollment Figures for Medicare, Medicaid, and Children's Health Insurance Program (CHIP)*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Dec. 21, 2021), https://www.cms.gov/newsroom/news-alert/cms-releases-latest-enrollment-figures-medicare-medicaid-and-childrens-health-insurance-program-chip [https://perma.cc/KWQ8-LVSA] (noting that Medicare enrollment is just under 64 million as of October 2021).

69. *See, e.g.*, Joseph R. Biden, Jr., President of the U.S., Remarks by President Biden on Medicare and the Inflation Reduction Act (Sept. 27, 2022), https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/09/27/remarks-by-president-biden-on-medicare-and-the-inflation-reduction-act/ [https://perma.cc/NP67-QG8B] ("I haven't given up on this. You know, we're going to go back at this, and we're going to lower the cost of lifesaving insulin for children as well as families for everybody, whether they're on Medicare or not.").

70. For example, drugs for strokes and heart disease are heavily used by populations covered by Medicare. The Assistant Secretary for Planning and Evaluation notes that "Medicare enrollees are at higher risk of blood clots due to age and other comorbidities present among this population," and that "about 28 percent of Medicare enrollees have diabetes, which also increases individuals' risk for heart disease and stroke." OFF. OF HEALTH POL'Y, U.S. DEP'T OF HEALTH AND HUMAN SERVS., MEDICARE ENROLLEES' USE AND OUT-OF-POCKET EXPENDITURES FOR DRUGS SELECTED FOR NEGOTIATION UNDER THE MEDICARE DRUG PRICE NEGOTIATION PROGRAM 4 (Aug. 29, 2023), https://aspe.hhs.gov/reports/aspe-ira-drug-negotiation-fact-sheet [https://perma.cc/YXM3-LJNH].

71. Expenditures for such products are unlikely to be zero, however, because of the overlap between Social Security Disability Income eligibility and Medicare, *see Medicare Information*, SOC. SEC. ADMIN., https://www.ssa.gov/disabilityresearch/wi/medicare.htm [https://perma.cc/E8P6-L5Q7], but they are unlikely to be high, especially relative to other payers' expenses. As one example, consider Makena, which received approval (subsequently withdrawn) for the treatment of recurrent preterm birth. Between 2018 and 2021, Medicare spent nearly $11 million on Makena — a non-trivial amount, but far smaller than the nearly $700 million paid by Medicaid over the same period. OFF. OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., DELAYS IN CONFIRMATORY TRIALS FOR DRUG APPLICATIONS

unlikely to be impacted by the IRA. The law explicitly excludes certain drugs for rare diseases from negotiation as well.[72]

At the same time, though, Medicare covers individuals who are more likely to need costly prescription drugs, so it assumes an outsized share of U.S. biopharmaceutical spending (thirty percent of retail drug spending in 2017)[73] relative to its population coverage. For at least some drugs that might be subject to negotiation, Medicare market share is even more substantial. Consider, for example, Regeneron's Eylea, a biologic for macular degeneration approved in 2011[74] that represented, by 2019,[75] the largest drug expenditure in Medicare Part B (the portion of the Medicare benefit that pays for services provided in physicians' offices, and in doing so often covers drugs which are injected or infused in that setting). For that year, Medicare Part B also represented 62.4 percent of total U.S. Eylea sales.[76] Suppose that by the time drugs are selected for the negotiation program for 2028, when price discounts for drugs covered under Part B take effect,[77] Eylea does not have biosimilar competition. Although this scenario is not necessarily likely — various firms have projected that they will enter the market with biosimilars before that time[78] — it is a possibility given the arsenal of

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GRANTED FDA'S ACCELERATED APPROVAL RAISE CONCERNS app. at 12 (2022), https://oig.hhs.gov/oei/reports/OEI-01-21-00401.pdf [https://perma.cc/M22K-W2CK]; News Release, U.S. Food & Drug Admin., FDA Commissioner and Chief Scientist Announce Decision to Withdraw Approval of Makena (Apr. 6, 2023), https://www.fda.gov/news-events/press-announcements/fda-commissioner-and-chief-scientist-announce-decision-withdraw-approval-makena [https://perma.cc/C8HB-W4H6].

72. *See* Inflation Reduction Act of 2022, Pub. L. No. 117-169, sec. 11001(a), § 1192(e)(3)(A), 136 Stat. 1818, 1833 (amending Title XI of the Social Security Act § 1192(e)(3)(A)).

73. *10 Essential Facts About Medicare and Prescription Drug Spending*, KAISER FAM. FOUND. (Jan. 29, 2019), https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/ [https://perma.cc/8NJ6-RY8Q].

74. Letter from Edward Cox, Dir., Off. of Antimicrobial Prods., Ctr. for Drug Evaluation & Rsch., to Laura Pologe, Assoc. Dir., Regul. Affs., Regeneron Pharms, Inc. (Nov. 18, 2011), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/125387s000ltr.pdf [https://perma.cc/GKZ5-5HZ3] (approving Eylea's 2011 biologics license application).

75. Juliette Cubanski & Tricia Neuman, *Relatively Few Drugs Account for a Large Share of Medicare Prescription Drug Spending*, KAISER FAM. FOUND. (Apr. 19, 2021), https://www.kff.org/medicare/issue-brief/relatively-few-drugs-account-for-a-large-share-of-medicare-prescription-drug-spending/ [https://perma.cc/6BD4-HQ5H]. As the authors note, data from the Medicare Part B dashboard reflects average sales price to nonfederal purchasers and includes all discount and rebates.

76. This figure was calculated by determining the percentage of U.S. net income from Eylea in 2019 ($4.644 billion, according to Regeneron's financial results report for 2019). Press Release, Regeneron, Regeneron Reports Fourth Quarter and Full Year 2019 Financial and Operating Results (Feb. 6, 2020), https://www.sec.gov/Archives/edgar/data/872589/000153217620000005/exhibit991q42019.htm [https://perma.cc/6SSZ-U7NK], represented by Medicare Part B spending in that year ($2.9 billion).

77. As noted *supra* note 47, the Part B negotiation aspect of the law phases in over time.

78. *Regeneron's Eylea Could Return to Growth after Nod to High-Dose Version-Analysts*, REUTERS (Aug. 21, 2023), https://www.reuters.com/business/healthcare-

patents on which Regeneron is currently suing would-be entrants.[79] In the event that Regeneron can use its Eylea patents to fend off entry until Eylea would be selected for negotiation in 2028, the branded biologic will be deemed to have reached seventeen years of market exclusivity.[80] In that case, it would be subject to at least a sixty percent discount.

Thus, while Medicare spending directly[81] affects only a fraction of the drug market, it is a large fraction, and even larger for certain drugs. Changes to the payment structures of Medicare are likely to matter a great deal to the pharmaceutical industry,[82] particularly for drugs that may be more likely to be prescribed to seniors. We now turn to whether and how the IRA might impact companies' decisions regarding patent assertion and acquisition practices.

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pharmaceuticals/regenerons-eylea-could-return-growth-after-nod-high-dose-version-analysts-2023-08-21/ [https://perma.cc/EQB7-822N] (noting that biosimilars for standard dose version of Eylea are expected in 2024).

79. *See, e.g.*, Christopher Yasiejko, *Amgen Pushes to Unseal Regeneron-Viatris Eylea Case Filings*, BLOOMBERG L. (May 24, 2023), https://news.bloomberglaw.com/ip-law/amgen-pushes-to-unseal-regeneron-viatris-eylea-case-filings [https://perma.cc/XSS8-P6L5] (discussing patent infringement lawsuit against biosimilar from Viatris).

80. *See* Cox, *supra* note 74 (notifying Regeneron of Eylea's approval in 2011, seventeen years before price discounts for drugs take effect in 2028).

81. Even among drugs where Medicare really does just cover a relatively small fraction of prescriptions, it's possible that Medicare negotiations will impact the prices paid by non-Medicare payers. For a thorough analysis of this question, see Loren Adler, *Cost-Shifting in Drug Pricing, or the Lack Thereof*, USC-BROOKINGS SCHAEFFER ON HEALTH POL'Y (Sept. 24, 2022) https://www.brookings.edu/articles/cost-shifting-in-drug-pricing-or-the-lack-thereof/ [https://perma.cc/JH3M-K8WY]. One possibility is that other payers could wind up paying *more* for the drug than Medicare does, a form of cost-shifting, on the notion that manufacturers will need to squeeze those lost profits from someone. *See, e.g.*, Letter from the American Benefits Council, Corp. Health Care Coal., Econ. All. for Mich., ERISA Indus. Comm., HR Pol'y Ass'n, Nat'l All. of Healthcare Purchaser Coals. et al. to Senator Ron Wyden (Sept. 7, 2021), https://www.pbgh.org/wp-content/uploads/2021/09/Employer-Group-Letter-on-Drug-Pricing-to-Hon.-Ron-Wyden.pdf [https://perma.cc/6EX2-7USH]. This suggestion, of course, raises the question of why, if manufacturers had the leverage to squeeze private payers for higher rates, they wouldn't have already done so regardless of Medicare's actions. *See* Adler, *supra*. In some instances, there are explicit price linkages that may lead to some compensating impacts, but Loren Adler points out that the IRA does not add any new linkages and may in fact weaken some that already exist. *Id.* The alternate possibility is that Medicare payment negotiations might instead have an anchoring effect, so that other payers' prices might move in tandem with Medicare's, thus lowering more generally when Medicare negotiations take place. Empirical evidence on pharmaceutical cost-shifting is unfortunately lacking. In the quasi-parallel situation of hospital pricing, multiple studies find little evidence that lower Medicare prices lead to higher prices for other payers. *Id.* (citing, e.g., Chapin White, *Contrary to Cost-Shift Theory, Lower Medicare Hospital Payment Rates for Inpatient Care Lead to Lower Private Payment Rates*, 32 HEALTH AFFS. 935 (2013)).

82. *See, e.g.*, Bhanvi Satija, *AstraZeneca sues US over Medicare Drug Price Negotiation Plans,* REUTERS (Aug. 25, 2023), https://www.reuters.com/legal/astrazeneca-files-litigation-challenge-inflation-reduction-act-2023-08-25/ [https://perma.cc/Y8E8-P3J7] (noting that eight separate drug companies had sued to block the IRA's drug negotiation provisions).

III. IMPACTS ON PATENT ASSERTION

As described above, the IRA's effects can usefully be divided into assertion and acquisition of pharmaceutical patents. In this Section, we discuss reasons why the IRA's impact on patent assertion may be somewhat modest in the small molecule context but more substantial in the biologics context. Indeed, in the context of biologics patent assertion, affirmative efforts by originators to encourage biosimilar launch may emerge. These efforts might involve not only fewer efforts to assert patents but also affirmative transfer of tacit knowledge.

A. Small Molecule Patent Assertion

With certain exceptions,[83] assertion of small molecule patents has operated since 1984 against the background of the Hatch-Waxman Act,[84] which governs entry by generic firms in the small molecule context. Although the operations of Hatch-Waxman are the subject of an extensive literature, we review here a few principles particularly relevant to the impact of the IRA.

Hatch-Waxman sets up a procedure through which would-be generic competitors can generally reach market by demonstrating in vitro "bioequivalence" to a currently marketed branded drug.[85] The low cost of *in vitro* studies, coupled with the low cost of manufacturing, means that generics often need to invest only a few million dollars to reach market.[86]

Additionally, before marketing (and thus without fear of being held liable for infringement damages), generics can use Article III courts to challenge the validity and/or scope of the branded firm's patents. More specifically, the generic firm can test certain patents that the branded firm has, by virtue of placing the patents in the Orange Book, asserted cover its product.[87] The statute encourages such generic challenges by providing a non-transferable 180-day period of exclusivity to the generic firm that is the first to test invalidity or non-infringement (regardless of whether the test is successful)[88] — a reward which, for a drug

83. Only active ingredient, formulation/composition, and method-of-use patents are listed on the Orange Book. 21 C.F.R. § 314.53 (2019).

84. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 156, 271, 355(b), 355(j), 355(l)).

85. 21 U.S.C. § 355(j)(2)(A)(iv) (2022) (specifying the need for bioequivalence).

86. Henry Grabowski, Tracy Lewis, Rahul Guha, Zoya Ivanova, Maria Salgado & Sally Woodhouse, *Does Generic Entry Always Increase Consumer Welfare?*, 67 FOOD & DRUG L.J. 373, 390 (2012) (estimating the approval costs of small molecule generic drugs at $2 million).

87. 21 U.S.C. § 355(j)(1)(A)(viii) (2022) (stating that branded firm must place on the Orange Book "the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted").

88. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2022).

with billions of dollars in annual sales, could be worth hundreds of millions of dollars.[89]

Hatch-Waxman procedures are widely used. Perhaps not surprisingly, they tend to be invoked particularly often for drugs with large sales.[90] Moreover, in the small number of challenges litigated to completion against so-called secondary patents (that is patents on aspects of the drug other than the molecule itself), challenger win rates have been high.[91]

Once generics enter the market, various regulatory and market features facilitate uptake. Nineteen states require, and the remainder permit, pharmacists to substitute generics automatically for the branded drug,[92] and formulary management for both privately insured individuals and Medicare Part D beneficiaries favors generic substitution.[93]

Accordingly, despite the rising number of patents that cover small molecule drugs, and various tactics (e.g., product hopping, discussed in *infra* Section III.C) that can be attempted to delay generic competition,[94] we often see a substantial amount of competition. This level of competition is reflected in three interrelated statistics. First, competition comes more quickly for small molecule drugs than for biologics. According to one recent study, the median term of exclusivity for small molecule drugs that faced generic competition in the period between

89. FTC. v. Actavis, Inc., 570 U.S. 136, 144 (2013) ("[T]his 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars.'") (citing Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1579 (2006)). The precise amount of reward accrued during this 180-day period may depend on factors such as whether the branded firm launches an authorized generic, thereby creating triopoly competition between the branded drug, the authorized generic, and the competitor generic. *See, e.g.*, Murray Aitken, Ernst R. Berndt, Barry Bosworth, Iain M. Cockburn, Richard Frank, Michael Kleinrock et al., *The Regulation of Prescription Drug Competition and Market Responses: Patterns in Prices and Sales Following Loss of Exclusivity*, *in* 76 MEASURING AND MODELING HEALTH CARE COSTS 243, 259 (Ana Aizcorbe, Colin Baker, Ernst R. Berndt & David M. Cutler eds., 2018) (examining, for four heavily prescribed drugs that experienced triopoly competition between 2009–13, price drops and market share in this triopoly context).

90. C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 328 (2012).

91. C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1356, 1386–87 (2013) ("Of the 48% of cases litigated to completion (not settlement), the branded firm nearly always wins a suit asserting an active ingredient patent (92%), but usually loses asserting secondary patents (32% wins)").

92. Chana A. Sacks, Victor L. Van de Wiele, Lisa A. Fulchino, Lajja Patel, Aaron S. Kesselheim & Ameet Sarpatwari, *Assessment of Variation in State Regulation of Generic Drug and Interchangeable Biologic Substitutions*, 181 JAMA INTERNAL MED. 16, 16 & 22 fig.1 (2021).

93. *See* CONG. BUDGET OFF., PRESCRIPTION DRUGS: SPENDING, USE, AND PRICES 10–11 (2022), https://www.cbo.gov/publication/57772 [https://perma.cc/T8TX-KQ9Y] (explaining formulary management factors that increase use of generic drugs).

94. *See* Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 168 (2016).

2012–18 was 14.4 years.[95] This median of 14.4 years represents a relatively small increase from the median of 12.6 years that Hemphill and Sampat found for drugs that faced generic entry between 2001–10.[96] And it is roughly comparable to the eleven to fourteen years found by analysts looking at generic entry between 1995–2005.[97]

Second, because of the relative ease of showing "bioequivalence" to branded drugs, generic drugs can typically enter the market with just a few million dollars in investment and are generally priced much lower than branded drugs. One FDA study that examined small molecules facing generic entry between 2015–17 found that, with one generic producer, the generic average manufacturer's price ("AMP") was thirty-nine percent lower than the branded AMP before generic competition. With two generic producers, generic prices were fifty-four percent lower. And with four competitors, generic prices were seventy-nine percent less than the branded drug price before generic entry.[98] Other studies have found significant price decreases as well, though not quite as large in magnitude.[99]

Third, because of generic substitution laws and because branded drugs do not typically attempt to compete on price after generics enter, low generic prices result in significant erosion of branded market share. According to one study, for small molecules experiencing initial

95. Benjamin N. Rome, ChangWon C. Lee & Aaron S. Kesselheim, *Market Exclusivity Length for Drugs with New Generic or Biosimilar Competition, 2012–2018*, 109 CLINICAL PHARMACOLOGY & THERAPEUTICS 367, 369 (2021). Similarly, a report from Henry Grabowski and colleagues found that the median market exclusivity term for small molecules experiencing generic entry between 2017–19 was 14.1 years. Henry Grabowski, Genia Long, Richard Mortimer & Mehmet Bilginsoy, *Continuing Trends in U.S. Brand-Name and Generic Drug Competition*, 24 J. MED. ECON. 908, 911 (2021). The term for drugs with greater than $250 million in sales prior to generic entry was shorter: 13.0 years. *Id.* at 912. The shorter term results because lucrative drugs attract more generic patent challengers. *See id.*

96. Hemphill & Sampat, *supra* note 90, at 330.

97. *See* Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 MANAGERIAL & DECISION ECON. 491, 495, 496 (2007).

98. RYAN CONRAD & RANDALL LUTTER, U.S. FOOD & DRUG ADMIN., GENERIC COMPETITION AND DRUG PRICES: NEW EVIDENCE LINKING GREATER GENERIC COMPETITION AND LOWER GENERIC DRUG PRICES 2–3 (2019), https://www.fda.gov/media/133509/download [https://perma.cc/PT8P-NPLA].

99. *See, e.g.*, Chintan V. Dave, Abraham Hartzema & Aaron S. Kesselheim, *Prices of Generic Drugs Associated with Numbers of Manufacturers*, 377 NEW ENG. J. MED. 2597, 2598 (2017) (examining the period between 2008 and 2014 and finding a thirteen percent drop with one generic competitor, a twenty-three percent drop with two, a forty percent drop with three, and a seventy-four percent drop with eight); Sean R. Dickson & Tyler Kent, *Association of Generic Competition with Price Decreases in Physician-Administered Drugs and Estimated Price Decreases for Biosimilar Competition*, JAMA NETWORK OPEN, Nov. 2021, at 1, 5 (2021) (examining the period between 2015 and 2019 and finding a 14.9 percent drop with one generic competitor, a 32.7 percent drop with two, a 52.0 percent drop with three, and a 68.6 percent drop with four or more).

generic entry between 2017–19, branded firms' average market share one year after generic entry was just twenty-three percent.[100]

Under these circumstances, an originator small molecule firm faced with the prospect of a twenty-five to thirty-five percent minimum discount under the IRA (twenty-five percent for a drug that had been marketed for nine to eleven years and thirty-five percent for a drug that had been marketed for twelve to fifteen years)[101] would probably prefer to try to keep generic competition at bay through the assertion of patents.[102] In many cases, the decline in total profits caused by loss of market share to generics might exceed profit loss from a twenty-five to thirty-five percent discount; without competition the branded manufacturer can retain one hundred percent market share. Only in the event that a small molecule drug had been marketed for sixteen or more years without competition and thus faced a sixty percent minimum discount might the calculus of the small molecule drug manufacturer potentially change.[103]

Thus, we expect to see some modest, but not necessarily substantial, impact of the IRA on patent assertion strategies by small molecule drug manufacturers. In other words, most originator small molecule firms will likely continue pursuing patent assertion strategies despite the IRA's newly introduced minimum discounts. However, the same is not true in the very different context of patent assertion by branded biologics, to which we turn next.

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100. Henry Grabowski, Genia Long, Richard Mortimer & Mehmet Bilgin soy, *Continuing Trends in U.S. Brand-Name and Generic Drug Competition*, 24 J. MED. ECON. 908, 913 (2021).

101. Inflation Reduction Act of 2022, Pub. L. No. 117-169, secs. 11001(a), § 1194(c), 136 Stat. 1818, 1833 (amending Title XI of the Social Security Act § 1194(c)). However, if the Part D net price is already below this minimum discount, the ceiling is that Part D net price. *Id*.

102. Indeed, in the case of at least some top-selling small molecule drugs, they already provide rebates/discounts to health plans of close to that magnitude in order to compete for formulary placement against branded drugs in the small biochemical class (typically separately patented drugs that act on the same molecular target). For those drugs, the IRA would be particularly unlikely to produce any change in patent assertion behavior. *See* Cathy Kelly, *Part D Price Negotiation Round One: Several Likely Candidates May Not Feel the Cut*, PINK SHEET (Aug. 9, 2022), https://pink.pharmaintelligence.informa.com/PS146839/Part-D-Price-Negotiation-Round-One-Several-Likely-Candidates-May-Not-Feel-The-Cut [https://perma.cc/Z8NK-UKUX].

103. The calculus is complicated because the pricing dynamics get complicated. One might expect a branded drug maker to compete with generics on price, but in at least some circumstances they do not, instead maintaining or raising their price. *See, e.g.*, Richard G. Frank & David S. Salkever, *Generic Entry and the Pricing of Pharmaceuticals*, 6 J. ECON. & MGMT. STRAT. 75, 83 (1997) (finding a fifty percent brand-name price increase five years after generic entry). Entry and pricing dynamics may also differ for drugs with small markets or otherwise unusual features, though those are unlikely to be subject to negotiation in the first place and thus are not our focus here. *See, e.g.*, Richard G. Frank, Thomas G. McGuire & Ian Nason, *The Evolution of Supply and Demand in Markets for Generic Drugs*, 99 MILBANK Q. 828, 840–46 (2021) (finding substantial differences in generic entry and pricing dynamics in smaller market drugs relative to medium and large market drugs).

B. Biologics Patent Assertion (and Related Trade Secrecy Implications)

Biologics have historically faced little competition. Among other things, they are not covered by the Hatch-Waxman Act framework, either doctrinally (because biologics are approved under a different statute than are small molecule drugs) or practically (because the complexity of biologics means that the technology has not existed to make "generic" biologics). The 2010 Biologics Price Competition and Innovation Act attempted to stimulate competition against branded biologics by allowing firms to market "biosimilar" competitors.[104] However, in contrast with competition against branded small molecule drugs, competition against originator biologics has been quite anemic thus far. Remarkably, against this backdrop, the changed incentives created by the IRA may soon drive the process of competitive market entry.

A key feature that distinguishes biologics from small molecules is relative biological complexity and, relatedly, complexity of manufacturing. The BPCIA addresses this difference by focusing on competition through a showing of "similarity" rather than "equivalence." Even so, the costs of building a biosimilar manufacturing facility, and of satisfying the FDA by producing clinical trial evidence regarding sufficient "similarity," can rise into the hundreds of millions.[105] Additionally, the BPCIA does not provide competitors exclusivity incentives to challenge patents. It relies instead on an optional system of patent information exchange prior to litigation.[106]

Since the BPCIA passed in 2010, only ten biologics approved by the FDA have faced biosimilar competition.[107] Additionally, according to one study that examined claims data to determine the market exclusivity period for the four biologic drugs that faced biosimilar competition between 2012–18, the median time that the originators enjoyed market exclusivity was over twenty-one years.[108] This contrasted with a median of 14.4 years of market exclusivity for the 264 small molecule drugs that faced generic competition during that period.[109] To be sure, the comparison of twenty-one years vs. 14.4 years is inexact — the four

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104. *See* Biologics Price Competition and Innovation Act, Pub. L. No. 111-148, secs. 7001–03, 124 Stat. 119, 804–23 (2010).

105. *See, e.g.*, Miriam Fontanillo, Boris Körs & Alex Monnard, *Three Imperatives for R&D in Biosimilars*, MCKINSEY & CO. (Aug. 19, 2022), https://www.mckinsey.com/industries/life-sciences/our-insights/three-imperatives-for-r-and-d-in-biosimilars [https://perma.cc/H5HU-HA8Z].

106. *See* 42 U.S.C. § 262(l).

107. *Biosimilar Approval Status*, BIOSIMILARS REV. & REPORT, https://www.biosimilarsrr.com/us-biosimilar-filings [https://perma.cc/5QN4-LM23] (listing marketing of biosimilars to ten originators).

108. Rome et al., *supra* note 95, at 368.

109. *Id.*

biologics in question (and other biologics) could have faced competition earlier had the BPCIA been enacted earlier. Nonetheless, as matters currently stand, the comparison in years of exclusivity is stark.

Even when biosimilars do enter, they generally have only limited market penetration and price discounting. On the market penetration front, demand side factors such as physician reluctance to switch existing patients from the originator therapy to a biosimilar play a significant role, buttressed by dubious tactics by originators to leverage that market stickiness to block biosimilar uptake even among new patients.[110] Biosimilar firms, meanwhile, do not offer the same price discounts as generic small molecule producers due in part to the greater total costs of biosimilar approval and manufacturing.[111] Lower price discounts also reduce biosimilar market share. The result is an inversion of the cycle we see with small molecules.

