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CRYPTIC PATENT REFORM THROUGH THE INFLATION REDUCTION ACT

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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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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); *see also infra* note 33 (describing complexities associated with

difficulty affording their prescription drugs; the 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 65 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

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measuring value).

[2] Liz Hamel et al., *Public Opinion on Prescription Drugs and Their Prices*, KAISER FAMILY FOUND. (April 5, 2022).

[3] People who are age 65 or older, those who have received disability benefits for a certain amount of time (typically 24 months, but individuals with some conditions – such as ALS – are entitled to immediate Medicare eligibility), and patients with end-stage renal disease are eligible for Medicare. *See* Ctrs. for Medicare & Medicaid Servs., *Medicare Program – General Information* (2022), https://www.cms.gov/Medicare/Medicare-General-Information/MedicareGenInfo.

[4] *See* Stacie B. Dusetzina et al., *Many Medicare Beneficiaries Do Not Fill High-Price Specialty Drug Prescriptions*, 41 HEALTH AFFAIRS 487, 487 (2022).

[5] Hamel, *supra* note 2.

[6] Antonio Olivo, *He Lost His Insurance and Turned to a Cheaper Form of Insulin. It Was a Fatal Decision.*, WASHINGTON 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

[7] Hamel, *supra* note 2. (noting that 83% of Americans 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, 327 (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 (2020).

of those choosing drugs,[9] international pricing dynamics,[10] 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 supra-competitive prices for as long as they can. A substantial scholarly literature considers how much patents matter for

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

[10] 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).

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

[12] Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 862 (2016); 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] Mello, supra note 10, at 2279–86.

[14] *Cf.* Gerard F. Anderson et al., *It's the Prices, Stupid: Why the United States Is So Different from Other Countries*, 22 HEALTH AFFAIRS 89, 90 (2003) (concluding that higher 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); Kesselheim et al.*, supra* note 12, at 861 ("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*, in ENTREPRENEURSHIP AND INNOVATION POLICY AND THE ECONOMY (Benjamin Jones & Josh Lerner, eds.) (forthcoming) (describing pricing dynamics for post- patent generic drugs).

[16] 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).

biopharmaceutical innovation,[17] how drug companies use them,[18] 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, 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]

In August 2022, Democrats enacted the Inflation Reduction Act (IRA),

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[17] *See, e.g.*, Eric Budish, Benjamin N. Roin, and Heidi Williams, *Do Firms Underinvest in Long-Term Research*: *Evidence from Cancer Clinical Trials,* 105 AM. ECON. REV. 2044 (2015) (showing pharmaceutical firm 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 et al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH. L.J. 1255, 1286 (2009); Wesley M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* 2, 12 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000), http://www. nber.org/papers/w7552 [https://perma.cc/M8C5-LSCJ] (survey data on the importance of patents to life science entrepreneurs and R&D managers).

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

[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 (2018) (arguing 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 drug company acquisition of later-expiring patents may be consonant with Congressional intentions).

[20] *See*, *e.g.*, Kesselheim, *supra* note 12, 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 APP. HEALTH ECON. & HEALTH POL'Y 653, 653 (2018).

[21] *See, e.g.,* W. Nicholson Price II, *Expired Patents, Trade Secrets, and Stymied Competition*, 92 NOTRE DAME L. REV. 1611 (2017).

[22] For reasons discussed further below, *see infra* text accompanying note 117, 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.

which significantly reformed existing drug pricing law within Medicare.[23] The IRA includes three primary elements:[24] it lets Medicare 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. 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.

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—failure to comply can result in extremely significant financial penalties.[27] When it takes effect, 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—

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[23] Jim Tankersley, *Biden Signs Expansive Health, Climate and Tax Law,* N.Y. TIMES (Aug. 16, 2022),

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

[25] 35 U.S.C. § 271(a).

[26] In Part I, *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] IRA § 11003. Although the bill describes a tax rate escalating to 95 percent, Hemel and Ouellette argue that the actual effective tax rate is 1,900%. *See* Hemel & Ouellette, *infra* note 33, at *50.

affecting phenomena like evergreening and patent thickets coupled with trade secrecy indefinitely blocking all competition—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, including grants,[28] food and drug regulation,[29] trade secrets,[30] health law,[31] and other doctrines[32] 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.

A note on normative scope: we focus in this article not on a first-best system for incentivizing and allocating biomedical innovation, itself the subject of a substantial and contentious literature,[33] 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 U.S., the status quo is quite flawed: industry profits are often disconnected from clinical benefit, and even drugs providing clinical benefits are often unaffordable to patients.

In Part I, we briefly summarize the IRA and its drug pricing reform changes, primarily within Medicare. In Part II, we analyze the IRA's likely impacts on patent assertion. We argue that the IRA is quite likely to impact patent assertion behavior, especially in the biologic drug context that represents more than 40% of total U.S. biopharmaceutical spending.[34] We dive deeply into a case study involving one possible gaming strategy biologics manufacturers might seek to use to evade the

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[28] W. Nicholson Price II, *Grants*, 34 BERK. TECH. L.J. 1 (2019)

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

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

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

[32] Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 TEX. L. REV. 303 (2013).

[33] *See*, *e.g.*, Lietzan, *supra* note 19 (arguing incentives are too low); Feldman & Frondorf, *supra* note 19 (arguing incentives are too complex and gameable); Daniel J. Hemel & Lisa Larrimore Ouellette, *Valuing Medical Innovation*, STAN. L. REV. (forthcoming 2023) (arguing prices and incentives are too low for some drugs and too high for others); Christopher Buccafusco & Jonathan S. Masur, *Drugs, Patents, and Well-Being,* 98 WASH. U.L. REV. 1403 (2020) (arguing incentives are misaligned).

[34] IQVIA, *Biosimilars in the United States 2020-2024* (2020), https://www.bigmoleculewatch.com/wp-content/uploads/sites/2/2020/10/iqvia-institute-biosimilars-in-the-united-states.pdf

brunt of the IRA's negotiation provisions. Part III 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:

Potentially Impacted Areas of Biopharmaceutical Patent Strategy

	Small-Molecule Drugs	***Biologic Drugs***
Patent Assertion	Modest	Major
Patent Acquisition	Minor	Minor

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; more than a decade after Congress passed the Biologics Price Competition and Innovation Act (BPCIA) to galvanize such competition, U.S. biosimilar entry remains feeble, reflecting underlying technical challenges and impressively successful patent litigation strategies. 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,[35] the IRA's potential to break the pattern and actually *promote* 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. In keeping with the Congressional Budget Office projections that allowed the IRA to be passed as part of a budget reconciliation measure, Medicare

[35] *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 (2011) (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).

should realize savings.

Part IV of the 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 entry. 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 US Patent and Trademark Office (PTO).

I. THE INFLATION REDUCTION ACT'S CHANGES

The Inflation Reduction Act (IRA) 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, with high penalties for companies that do not agree.[36] 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 have pursued for several decades.[37] However, this negotiation program is also quite targeted. Medicare may only select a small number of drugs for negotiation each year,[38] and a drug cannot be subject to a negotiated price until it has been

[36] Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 11001 (2022).

