

2019

The "Evergreening" Metaphor in Intellectual Property Scholarship

Erika Lietzan

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Lietzan, Erika (2019) "The "Evergreening" Metaphor in Intellectual Property Scholarship," *Akron Law Review*. Vol. 53 : Iss. 4 , Article 2.

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**THE “EVERGREENING” METAPHOR IN INTELLECTUAL
PROPERTY SCHOLARSHIP**

*Erika Lietzan**

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* Associate Professor of Law, University of Missouri (Columbia). I am grateful to Kristina Acri née Lybecker, Krista Carver, (the Hon.) Ryan Holte, Camilla Hrdy, David Korn, Glynn Lunney, Jr., Michael Madison, Liam O’Mellin, Zahr Said, Joshua Sarnoff, and Hans Sauer for comments on drafts of this article, and to Kristina Acri née Lybecker, David Lund, and Mark Schultz for the inspiration to write the article. I am also grateful to Henry Adams (University of Missouri School of Law, Class of 2020), Mike Figenshau (Class of 2021), Evan Weidner (Class of 2021), and as always Cynthia Shearrer (Associate Law Librarian), for research assistance.

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ABSTRACT

This article is a plea for changes in the scholarly dialogue about “evergreening” by drug companies. Allegations that drug companies engage in “evergreening” are pervasive in legal scholarship, economic scholarship, medical and health policy scholarship, and policy writing, and they have prompted significant policymaking proposals. This Article was motivated by concern that the metaphor has not been fully explained and that policymaking in response might therefore be premature. It canvasses and assesses the scholarly literature—more than 300 articles—discussing or mentioning “evergreening.” It catalogues the definitions, the examples, and the empirical studies. Scholars use the term when describing certain actions taken by the innovative companies that develop and introduce new medicines to market. But they are inconsistent in their descriptions of the circumstances to which the term applies. And though most claim the innovator has “extended” something in these circumstances, they do not agree on the particulars. The literature is similarly in disarray about what has been “evergreened”—an invention, a product, a price, a patent, or something else entirely. All of this makes it hard to know from the literature what exactly scholars are writing about. After sorting through the definitions and examples—and considering the legal framework and practical landscape in which drug innovators and their generic competitors operate—this Article offers an answer and, more importantly, identifies the implicit normative claim. In simple terms, the normative claim in the literature is something like this: “an innovator should not enjoy an exclusive market and supra-competitive pricing for innovations that stem in some fashion from a separate innovation for which it already enjoyed a 20-year patent term. Or at least, a drug innovator should not.” This Article does not defend, or reject, this normative claim. Instead, it makes a different claim: that policymaking should be based on descriptive scholarship that is careful and precise about the relevant law and facts, normative work that is clear and candid about its claim and thorough in its reasoning, and empirical studies that document the actual problem the normative proposals and

policymaking proposals are meant to address. Significant policymaking would be premature today, because we have not yet produced this body of work. Constant use of the "evergreening" metaphor may be obscuring this failure. The Article concludes with recommendations for scholars continuing to work on these topics, focusing on ways that we can provide quality work to assist policymakers considering the normative claim.

I. INTRODUCTION

Allegations that drug companies engage in "evergreening" pervade legal scholarship, economic scholarship, medical and health policy scholarship, and policy writing.¹ English language dictionaries tell us that the primary meaning of "evergreen" is literal; unlike a deciduous tree, an evergreen tree or shrub has green foliage all year round.² An evergreen leaf lasts from one season to the next.³ Even when the term does not refer to non-deciduous plants, its primary meaning is literal; an evergreen landscape is always green.⁴ But the term also has a figurative meaning.⁵ Something is "evergreen" if it is "always fresh" or "never failing" or "enduring."⁶

In the literature relating to drug companies, the term "evergreening" is a metaphor. The writer invokes a concrete image familiar to the audience to convey an abstract concept relating to legal and factual circumstances in the real world.⁷ Metaphors are common in legal writing and especially common in intellectual property writing.⁸ They are powerful because they turn the complex and unfamiliar into something simple and familiar, and sometimes they are also powerful because they

1. See *infra* Part III.

2. *Evergreen*, MERRIAM-WEBSTER DICTIONARY, at 1, <https://www.merriam-webster.com/dictionary/evergreen> [<https://perma.cc/Z2ST-7HEB>]; see also *Evergreen*, OXFORD ENGLISH DICTIONARY [hereinafter OED], <https://www.oed.com/view/Entry/65314?redirectedFrom=evergreen#eid> [<https://perma.cc/JF9T-NYDQ>]; *Evergreen*, THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE, <https://ahdictionary.com/word/search.html?q=evergreen> [<https://perma.cc/YP2T-VJDP>].