One recent analysis of seven originator drugs with biosimilar competition underscores the sharp divergence from small molecules. According to this analysis, five of these seven originators have retained a market share of over seventy-five percent even without dropping their price to any significant degree after biosimilar entry.[112] As a consequence, in the range of one to three entrants, average price weighted by market share has fallen by only 5.4 to seven percent per biosimilar entrant.[113] For any given originator, this discount is substantially less than the thirty-five percent minimum discount that could be required by the government if the post-approval exclusivity mark approached with no biosimilar on the horizon. Under that circumstance, one could imagine an originator concluding that entry by a biosimilar (and the related exclusion from negotiation eligibility) would be superior to the result of negotiation with the government.

For their part, biosimilar manufacturers would themselves want to avoid having a ceiling effectively set by the price discount that the government secured from the originator. This additional incentive to enter would layer onto the usual benefit of immediate cash flow. A

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110. *See* NITZAN ARAD, ELIZABETH STATON, MARIANNE HAMILTON LOPEZ, SAMSON GORIOLA, APARNA HIGGINS, MARK MCCLELLAN ET AL., REALIZING THE BENEFITS OF BIOSIMILARS: OVERCOMING REBATE WALLS, DUKE-MARGOLIS CTR. FOR HEALTH POL'Y (2022), https://healthpolicy.duke.edu/publications/realizing-benefits-biosimilars-overcoming-rebate-walls [https://perma.cc/LLG9-Z7WG]. For a discussion of four categories of arguments that biologic firms have made against biosimilars, see Michael A. Carrier, *Don't Die! How Biosimilar Disparagement Violates Antitrust Law*, 115 NW. U. L. REV. ONLINE 119, 125–28 (2020).

111. Grabowski et al., *supra* note 86, at 390 (estimating the approval costs of biosimilars at $200 million).

112. Richard G. Frank, Mahnum Shahzad, Aaron S. Kesselheim & William Feldman, *Biosimilar Competition: Early Learning*, 31 HEALTH ECON. 647, 652 (2022) (giving high market share and low price reduction figures for Avastin, Epogen, Herceptin, Remicade, and Rituxan).

113. *Id.* at 647.

convergence of opposing sides' incentives *towards* market entry represents a contrast with the controversial "pay-to-delay market entry" agreements between originators and would-be competitors that were once common under Hatch-Waxman.[114] Put bluntly, in the biologics context, the IRA may foster "pay (or at least permit) to launch" agreements specifically to enable innovator firms to avoid the negotiation process. This represents a remarkable potential departure from the status quo of robust, patent-girded monopolies in the biologic space.

The drafters of the IRA may have anticipated a version of this scenario. For biologics that will have been on the market between thirteen and fifteen years at the time of a potential price discount, the IRA provides that a biosimilar manufacturer can request that a particular originator biologic that would otherwise be selected for negotiation be delayed if the biosimilar manufacturer submits information demonstrating to the HHS Secretary a "high likelihood" that biosimilar entry is imminent.[115] However, such a request is not permitted in a range of circumstances, including if the biosimilar manufacturer has an agreement with the biological manufacturer that either (i) incentivizes the biosimilar manufacturer to submit the application for delay, or (ii) restricts the quantity of biosimilar product that may be sold in the United States.[116] Such a request is also not permitted if the biosimilar manufacturer is the same as the manufacturer of the originator.[117]

This provision appears to demonstrate Congressional intent to foster competition unconstrained by certain types of side agreements between the originator and potential biosimilar entrants. Meaningful competition does not exist, in other words, if a biosimilar enters the market only as a result of an agreement with the originator to limit the quantity of the biosimilar that can be sold. However, it may not cover all of the ways in which originators could work with biosimilar entrants. For example, an originator might be able to time agreements with biosimilar manufacturers so that entry occurred prior to the opening of the ordinary negotiation period (eleven years).

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114. In *FTC v. Actavis*, the Supreme Court determined that payments from originator patentee to would-be generic entrants that operated to delay generic entry represented an antitrust violation, at least if the payments exceeded litigation costs and generic services. 570 U.S. 136, 141 (2013). These agreements are now much less common, but some do still exist. BUREAU OF COMPETITION, FED. TRADE COMM'N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2014, at 2 (2016). https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/160113mmafy14rpt.pdf [https://perma.cc/AE3F-9K8A].

115. *See* Inflation Reduction Act of 2022, Pub. L. No. 117-169, sec. 11002, § 1192(f), 136 Stat. 1818, 1854–62 (amending Title XI of the Social Security Act § 1192(f)).

116. *Id.* (amending Title XI of the Social Security Act § 1192(f)(2)(D)(iv)).

117. *Id.* (amending Title XI of the Social Security Act § 1192(f)(1)(B)(i)).

How any such pay (or permit) to launch agreements would be evaluated under antitrust law poses an interesting question.[118] On one hand, unlike with pay-to-delay agreements, the collusion between competitors would be channeled at least to some extent towards encouraging competition.[119] On the other hand, unlike with conventional competition, in this case the price to Medicare and its beneficiaries would actually be higher than it would have been, post-IRA, from a single source supplier. Higher prices would be particularly likely to the extent that the originator, having avoided significant price discounting by allowing one competitor on the market, felt unconstrained in its ability to enforce its patents against would-be *subsequent* biosimilar entrants. In other words, brand biologics would likely seek to permit entry by a single competitor, but enforce patents (or other IP) vigorously against other competitors, resulting in a potentially durable duopoly (likely where the brand biologic retains a significant market share advantage over the biosimilar) rather than the present monopoly-focused strategy.[120]

Of course, in any given case, the IRA's impact will likely depend on the manufacturer's Medicare market share relative to its private market share. Not surprisingly, however, Medicare market share is substantial for at least some drugs that might be subject to negotiation. As noted earlier, Eylea, a biologic for macular degeneration approved in 2011, not only represented Medicare Part B's biggest expenditure in 2019,

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118. Even under the current Supreme Court's relatively parsimonious view of antitrust, neither the IRA nor the BPCIA sets up the type of sector-specific regulatory regime designed to target anticompetitive conduct that might be deemed to obviate the need for additional antitrust scrutiny. *Cf.* Credit Suisse v. Billing, 551 U.S. 264 (2007) (finding that detailed regulatory scheme administered by the Securities and Exchange Commission ("SEC") sufficiently addressed anticompetitive conduct). At the same time, the statutes in question clearly intend to promote robust competition, so their goals are consonant with those of antitrust law. Professor Michael Carrier has argued that any regulatory regime must not only exist, but also be effective. *See* Carrier, *supra* note 39, at 70–71.

119. We put aside here the possibility that an innovator firm might agree with a biosimilar competitor in a way that limits the competitor's entry, such as on a volume basis. *See, e.g.*, Fraiser Kansteiner, *Bristol Myers Inks Another Revlimid Patent Settlement — This Time with Sun Pharma — as Copycats Near*, FIERCE PHARMA (June 22, 2021), https://www.fiercepharma.com/manufacturing/bristol-myers-settles-sun-pharma-for-limited-revlimid-generic-launch-2022 [https://perma.cc/T6WF-LQF8].

120. That said, if the market share advantage for the originator were too large, Medicare might determine that the biosimilar's entry, even though formally unconstrained by any side restrictions on volume, still did not represent what Medicare has called "bona fide" marketing. Medicare has stated in its guidance that it will use the standard of bona fide marketing to determine whether a drug should be selected as a qualifying single source drug. MEENA SESHAMANI, CTRS. FOR MEDICARE & MEDICAID SERVS., DEP'T OF HEALTH & HUMAN SERVS., MEDICARE DRUG PRICE NEGOTIATION PROGRAM: REVISED GUIDANCE, IMPLEMENTATION OF SECTIONS 1191 – 1198 OF THE SOCIAL SECURITY ACT FOR INITIAL PRICE APPLICABILITY YEAR 2026, at 72 (2023) https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf [https://perma.cc/4VT6-DGA2] [hereinafter CMS REVISED GUIDANCE]. According to Medicare, bona fide marketing means more than "token or de minimis availability" and will be determined by looking at Prescription Drug Event ("PDE") data and Average Manufacturer Price ("AMP") data, among other sources. *Id.* at 74.

but Medicare also paid for 62.4 percent of total Eylea sales in the United States. By 2028, when Part B drug price discounts begin, Eylea may have reached seventeen years of exclusivity without biosimilar entry. In that case, it would be subject to at least a sixty percent discount.

According to one NGO source, Eylea has secured ninety-two relevant patents, and a majority of these patents were filed after the drug was approved by the FDA in 2011.[121] Accordingly, if biosimilars have not entered at the time drugs are selected for the negotiation program for 2028 approaches, Regeneron will have a decision to make about continued deployment of its patent arsenal. It is possible that Regeneron would allow biosimilar competition, even if by only one competitor. Such competition, particularly if it could be limited to a duopoly, might well be substantially more attractive than a significant price cut from Medicare. That possibility raises a stark contrast with firms like AbbVie, which deployed the large patent arsenal it had built around its blockbuster biologic Humira to sue many would-be biosimilar entrants.[122] AbbVie was then able to negotiate settlements that allowed it to maintain exclusivity in the United States through 2023 — twenty-one years after FDA approval, all the while continuing to raise the prices of the drug.[123]

The IRA's push towards competition suggests optimism by politicians about the potential for biosimilar competition to reduce prices over time as compared to a regime that presumed biologics production had to be a natural monopoly and imposed price regulation accordingly. In that sense, it is a rejection of the position prominently taken by in recent years by policy experts like Preston Atteberry, Peter Bach, Jennifer Ohn, and Mark Trusheim.[124] According to these experts, given the high costs of FDA approval and manufacturing for any given biosimilar

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121. I-MAK, OVERPATENTED, OVERPRICED 6 (2022), https://www.i-mak.org/wp-content/uploads/2022/09/Overpatented-Overpriced-2022-FINAL.pdf [https://perma.cc/8Q6X-QN5S]. Eylea's patent estate is also being scrutinized by potential competitors. Mylanhas filed administrative inter partes review challenges to five of Regeneron's patents. *See* Emily Rapalino, *Mylan Files IPR on Regeneron Aflibercept Patent*, JD SUPRA (Nov. 7, 2022), https://www.jdsupra.com/legalnews/mylan-files-ipr-on-regeneron-4623683/ [https://perma.cc/LRF3-45D2]. Notably, all of the patents that Mylan is questioning were filed after Eylea was approved.

122. *See* Ed Silverman, *AbbVie is Sued for Using Humira Patent Deals to Block Competition in the U.S.*, STAT (Mar. 20, 2019), https://www.statnews.com/pharmalot/2019/03/20/abbvie-humira-patents-antitrust [https://perma.cc/H5X6-EG96].

123. Danny Hakim, *Humira's Best-Selling Drug Formula: Start at a High Price. Go Higher.*, N.Y. TIMES (Jan. 6, 2018), https://www.nytimes.com/2018/01/06/business/humira-drug-prices.html [https://perma.cc/28AH-3A7Y] ("The price of Humira, an anti-inflammatory drug dispensed in an injectable pen, has risen from about $19,000 a year in 2012, to more than $38,000 today, per patient, after rebates.").

124. *See, e.g.*, Preston Atteberry, Peter B. Bach, Jennifer A. Ohn & Mark R. Trusheim, *Biologics Are Natural Monopolies (Part 1): Why Biosimilars Do Not Create Effective Competition*, HEALTH AFFS. FOREFRONT (Apr. 15, 2019), https://www.healthaffairs.org/content/forefront/biologics-natural-monopolies-part-1-why-biosimilars-do-not-create-effective-competition [https://perma.cc/6BNC-78NQ].

producer, we can presume that efficiency requires one (price-regulated) producer per originator molecule.[125] The IRA effectively rejects that presumption.

That said, the IRA does place a burden on originators to show that they are *not* natural monopolies in order to avoid the negotiation system (i.e., by showing that a competitor has entered).[126] This placement of the burden strikes a compromise between the general reluctance of U.S. competition law to find natural monopolies and the demonstrable history of weak biosimilar competition.[127]

In addition to changes in patent assertion patterns by biologics originators, the IRA may also affect related trade secrecy patterns. To be sure, patents disclose information regarding originator biologics. More generally, public scientific knowledge surrounding biologics has advanced considerably in recent decades. Nonetheless, for complex biologics like monoclonal antibodies (and even more so for cell and gene therapies) knowing precise details regarding method of production is important. And these precise details are often held as trade secrets.[128]

In some cases, the desire of originators to have a biosimilar on the market may induce not only a decision to decline to assert existing patents, but even some affirmative sharing of trade secret information. Of

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125. *Id.*

126. *See* Inflation Reduction Act of 2022, Pub. L. No. 117-169, sec. 11001(a), §§ 1192(e), 136 Stat. 1818, 1833 (amending Title XI of the Social Security Act § 1192(e) and defining "qualifying single source drug" as limited to a drug or biological product that does not have generic or biosimilar competition).