[37] *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.

[38] The negotiation provisions of the law phase in over time. Medicare will implement negotiated prices for 10 Part D drugs in 2026, an additional 15 Part

on the market for several years: nine years for small-molecule drugs and thirteen years for biologic drugs.[39] These drugs must also be among the most costly products to Medicare[40] and must lack competition from small-molecule generic or biosimilar products.[41] Negotiated prices must fall below a cap based on how long the drug has been marketed at the time of the negotiation, defined as a percentage of the manufacturer's price for non-federal buyers: 75% for drugs with 9–11 years on the market (a 25% discount), 65% for those with 12–15 years of marketing (a 35% discount), and 40% for 16 or more years (a 60% discount).[42]

Notably, the IRA's negotiation framework is designed to provide higher reimbursement for products that provide greater marginal clinical benefits for patients. 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 "comparative 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."[43]

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.[44] This legal authority has long existed within the Medicaid program,[45] which covers lower-income Americans, and government estimates suggest that these inflation-based rebates are a significant contributor to the lower prices

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D drugs in 2027, an additional 15 drugs drawn from both Parts B and D in 2028, and an additional 20 drugs drawn from both Parts B and D in 2029 and each subsequent year. *See* Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 1192(a)(1-4) (2022).

[39] *Id.* at § 1191(b)(3); 1192(e)(1).

[40] *Id.* at § 1192(d)(1).

[41] *Id.* at § 1192(e)(1). As we discuss below, exactly what counts as drug without competition may be a complex question. *See infra* note 142 and accompanying text.

[42] *Id.* at § 1194(c). If the federal government is already paying less than this amount, the cap is what it already pays. *Id.*

[43] *Id.* at § 1194(e)(2). These factors do not necessarily allow Medicare to go as far as regulators in, for example, the UK, who can use full-blown cost-effectiveness measures such as cost per quality-adjusted-life-year gained to determine coverage. *See* Nitzan Arad and Mark McClellan, *Drug Pricing Reform in the Inflation Reduction Act: What Are the Implications*, HEALTH AFFAIRS FOREFRONT, December 14, 2022 (noting this point). But they do take a substantial step towards payment for health value, a proposition long advocated by many analysts.

[44] *Id.* at § 11101; 11102.

[45] 42 U.S.C. § 1396r-8(c)(2)(A).

Medicaid is able to obtain.[46] Likely because both 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.[47]

Third, the IRA restructures Medicare Part D, the portion of Medicare that provides a stand-alone pharmacy benefit to seniors, in two ways. The IRA both provides seniors with greater financial protections in Part D by capping their out-of-pocket costs[48] and gives Part D plans substantially greater financial incentives to control costs over time,[49] encouraging plans to identify opportunities to provide lower-priced products as compared with higher-priced ones.[50]

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 over the next decade, even though the negotiation provisions do not phase in for several years.[51] Benjamin Rome and colleagues recently concluded that applying the negotiation framework from 2018 to 2020 would have saved $26.5 billion.[52] And policy experts at the Kaiser Family Foundation have concluded that millions of seniors are likely to benefit directly from the law's new limits on their out-of-pocket costs.[53]

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[46] DEP'T OF HEALTH AND HUMAN SERVS. OFFICE OF INSPECTOR GEN., MEDICAID REBATES FOR BRAND-NAME DRUGS EXCEEDED PART D REBATES BY A SUBSTANTIAL MARGIN 7 (2015).

[47] *See* Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 11101(a) (phasing in at the beginning of 2023 for Part B products); 11102(a) (phasing in at the end of 2022 for Part D products).

[48] *Id.* at § 11201(a)(3).

[49] *Id.* at § 11201(b). *See also* Arad & McClellan, *supra* note 64 ("While removing financial barriers for beneficiaries that limit drug use, the redesign creates much greater incentives for plans to negotiate aggressively . . .")

[50] MEDICARE PAYMENT ADVISORY COMM'N (hereinafter MEDPAC), REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY 416, 419 (March 2021), https://www.medpac.gov/wp-content/uploads/2021/10/mar21_medpac_report_ch13_sec.pdf.

[51] CONG. BUDGET OFFICE, ESTIMATED BUDGETARY EFFECTS OF PUBLIC LAW 117-169, at 5 (Sept. 7, 2022), https://www.cbo.gov/system/files/2022-09/PL117- 169_9-7-22.pdf.

[52] 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*, 4 JAMA HEALTH FORUM e225218 (2023), doi:10.1001/jamahealthforum.2022.5218.

[53] *See, e.g.*, Juliette Cubanski et al., *Millions of Medicare Part D Enrollees Have Had Out-of-Pocket Drug Spending Above the Catastrophic Threshold Over Time*, KAISER FAMILY FOUNDATION (July 23, 2021), https://www.kff.org/medicare/issue-brief/millions-of-medicare-part-d-enrollees-

B. Impacts Outside Medicare

Though the IRA's drug pricing reforms are significant, they are almost entirely limited to Medicare.[54] In particular, the IRA squarely 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.[55] 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.[56]

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. A very expensive treatment indicated primarily for pregnant

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have-had-out-of-pocket-drug-spending-above-the-catastrophic-threshold-over-time/.

[54] 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 51 votes (including the Vice President, if necessary) rather than the 60 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/ (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 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* Sachs, *supra* note 24.

[55] *See, e.g.*, Centers for Medicare & Medicaid Servs., CMS Releases Latest Enrollment Figures for Medicare, Medicaid, and Children's Health Insurance Program (CHIP) (Dec. 21, 2021), https://www.cms.gov/newsroom/news-alert/cms-releases-latest-enrollment-figures-medicare-medicaid-and-childrens-health-insurance-program-chip (noting that Medicare enrollment is just under 64 million).

[56] *See, e.g.*, President Joe Biden, 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/ ("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. ").

people, for instance, would be very unlikely to be subject to Medicare negotiations.[57] Similarly, treatments focused on pediatric illnesses are unlikely to be impacted by the IRA. The law explicitly excludes certain drugs for rare diseases from negotiation as well.[58]

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 (over 40%) 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, Eylea, a biologic for macular degeneration approved in 2011 that represented 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)[59] in 2019.[60] For that year, Medicare Part B also represented 62.4% of total U.S. Eylea sales.[61] By 2028, when Part B drug price discounts begin,[62] Eylea may have reached 17 years of market exclusivity

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[57] Expenditures for such products are unlikely to be zero, however, because of the overlap between Social Security Disability Income eligibility and Medicare, see Social Security Administration, Medicare Information (2022), https://www.ssa.gov/disabilityresearch/wi/medicare.htm, but they are unlikely to be high, especially relative to other payers' expenses. As one example, consider Makena, which is currently approved 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. *See, e,g.*, U.S. DEP'T OF HEALTH & HUMAN SERVS. OFFICE OF INSPECTOR GENERAL, DELAYS IN CONFIRMATORY TRIALS FOR DRUG APPLICATIONS GRANTED FDA'S ACCELERATED APPROVAL RAISE CONCERNS at 12 (Sept. 2022), https://oig.hhs.gov/oei/reports/OEI-01-21-00401.pdf.