3. *Evergreen*, OED, *supra* note 2, at 1b.

4. *Id.* at 2a.

5. *Evergreen*, MERRIAM-WEBSTER, *supra* note 2, at 2a (defining "figurative" as "expressing one thing in terms normally denoting another with which it may be regarded as analogous").

6. *Evergreen*, OED, *supra* note 2, at 2b; *Evergreen*, MERRIAM-WEBSTER, *supra* note 2, at 2a ("retaining freshness or interest"), 2b ("universally and continually relevant"); *Evergreen*, AMERICAN HERITAGE, *supra* note 2, at 3 ("automatically renewed or repeatedly made valid").

7. See Jacob Carpenter, *Persuading with Precedent: Understanding and Improving Analogies in Legal Argument*, 44 CAP. U.L. REV. 461, 464 (2016) (explaining how metaphors work in legal argument).

8. Brian L. Frye, *IP as Metaphor*, 18 CHAP. L. REV. 735, 736 (2015) ("[T]he rhetoric of intellectual property is metaphorical.").

trigger emotional responses that fill gaps left open by the writer.⁹ For these reasons, metaphors can be dangerous in legal writing.¹⁰ Though sometimes helpful in advancing understanding, they are not literally true, and the implicit analogy is rarely (if ever) a perfect fit.¹¹ The gap-filling that audiences instinctively perform is no substitute for reasoning from solid evidence. Metaphors can lead both author and audience to error.¹²

Despite these reasons for caution, the metaphor of “evergreening” by drug companies has crept into the popular press, court filings and decisions, and policymaking discussions.¹³ And policymakers have been considering proposals to make significant changes to antitrust law, intellectual property law, and the regulatory framework governing new medicines in response to allegations of “evergreening.”¹⁴

This Article was motivated by concern that the metaphor has not been fully explained and that policymaking in response to the metaphor might therefore be premature. It canvasses and assesses the scholarly literature—342 articles in legal, medical and scientific, and economic journals—that discusses or references “evergreening.”¹⁵ It explains that scholars use the term when describing certain actions taken by the companies that develop and introduce new medicines to market (“innovators”).¹⁶ For example, some use the term when a company introduces its medicine first in an immediate release form and later in an extended release form (which can be taken less often) if the new form has a patent expiring later than the patent covering the active ingredient.¹⁷ In addition to examples, the literature includes empirical studies—for

9. *E.g.*, *id.* at 742 (noting use of “agrarian metaphors to describe intellectual property owners” and “criminal metaphors to describe intellectual property infringers”); *id.* at 744–51 (discussing use of “troll” metaphor in intellectual property law). *See also* Carpenter, *supra* note 7, at 476; Margaret M. Blair, *On Models, Metaphors, Rhetoric, and the Law*, 41 TULSA L. REV. 513, 513 (2006).

10. *E.g.*, Michael R. Smith, *Levels of Metaphor in Persuasive Legal Writing*, 58 MERCER L. REV. 919, 923 (2007).

11. Blair, *supra* note 9, at 513.

12. *Berkey v. Third Ave. Ry.*, 155 N.E. 58, 61 (N.Y. 1926) (noting the risk with metaphors, that despite “starting as devices to liberate thought, they end often by enslaving it”).

13. *See* authorities cited *infra* note 122.

14. *E.g.*, Affordable Prescriptions for Patients Act of 2019, S.1416, 116th Cong. § 27(b)(1) (introduced May 9, 2019) (proposing to presume it an “unfair method of competition in or affecting commerce” to obtain certain additional later-expiring patents in the same patent family or portfolio as an already issued patent that claims an approved drug).