127. To be sure, as skeptics have argued, profits that the IRA takes from the originator would have (at least in part) been channeled into future innovation. Along similar lines, the nonpartisan Congressional Budget Office ("CBO") has released estimates indicating that the legislation may reduce the numbers of new drugs developed in the future. However, this reduction appears very modest, only on the order of about one percent. CONG. BUDGET OFF., SUMMARY: ESTIMATED BUDGETARY EFFECTS OF PUBLIC LAW 117–169, at 15 (2022), https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf [https://perma.cc/3UZT-UGS3] ("CBO estimates that under P.L. 117-169, the number of drugs that would be introduced to the U.S. market would be reduced by about 1 over the 2023–2032 period, about 5 over the subsequent decade, and about 7 over the decade after that. CBO expects that under current law about 1,300 drugs will be approved over the next 30 years."). Equally important, it is difficult to defend a system that raises innovation funding by incentivizing comparatively trivial patents.

The better question is how to measure innovation not in terms of numbers of drugs but in terms of clinical benefits to patients—a question the CBO report does not attempt to answer. *Id.* at 15 ("CBO did not identify the classes or types of drugs that would be affected or analyze the effects of foregone innovations on public health."). The IRA negotiation framework, in contrast, does set up a system for linking clinical benefit and financial reward. As noted earlier, the government is supposed to look at clinical benefit when negotiating price. As we discuss further in Part V *infra*, IRA implementation should take full advantage of this emphasis on clinical benefit.

128. *See Genentech Dispute Highlights Growing Importance of Trade Secrets for Life Sciences Companies*, KEKER VAN NEST & PETERS (Sept. 16, 2019), https://www.keker.com/news/news-items/genentech-dispute-highlights-growing-importance-of-trade-secrets-for-life-sciences-companies-intellectual-asset-management [https://perma.cc/BA9Z-Z7CF] (discussing settlement of Genentech trade secret lawsuit over misappropriation of manufacturing process information).

course, the originator may be interested in sharing only with one would-be biosimilar entrant. Sharing might then represent a type of collusion to protect duopoly. On the other hand, even limited sharing could have potential benefits in terms of additional formalization of tacit knowledge and future spillover possibilities.

C. Possible Product Hopping Implications

Our discussion thus far has assumed that the definition of what constitutes a single source "product" is not subject to dispute, so that the branded firm will in some cases have to make a hard choice between maintaining product exclusivity through patent assertion, thereby potentially facing a lower reimbursement rate, or simply allowing competition. But that is not the case. In fact, branded firms have long attempted to forestall competition by capitalizing on FDA definitions that characterize different formulations and dosages of a given molecule as different products.[129] Going forward, in the case of both small molecule and biologic drugs, firms may believe that they can avoid difficult choices under the IRA by doubling down on this "product hopping." In this Section, we briefly describe the phenomenon of product hopping, outline the relevant IRA provisions and related CMS guidance, and map out some possibilities for hypothetical product-hopping scenarios.

1. Product Hopping Defined

In general, product hopping refers to situations in which "a brand-name pharmaceutical company switches from one version of a drug to another"[130] in an effort to extend its effective monopoly, taking advantage of its exclusive rights over the newer version while its patents or FDA-administered clinical trial data or market exclusivity periods on the older version expire. These switches can take many forms — from a capsule to a tablet,[131] from a twice-daily version to an extended-release formula,[132] or from an injected version to an auto-injector,[133] as just a few examples.

Product hopping is controversial. The concern is that companies may make this switch to a new version of the drug in a way that has no

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129. Arti K. Rai & Barak D. Richman, *A Preferable Path for Thwarting Pharmaceutical Product Hopping*, HEALTH AFFS. FOREFRONT (May 22, 2018), https://www.healthaffairs.org/do/10.1377/forefront.20180522.408497/full/ [https://perma.cc/7DEQ-M7KY].

130. Carrier & Shadowen, *supra* note 94, at 167.

131. *Id.* at 168.

132. New York *ex rel.* Schneiderman v. Actavis, 787 F.3d 638, 646–47 (2d Cir. 2015).

133. Rachel E. Sachs, Kyle A. Gavulic, Julie M. Donohue & Stacie B. Dusetzina, *Changes in the Use of Hydroxyprogesterone Caproate Injection After Confirmatory Trial Failure*, 182 JAMA INTERNAL MED. 226 (2022).

significant clinical benefits for patients, while simultaneously harming generic or biosimilar competition for the older version.[134] Some companies have removed the original drug from the market as the new version is introduced, which legally prevents generic market entry.[135] Antitrust scrutiny of these "hard switch[es],"[136] however, has meant that companies may prefer to try to shift existing patients from the older formulation of the drug to its newer version while both remain on the market, engaging in a "soft switch."[137] If the company succeeds in shifting patients to the newer version, subsequent generic or biosimilar competition for the older version will not significantly harm their market share.[138] Indeed, if market share for the older version is sufficiently low, the branded firm's actions might deter generic or biosimilar competition for the older version from entering the market in the first place.

2. Product Hopping in the IRA

The IRA may impact companies' existing incentives to engage in product hopping, though these effects are likely to be complex and may differ based on the type of product at issue. The IRA instructs CMS to negotiate prices only for "qualifying single source drugs," which are limited to (1) those small molecule drugs that are approved "under section 505(c)" of the FDCA and that are "not the listed drug for any drug that is approved and marketed under section 505(j)" of the law, and (2) those biological products that are licensed "under section 351(a)" of the Public Health Service Act and that are "not the reference product for any biological product that is licensed and marketed under section 351(k)" of the law.[139] Essentially, these categories include (1) small molecule drugs without any competing generics; and (2) biologics without any competing biosimilars.[140]

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134. Carrier & Shadowen, *supra* note 94, at 168; *see also* Karshtedt, *supra* note 39, at 1136–37.

135. Vrushab Gowda, Reed F. Beall, Aaron S. Kesselheim & Ameet Sarpatwari, *Identifying Potential Prescription Drug Product Hopping*, 39 NATURE BIOTECHNOLOGY 414, 414–15 (2021). A "hard switch" also requires an additional step, such as removal of the drug from the National Drug Data File. *See, e.g.*, Abbott Lab'ys v. Teva Pharms. USA, Inc., 432 F. Supp. 2d 408, 416 (D. Del. 2006).

136. *Schneiderman*, 787 F.3d at 654.

137. Gowda et al., *supra* note 135, at 414–15.

138. The brand firm benefits financially from conducting a switch before competitors enter against the original version. *See* Carrier & Shadowen, *supra* note 94, at 177–78.

139. *See* Inflation Reduction Act of 2022, Pub. L. No. 117-169, sec. 11001(a), §§ 1192(e)(1), 136 Stat. 1818, 1833 (amending Title XI of the Social Security Act § 1192(e)(1)).

140. This framing is slightly simplified. As one example, the IRA instructs CMS to treat an "authorized" generic or biosimilar —a product that is often marketed by the branded manufacturer itself —as the same qualifying single source drug for negotiation purposes. *See id.* (amending Title XI of the Social Security Act § 1192(e)(2)). Such products are not likely to

Could a product-hopping company delay negotiations for its products through the interaction of this provision and the prohibition against negotiation for the first several years a product is on the market?[141] The argument would be that a company could receive authorization to market a new formulation through a new Section 505(c) or Section 351(a) authorization (as with Namenda's extended-release version,[142] Makena's auto-injector formulation,[143] or Humira's high-concentration version[144]), switch patients to that new formulation, and escape negotiation for that new formulation for a new period of nine or thirteen years — exacerbating existing incentives to engage in product hopping.

However, other provisions of the statute seem designed to guard against this possibility. For instance, in determining whether a qualifying single source drug has high enough expenditures to be eligible for negotiation, the IRA states that CMS "shall use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation."[145] CMS would therefore be required to combine spending across the different versions of a drug in order to assess whether it satisfies the spending conditions for negotiation eligibility. Firms therefore cannot split the spending on their drug across different formulations in an effort to avoid being selected for the negotiation process.

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constitute true competition, given the control the branded manufacturer continues to exert over their pricing and marketing. More generally, as discussed *supra* note 120, Medicare guidance aims to ensure bona fide competition for any product to fall outside the single source category.

141. At least some experts expect industry to try this tactic. *See* Berkeley Lovelace, Jr., *The Inflation Reduction Act Aims to Lower Drug Costs — But Here's How Big Pharma Could Get Around It*, NBC NEWS (Sept. 20, 2022), https://www.nbcnews.com/health/health-news/inflation-reduction-act-aims-lower-drug-costs-s-big-pharma-get-rcna48341 [https://perma.cc/AE4Q-6L2K].

142. Letter from Russell Katz, Dir., Div. of Neurology Prods., Ctr. for Drug Evaluation & Rsch., to Michael P. Niebo, Asst. Dir. of Regul. Affs., Forest Lab'ys, Inc. (June 21, 2010), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/022525s000ltr.pdf [https://perma.cc/3PFA-A3SX] (approving Namenda's 2010 new drug application).

143. Letter from Hylton V. Joffe, Dir., Div. of Bone, Reprod. & Urologic Prods., Ctr. for Drug Evaluation & Rsch., to David A. Knauss, Senior Manager of Regul. Affs., AMAG Pharma USA, Inc. (Feb. 14, 2018), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/021945Orig1s012ltr.pdf [https://perma.cc/3S89-SXEC] (approving Makena's 2018 supplemental new drug application).

144. Letter from Badrul A. Chowdhury, Dir., Div. of Pulmonary, Allergy & Rheumatology Prods., Ctr. for Drug Evaluation & Rsch., to Richard J. Perner, Manager of Regul. Affs., AbbVie Inc. (Nov. 23, 2015), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/125057Orig1s394ltr.pdf [https://perma.cc/5LCQ-6EWT] (approving Humira's 2015 supplemental biologics license application).

145. Inflation Reduction Act of 2022, Pub. L. No. 117-169, sec. 11001(a), § 1192(d)(3)(B), 136 Stat. 1818, 1833 (amending Title XI of the Social Security Act § 1192(d)(3)(B)).

3. CMS Guidance

June 2023 revised guidance from CMS explaining how it intends to implement the negotiation program in 2026 sheds light on these potential strategies.[146] In keeping with the IRA's above-described instruction to aggregate spending across forms of the drug, CMS intends to group together "all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA), inclusive of products that are marketed pursuant to different NDAs."[147] As a result, Namenda's manufacturer, for instance, would not be able to argue that its sales from the extended-release version of the drug ought to be separated from its sales of the twice-daily version for purposes of determining its eligibility for negotiation. Humira's manufacturer would not be able to argue that its sales from the high-concentration version of the product ought to be separated from its sales of the low-concentration version of the product.

At the same time, though, the guidance notes that "[i]f any strength or dosage form of a potential qualifying single source drug is the listed drug or reference product" for a generic or biosimilar competitor, "the potential qualifying single source drug will not be considered a qualifying single source drug."[148] In other words, a generic version of the non-extended release version of Namenda or a biosimilar for the low-concentration of Humira would mean that the newer versions of those products would not be eligible for the negotiation program. The bottom line is that, according to CMS, different dosages and strengths are the "same" for purposes of negotiation.[149]

4. Mapping Product-Hopping Scenarios

Some hypothetical examples are helpful in analyzing how the interaction between these provisions of the law might work in practice.

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146. *See* CMS REVISED GUIDANCE, *supra* note 120. Although on several topics the revised guidance contains additional changes and clarifications from the initial memorandum, CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE DRUG PRICE NEGOTIATION PROGRAM: INITIAL MEMORANDUM, IMPLEMENTATION OF SECTIONS 1191-1198 OF THE SOCIAL SECURITY ACT FOR INITIAL PRICE APPLICABILITY YEAR 2026, AND SOLICITATION OF COMMENTS (Mar. 15, 2023), https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf [https://perma.cc/PB9L-58L7] [hereinafter CMS INITIAL MEMORANDUM], on this issue the revised guidance and initial memorandum are in accord.

147. *See* CMS REVISED GUIDANCE, *supra* note 120, at 99; CMS INITIAL MEMORANDUM, *supra* note 146, at 8.

148. CMS REVISED GUIDANCE *supra* note 120, at 102; CMS INITIAL MEMORANDUM, *supra* note 146, at 10.

149. The CMS guidance would not, however, encompass product hopping that involves a combination product—that is, a hop in which one active moiety was combined with another active moiety. *See* CMS REVISED GUIDANCE, *supra* note 120, at 100; *See* CMS INITIAL MEMORANDUM, *supra* note 146, at 9. We thank Sean Tu for this point.