[58] *See* Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 1192(e)(3)(A).

[59] *See* MEDPAC, REPORT TO THE CONGRESS: MEDICARE AND THE HEALTHCARE DELIVERY SYSTEM 83 (June 2022), https://www.medpac.gov/document/june- 2022-report-to-the-congress-medicare-and-the-health-care-delivery-system/.

[60] Juliette Cubanski and Tricia Neuman, *Relatively Few Drugs Account for a Large Share of Medicare Prescription Drug Spending*, Kaiser Family Foundation (April 19, 2021), https://www.kff.org/medicare/issue-brief/relatively- few-drugs-account-for-a-large-share-of-medicare-prescription-drug- spending/.As the authors note, data from the Medicare Part B dashboard reflects average sales price to non-federal purchasers and includes all discount and rebates.

[61] This figure was calculated by determining the percentage of U.S. net income from Eylea in 2019 ($4.644 billion, according to an SEC report, see 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, represented by Medicare Part B spending in that year ($2.9 billion).

[62] As noted *supra* in note 38, the Part B negotiation aspect of the law phases

without biosimilar entry.[63] In that case, it would be subject to at least a 60% discount.[64]

As a result, while Medicare spending directly[65] affects only a fraction

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in over time.

[63] *See* Food & Drug Admin., *Letter to Regeneron Pharmaceuticals, Inc.* (Nov. 18, 2011), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/125387s000ltr.pdf (notifying Regeneron of Eylea's approval).

[64] *See* Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 1194(c)(3)(C). Eylea is a particularly apt example because it is an older drug under Part B. These sorts of drugs may be less vulnerable to gaming tactics that rely on linkages between unrestricted commercial markets and restricted Medicare markets. For example, some have argued that manufacturers could try to use the lack of price restriction in commercial markets, coupled with the fact that commercial market list prices nonetheless factor into the base price against which Medicare Part D inflationary discounts are calculated, to argue that manufacturers could substantially increase their Medicare base price by charging very high commercial list prices (suitably rebated so the commercial health buyer would not actually be paying more and the plan would therefore not lose customers in the commercial market). *See* Nitzan Arad and Mark McClellan, *Drug Pricing Reform in the Inflation Reduction Act: What Are the Implications*, HEALTH AFFAIRS FOREFRONT, December 14, 2022.

[65] 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 POLICY, https:/ww.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/09/24/cost-shifting-in-drug-pricing- or-the-lack-thereof/ (Sept. 24, 2022). 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 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. 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. 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 finds little evidence of 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*

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, 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.

II. 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,[66] assertion of small molecule patents has operated since 1984 against the background of the Hatch-Waxman statute, 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.[67] 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.

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. The statute encourages such generic challenges by

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Payment Rates, 32 HEALTH AFF. 935 (2013); Kathryn Wagner, *Shock, But No Shift: Hospitals' Responses to Changes in Patient Insurance Mix*, 49 J. HEALTH ECON. 46 (2016)).

[66] Not all patents are covered by Hatch-Waxman. For example, patents for manufacturing methods cannot be listed on the FDA's Orange Book, and litigation over the validity of those patents does not operate under Hatch-Waxman's special provisions.

[67] 21 U.S.C. § 355(j).

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)[68]—a reward which, for a drug with billions of dollars in annual sales, could be worth hundreds of millions of dollars.[69]

Hatch-Waxman procedures are widely used. Perhaps not surprisingly, they tend to be invoked particularly often for drugs with large sales.[70] Moreover, in the small number of challenges litigated to completion against secondary patents, challenger win rates have been high.[71]

Once generics enter the market, various regulatory and market features facilitate uptake. In every state, pharmacists are allowed (and in many states are mandated) to substitute generics automatically for the branded drug,[72] and formulary management for both privately insured individuals and Medicare Part D beneficiaries favors generic substitution.

Accordingly, despite the rising number of patents that cover small molecule drugs, and various tactics (e.g. product hopping, discussed in section C below) that can be attempted to delay generic competition,[73] 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 2012-2018 was 14.4 years.[74] This median of 14.4 years represents a relatively small increase

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[68] 21 U.S.C. § 355(j)(5)(B)(iv).

[69] F.T.C. v. Actavis, Inc., 570 U.S. 136, 144 (2013) ("180–day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars'"). 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 et al., *The Regulation of Prescription Drug Competition and Market Responses: Patterns in Prices and Sales Following Loss of Exclusivity* (examining, for four heavily prescribed drugs that experienced triopoly competition between 2009- 2013, price drops and market share in this triopoly context) in ANA AIZCORBE ET AL., MEASURING AND MODELING HEALTH CARE COSTS 243, table 8.4 (2018).

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

[71] C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1356 (2013).

[72] Chana A. Sacks et al., *Assessment of Variation in State Regulation of Generic Drug and Interchangeable Biologic Substitutions*, 221 JAMA INTERNAL MED. 16, 16 (2021).

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

[74] Benjamin N. Rome et al., *Market Exclusivity Length for Drugs with New*

from the median of 12.6 years that Hemphill and Sampat found for drugs that faced generic entry between 2001 and 2010.[75] And it is roughly comparable to the 13-14 years found by analysts looking at generic entry between 1995-2005.[76]

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 2015-2017 found that, with one generic producer, the generic average manufacturer's price (AMP) was 39% lower than the branded AMP before generic competition. With two generic producers, generic prices were 54% lower. And with four competitors, generic prices were 79% less than the branded drug price before generic entry.[77] Other studies have found significant price decreases as well, though not quite as large in magnitude.[78]

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 generic entry between 2017-19, branded firms' average market share one year

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Generic or Biosimilar Competition, 2012-2018, 109 CLINICAL PHARMACOLOGY & THERAPEUTICS 367 (2020). Similarly, a report from Henry Grabowski and colleagues found that the median market exclusivity term for small molecules experiencing generic entry between 2017-2019 was 14.1 years. Henry Grabowski et al., *Continuing Trends in U.S. Brand-Name and Generic Drug Competition*, 24 JOURNAL OF MEDICAL ECONOMICS 908 (2021). The term for drugs with greater than $250 million in sales prior to generic entry was shorter: 13.0 years. The shorter term results from lucrative drugs attracting more generic patent challengers. *See id.*

[75] Hemphill & Sampat, *supra* note 105, at 330.

[76] *See generally* Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 MANAGERIAL & DECISION ECON. 491 (2007).

[77] Ryan Conrad and Randall Lutter, U.S. Food & Drug Admin, Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices (Dec. 2019), https://www.fda.gov/media/133509/download.