15. This is not all academic articles published in the United States that use the term “evergreening” in connection with drugs. But it includes 313 articles in academic law journals (or comparable legal publications), which are virtually all legal scholarship, excluding books.

16. Some call these companies “brand” companies, because their products usually bear brand names.

17. *See infra* Part III.A.

instance, showing that innovators introduce a variety of related products, and that later-introduced products are often protected by later-expiring intellectual property.¹⁸ The literature also treats "evergreening" as bad; scholars using the term generally criticize the actions.¹⁹

The actions at issue in this scholarship take place within a complex landscape of federal and state laws governing regulatory approval of new medicines, intellectual property, and healthcare professionals (doctors and pharmacists), and each example is burdened with unique factual circumstances (such as the response of patients and payers to clinical and economic factors specific to that medicine).²⁰ The articles tend not to consider or describe the nuances of this landscape, however, even when offering specific examples. Scholars are also inconsistent in their descriptions of the circumstances to which the label (the metaphor) applies.²¹ And though most claim the innovator has "extended" something in these circumstances, they do not agree on the particulars.²² The literature is similarly in disarray about what has been "evergreened"—an invention, a product, a price, a patent, or something else entirely.²³ All of

18. See *infra* Part III.C.

19. See *infra* Part III.A. Exceptions are rare. *But see* Jonathan J. Darrow, *Debunking the "Evergreening" Patents Myth*, 131 HARV. L. REC., December 8, 2010, at 6 (arguing that characterizations of "evergreening" have "little basis in United States patent law and perpetuate the myth that patents can be 'extended' by minor modifications to existing products"); Christopher M. Holman, *In Defense of Secondary Pharmaceutical Patents: A Response to the UN's Guidelines for Pharmaceutical Patent Examination*, 50 IND. L. REV. 759, 776–77 (2017) (discussing a U.K. court decision noting that "the patent on escitalopram did not prevent a number of manufacturers from selling generic versions of" CipraleX, and adding that this is "yet another example illustrating the fallacy of the premise that patents on enantiomers somehow provide 'evergreened' protection for products whose patents have expired"); Emily Michiko Morris, *Much Ado About the TPP's Effect on Pharmaceuticals*, 20 SMU SCI. & TECH. L. REV. 135, 142–43 (2017) (noting that "sequential patents on new uses are . . . separate patents that must satisfy all of the same patentability requirements that active ingredient patents must satisfy," that a patent on a new use is "much narrower in scope" than a patent on the active ingredient, and that once the patent on the active ingredient expires, "it can be freely used for any unpatented use, including the use for which it was originally patented"); Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 245, 260 (2012) (stating that there is "plenty of reason to doubt that such sequential innovation patents are nearly as suspect as the critics would make out"); see also Dorothy Du, *Novartis AG v. Union of India: "Evergreening," TRIPs, and "Enhanced Efficacy" Under Section 3(d)*, 21 J. INTELL. PROP. L. 223, 240 (2014) (noting that some call it evergreening when a company patents "a new commercial embodiment of a drug" that is "no better than the original commercial embodiment," but arguing that this theory "lacks merit" because if the second version were no better, consumers would demand the first version).

20. See *infra* Part III.A.

21. See *infra* Part III.A.

22. See *infra* Part III.A.

23. See *infra* Part III.A.

this makes it hard to know from the literature *what exactly* scholars are writing about.

There is, in other words, an ontological problem in the literature. Locating the extension—the “evergreening”—the *thing* about which scholars are writing—is a challenge. These situations never involve extension of patents or an extension of the company’s proprietary rights in its research data, which would be legally impossible.²⁴ No matter what sorts of new products an innovator patents and launches, once the patent on an active ingredient expires, a generic company can use the ingredient in its own product *and* obtain approval relying on the research the innovator performed.²⁵ To give a concrete example, though the U.S. Food and Drug Administration (FDA) may approve the innovator’s new dosage form, this approval does not prevent a generic company from copying the innovator’s old dosage form. No barriers prevent this generic company from promoting its competing product to doctors, payers, and patients.²⁶ No barriers prevent payers from requiring that their insured patients use the generic company’s product.²⁷

The question then, is this: what—precisely—has been extended in the scenarios that scholars call “evergreening”? What does “evergreening” mean?