Consider a company that wishes to try to engage in product hopping and has introduced a new version of its product, as the active ingredient is becoming eligible for negotiation (the precise timing of which would depend on whether the relevant product is a small molecule or biologic drug). The analysis varies based on whether there is already competition for the initially approved version of the product. In Case 2 (existing competition), moreover, the analysis further varies according to whether the product is primarily reimbursed under Medicare Part B or Part D.

Case 1: No initial competition: If there is not yet generic or biosimilar competition for the initially approved version of the product, the result is straightforward. The active ingredient may become eligible for negotiation and the IRA's provisions requiring CMS to aggregate spending across formulations of the drug would result in the spending on both the older and newer versions being considered in determining the relevant spending amount for negotiation purposes.[150]

Case 2: Existing competition: If there is generic or biosimilar competition for the initially approved version of the product, however, the result would be substantially more complex. In that case, according to CMS's guidance, the product would not be eligible for negotiation, even if newer versions of the drug did not have competitors. In this case, branded manufacturers might find product hopping quite attractive.[151]

Part D implications for Case 2: That said, in the second case, if the product in question is a drug primarily reimbursed under Part D (essentially all small molecule drugs and some but not all biologics), other IRA provisions may operate to minimize the attractions of product hopping. The IRA restructures the Part D benefit to increase Part D plans' financial responsibilities.[152] This restructuring should encourage Part D plans to employ utilization management strategies like prior

150. It is possible that provisions of the law requiring CMS to consider the "[c]omparative effectiveness" of a drug selected for negotiation and "therapeutic alternatives" to the drug in making its pricing offer to the manufacturer may enable CMS to consider whether there is evidence suggesting the newer version of the drug is likely to provide therapeutic benefits for patients, potentially impacting CMS's pricing offer. *See* Inflation Reduction Act § 11002 (amending Title XI of the Social Security Act § 1194(e)(2)).

151. We put aside here consideration of whether other areas of legal doctrine, such as antitrust law, might assume greater significance in these situations. It may be that soft switches do not draw antitrust or other legal scrutiny under pre-IRA law, but to the extent that manufacturers would engage in soft switches as an effort to avoid the IRA's negotiation provision, that baseline analysis may change.

152. *See supra* text accompanying notes 53–54 for a description of these changes and their intended effects.

authorization[153] or step therapy[154] to promote use of the generic or biosimilar competitors to the older version of the drug relative to the newly introduced version, making the "soft switch" more difficult for companies to implement. This is because the IRA gives Part D plans greater financial responsibility than they had previously for absorbing the costs of high-priced drugs, increasing plans' incentives to combat companies' existing gaming strategies and ensuring generics and biosimilars are used as frequently as possible. It should therefore be more difficult for companies to shift patients over to their newer formulations, and existing antitrust doctrine should limit their ability to engage in "hard switching."[155] In sum, if product hopping permits some manufacturers to avoid negotiations for certain versions of their products, plans will have stronger incentives to push back against soft switches, and courts may still push back against hard switches. Overall, the financial incentives to engage in product hopping may be substantially reduced relative to pre-IRA incentives in the Part D context.

Part B implications for Case 2: If the product in question is primarily reimbursed under Part B, typically an infused drug or biologic, the waters are muddier. CMS guidance for the fee-for-service Medicare Part B program historically discouraged use of utilization management strategies,[156] and policy experts have expressed concern that the existing payment formulas in Part B are not well-suited to the task of encouraging biosimilar usage where biosimilars do exist. Fee-for-service

153. "Prior authorization" describes the situation in which a health insurer requires patients or providers to obtain approval for a health care good or service before the care can be provided and paid for. *See, e.g.*, Kaye Pestaina & Karen Pollitz, *Examining Prior Authorization in Health Insurance*, KAISER FAM. FOUND. (May 20, 2022), https://www.kff.org/policy-watch/examining-prior-authorization-in-health-insurance/ [https://perma.cc/Y8QU-A24E].

154. "Step therapy" is a form of prior authorization in which patients "begin[] medication for a medical condition with the most preferred drug therapy and progress[] to other therapies only if necessary." *See* CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE ADVANTAGE PRIOR AUTHORIZATION AND STEP THERAPY FOR PART B DRUGS, (Aug. 7, 2018), https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs [https://perma.cc/X2XT-K6LU].

155. If the manufacturer removes both its initially approved version and any competition for that version from the market, its subsequently approved versions may then even become eligible for negotiation once again.

156. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE ADVANTAGE PRIOR AUTHORIZATION AND STEP THERAPY FOR PART B DRUGS, (Aug. 7, 2018), https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs [https://perma.cc/X2XT-K6LU]. Recent regulatory changes now permit Medicare Advantage plans to use utilization management in Part B. *See id.* Given the increasing share of Medicare beneficiaries choosing Medicare Advantage plans, the influence of Medicare Part B fee-for-service dynamics may be somewhat muted. *See* Nancy Ochieng, Jeannie Fuglesten Biniek, Meredith Freed, Anthony Damico & Tricia Neuman, *Medicare Advantage in 2022: Enrollment Update and Key Trends*, KAISER FAM. FOUND. (Aug. 9, 2023), https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2023-enrollment-update-and-key-trends [https://perma.cc/TB25-H5YP] (showing that the share of beneficiaries enrolled in Medicare Advantage plans has risen from nineteen percent in 2007 to fifty-one percent in 2023).

Medicare Part B is less likely, therefore, to be able to resist the increased costs of a negotiation-avoiding soft product hop, meaning that firms may still have incentives to pursue those hops. As a result, the IRA may put increasing pressure on CMS and Congress to adopt one of several reforms that have been proposed to the Part B payment structure in an effort to encourage biosimilar use,[157] a topic discussed in more detail infra.[158]

* * * * *

These many ambiguities and complexities make it difficult to answer the question at the beginning of this Section — whether and how the IRA might impact companies' incentives to engage in product hopping, especially with respect to Part B biologics. It may be that the IRA's effects on the *frequency* with which companies engage in product hopping depends on the above factors, but that the product hopping observed in any given case will be less financially harmful for patients and our healthcare system.

Consider the example above that may create the most concern: an older Part B biological product which has biosimilar competition by year thirteen after approval (rendering it ineligible for negotiation) while the manufacturer attempts to shift patients to a new formulation. Arguably, in any given case, this situation could be an improvement over our current system, which already includes incentives for product hopping and in which manufacturers (particularly biologic manufacturers) frequently are able to block *any* competition far beyond thirteen years.[159] Post-IRA, if the manufacturer has forestalled biosimilar competition, their products will be eligible for negotiation. And if the manufacturer *permits* competition, those cheaper biosimilars will be available not only for Medicare patients, but also for Americans with other forms of insurance (or who lack insurance), providing them with new treatment options. All that said, to the extent that soft product hopping *frequency* increases, the overall impact of this product hopping may be more acute. If Part B biologics product hopping does increase in frequency, the resulting questions about policies to promote biosimilar uptake on the demand side won't be new ones. We discuss these policies in Part V.

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157. *See, e.g.*, MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM, MEDICARE PAYMENT ADVISORY COMMISSION 86 (2022), https://www.medpac.gov/wp-content/uploads/2022/06/Jun22_MedPAC_Report_to_Congress_v4_SEC.pdf [https://perma.cc/5D25-GXJZ].

158. *See infra* Section V.A.

159. *See, e.g.*, Benjamin N. Rome, ChangWon C. Lee & Aaron S. Kesselheim, *Market Exclusivity Length for Drugs with New Generic or Biosimilar Competition, 2012–2018*, 109 CLINICAL PHARMACOLOGY & THERAPEUTICS 367, 369 (2021) (finding that small molecule drugs had a median of 14.4 years of exclusivity as compared to 21.5 years for biologic drugs).

Ultimately, the IRA might therefore serve as a type of ex post patent reform, reducing the impact of patents that have already been granted. As we discuss in the next Part, however, the statute is less likely to have significant ex ante effects and is comparatively unlikely to impact the accumulation of patents in the first instance.

IV. IMPACTS ON PATENT ACQUISITION

In this Part we begin by briefly laying out the background landscape of drug patent acquisition as it exists today. We then consider how the IRA might affect patent acquisition behavior, concluding that for both small molecules and biologics, the impacts are likely to be relatively minor.

A. Drug Patent Acquisition in General

The biopharmaceutical industry invests a tremendous amount of effort in the acquisition of patents, impacting the development and marketing of both small molecule and biologic drugs. Firms spend substantial resources prosecuting patents, including vigorous pushes (not always successful) to develop new law on what is patentable and how patents are enforced.[160] Although this story has been thoroughly explored, we retell it briefly here as background.

The most fundamental patents for drugs, either small molecule or biologic, are composition-of-matter patents on the drug molecule itself. These "primary" patents are the strongest: a competitor cannot evade ("invent around," in patent parlance) those patents if it intends to market the "same" drug.[161] However, firms usually seek these primary patents quite early in a drug's development,[162] well before the clinical trials and regulatory approval necessary to market a drug. In line with

160. *See, e.g.*, Fraiser Kansteiner, *Teva Takes 'Skinny' Label Dispute with GlaxoSmithKline to the Supreme Court: Reports*, FIERCE PHARMA (Feb. 17, 2022), https://www.fiercepharma.com/pharma/teva-takes-skinny-labels-legal-odyssey-to-supreme-court-report [https://perma.cc/598L-CQ5F] (discussing branded firms' successful efforts to strengthen pharmaceutical method-of-use patents by securing an appeals court victory that limits the ability of generics to avoid infringement liability); Ashleigh Furlong, Sarah Anne Aarup & Samuel Horti, *Who Killed the COVID Vaccine Waiver?*, POLITICO (Nov. 10, 2022), https://www.politico.com/amp/news/2022/11/10/who-killed-the-covid-19-vaccine-waiver-00066137 [https://perma.cc/DW23-T44Q] (recounting lobbying efforts by the pharmaceutical industry to block a proposal to internationally waive patent rights related to COVID-19 inventions).

161. Competitors can still potentially compete with a patent drug by developing branded "me-too" drugs that fill the same market niche. This strategy has its own social downsides, and is rather complex; we focus instead on the dynamics of competition for the "same" drug via generic or biosimilar strategies. *See, e.g.*, W. Nicholson Price II, *The Cost of Novelty*, 120 COLUM. L. REV. 769, 769–70, 797–801 (2020) (describing the problems of "me-too" drugs).

162. Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 529 (2009).

theories of patents that analogize patents to mining prospects, primarily necessary to promote development towards marketing,[163] the drug patent serves to fence off the R&D territory in question from other developers that might also be working in that arena. Although the Hatch-Waxman Act allows branded drug manufacturers to extend patent terms to partially account for this timing issue, a substantial fraction of the primary patent's term has still typically expired by the time a drug comes to market.[164]

Accordingly, firms typically pursue a set of secondary patents as well, covering other inventions surrounding a drug.[165] These can include patents on the drug's formulation (tablet versus capsule, compositions with other pharmaceutically acceptable ingredients, etc.), methods of treatment using the drug, methods of distribution and controlled access, and methods of manufacturing the drug.[166] These patents typically are applied for later in the drug development process, either because the inventions themselves happen later or for strategic reasons, since later-filed patents expire later.[167] The ongoing acquisition of patents on an existing drug is widely known as "evergreening," though the biopharmaceutical industry typically prefers the more anodyne "product life cycle management."[168] A robust literature describes the controversies describing the acquisition (and, more commonly, the assertion) of secondary patents.[169] As described below, these patents are typically asserted, either directly or *in terrorem*, to keep competitors off the market, especially generic versions of small molecule drugs and biosimilar versions of biologic drugs.

The number of patents associated with each drug has grown over time. For small molecule drugs, Professor Lisa Ouellette found an average of 3.5 patents associated with each drug in 2005, a number that had grown from an average of 2.5 patents per drug in the 1980s.[170] In Ouellette's study, the top-selling drugs had more patents: an average of

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163. The classic citation is Edmund Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 265–66, 268 (1977).

164. *See, e.g.*, Reed F. Beall, Jonathan J. Darrow & Aaron S. Kesselheim, *Patent Term Restoration for Top-Selling Drugs in the United States*, 24 DRUG DISCOVERY TODAY 20, 20–21 (2019) (finding that about half of the 170 bestselling drugs had their patent terms extended under the Hatch-Waxman Act and pediatric exclusivity provisions, many to the statutory limit of fourteen years after FDA approval).

165. *See* Amy Kapczynski, Chan Park & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, PLOSONE, Dec. 2012, at 1, 1.

166. *See, e.g.*, Michael A. Carrier & Brenna Sooy, *Five Solutions to the REMS Patent Problem*, 97 B.U. L. REV. 1661, 1668–71 (2017) (describing such patents).