[78] *See*, *e.g.*, Chintan V. Dave, Abraham Hartzema, & Aaron S. Kesselheim, *Prices of Generic Drugs Associated with Numbers of Manufacturers*, 377 NEJM 2597, 2598 (2017) (examining the period between 2008 and 2014 and finding a 13% drop with one generic competitor, a 23% drop with two, a 40% drop with three, and a 74% 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*, 4 JAMA NETW. OPEN e2133451, 5 (2021) (examining the period between 2015 and 2019 and finding a 14.9% drop with one generic competitor, a 32.7% drop with two, a 52.0% drop with three, and a 68.6% drop with four or more).

after generic entry was just 23%.[79]

Under these circumstances, an originator small-molecule firm faced with the prospect of a 25-35% mandatory discount under the IRA (25% for a drug that had been marketed for 9-11 years and 35% for a drug that had been marketed for 12-15 years)[80] would probably prefer to try to keep generic competition at bay through the assertion of patents.[81] In many if not most cases, the decline in total profits caused by loss of market share to generics would exceed profit loss from 25-35% discount; without competition the branded manufacturer can retain 100% market share. Only in the event that a small molecule drug had been marketed for 16 or more years without competition and thus faced a 60% mandatory discount might the calculus of the small molecule drug manufacturer potentially change.[82]

Thus, we expect to see some, but not necessarily substantial, impact of the IRA on patent assertion strategies by small-molecule drug manufacturers. However, the same is not true in the very different context of patent assertion by branded biologics, to which we turn next.

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

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[79] Henry Grabowski et al., *Continuing Trends in U.S. Brand-Name and Generic Drug Competition*, 24 J. MED. ECON. 908 (2021).

[80] Inflation Reduction Act § 1194(c).

[81] 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.

[82] 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 50% 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).

Biologics, which are much larger than small-molecule drugs and which are produced by living organisms rather than through traditional medicinal chemistry, have long faced little in the way of 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 (BPCIA) attempted to stimulate competition against branded biologics by allowing firms to market "biosimilar" competitors. 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 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.[83] 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.

Since the BPCIA passed in 2010, only nine of the 218 biologics approved by the FDA have faced biosimilar competition.[84] 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 2012-2018, the median time that the originators enjoyed market exclusivity was over 21 years. 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.[85] To be sure, the comparison of 21 years vs. 14.4 years is inexact – the four biologics in question (and other biologics) could have faced competition earlier had

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[83] *See, e.g.*, McKinsey, *Three Imperatives for R&D in Biosimilars* (Aug. 19, 2022), https://www.mckinsey.com/industries/life-sciences/our-insights/three-imperatives-for-r-and-d-in-biosimilars.

[84] Biosimilars Review & Report, https://biosimilarsrr.com/us-biosimilar-filings/ (accessed September 11, 2022) (listing marketing of biosimilars to 9 originators); Compilation of CDER NME and New Biologic Approvals 1985-2021, https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-apprtimeovals (accessed September 11, 2022) (listing 218 originator BLAs)

[85] Benjamin N. Rome et al., *Market Exclusivity Length for Drugs with New Generic or Biosimilar Competition, 2012-2018,* 109 CLINICAL PHARMACOLOGY & THERAPEUTICS 367 (2020).

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.[86] Biosimilar firms, meanwhile, are not able to offer the same price discounts as generic small molecule producers due to the greater total costs of biosimilar approval and manufacturing. Lower price discounts of course 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 75% even without dropping their price to any significant degree after biosimilar entry.[87] As a consequence, average price weighted by market share has fallen by an average of only 4 to 10% per biosimilar entrant.[88] For any given originator, this discount is substantially less than the 35% 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 price 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 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.[89] To put the point bluntly, in the

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[86] Nitzan Arad et al., *Realizing the Benefits of Biosimilars: Overcoming Rebate Walls* (Duke/Margolis 2021). 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).

[87] Richard Frank et al., Biosimilar Competition: Early Learning, NBER Working Paper No. 28460 at 10 (2021) (giving high market share and low price reduction figures for Avastin, Epogen, Herceptin, Remicade, and Rituxan).

[88] *Id*.

[89] In the *FTC v. Actavis* case, 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

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. The IRA provides that a biologic or biosimilar manufacturer can request that a particular originator biologic that would otherwise be selected for negotiation be excluded if the biosimilar manufacturer submits information demonstrating to the HHS Secretary a "high likelihood" that biosimilar entry is "imminent." However, such a request is *not* permitted 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 US.[90] Such a request is also not permitted if the biosimilar maker is the same as the originator (and therefore the biosimilar would be an "authorized" biosimilar).[91]

This provision demonstrates 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 (11 years).

How any such pay (or permit) to launch agreements would be evaluated under antitrust law poses an interesting question.[92] On one hand, unlike with pay-to-delay agreements, the collusion between competitors would be channeled at least to some extent towards

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exceeded litigation costs and generic services. 570 U.S. 136 (2013). These agreements are now much less common, but some do still exist.

[90] *See* Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 1192(f)(2)(D)(iv).

[91] *Id.* at § 1192(f)(1)(B)(i).

[92] 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 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* Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 70-71 (2009).

encouraging competition.[93] 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 rather than the present monopoly-focused strategy.

Of course, in any given case, the IRA's impact will likely depend on the manufacture's Medicare market share relative to its private market share. Not surprisingly, however, for at least some drugs that might be subject to negotiation, Medicare market share is substantial. As noted earlier, Eylea, a biologic for macular degeneration approved in 2011, not only represented Medicare Part B's biggest expenditure in 2019, but Medicare also paid for 62.4% of total Eylea sales in the U.S. By 2028, when Part B drug price discounts begin, Eylea may have reached 17 years of exclusivity without biosimilar entry. In that case, it would be subject to at least a 60% discount.

According to one NGO source, Eylea has secured 92 relevant patents, and a large percentage of these patents were filed after the drug was approved by the FDA in 2011.[94] Accordingly, it seems likely that as 2028 approaches, Regeneron will have a decision to make about how to deploy its patent arsenal. It is possible, perhaps even likely, that Regeneron will 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

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[93] 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.*, Fraisier Kansteiner, *Bristol Myers Inks Another Revlimid Patent Settlement – This Time With Sun Pharma – as Copycats Near*, FIERCEPHARMA (June 22, 2021), https://www.fiercepharma.com/manufacturing/bristol-myers-settles-sun-pharma-for-limited-revlimid-generic-launch-2022.

[94] I-Mak, *Overpatented*, *Overpriced*, https://www.i-mak.org/wp-content/uploads/2022/09/Overpatented-Overpriced-2022-FINAL.pdf (2022). Eylea's patent estate is also being scrutinized by potential competitors. Mylan – now part of Viatrix – has 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/. Notably, all of the patents that Mylan is questioning were filed after Eylea was approved.

biologic Humira to sue many would-be biosimilar entrants. AbbVie was then able to negotiate settlements that allow it to maintain exclusivity in the U.S. through 2023—21 years after FDA approval, all the while continuing to raise the prices of the drug.[95]

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.[96] According to these experts, given the high costs of FDA approval and manufacturing for any given biosimilar producer, we can presume that efficiency requires one (price-regulated) producer per originator molecule. The IRA effectively rejects that presumption, preferring to remain agnostic on the question.