After sorting through the definitions and examples in the literature—and considering the legal framework and practical landscape in which innovators and generic companies operate—this Article offers an answer. The wildly varying circumstances described are similar in one respect: The innovator is able to market at least *some* drug products that would not exist *but for* its initial active ingredient discovery, without generic copies of *these* products in the market, and thus perhaps with supra-competitive pricing, and it can market these products *after* expiration of the patent on the active ingredient itself. To call this an “extension” is puzzling, however, because no law provides a basis for stating a time limit on the innovator’s ability to do so. And to say that this is wrong, that this should not be so, is a normative claim. Restated, the normative claim would be something like this: an innovator should not enjoy an exclusive market and supra-competitive pricing for innovations that stem in some fashion from a separate innovation for which it already enjoyed a 20-year patent term. Or at least, a drug innovator should not.

24. *See infra* Part IV.A.

25. *See infra* Part IV.B.

26. *Id.*

27. *Id.*

This Article does not take up this normative claim. Instead, this Article focuses on a different claim: that policymaking should be based on descriptive scholarship that is careful and precise about the relevant law and facts, normative work that is clear and candid about its claim and thorough in its reasoning, and empirical studies that document the actual problem the normative proposals and policymaking proposals are meant to address. Significant policymaking would be premature today because we have not yet produced this scholarship. Rampant use of the "evergreening" metaphor is obscuring this failure.

The Article proceeds as follows. Part II describes the federal and state legal landscape that governs regulatory approval, promotion, prescribing, and dispensing of new medicines (including generic medicines) as well as the intellectual property available. It focuses on aspects of this landscape that non-specialist readers of the evergreening literature may not appreciate. Part III catalogues definitions of "evergreening" in the scholarly literature as well as examples offered by scholars and empirical studies in that literature. Part IV considers the definitions, examples, and studies in context, identifying the "extension" apparently at issue and thus the underlying normative claim. Part V, which also serves as a conclusion, provides recommendations for scholars continuing to work on these topics, focusing on ways that we can provide quality work to assist policymakers considering the normative claim.

II. THE CONTEXT FOR "EVERGREENING" ALLEGATIONS

The events that trigger the "evergreening" label occur at the intersection of several bodies of law: the federal framework requiring premarket approval of new medicines and their copies, federal intellectual property laws, federal and state laws governing promotion of medicines, and federal laws and practices and state laws relating to prescribing and dispensing of medicines. Certain basic points about these intersecting frameworks are well understood. New medicines require premarket testing and approval from FDA.²⁸ When they are first launched, they tend to be sold under brand names and protected by patents. These patents, combined with statutory rights in the testing data, delay the approval of cheaper copies.²⁹ Eventually FDA approves cheaper copies, which pharmacists usually dispense automatically, even when doctors prescribe the branded product by name.³⁰ As this Part explains, however, despite

28. *See infra* Part II.A.

29. *See infra* Part II.B.

30. *See infra* Part II.C.

these simple truths, the landscape is more complex and nuanced. FDA approves specific drug *products*, rather than new medicines in some abstract sense. A generic drug company copies a specific *product*, and it must contend with the patents relevant to *that product*—not other patents the innovator might hold. And it need not market a perfect copy. Thus, a generic company has some freedom to operate. Finally, although conventional wisdom holds that generic companies depend on automatic pharmacy substitution to obtain market share, the truth may be more complicated.

A. *Approval of Medicines*

Federal law requires that every “new drug” be approved by FDA before it is introduced to the market.³¹ Both innovative (branded) drugs and generic drugs require preapproval. For an innovative drug, the applicant submits either a new drug application (NDA) or a biologics license application (BLA), depending on whether the product—as a practical matter, whether its active ingredient—is biological.³² The active ingredient is the component meant to furnish the medicine’s effect, such as treatment of a particular disease.³³ FDA also calls the active ingredient a “drug substance.”³⁴ Most scholarship that discusses “evergreening” focuses on non-biological drugs, and this Article takes the same approach.³⁵

31. 21 U.S.C. § 355(a) (2018). “Drugs” include items intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease, as well as items (other than food) intended to affect the structure or function of the body. 21 U.S.C. § 321(g)(1) (2018). Subject to caveats not relevant here, “new drugs,” which require preapproval, are “drugs” “not generally recognized . . . as safe and effective for use under the conditions described . . . in th[eir] labeling.” 21 U.S.C. § 321(p)(1) (2018).