167. Eisenberg, *supra* note 31, at 354.

168. Kapczynski et al., *supra* note 165, at 1.

169. *See infra* notes 170–175 and accompanying text.

170. Lisa L. Ouellette, *How Many Patents Does It Take to Make a Drug? Follow-On Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMM. & TECH. L. REV. 299, 316 (2010).

five per drug.[171] Other studies have found similar increases in the number of patents per drug, though there is variability across drugs.[172]

Biologics typically have many more associated patents than small molecule drugs.[173] One 2022 study found that the top-ten selling drugs in the United States — mostly biologics — had an average of seventy-four patents each.[174] In the most famous case, AbbVie has a widely publicized strategy of putting up a "wall" of over one hundred patents around its blockbuster biologic, Humira.[175] Companies are able to obtain large numbers of patents in part due to the potential complexities associated with producing and using biologic drugs, including technical challenges of formulation, analysis, and manufacturing. Regardless of the reason, biologics often have particularly robust evergreening strategies, including the acquisition of patents well after the drug's approval.[176]

Finally, patent acquisition should be considered against the value of keeping information as a trade secret. A 1994 survey of pharmaceutical firms found patents and trade secrecy useful for protecting roughly equivalent proportions of products.[177] Trade secrets are relatively more

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171. *Id.* at 300, 321 (examining data from 2002–2004).

172. *See, e.g.*, C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents*, 8 J. EMP. L. STUD. 613, 619–20 (2011) (finding an increase in the mean number of patents per drug from 1.9 to 3.9 between the 1985–87 and 2000–02 drug approval cohorts); Robin Feldman, *May Your Drug Price Be Evergreen*, J.L. & BIOSCIENCES 590, 631 (2018) (finding increases in patents per drug between 2005 and 2015).

173. Victor L. Van de Wiele, Aaron S. Kesselheim & Ameet Sarpatwari, *Barriers to US Biosimilar Market Growth: Lessons from Biosimilar Patent Litigation*, 40 HEALTH AFFS. 1198, 1201 (2021).

174. I-MAK, *supra* note 121, at 3. The methodologies for the I-Mak and other studies are not directly comparable: I-Mak conducted manual patent landscapes for each drug, while Ouellette and others relied on the Orange Book, which, among other things, does not list manufacturing patents or patents that manufacturers choose not to list.

175. Cynthia Koons, *This Shield of Patents Protects the World's Best-Selling Drug*, BLOOMBERG (Sept. 7, 2017), https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug [https://perma.cc/RF63-XUVB]. Biologics are not the only drugs with large numbers of patents; Humira has a similar strategy for its small molecule drug, Imbruvica. Eric Sagonowsky, *AbbVie, Already Famous for its Humira Strategy, Forms Another 'PatentWall' Around Imbruvica: Report*, FIERCE PHARMA, (July 21, 2020), https://www.fiercepharma.com/pharma/AbbVie-already-famous-for-its-humira-strategy-forms-another-patent-wall-for-imbruvica-report [https://perma.cc/C5DX-82AB].

176. Victor L. Van de Wiele, Reed F. Beall, Aaron S. Kesselheim & Ameet Sarpatwari, *The Characteristics of Patents Impacting Availability of Biosimilars*, 40 NATURE BIOTECHNOLOGY 22, 23 (finding that only nine percent of patents asserted in biosimilar litigation were filed before approval of the originator biologic); Arti K. Rai & W. Nicholson Price II, *An Administrative Fix for Manufacturing Process Patent Thickets*, 39 NATURE BIOTECHNOLOGY 20, 21 (2021) (finding that sixty-three percent of patent assertions in biosimilar litigation were of patents filed more than one year after the biologic was approved).

177. Wesley M. Cohen, Richard R. Nelson & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* 33 tbl.1 (Nat'l Bureau of Econ. Rsch., Working Paper No. 7552, 2000), https://www.nber.org/system/files/working_papers/w7552/w7552.pdf [https://perma.cc/WYV8-RKYN].

effective — and are perceived as more attractive[178] — for manufacturing methods, and more so for biologic manufacturing than small molecule manufacturing. Manufacturing method patents are weaker than other secondary patents for multiple reasons.[179] Such patents are difficult to enforce because manufacturing methods are typically not observable.[180] Manufacturing patents for small molecule drugs also may not be listed in the Orange Book, and thus do not trigger an automatic thirty-month stay of generic approval (an otherwise-important bolster for weak patents).[181]

For biologics, trade secrecy for manufacturing methods has an additional benefit over patents: biologic production is notoriously finicky and producing a biosimilar may require close reverse engineering of the original manufacturer's method.[182] Keeping that method secret can result in long periods of blocked competition.[183]

Nevertheless, we do not mean to overstate the point: manufacturers certainly acquire patents on methods of manufacturing. Indeed, in the case of biologics, where patents often coexist with trade secrecy, almost fifty percent of the patents asserted in litigation against biosimilars are manufacturing process patents.[184]

B. IRA Impacts on Patent Acquisition

Despite arguing in Part III that the IRA will have substantial impacts on patent *assertion*, we think it likely that the IRA's impact on patent acquisition will be relatively muted. On the one hand, it would be surprising if there were no link at all between changes in patent assertion strategy and changes in acquisition strategy; the most obvious use of patents is to enforce them. On the other hand, three factors blunt that effect: the relatively low cost of patent acquisition relative to patent assertion, the option value of patents for licensing, and the differing time horizons between acquisition and assertion.[185]

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178. *Id.* at 34 tbl.2 (reporting firm perceptions that sixty-eight percent of process innovations were protectable by secrecy, compared to thirty-six percent for patents).

179. W. Nicholson Price II, *Making Do in Making Drugs*, 55 B.C. L. REV. 491, 526–28 (2014).

180. *Id.* at 526.

181. 21 U.S.C. § 355(b)(1)(A)(viii) (providing that new drug applications include information regarding patents that claim the relevant drug substance, drug product, or method of use).

182. Rai & Price, *supra* note 176, at 1028.

183. *Id.*

184. Rai & Price, *supra* note 176, at 21 tbl.183.

185. Of course, patents have value besides licensing or enforcement; for instance, they can be used to signal inventiveness to competitors and sources of capital, though this function is more important to small firms and venture capital, rather than the larger drug firms that we consider here. *See, e.g.*, Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625 (2002). We focus on what seem to us likely the most important factors in this context: low cost, licensing, and timing.

1. The Prima Facie Case for IRA Impact

Patents provide the right to exclude others from making, using, and selling the patented invention. But that right is not self-enforcing.[186] If patents' principal function is a license to sue, then, we should expect the value of patents to rise and fall with their value as a tool for suit. If assertion becomes harder or less valuable (e.g., because the IRA's negotiation system reduces the value of maintaining a monopoly position), patent acquisition should follow a similar pattern. Accordingly, we assume that as the IRA limits the incentives for some sorts of enforcement, patents acquisition should also be less attractive — at least on the margins.

2. Low Acquisition Cost

The link between patent acquisition and assertion is limited by, among other things, a substantial difference in the cost of the two endeavors: while patents are costly to acquire, that cost pales in comparison with the costs of asserting those patents. Patent litigation has been dubbed "the sport of kings,"[187] costing millions of dollars in a typical case.[188] And the marginal profits that can be secured by extending important drug monopolies through secondary patents can run into the hundreds of millions or billions of dollars.[189] By comparison, at least when one is talking about acquiring patents in the United States,[190] the tens or even hundreds of thousands of dollars at stake[191] in the process of patent acquisition are akin to a rounding error in the broader calculations, likely worth the cost even as an insurance mechanism in case of unforeseen change.

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186. *See, e.g.*, Rebecca C. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 388 (2007).

187. Douglas J. Kline, *Patent Litigation: The Sport of Kings*, MIT TECH. REV. (Apr. 28, 2004), https://www.technologyreview.com/2004/04/28/232981/patent-litigation-the-sport-of-kings/ [https://perma.cc/NNE8-R86F]; *see also* Colleen V. Chien, *Of Trolls, Davids, Goliaths, and Kings: Narratives and Evidence in the Litigation of High-Tech Patents,* 87 N.C. L. REV. 1571, 1584 (2009) (describing the "sport of kings" narrative); *id.* at 1577 (pointing out other narratives).

188. Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL'Y, L. & ETHICS 293, 324 (2015).

189. Feldman & Frondorf, *supra* note 19, at 503 n.23.

190. The calculus appears to be different in Europe and other jurisdictions that have more challenging patent examination requirements as well as comprehensive price regulation. *See* Rachel Goode & Bernard Chao, *Biological Patent Thickets and Delayed Access to Biosimilars: An American Problem*, J.L. & BIOSCIENCES, July-Dec. 2022, at 1, 23–24 (finding that branded biologics firms secure many fewer patents in Europe).

191. The cost of obtaining and maintaining one subset of U.S. biologics patents has been estimated in the range of $25,000. *Id.* at 19. But costs can vary depending on whether the application is a new or refiled application, the number of claims and drawings included in the application, and the number and nature of rejections from the USPTO.

3. Partial Exclusion and Licensing

Even if companies become less likely to aggressively exclude all competitors, they will still want to exclude on their own terms, and patents provide a useful resource in licensing and other negotiations. Only products without generic or biosimilar competition are eligible for negotiation under the IRA — meaning that if biopharmaceutical companies facilitate or at least allow some competition, negotiations can be avoided. A robust patent portfolio may give firms the leverage to help determine who their competitors are, and to limit the number of competitors to one rather than many. This may be especially important for biologics, where potential biosimilar entrants can have their own patent portfolios available for cross-licensing.[192] Innovator firms may simply choose to license their patents covering a single drug to one selected competitor at the relevant time if that permits them to avoid negotiation, rather than pushing flat-out to exclude all possible competitors from the market. We need not look far to see similar dynamics in action in a related arena: innovator firms bargain robustly with competitors in the context of patent litigation settlements, setting the contours of market entry with the first generic company (or companies) to challenge patents and enter the market.[193]

In essence, while we are accustomed to thinking of patents as tools to enforce an approximate monopoly on a drug, in the context of IRA-created negotiation requirements, that view may be too stark. Instead, there remains value in patents in forestalling the bulk of competition, even if all competitors cannot or will not be excluded. A duopoly, after all, is more profitable for each competitor than an oligopoly with three or more competitors. In sum, the value of patents to effect partial exclusion, and to select the competitor, remains even in the face of a negotiation program.

4. Differing Time Horizons

The IRA's impact on patent acquisition should also be blunted because the time horizons for acquisition and assertion are substantially different. The acquisition of a patent portfolio is a slow, stretched-out process, taking place over the years of a drug's development and life

192. *See, e.g.*, Evelien Moorkens, Nicolas Meuwissen, Isabelle Huys, Paul Declerck, Arnold G. Vulto & Steven Simoens, *The Market of Biopharmaceutical Medicines: A Snapshot of a Diverse Industrial Landscape*, FRONTIERS PHARMACOLOGY, June 2017, at 1, 9 (finding that almost all biosimilar developers also develop original biologics).

193. Feldman & Frondorf, *supra* note 19, at 510–24 (describing the many varied bargains struck between generic and brand-name firms making small molecule drugs).

cycle (and the years of prosecution for each individual patent[194]).[195] The decision to enforce certain patents, on the contrary, falls within a much shorter time window, typically the moment of generic or biosimilar entry. Both the Hatch-Waxman Act[196] and the Biologics Price Competition and Innovation Act[197] specify times when competitors are allowed to apply for approval while challenging patents (four years after approval for the generic version of a small molecule new chemical entity or twelve years after approval for a biosimilar version of a new biologic).[198] To be sure, patents can be asserted after that time, but the bulk of the action is around the time that regulatory exclusivity expires.[199]

Potential assertion decisions also happen much later, at least several years after the acquisition of early patents in the patent portfolio. When firms acquire patents, assertion decisions are still relatively far in the future. While firms may have beliefs about whether their drug is likely to be such an exceptionally valuable product years in the future as to merit Medicare negotiation, they cannot know that for certain, meaning that IRA impacts on assertion are probabilistic and future-discounted at the time of patent acquisition.

And of course, political economy may change and alter existing law. For firms debating whether to acquire patents any time before the 2020s, the IRA was an unlikely regime to take into consideration, given that Congress had not authorized Medicare to directly negotiate the price of drugs. Acquisition decisions going forward must similarly account for the possibility of future political changes. Who can say what U.S. drug-price negotiations will look like in 2040?

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194. The average time from patent filing to final disposition (issued or abandoned) was 24.9 months in August 2022. *Patent Pendency Data August 2022*, U.S. PAT. & TRADEMARK OFF. (2023), https://www.uspto.gov/dashboard/patents/pendency.html [https://perma.cc/C7UV-QY7F].