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). 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.[97]

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[95] 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 ("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.").

[96] *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 AFFAIRS FOREFRONT (April 15, 2019), https://www.healthaffairs.org/do/10.1377/forefront.20190405.396631/full/.

[97] 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 non-partisan 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 the order of only about 1%. CONG. BUDGET OFFICE, SUMMARY: ESTIMATED BUDGETARY EFFECTS OF PUBLIC LAW 117-169, at 15 (Sept. 7, 2022), https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf ("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

In addition to changes in patent assertion patterns by biologics originators, the IRA may also affect trade secrecy patterns. Scientific knowledge surrounding biologics has advanced considerably in recent decades. Nonetheless, for complex biologics like monoclonal antibodies, the products remain difficult to characterize fully as a structural matter. The monoclonal antibody product is still best characterized by its method of production. Accordingly, trade secrecy associated with manufacturing of complex biologics is pervasive. Indeed, the reason that the initial production of a biosimilar product still costs several hundred million dollars (as contrasted with $5 million or less for a small molecule) is that the would-be biosimilar manufacturer must attempt to guess the originator's process, replicate it to the best extent possible, and then do clinical trials to prove to the FDA that its product is "similar."

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 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

For both small-molecule and biologic drugs, the IRA may impact firm incentives to engage in "product hopping." In general, product hopping refers to situations in which "a brand-name pharmaceutical company switches from one version of a drug to another"[98] 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,[99] from a twice-daily version to an extended-release formula,[100] or from an injected version to

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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 innovation 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 IV, IRA implementation should take full advantage of this emphasis on clinical benefit.

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

[99] *Id*. at 168.

[100] New York ex rel. Schneiderman v. Actavis, 787 F.3d 638, 646-47 (2d Cir.

an auto-injector,[101] 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 significant clinical benefits for patients, but simultaneously harms generic or biosimilar competition for the older version.[102] Some companies have removed the original drug from the market as the new version is introduced, which legally prevents generics from entering the market at all.[103] Antitrust scrutiny of these "hard switches,"[104] 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."[105] 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.[106] 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 coming onto the market in the first place.

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 drugs 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.[107] Essentially, these categories include 1) small-molecule drugs without any competing generics; and 2) biologics without any competing biosimilars.[108]

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[101] Rachel E. Sachs et al., *Changes in the Use of Hydroxyprogesterone Caproate Injection After Confirmatory Trial Failure*, 182 J. AM. MED. ASS'N INTERNAL MEDICINE 226 (2022).

[102] Carrier & Shadowen, *supra* note 132, at 168; *see also* Karshtedt, *supra* note 35, at 1136–37.

[103] Vrushab Gowda et al., *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).

[104] *Actavis*, 787 F.3d at 654.

[105] Gowda, *supra* note 7, at 415.

[106] The brand firm benefits financially from conducting a switch before competitors enter against the original version. *See* Carrier & Shadowen, *supra* note 132, at 177-78.

[107] *See* Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 1192(e)(1)..

[108] This framing is slightly simplified. As one example, the IRA instructs CMS to treat an "authorized" generic or biosimilar – a product that is often

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?[109] The argument would be that a company could receive authorization to market a new formulation through a new § 505(c) or § 351(a) authorization (as with Namenda's extended-release version,[110] Makena's auto-injector formulation,[111] or Humira's high-concentration version[112]), switch patients to that new formulation, and escape negotiation for that new formulation for a new period of 9 or 13 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."[113] 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.

March 2023 guidance from CMS explaining how it intends to implement the negotiation program in 2026 sheds light on these potential strategies.[114] In keeping with the IRA's above-described instruction to

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marketed by the branded manufacturer itself – as the same qualifying single-source drug for negotiation purposes. *See id.* at § 1192(e)(2). Such products are not likely to constitute true competition, given the control the branded manufacturer continues to exert over their pricing and marketing.

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

[110] Food & Drug Admin., *Letter to Forest Laboratories, Inc.: NDA Approval for Namenda XR* (June 21, 2010), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/022525s000ltr.pdf.

[111] Food & Drug Admin., *Letter to AMAG Pharma USA, Inc.: Supplement Approval for Makena Auto-Injector* (Feb. 14, 2018), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/021945Orig1s012ltr.pdf.

[112] Food & Drug Admin., *Letter to AbbVie, Inc.: Supplement Approval for Humira Injection* (Nov. 23, 2015), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/125057Orig1s394ltr.pdf.

[113] *See* Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 1192(d)(3)(B).

[114] 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*

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."[115] 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, and similarly with Humira's manufacturer and the high-concentration and low-concentration versions of the product or other soft- switch products.

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."[116] 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.

A hypothetical example is helpful in analyzing how the interaction between these provisions of the law might work in practice. 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).

If there is *not yet* generic or biosimilar competition for the initially-approved version of the product, then 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.[117]

If there *is* generic or biosimilar competition for the initially-approved version of the product, however, the result would be quite different. In

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Comments (March 15, 2023), https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf."

[115] *Id*. at 8.

[116] *Id*. at 10.

[117] It is possible that provisions of the law requiring CMS to consider the "comparative 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' pricing offer. *See* Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 1194(e)(2).

that case, according to CMS' March 2023 guidance, the product would not be eligible for negotiation, even if newer versions of the drug did not have competitors. In the second case, branded manufacturers might find product hopping quite attractive.[118] That said, in the second situation, if the product in question is a Part D-eligible drug (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.[119] This restructuring should encourage Part D plans to employ utilization management strategies like prior authorization[120] or step therapy[121] 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."[122] 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

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[118] 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.

[119] See *supra* text accompanying notes 48-50 for a description of these changes and their intended effects.

[120] "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 FAMILY FOUND. (May 20, 2022), https://www.kff.org/policy-watch/examining-prior-authorization-in-health-insurance/.

[121] "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." 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.

[122] 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.

hopping may be substantially reduced relative to pre-IRA incentives in the Part D context.

If the product in question is a Part B-eligible biologic, typically an infused drug, the waters are muddier. The fee-for-service Medicare Part B program has historically made less use of utilization management strategies than has the stand-alone Medicare Part D program,[123] 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 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,[124] a topic discussed in more detail *infra*.[125]

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 even the example above that may create the most concern: an older Part B biologic product which has biosimilar competition by year 13 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

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[123] Recent regulatory changes now permit Medicare Advantage plans to use utilization management in Part B, *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 , and given the increasing share of Medicare beneficiaries choosing Medicare Advantage plans, *see* Meredith Freed et al., *Medicare Advantage in 2022: Enrollment Update and Key Trends*, KAISER FAMILY FOUNDATION (Aug. 25, 2022),https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-enrollment-update-and-key-trends/ (showing that the share of beneficiaries enrolled in Medicare Advantage plans has risen from 19% in 2007 to 48% in 2022), these dynamics may be somewhat muted.