32. A “biological product” [is] a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein . . . , or analogous product, or arsphenamine or derivative of arsphenamine . . . applicable to the prevention, treatment or cure of a disease or condition [in] human beings.” 42 U.S.C. § 262(i) (2018).

33. 21 C.F.R. § 314.3(b) (2020) (“*Active ingredient* is any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals.”).

34. *Id.* § 314.3(b) (2020) (“*Drug substance* is an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates used in the synthesis of such ingredient.”).

35. Most allegations of “evergreening” ultimately relate to an innovator’s position in the market and potential competition from generic drugs, which are approved under a 1984 statute. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585. Innovative biological products face competition instead from biosimilar biologics and interchangeable biologics licensed under a statutory provision that is barely a decade old. Biologics Price Competition and Innovation Act of 2009, Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119.

Although each “new drug” requires an approved application, FDA approves drug *products*.³⁶ A drug product is a medicine in its finished form, meaning the form that will be sold in the market and administered to patients.³⁷ The marketing application describes the composition, manufacturing process, and specifications of both the drug substance (active ingredient) and this final drug product.³⁸ It also includes laboratory, animal (preclinical), and human (clinical) testing data showing that this product is safe and effective.³⁹ FDA approves the product described in the application—the specific formulation (of active and inactive ingredients⁴⁰), in a particular dosage form (such as capsule or tablet), for a particular route of administration, at a particular strength, for particular medical uses (also known as the product’s “indications”), manufactured as described in the application, and accompanied by labeling written for prescribers based on the data in the application.⁴¹

FDA then adds the product to a publicly available list of products approved based on safety and effectiveness.⁴² This publication, known as the ORANGE BOOK, lists specific drug *products* approved by FDA.⁴³ For instance, it lists Eli Lilly’s 5 mg tablets of Zyprexa (olanzapine) intended for oral administration, approved under NDA 20592 on September 30, 1996, *separately* from other products containing olanzapine marketed by the same company and others.⁴⁴

Because FDA approval is specific to the product proposed in a particular application, a company that wants to change its product—to market something not covered by the approved application—must seek

36. Premarket approval is required if the *product* is new, even if the active ingredient has been marketed in the past. *See generally* United States v. Generix Drug Corp., 460 U.S. 453, 459 (1983) (holding that a generic drug product is a “drug” and a “new drug” even if the active ingredient has been marketed previously).

37. 21 C.F.R. § 314.3(b) (2020) (“*Drug product* is a finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.”).

38. 21 C.F.R. § 314.50 (2020) (describing content and format of a new drug application).

39. 21 U.S.C. §§ 355(b), (e) (2018); *see generally* Erika Lietzan, *The Drug Innovation Paradox*, 83 MO. L. REV. 39, 49–56 (2018) (describing the new drug research and development process).

40. An “[i]nactive ingredient is any component other than the active ingredient” and might include an excipient, preservative, solvent, buffer, or coating, among other things. 21 C.F.R. § 314.3 (2020).

41. 21 U.S.C. § 355(d) (2018); *see also* 21 C.F.R. § 314.70 (2020) (requiring approval of a supplemental application if changes are made to any conditions established in the approved application).

42. 21 U.S.C. § 355(j)(7) (2018).

43. FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (40th ed. 2020) [hereinafter “ORANGE BOOK”].

44. *Id.* at 3-325–3-327.

FDA approval again.⁴⁵ Depending on the nature of the change, the company might need preapproval or it might be allowed to make the change and seek approval at the same time.⁴⁶ For example, if it wants to market a new strength of the product or add a new use to the labeling, it must get preapproval.⁴⁷ Also depending on the nature of the change, it might need to file a separate marketing application, or it might be allowed to file a “supplement” to its existing application.⁴⁸

Although FDA may not approve new drugs without proof of safety and effectiveness, in some cases an applicant need not perform all the research itself. Federal law permits the submission of “abbreviated” marketing applications referencing drugs listed in the ORANGE BOOK as approved based on safety and effectiveness.⁴⁹ An abbreviated application contains data sufficient to create a scientific bridge to the listed drug and then relies on the safety and effectiveness data in the application that covered the listed drug.⁵⁰ The earlier-approved product is known as the new product’s “reference” listed drug.