195. For instance, in a study of all biosimilar litigation from the enactment of the BPCIA until August 2020, the patents enforced in such litigation ranged in filing date from twelve years before the product's market entry to a remarkable *twenty-four* years after market entry. Victor L. Van de Wiele, Reed F. Beall, Aaron S. Kesselheim & Ameet Sarpatwari, *The Characteristics of Patents Impacting Availability of Biosimilars,* 40 NATURE BIOTECHNOLOGY 22, 24 (2022).

196. The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 15 U.S.C. §§ 68b–68c, 70b; 21 U.S.C. §§ 301, 355, 360cc; 28 U.S.C. § 2201; and 35 U.S.C. §§ 155, 155A, 156, 271, and 282).

197. Biologics Price Competition and Innovation Act, Pub. L. No. 111-148, secs. 7001–03, 124 Stat. 119, 804–23 (2010) (passed as part of the Patient Protection and Affordable Care Act).

198. 21 U.S.C. § 355(j)(5)(F)(ii) (small molecule drugs); 42 U.S.C. § 262(k)(7) (biologics).

199. C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents*, 8 J. EMPIRICAL LEGAL STUD. 613, 625–26 (2011). Because the BPCIA is still new, we lack good empirical data about the equilibrium timing of biosimilar entry, especially since entry may be delayed for reasons beyond the BPCIA's twelve-year floor. *See, e.g.*, Price & Rai, *supra* note 32, at 1046–48 (describing secrecy-based barriers to entry).

V. POTENTIAL POLICY IMPLICATIONS

These analyses of how the IRA may impact pharmaceutical firms' intellectual property assertion and acquisition strategies have broader implications for policy reform going forward. First, in implementing the IRA, CMS and other policy actors should recognize that they are making patent and innovation policy as well as health policy. Accordingly, they should be fully prepared for attempts to adapt prior patent gaming techniques to the new environment. At the same time, they should also fully utilize IRA provisions that allow higher reimbursement for clinically valuable innovation. In Section V.A, we highlight key implementation considerations. Second, given the significant changes to patent incentives the IRA may create, it may reshape policymakers' existing interests in patent reform. The IRA may create additional support for pursuing interventions regarding product hopping, for instance, while de-emphasizing other proposals that had been put forth. In Section V.B, we compare and evaluate "cryptic" patent reform through the IRA with reform proposals that explicitly target biopharmaceutical patents.

A. Implementing the IRA

As the federal government implements the negotiation provisions of the IRA, it should simultaneously pursue policy strategies that mitigate the law's potential incentives for gaming while supporting important policy goals of the law, such as its recognition of the importance of comparative effectiveness information and its efforts to curb the indefinite duration of patent-protected pricing.[200] To take a specific example: we argued above in Section III.C that product hopping might help companies avoid negotiation requirements, at least in some circumstances. How might policymakers reduce incentives for product hopping, particularly among biologics?[201]

One strategy involves payment. CMS could, for example, advance policy proposals that encourage biosimilar use within Medicare Part B. Currently, Part B assigns separate billing codes to originator biologics and biosimilars.[202] Policy experts, including Congress' own Medicare

200. *Cf.* Michelle M. Mello & Rebecca E. Wolitz, *Legal Strategies for Reining In "Unconscionable" Prices for Prescription Drugs*, 114 NW. U. L. REV. 859, 864 (2020) (noting resistance to gaming as an important element of effective drug pricing policy).

201. As analyzed in *supra* notes 150–151, the IRA's restructuring of Part D financial incentives may mitigate these drivers in the small molecule drug space.

202. MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 157, at 86. This is not the case for small molecule drugs within Medicare, where the branded and generic versions are paid under a single billing code. *See* Benjamin N. Rome & Ameet Sarpatwari, *Promoting Biosimilar Competition by Revising Medicare Reimbursement Rules*, JAMA NETWORK OPEN, Nov. 2021, at 1, 1 (2021).

Payment Advisory Commission ("MedPAC"), have argued that this practice "undermines price competition"[203] by delinking the prices of these products, such that providers have limited incentives to choose lower-priced options for their patients.[204] MedPAC has also argued that the Part B payment structure — which reimburses providers based on the average sales price of the relevant drug — "can also play a role in providers' choice of drugs,"[205] by paying providers more for providing higher-priced branded biologics rather than lower-priced biosimilars.

MedPAC has proposed options for policy change that would group originator biologics and their lower-priced biosimilars together for reimbursement purposes, with the goal of providing manufacturers with "incentive[s] to lower their prices relative to competitors to make their products more attractive to providers and garner market share."[206] CMS might use its existing authority through the Centers for Medicare and Medicaid Innovation to pilot a policy model to study these outcomes,[207] though Congress might also provide CMS with this authority directly.[208] Ideally, such a policy change could not only help increase uptake of lower-priced biosimilars generally, but also help mitigate potential incentives for product hopping in the biologic context, by making soft switches to more expensive branded biologics less attractive to providers and hence more challenging to implement.

Other federal actors might also contribute to efforts to mitigate incentives for product hopping. In the context of small molecule drugs, FDA might use its existing authority to speed generic competition to market for the newly introduced version of a drug using its "suitability" pathway.[209] One of us has previously explained, for example, how FDA might alter its approach to the use of suitability petitions to encourage

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203. MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 157, at 86.

204. *See id.* (suggesting that consolidating originator biologics and biosimilars in a single billing code would encourage manufacturers to lower their prices when compared to competitors). Other independent policy experts have also echoed these calls. *See, e.g.*, *Can Biosimilar Drugs Lower Medicare Part B Drug Spending?*, PEW CHARITABLE TR. (Jan. 2017), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2017/01/can-biosimilar-drugs-lower-medicare-part-b-drug-spending [https://perma.cc/65XT-522R]; Rome & Sarpatwari, *supra* note 202, at 2.

205. *Id.* at 87.

206. *Id.* at 86–87.

207. *See* NITZAN ARAD, DERICK RAPISTA, MARIANNE HAMILTON LOPEZ & MARK MCCLELLAN, ORIGINATOR BIOLOGICS AND BIOSIMILARS: PAYMENT POLICY SOLUTIONS TO INCREASE PRICE COMPETITION WHILE MAINTAINING MARKET SUSTAINABILITY IN MEDICARE PART B 8 (2021), https://healthpolicy.duke.edu/sites/default/files/2021-11/Realizing%20the%20Benefits%20of%20Biosimilars%20Part%20B.pdf [https://perma.cc/JRZ3-WNPZ].

208. MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 157, at 86.

209. 21 U.S.C. § 355(j)(2)(C).

earlier generic competition for small molecule products experiencing product hops.[210]

In addition, for biologics covered under Part D that are provided at the pharmacy counter, measures that promote so-called "interchangeable" biosimilar development and dissemination for these products could mitigate firms' efforts to game the IRA through soft switches. All states now have laws that permit substitution of interchangeable biosimilars.[211] The FDA has approved few interchangeable biosimilars thus far, and it could do much more to promote their development and approval.[212] A wider set of interchangeable biosimilars would increase the impact of any CMS efforts to provide reimbursement under Part D for interchangeable biosimilar versions of older biologics, helping to counter efforts on the part of innovator firms to implement soft switches.

More generally, CMS will need to engage in a range of administrative decisionmaking to implement the law, particularly its negotiation provisions. The IRA contemplates that much of this implementation will initially occur through "program instruction or other forms of program guidance"[213] rather than notice-and-comment rulemaking, likely given the short timeframe CMS has to engage in these decisions before the negotiation program begins for the 2026 cycle. Many of CMS' decisions, such as those regarding the definition of qualifying drugs, will implicate pharmaceutical companies' efforts to avoid inclusion in the negotiating program, as described in Part III. Some of these efforts may also implicate antitrust concerns. Accordingly, CMS should establish regular channels of communication with antitrust authorities (e.g., Federal Trade Commission ("FTC") and Department of Justice ("DOJ") Antitrust) and perhaps even establish in-house expertise. Other administrative questions will also arise.[214]

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210. Arti K. Rai & Barak D. Richman, *A Preferable Path for Thwarting Pharmaceutical Product Hopping*, HEALTH AFFS. FOREFRONT (May 22, 2018), https://www.healthaffairs.org/do/10.1377/forefront.20180522.408497/full/ [https://perma.cc/2RKQ-HEM9].

211. *See Oklahoma Becomes Final State to Permit Biosimilar Substitution*, SAFEBIOLOGICS (Apr. 2021), https://safebiologics.org/2021/05/oklahoma-becomes-final-state-to-permit-biosimilar-substitution/ [https://perma.cc/C9YH-K53R]; *see also* Gary M. Fox, *Suggestions for State Laws on Biosimilar Substitution*, 24 MICH. TELECOMM. & TECH. L. REV. 253 (2018) (analyzing state substitution laws).

212. *Cf.* Louise C. Druedahl, Sofia Kälvemark Sporrong, Timo Minssen, Hans Hoogland, Marie Louise De Bruin, Marco van de Weert et al., *Interchangeability of Biosimilars: A Study of Expert Views and Visions Regarding the Science and Substitution*, PLOS ONE, Jan. 11, 2022, at 1, 3, 5–9 (cataloging stakeholder views, noting regulatory variation, and arguing for the importance of increased regulatory trust).

213. Inflation Reduction Act of 2022, Pub. L. No. 117-169, sec. 11001(a), 136 Stat. 1818, 1851–54 (amending Title XI of the Social Security Act § 1198(c)).

214. For instance, some administrative implementation questions central to innovation will implicate the contours of the negotiation process. Because the mandatory discounts are a ceiling rather than a floor, the process may have considerable implications for innovation. One

B. Re-Examining Patent Reform Proposals

Cryptic though it may be, the IRA is arguably the largest pharmaceutical patent reform effort since the America Invents Act of 2011.[215] As we have discussed, the IRA may not only significantly impact how pharmaceutical firms choose to acquire and enforce their patents, but it may also shift their patent gaming strategies towards product hopping rather than patent assertion, at least for some types of products. To the extent these strategy changes materialize, they will cast in a new light direct patent reform efforts in Congress.

More generally, from a comparative institutional perspective, the IRA is likely to show that patent strategy in the pharmaceutical industry can change substantially even without new patent caselaw from the Federal Circuit or Supreme Court or Congressional intervention in the patent statute (Title 35). In other words, statutory and regulatory changes to health law and food and drug regulation also impact companies' patent-related decisions, making it less (or more) useful to engage in certain types of patent acquisition and assertion strategies.

In fact, the IRA has the potential to affect a larger shift in patent practice, at least in the pharmaceutical industry, than many recent patent reform proposals. As one of us has discussed at length in prior works,[216] even the administrative patent challenge proceedings set up by the America Invents Act of 2011 — widely considered the biggest patent reform since 1952 — have had little impact on biopharmaceutical patents. The picture is similarly modest when one turns to the last several years. Recently, there has been substantial Congressional interest in both substantive and procedural reforms to various aspects of patent law, as expressed through both the filing of bills and the holding of hearings.[217] Particularly important are bills filed or hearings held in the Judiciary Committees of both houses of Congress, which have

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of the most important clarifications will involve how comparative effectiveness will be evaluated. Although the IRA appears to prohibit the use of one common measure, the quality-adjusted life year, the use of other measures would seem both permissible and appropriate. In addition to comparative effectiveness, the IRA allows consideration of many other factors. For instance, the IRA requires CMS to consider the "research and development costs of the manufacturer for the drug," *id.* § 11001(a) (amending Title XI of the Social Security Act § 1192(e)), which appears to require CMS to define exactly what costs might be included under that heading. CMS' 2023 guidance provides significant clarity regarding the types of costs it will consider here. *See* CMS REVISED GUIDANCE, *supra* note 120, at 188–91.

215. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

216. Arti K. Rai, Saurabh Vishnubhakat, Jorge Lemus & Erik Hovenkamp, *Post-Grant Adjudication of Drug Patents: Agency and/or Court*, 37 BERKELEY TECH. L.J. 139 (2022); Erik Hovenkamp, Jorge Lemus, Arti Rai & Saurabh Vishnubhakat, *Has the PTAB Made a Difference in Drug Settlements and Generic Entry*, 40 NATURE BIOTECHNOLOGY 1569 (2022).