[124] *See, e.g.*, MEDPAC, JUNE 2022 REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM, MEDICARE PAYMENT ADVISORY COMMISSION, at 86 (June 15 2022), https://www.medpac.gov/wpcontent/uploads/2022/06/Jun22_Ch4_MedPAC_Report_to_Congress_SEC.pdf.

[125] *See infra*, Part IV.A.

manufacturers) frequently are able to block *any* competition far beyond 13 years.[126] 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 IV.

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.

III. 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 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.[127] Although this story has been thoroughly

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[126] *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, 367 (2021) (finding that small-molecule drugs had a median of 14.4 years of exclusivity as compared to 21.5 years for biologic drugs).

[127] *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 (discussing efforts to strengthen pharmaceutical method-of-use patents); Ashleigh Furlong, Sarah Anne Aarup, & Samuel Horti, *Who Killed the Covid-19 Vaccine Waiver?*, POLITICO (Nov. 10, 2022), https://www.politico.com/amp/news/2022/11/10/who-killed-the-covid-19-vaccine-waiver-00066137 (recounting lobbying efforts by the pharmaceutical

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.[128] However, firms usually seek these primary patents quite early in a drug's development,[129] well before the clinical trials and regulatory approval necessary to market a drug. In line with theories of patents that analogize patents to mining prospects, primarily necessary to promote development towards marketing,[130] 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 small molecule 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.[131] As for biologics, the Biologics Price Competition and Innovation Act establishing biosimilar entry has no term extension.

Accordingly, firms typically pursue a set of secondary patents as well, covering other inventions surrounding a drug.[132] 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,[133] and methods of manufacturing the drug. These patents

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industry to block a proposal to internationally waive patent rights related to COVID-19 inventions).

[128] 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, 797–801 (2020) (describing the problems of "me-too" drugs); *see also* Arti K. Rai, *Competition Failures in Biopharmaceutical Markets: Implications for Patent Law* (working paper) (arguing that pervasive competition failures have mixed implications for how biopharmaceutical patent scope should be addressed).

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

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

[131] *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 DISC. TODAY 20, 21 (2019) (finding that about half of the 170 bestselling drugs had their patent terms extended under the HWA and pediatric exclusivity provisions, many to the statutory limit of 14 years after FDA approval).

[132] *See* Amy Kapczynski, Chan Park, & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, 7 PLOS ONE e49470 (2012).

[133] *See*, *e.g.*, Michael A. Carrier & Brenna Sooy, *Five Solutions to the REMS*

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. The ongoing acquisition of patents on an existing drug is widely known as "evergreening," though the biopharmaceutical industry typically prefers the more anodyne "product lifecycle management."[134] A robust literature describes the controversies describing the acquisition (and, more commonly, the assertion) of secondary patents. 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.[135] In Ouellette's study, the top-selling drugs had more patents: an average of five per drug. Other studies have found similar increases in the number of patents per drug, though there is variability across drugs.[136]

Biologics typically have many more associated patents than small-molecule drugs.[137] One 2022 study found that the top-selling dozen drugs in the United States—mostly biologics—had an average of 74 patents each.[138] In the most famous case, AbbVie has a widely publicized strategy of putting up a "wall" of over 100 patents around its blockbuster biologic, Humira.[139] Companies are able to obtain large numbers of patents in part

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Patent Problem, 97 B.U. L. Rev. 1661, 1668–71 (2017) (describing such patents).

[134] Kapczynski et al., *supra* note 71.

[135] 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 (2010).

[136] *See*, *e.g.*, C. Scott Hemphill and 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. & BIOSCI. 590, 631 (2018) (finding increases in patents per drug).

[137] Victor L. van de Wiele, Aaron S. Kesselheim & Ameet Sarpatwari, *Barriers to US Biosimilar Market Growth: Lessons from Biosimilar Patent Litigation*, 40 HEALTH AFF. 1198, 1201 (2021).

[138] I-Mak, *Overpatented*, *Overpriced*, https://www.i-mak.org/wp-content/uploads/2022/09/Overpatented-Overpriced-2022-FINAL.pdf (2022). 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.

[139] 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). Biologics

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.[140]

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.[141] Trade secrets are relatively more effective—and are perceived as more attractive[142]—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.[143] Such patents are difficult to enforce because manufacturing methods are typically not observable. Manufacturing patents for small-molecule drugs also may not be listed in the Orange Book, and thus do not trigger an automatic 30-month stay of generic approval (an otherwise-important bolster for weak patents).

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.[144] Keeping that method secret can result in long periods of blocked competition.[145]

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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 'Patent Wall' Around Imbruvica: Report*, FIERCEPHARMA, (July 21, 2020) https://www.fiercepharma.com/pharma/AbbVie- already-famous-for-its-humira-strategy-forms-another-patent-wall-for- imbruvica-report.

[140] Victor L. Van de Wiele, Reed F. Beall, Aaron S. Kesselheim, & Ameet Sarpatwari, *The Characteristics of Patents Impacting Availability of Biosimilars*, 40 NAT. BIOTECH. 22, 23 (finding that only 9% 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 NAT. BIOTECH. 20, 21 (2021) (finding that 67% of patent assertions in biosimilar litigation were of patents filed more than one year after the biologic was approved).

[141] Wesley M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* 33 tbl.1 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000), http://www.nber.org/papers/w7552.

[142] *Id*. at 34 tbl.2 (reporting firm perceptions that 68% of process innovations were protectable by secrecy, compared to 36% for patents).

[143] W. Nicholson Price II, *Making Do in Making Drugs*, 55 B.C. L. Rev. 491, 526–28 (2014).

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

[145] *Id*.

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 50% of the patents asserted in litigation against biosimilars are manufacturing process patents.[146]

B. IRA impacts on patent acquisition

Despite arguing in Part II 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.[147]

1. The prima facie case

Patents provide the right to exclude others from making, using, and selling the patented invention. But that right is not self-enforcing.[148] 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

[146] Rai and Price, *supra* note 83.

[147] 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 likely the most important factors in this context: low cost, licensing, and timing.

[148] Rebecca C. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 388 (2007).

has been dubbed "the sport of kings,"[149] costing millions of dollars in a typical case.[150] 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.[151] By comparison, at least when one is talking about acquiring patents in the United States,[152] the tens or even hundreds of thousands of dollars at stake 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.

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.[153] 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

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[149] Douglas J. Kline, *Patent Litigation: The Sport of Kings,* MIT TECH. REV. (Apr. 28, 2004), http://www.technologyreview.com/business/13562/; 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).

[150] 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).

[151] Feldman & Frondorf, *supra* note 19, at 503 & n. 23.

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

[153] *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*, 8 FRONTIERS PHARMACOLOGY Art. 314, 9 (2017) (finding that almost all biosimilar developers also develop original biologics).