The statute permits two types of abbreviated applications. *First*, a company may submit an “abbreviated new drug application” (ANDA) for a drug that essentially duplicates the reference drug.⁵¹ This is also known as a “generic” drug application, and the duplicate is known as a “generic” drug. Ordinarily, the company shows that its generic drug has the same active ingredient, route of administration, dosage form, strength, and labeling as the reference drug.⁵² The generic drug does not have to have the same formulation. It must be “bioequivalent” to the listed drug

45. 21 C.F.R. § 314.70 (2020) (governing changes to an approved NDA); *id.* § 314.97 (governing changes to an approved ANDA).

46. *Compare* 21 C.F.R. § 314.70(b) (2020) (changes requiring preapproval) *with id.* § 314.70(c) (2020) (changes requiring supplement submission 30 days before distribution). Some minor changes can be described in the company’s annual report to FDA. *id.* § 314.70(d) (2020).

47. 21 C.F.R. § 314.70(b) (2020).

48. *See generally* FDA, SUBMITTING SEPARATE MARKETING APPLICATIONS AND CLINICAL DATA FOR PURPOSES OF ASSESSING USER FEES: GUIDANCE FOR INDUSTRY (Dec. 2004) [hereinafter “SEPARATE APPLICATIONS GUIDANCE”], <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submitting-separate-marketing-applications-and-clinical-data-purposes-assessing-user-fees> [<https://perma.cc/R3M5-WUPZ>].

49. 21 U.S.C. §§ 355(b)(2), (j) (2018).

50. *E.g.*, DETERMINING WHETHER TO SUBMIT AN ANDA OR A 505(B)(2) APPLICATION 4, FDA, May 2019, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/determining-whether-submit-anda-or-505b2-application> [<https://perma.cc/STF5-JJ83>] (“The [505(b)(2)] applicant is expected to establish a bridge (e.g., by using comparative bioavailability data) between the proposed drug product and each listed drug that the applicant seeks to rely upon to demonstrate that reliance on the listed drug is scientifically justified.”).

51. 21 U.S.C. § 355(j)(2) (2018).

52. *Id.* § 355(j)(2)(A)(iii) (2018); *id.* §§ 314.94(a)(5)–(6) (2020).

however, meaning that its active ingredient must reach the site of action in the body to the same extent and at the same rate as the active ingredient of the listed drug.⁵³ An ANDA is much smaller than an innovator's full application: cheaper and faster to prepare, with comparatively few data.⁵⁴

A generic drug proposed in an ANDA does not have to be a perfect copy. If the generic company wants to change the route of administration, dosage form, or strength (for instance, to avoid patent infringement) and still submit an ANDA, it may ask FDA's permission by filing a "suitability" petition.⁵⁵ FDA must approve this petition unless it decides more safety and effectiveness data are needed.⁵⁶ If FDA approves the petition, the generic company may submit an ANDA.⁵⁷ FDA holds this "petitioned ANDA" to the same standard as any other ANDA, with two exceptions. The labeling of the generic drug will be different to reflect the changes made.⁵⁸ And if the generic company cannot show its drug's bioequivalence, it may show that its drug "can be expected to have the same therapeutic effect as the [reference] listed drug" for each condition of use proposed for its labeling.⁵⁹

Second, a company may submit an abbreviated application that proposes differences from the listed product, such as modifications to avoid a patent or innovations that the company believes will be competitive in the market. This application is called a "505(b)(2) application," after the provision of law in which it appears.⁶⁰ Although the changes must be supported by new safety and effectiveness data, the generic company will otherwise rely on the innovator's research. This Article distinguishes between generic applications (ANDAs) and 505(b)(2) applications when the distinctions are relevant, and refers to them collectively as "abbreviated applications" when the distinctions are not. For simplicity's sake, it calls the applicants "generic companies" regardless of the type of abbreviated application at issue. In any case, the

53. 21 U.S.C. § 355(j)(8)(B) (2018).