217. *See, e.g.*, S. Sean Tu, Sarosh Nagar & Aaron S. Kesselheim, *Recent Patent Reform Bills and Their Implications for Prescription Drugs*, 329 JAMA 459, 459–60 (describing three bills).

jurisdiction over intellectual property law issues.[218] However, these efforts have typically been either narrow in scope or unlikely to have a significant impact on biopharmaceutical patents. As one example, most of the recent Congressional attention to substantive reforms of the patent law has focused on amendments to Section 101 and what types of inventions or discoveries are eligible to be patented.[219] This issue has captivated the patent bar and was the subject of three related hearings before the Senate Judiciary Committee in 2019.[220] Multiple bills have been introduced with the goal of expanding the scope of inventions or discoveries which are eligible to be patented.[221] Yet these bills would have had little, if any, impact on pharmaceuticals. Indeed, the Supreme Court's subject matter decisions, to which the recent flurry of Congressional effort is responding, have taken highly explicit (if doctrinally slippery) steps to carve out from their remit patents on biopharmaceutical therapeutics.[222]

Perhaps more interesting for drug pricing reform purposes are the hearings and bills that have proposed procedural changes to patent acquisition or assertion, typically limited to the pharmaceutical context, with the goal of promoting competition or reducing prices. Tellingly, not all of these bills would propose statutory changes to the patent statute itself (in title 35 of the U.S. Code), although some would. For

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218. *The Subcommittee on Courts, Intellectual Property, and the Internet*, H. COMM. ON THE JUDICIARY, https://judiciary.house.gov/subcommittees/courtsintellectual-property-and-internet-116th-congress/ [https://perma.cc/5UBK-WLP6]; *About the Committee*, SEN. COMM. ON THE JUDICIARY, https://www.judiciary.senate.gov/about/jurisdiction [https://perma.cc/ZN3G-ZSK4].

219. Much of this attention is likely a response to the Supreme Court's repeated interventions regarding Section 101 doctrine over the last decade, which have narrowed patent eligibility in some contexts. *See, e.g.*, Bilski v. Kappos, 561 U.S. 593 (2010); Mayo Collaborative Servs. v. Prometheus Lab'ys., Inc., 566 U.S. 66 (2012); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013), Alice Corp. v. CLS Bank Int'l., 573 U.S. 208 (2014). The Supreme Court's decisions also arguably created confusion in the doctrine more generally. *See, e.g.*, Am. Axle & Mfg, Inc. v. Neapco Holdings LLC, 966 F.3d 1347 (Fed. Cir. 2020) (denying rehearing en banc on a 6–6 vote); Am. & Mfg, Inc. v. Neapco Holdings LLC, 967 F.3d 1285, 1309 (Fed. Cir. 2020) (Moore, J., dissenting from panel rehearing) ("The majority's *Nothing More* test, like the great American work *The Raven* from which it is surely borrowing, will, as in the poem, lead to insanity.").

220. *The State of Patent Eligibility in America: Part I: Hearing Before the Sen. Comm. on the Judiciary, Subcomm. on Intellectual Property*, 116th Cong. (2019); *The State of Patent Eligibility in America: Part II: Hearing Before the Sen. Comm. on the Judiciary, Subcomm. on Intellectual Property*, 116th Cong. (2019); *The State of Patent Eligibility in America: Part III: Hearing Before the Sen. Comm. on the Judiciary, Subcomm. on Intellectual Property*, 116th Cong. (2019).

221. *See, e.g.*, Restoring America's Leadership in Innovation Act, H.R. 6264, 115th Cong. (2018); Patent Eligibility Restoration Act, S. 4734, 117th Cong. (2022).

222. *See* Arti K. Rai & Robert Cook-Deegan, *Moving Beyond "Isolated" Gene Patents*, 341 SCIENCE 137 (2013) (discussing Supreme Court decision striking down under Section 101 certain gene patents likely to cover diagnostic interventions but explicitly holding patent-eligible slightly different patents that generally cover therapeutics).

example, Representative Hank Johnson[223] introduced a bill which would reform the patent litigation process to limit the number of patents a biologic drug manufacturer can assert against a biosimilar applicant.[224]

Other bills propose reforms to the antitrust laws in an effort to limit patent gaming strategies. For example, Senator Amy Klobuchar[225] introduced a bipartisan bill in an effort to strengthen the FTC's review of potential "pay-for-delay" patent settlements.[226] A similar bipartisan bill, introduced by Senator John Cornyn,[227] aims to strengthen FTC review of product hopping.[228] A third bipartisan bill[229] would establish an interagency task force between the Patent Office and the FDA,[230] with the goal of "sharing information and providing technical assistance" between the agencies.[231] A coordinating body of this type could enable these agencies to respond more effectively to concerns regarding patent thickets in the biologic context, as some of us have argued.[232] Although these proposals are certainly worthwhile ones, industry has demonstrated an ability to develop innovative new gaming strategies that may escape the scope of these bills, even putting aside the fact that these bills have yet to become law.[233]

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223. Representative Johnson was at the time the Chair of the House Judiciary Committee's Subcommittee on Courts, Intellectual Property, and the Internet.

224. Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act, H.R. 2884, 117th Cong. (2021).

225. Senator Klobuchar is currently a member of the Senate Judiciary Committee and Chairwoman of its Subcommittee on Competition Policy, Antitrust, and Consumer Rights.

226. Preserve Access to Affordable Generics and Biosimilars Act, S. 64, 116th Cong. (2019).

227. Senator Cornyn is currently a member of the Senate Judiciary Committee and its Subcommittee on Intellectual Property.

228. Affordable Prescriptions for Patients Act of 2019, S. 1416, 116th Cong. (2019).

229. Interagency Patent Coordination and Improvement Act of 2022, S. 4430, 117th Cong. This bill was co-sponsored by five members of the Senate Judiciary Committee, including Senators Durbin and Grassley, the Chair and Ranking Member, respectively, of the Committee as a whole, and Senators Leahy and Tillis, the Chair and Ranking Member, respectively, of its Subcommittee on Intellectual Property. *Id.*

230. *Id.*

231. *Id.*

232. Rai & Price, *supra* note 18, at 21–22.

233. Unhampered by the interest group bickering that tends to derail direct patent reform in Congress, the Biden administration has taken some unilateral steps involving the USPTO to promote biopharmaceutical competition. In July 2021, the White House issued an Executive Order on "Promoting Competition in the American Economy" that directed the FDA and USPTO to engage in dialogue over patent system features that "unjustifiably delay generic drug and biosimilar competition." Exec. Order No. 11,609, 86 Fed. Reg. 36987, 36997 (July 22, 2021). An exchange of letters that followed this White House direction to the agencies has resulted in a USPTO commitment to examiner training on FDA resources and to the creation of formal mechanisms for USPTO-FDA cooperation on biopharmaceutical patent quality initiatives. Letter from Katherine K. Vidal, Dir., U.S. Pat. & Trademark Off., to Robert M. Califf, Comm'r, U.S. Food & Drug Admin. (July 6, 2022), https://www.uspto.gov/sites/

Nevertheless, given the narrow scope of the executive action taken to date, the mandatory price negotiation contemplated by the IRA may be the tactic most likely to limit the power of pharmaceutical patents. Although it is hardly impervious to gaming, it does squarely target the key policy question of how much should society pay for the clinical benefit provided by drugs.

How has the IRA thus far avoided analysis (and hence probable fierce opposition) from a patent perspective? One answer comes from the structure of Congressional committees and their jurisdiction. One of us has argued that fragmentation in the jurisdiction of Congressional committees may harm the development of innovation policy reforms.[234] More specifically, although the House and Senate Judiciary Committees have responsibility for statutory reforms to the patent system,[235] other committees (including the Senate Finance Committee and Health, Education, Labor and Pensions Committee and the House Energy and Commerce Committee and Ways and Means Committee)[236] have responsibility for health- and FDA-related reforms. This separation of authorities may impact not only any individual committee's understanding of how its legislative efforts might affect areas of law outside its purview, but may also serve to channel health care policymaking through particular legal avenues that may or may not be best suited to the resolution of particular problems.[237] To be sure, there are important examples of collaboration between the Judiciary Committee and other health-related committees that make simultaneous changes to both the patent laws and other health- or FDA-related statutes, such as

default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf [https://perma.cc/2X5E-FRE6] (noting specifics on this incipient cooperation between USPTO and FDA). Pursuant to the Executive Order, the USPTO has also issued a notice specifying patent applicant duties of disclosure, and examiner duties of inquiry, with respect to potentially patent-invalidating information submitted to the FDA. Duties of Disclosure and Reasonable Inquiry During Examination, Reexamination, and Reissue, and for Proceedings Before the Patent Trial and Appeal Board, 87 Fed. Reg. 45764 (July 29, 2022). As the notice points out, it aims to target scientifically inconsistent statements made to the two agencies and also encourage examiners to ask about FDA submissions on drug manufacturing that represent prior art. *Id.* at 45765 (inconsistent statements), 45766 (prior art). The USPTO has also issued a request for comments on various other actions that could limit biopharmaceutical patent thickets. Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, 87 Fed. Reg. 60130 (Oct. 4, 2022) (seeking comments on, inter alia, mechanisms to improve prior art search, limit various types of "repeat" patent applications, and limit patenting of obvious variations on existing patents). More generally, the Executive Order discusses the importance of procompetitive actions like expeditious FDA-HHS action on biosimilar education and interchangeable biosimilars. The order thereby promotes agency action that will be very important (as discussed above) to limit gaming of the IRA.

234. Rachel E. Sachs, *Integrating Health Innovation Policy*, 34 HARV. J.L. & TECH. 57, 91–92 (2020).

235. *See supra* note 218.

236. *See* Sachs, *supra* note 234, at 91–92.

237. *See id.* at 93–94.

the Hatch-Waxman Act.[238] But because Medicare drug pricing reform proposals including the IRA formally do not make changes to patent statutes, the Judiciary Committee did not appear to publicly evaluate the impact of drug pricing reform provisions on patent practice through holding hearings or other methods in the way that each of the health- and FDA-related committees did.[239]

The IRA raises broader questions about how Congress can or should make innovation policy without explicitly changing the patent statute. On the one hand, it could be argued that it is problematic that a large change to pharmaceutical patent policy — including on some of the issues raised by members of Congress (albeit in more modest ways) in the context of direct patent reform efforts — passed without formal consideration by the relevant committees of those issues *as* patent issues. On the other hand, the policy issues underlying these distinct substantive doctrines have significant overlap: the relevant health-related committees extensively discussed and debated the impact of drug pricing reforms on health innovation,[240] even if they did not focus on its impacts on patent strategy specifically. Additionally, there is overlap between the members of Congress sitting on the Judiciary Committee and those sitting on those committees with explicit jurisdiction over the IRA,[241] suggesting that members of Congress with relevant patent expertise would have reviewed and evaluated the legislation.

Ultimately, rather than concluding that the IRA is flawed simply because of the process by which it was enacted, one might conclude that approaching patent law indirectly, but nonetheless with significant attention to health innovation and allocation goals, is a palatable pragmatic approach. That said, as we have outlined, regulators will have to pay significant attention to mechanisms by which the statute can, and will, be gamed.

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238. *See, e.g.*, Sachs, *supra* note 46 (identifying and describing the hearings before the Judiciary Committee as well as the House Energy & Commerce Committee prior to the passage of the Hatch-Waxman Act).

239. *See, e.g.*, *Prescription Drug Price Inflation: An Urgent Need to Lower Drug Prices in Medicare: Hearing Before the Sen. Finance Comm.*, 117th Cong. (2022); *Why Does the US Pay the Highest Prices in the World for Prescription Drugs?: Hearing Before the Sen. Comm. on Health, Ed., Labor & Pensions*, 117th Cong. (2021); *Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs: Hearing Before the H. Comm. on Energy & Commerce, Subcomm. on Health*, 117th Cong. (2021); *The Cost of Rising Prescription Drug Prices: Hearing Before the H. Comm. on Ways & Means*, 116th Cong. (2019).

240. *See id.*

241. As one example, Senator Grassley served as the Chairman of the Senate Finance Committee as it worked to develop a drug pricing reform bill in 2019. *See* Rachel E. Sachs, Understanding the Senate Finance Committee's Drug Pricing Package, HEALTH AFFS. FOREFRONT (July 26, 2019), https://www.healthaffairs.org/do/10.1377/forefront.20190726.817822 [https://perma.cc/L96J-AQ2Q]. Senator Grassley then served as Ranking Member of the Senate Judiciary Committee in 2021 as it considered these patent- and antitrust-related issues.

VI. CONCLUSION

Remarkably enough, drug patent reform happened in a statute that spends essentially no words discussing drug patents. The IRA's effects are likely to be complex, context-dependent, and substantial, and will play out over the years to come. Administrative agencies implementing these rules should be aware of the incentives for pharmaceutical companies to shift their strategies, and react accordingly. Firms and activists should watch this space as the landscape changes and be prepared to consider and respond to those changes. And scholars should recognize anew that the deeply interconnected regimes of pharmaceutical innovation and allocation mean that changes in one legal arena are likely to have far-flung consequences in many others.