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.[154]

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 cycle (and the years of prosecution for each individual patent[155]).[156] 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[157] and the Biologics Price Competition and Innovation Act[158] 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 12 years after approval for a biosimilar version of a new biologic).[159] To be sure, patents can be asserted after that time, but the bulk of the action is around the

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[154] Feldman & Frondorf, supra note 19.

[155] The average time from patent filing to final disposition (issued or abandoned) was 24.9 months in August 2022. U.S. Patent & Trademark Office, *Patent Pendency Data August 2022*, https://www.uspto.gov/dashboard/patents/pendency.html.

[156] 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 et al., *The Characteristics of Patents Impacting Availability of Biosimilars,* 40 NAT. BIOTECH. 22, 24 (2022).

[157] 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).

[158] Pub. L. No. 111-148, Sections 7001-03, 124 Stat. 119, 804-21 (2010)) (passed as part of the Patient Protection and Affordable Care Act).

[159] 21 U.S.C. §355(j)(5)(F)(ii) (small-molecule drugs); 42 U.S.C. § 262(k)(7) (biologics).

time that regulatory exclusivity expires.[160]

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 an exceptionally valuable product years in the future, selling at such volumes and prices 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. 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?

IV. 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 Part 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 Part 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

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[160] C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents*, 8 J. EMP. L. 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 12-year floor. *See*, *e.g.*, W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023 (2016) (describing secrecy-based barriers to entry).

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. To take a specific example: we argued above 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?[161]

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.[162] Policy experts, including Congress' own[163] Medicare Payment Advisory Commission (MedPAC),[164] have argued that this practice "undermines price competition"[165] by delinking the prices of these products, such that providers have limited incentives to choose lower-priced options for their patients. 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,"[166] 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."[167] CMS might use its existing authority through the Centers for Medicare and Medicaid Innovation to pilot a policy model to study these outcomes,[168]

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[161] As analyzed *supra* in text accompanying notes 151-153, the IRA's restructuring of Part D financial incentives may mitigate these incentives in the small-molecule drug space.

[162] MEDPAC, *supra* note 155, 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*, 11 J. AM. MED. ASS'N NETWORK OPEN 1, 1 (2021).

[163] Jesse M. Cross & Abbe R. Gluck, *The Congressional Bureaucracy*, 168 UNIV. PENN. L. REV. 1541, 1550-51, 1595 (2020).

[164] Other independent policy experts have also echoed these calls. *See, e.g.*, PEW CHARITABLE TRUSTS, CAN BIOSIMILAR DRUGS LOWER MEDICARE PART B DRUG SPENDING?, at 2 (Jan. 2017), leveraging-biosimilars-to-lower-medicare- part-b.pdf (pewtrusts.org); Rome & Sarpatwari, *supra* note 160, at 2.

[165] MEDPAC, *supra* note 155, at 86.

[166] *Id.* at 87.

[167] *Id.* at 86-87.

[168] Nitzan Arad, Derick Rapista, Marianne Hamilton Lopez, & Mark McClellan, *Originator Biologics and Biosimilars: Payment Policy Solutions to*

though Congress might also provide CMS with this authority directly.[169] 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. One of us has previously explained, for example, how FDA might alter its approach to the use of suitability petitions to encourage earlier generic competition for small molecule products experiencing product hops.[170]

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.[171] The FDA has approved few interchangeable biosimilars thus far, and it could do much more to promote their development and approval.[172] 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

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Increase Price Competition While Maintaining Market Sustainability in Medicare Part B, at 8, DUKE MARGOLIS CENTER FOR HEALTH POLICY (Oct. 15, 2021), https://healthpolicy.duke.edu/sites/default/files/2021-11/Realizing%20the%20Benefits%20of%20Biosimilars%20Part%20B.pdf.

[169] MEDPAC, *supra* note 155, at 86.

[170] Arti K. Rai & Barak D. Richman, *A Preferable Path for Thwarting Pharmaceutical Product Hopping*, HEALTH AFFAIRS FOREFRONT (May 22, 2018), https://www.healthaffairs.org/do/10.1377/forefront.20180522.408497/full/.

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

[172] *Cf.* Louise C. Druedahl et al., *Interchangeability of Biosimilars: A Study of Expert Views and Visions Regarding the Science and Substitution*, 17 PLOS ONE e0262537 (2022) (cataloging stakeholder views, noting regulatory variation, and arguing for the importance of increased regulatory trust).

initially occur through "program instruction or other forms of program guidance"[173] 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 its interpretations regarding the definition of qualifying drugs, will implicate pharmaceutical companies' efforts to avoid inclusion in the negotiating program, as described in Section II. Some of these efforts may also implicate antitrust concerns. Accordingly, CMS should establish regular channels of communication with antitrust authorities (e.g. FTC and DOJ Antitrust) and perhaps even establish in-house expertise. Other administrative questions will also arise.[174]

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.[175] 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 patent reform efforts both in Congress and at the USPTO.

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 case law from the Federal Circuit or Supreme Court or Congressional intervention in the patent statute (Title 35). 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.

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[173] *See* Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 1198(c).

[174] For instance, some administrative implementation questions central to innovation will implicate the contours of the negotiation process. Because the mandatory discounts are a price ceiling rather than a floor, the process may have considerable implications for innovation. One 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.* at § 1192(e), which appears to require CMS to define exactly what costs might be included under that heading. CMS' March 2023 guidance provides significant clarity regarding the types of costs it will consider here. Ctrs. for Medicare & Medicaid Servs., supra note 114, at 82-85.

[175] Leahy-Smith America Invents Act, Pub. L. No. 112-29, 112th Cong. (2011), https://www.congress.gov/bill/112th-congress/house-bill/1249.

In fact, the IRA has the potential to effect 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 work,[176] 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.[177] Particularly important are bills filed or hearings held in the Judiciary Committees of both houses of Congress, which have jurisdiction over intellectual property law issues.[178] 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 35 U.S.C. § 101 and what types of inventions or discoveries are eligible to be patented.[179] This issue has captivated the patent bar and was the subject of three related hearings before the Senate Judiciary Committee in 2019.[180] Multiple bills have been introduced with

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[176] Arti K. Rai et al., *Post-Grant Adjudication of Drug Patents: Agency and/or Court*, 37(1) Berkeley Tech.L.J. _ (2022) (forthcoming); Erik Hovenkamp et al., *Has the PTAB Made a Difference in Drug Settlements and Generic Entry*, 40 NATURE BIOTECHNOLOGY 1569 (2022).

[177] *See*, *e.g.*, S. Sean Tu, Sarosh Nagar, & Aaron S. Kesselheim, *Recent Patent Reform Bills and Their Implications for Prescription Drugs*, JAMA (pub. online Jan. 13, 2023), doi:10.1001/jama.2022.24983 (describing three bills).

[178] U.S. House Comm. on the Judiciary, Subcommittees: Courts, Intellectual Property, and the Internet (2021), https://judiciary.house.gov/subcommittees/courtsintellectual-property-and-internet-116th-congress/; Senate Comm. on the Judiciary, Jurisdiction (2021), https://www.judiciary.senate.gov/about/jurisdiction.

[179] Much of this attention is likely a response to the Supreme Court's repeated interventions regarding § 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 Labs., Inc., 566 U.S. 66 (2012); Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 902 (2013), Alice Corp. Pty. Ltd. v. CLS Bank Intern., 573 U.S. 208 (2014), and arguably created confusion in the doctrine more generally, *see, e.g.*, American Axle & Manufacturing, Inc. v. Neapco Holdings LLC, 966 F.3d 1347 (Fed. Cir. 2020) (denying rehearing en banc on a 6-6 vote); American Axle & Manufacturing, Inc. v. Neapco Holdings LLC, 967 F.3d 1285, 1309 (Fed. Cir. 2020) (Moore, J., dissenting from the 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.").

[180] Senate Comm. On Judiciary, Subcomm. On Intellectual Property, Hearing: The State of Patent Eligibility in America: Part I (June 4, 2019); Senate Comm. On Judiciary, Subcomm. On Intellectual Property, Hearing: The State of

the goal of expanding the scope of inventions or discoveries which are eligible to be patented.[181] 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.[182]

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 example, Representative Hank Johnson[183] 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.[184]

Other bills propose reforms to the antitrust laws in an effort to limit patent gaming strategies. For example, Senator Amy Klobuchar[185] introduced a bipartisan bill in an effort to strengthen the Federal Trade Commission's (FTC) review of potential "pay-for-delay" patent settlements.[186] A similar bipartisan bill, introduced by Senator John Cornyn,[187] aims to strengthen FTC review of product hopping.[188] A third

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Patent Eligibility in America: Part II (June 5, 2019); Senate Comm. On Judiciary, Subcomm. On Intellectual Property, Hearing: The State of Patent Eligibility in America: Part III (June 11, 2019).

[181] *See, e.g.*, Restoring America's leadership in Innovation Act of 2018, H.R.6264, 115th Cong. (2018), https://www.congress.gov/bill/115th-congress/house-bill/6264?s=1&r=5; Patent Eligibility Restoration Act of 2022, S.4734, 117th Cong. (2022), https://www.congress.gov/bill/117th-congress/senate-bill/4734.

[182] 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 so-called cDNA patents that generally cover therapeutics).

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

[184] Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act, H.R. 2884, 117th Cong. (2021), https://www.congress.gov/bill/117th-congress/house-bill/2884.

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

[186] Preserve Access to Affordable Generics and Biosimilars Act, S. 64, 116th Cong. (2019), https://www.congress.gov/bill/116th-congress/senate-bill/64.

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

[188] Affordable Prescriptions for Patients Act of 2019, S. 1416, 116th Cong. (2019), https://www.congress.gov/bill/116th-congress/senate-bill/1416/.

bipartisan[189] bill would establish an interagency task force between the Patent Office and the FDA,[190] with the goal of "sharing information and providing technical assistance" between the agencies.[191] 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.[192] 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.

Unhampered by the interest group bickering that tends to derail direct patent reform in Congress, the executive branch 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"[193] that directed the FDA and USPTO to engage in dialogue over patent system features that "unjustifiably delay generic drug and biosimilar competition."[194] 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.[195] 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[196] as well as a request for comments on various

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[189] This bill was co-sponsored by five members of the Senate Judiciary Committee, including Senators Durbin and Grassley, the Chair and Ranking Member of the committee as a whole, and Senators Leahy and Tillis, the chair and Ranking Member of its Subcommittee on Intellectual Property. Interagency Patent Coordination and Improvement Act of 2022, S. 4430, 117th Cong. (2022), https://www.congress.gov/bill/117th-congress/senate-bill/4430.

[190] *Id.*

[191] *Id.*

[192] Arti K. Rai & W. Nicholson Price II, *An Administrative Fix for Manufacturing Process Patent Thickets*, 39 NATURE BIOTECHNOLOGY 20, 21-22 (2021).

[193] White House, *Executive Order on Promoting Competition in the American Economy* (July 9, 2021), https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/.

[194] *Id.* at Section 5(p)(vi).

[195] Letter from Katherine K. Vidal, USPTO Director, to Robert M. Califf M.D., FDA Commissioner, July 6, 2022, available at https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf (noting specifics on this incipient cooperation between USPTO and FDA).

[196] *Duties of Disclosure and Reasonable Inquiry During Examination, Reexamination, and Reissue, and for Proceedings Before the Patent Trial and*

other actions that could limit biopharmaceutical patent thickets.[197] More generally, the Executive Order discusses the importance of pro-competitive 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.

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.[198] More specifically, although the House and Senate Judiciary Committees have responsibility for statutory reforms to the patent system,[199] 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)[200] 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.[201] 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

Appeal Board, 87 FED. REG. 47504 (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 45785 (inconsistent statements) and 45786 (prior art).

[197] USPTO, Department of Commerce, Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, 87 Fed. Reg. 60130 (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).

[198] Rachel E. Sachs, *Integrating Health Innovation Policy*, 34 HARVARD J. L. & TECH 57, 91-92 (2020).

[199] *See supra* note 176.

[200] *See* Sachs, *supra* note 196, at 91-92.

[201] *See* Sachs, *supra* note 196, at 93-94.

statutes, such as the Hatch-Waxman Act.[202] 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.[203]

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,[204] 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,[205] suggesting that members of Congress with relevant patent

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[202] *See* Rachel E. Sachs, *The Accidental Innovation Policymakers*, DUKE L.J. (forthcoming 2023) (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).

[203] *See, e.g.*, Sen. Finance Comm., Hearing: Prescription Drug Price Inflation: An Urgent Need to Lower Drug Prices in Medicare (March 16, 2022), https://www.finance.senate.gov/hearings/prescription-drug-price-inflation-an-urgent-need-to-lower-drug-prices-in-medicare; Sen. Comm. On Health, Ed., Labor, & Pensions, Hearing: Why Does the US Pay the Highest Prices in the World for Prescription Drugs? (March 23, 2021), https://www.help.senate.gov/hearings/why-does-the-us-pay-the-highest-prices-in-the-world-for-prescription-drugs; House Comm. on Energy & Commerce, Subcomm. On Health, Hearing: Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs (May 4, 2021), https://energycommerce.house.gov/committee-activity/hearings/hearing-on-negotiating-a-better-deal-legislation-to-lower-the-cost-of; House Comm. on Ways & Means, Hearing: The Cost of Rising Prescription Drug Prices (Feb. 12, 2019), https://waysandmeans.house.gov/legislation/hearings/cost-rising- prescription-drug-prices.

[204] *See supra*.

[205] 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 AFFAIRS FOREFRONT (July 26, 2019), https://www.healthaffairs.org/do/10.1377/forefront.20190726.817822, and he then served as Ranking Member of the Senate Judiciary Committee in 2021 as it considered these patent- and antitrust-related issues.

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.

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.