54. Erika Lietzan, *The Myths of Data Exclusivity*, 20 LEWIS & CLARK L. REV. 91, 106–08 (2016).

55. 21 U.S.C. § 355(j)(2)(C) (2018).

56. *Id.*

57. *Id.* § 355(j)(2)(A).

58. *Id.* § 355(j)(2)(A)(v).

59. *Id.* § 355(j)(2)(A)(iv); 21 C.F.R. § 314.93 (2020).

60. 21 U.S.C. § 355(b)(2) (2018); APPLICATIONS COVERED BY SECTION 505(B)(2), FDA, Dec. 1999, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applications-covered-section-505b2> [<https://perma.cc/JXQ6-S3UH>]. A company may use the 505(b)(2) for other reasons, as well, such as when FDA rejects its suitability petition because clinical data are needed, or when it cannot satisfy the "sameness" standard due to the product's complexity. *Id.*

distinction between generic companies and innovator companies is artificial, in; any company may submit either type of application.

B. Intellectual Property Considerations

After approval of a reference listed drug, federal law ensures the innovator a period before the submission and approval of abbreviated applications citing its drug. This period stems from patents the innovator owns as well as the innovator's statutory "exclusivity" in its research data.⁶¹ It may also stem from other statutory exclusivity provisions in federal law.⁶² Whether a particular patent or statutory exclusivity affects a particular generic company's particular product depends on its scope as well as on what the generic company proposes and when it proposes to market its product.

1. Statutory Exclusivity

If the innovator's product contained a new active moiety (not approved before), the drug statute temporarily protects the innovator's exclusivity in its research data by specifying a point *in the future* after which generic companies may rely on the data in their abbreviated applications.⁶³ No company may submit an abbreviated application citing a listed drug containing a new chemical entity (active moiety) until five years after first approval of the new chemical entity.⁶⁴ The period before that date is known as "new chemical entity" data exclusivity. This period drops to four years if the generic company claims it has avoided—or challenges (as invalid)—a patent claiming the listed drug or an approved

61. For simplicity, this Article calls the innovator the "owner" of any patent it owns or exclusively licenses.

62. Other intellectual property laws, including state trade secret law and federal trademark law, may also protect the innovator's position in the market. This Article focuses on the role of patents and statutory exclusivity, because they play a direct role in the timing of submission and approval of abbreviated applications.

63. See generally Lietzan, *supra* note 54, at 117–18. The active moiety is the molecule responsible for the physiological or pharmacological action of the drug. 21 C.F.R. § 314.108 (2020). It may differ from the active ingredient, the substance before its introduction to the body. 21 C.F.R. § 314.3 (2020).

64. The statute refers to a new "active ingredient." 21 U.S.C. § 355(b)(3)(E)(ii) (2018) (applicable to 505(b)(2) applications); *id.* § 355(j)(5)(F)(ii) (applicable to ANDAs). See Lietzan, *supra* note 54, at 135 (explaining FDA's adopting the term "new chemical entity" and its further elaboration that this refers to a new "active moiety").

method of using the listed drug.⁶⁵ The next subpart describes these challenges.

If the innovator's product has no new chemical entity, but clinical data (other than bioavailability data) were necessary to secure its approval, FDA cannot approve an abbreviated application for the same active moiety for the same conditions of approval for three years.⁶⁶ For example, if a company developed a new treatment for breast cancer using an older active moiety that FDA approved decades ago (for another company), it would file a new drug application—probably a 505(b)(2) application—and receive three years of exclusivity. Or if a company developed a new chemical entity that would be administered through intravenous infusion, and it later found a way to administer the treatment (for the same disease) by capsule, it would generally file a new application and ordinarily receive three years of exclusivity on the *new* product. Three-year exclusivity operates differently from new-chemical-entity exclusivity because it prevents *approval* (rather than submission) of other applications, and it prevents approval *only* if those applications propose the same active moiety for the same condition of approval.

2. Patent-Based Statutory Exclusivity

Federal law allows a patent to issue for any new, useful, non-obvious invention.⁶⁷ For any particular drug product approved by FDA, the innovator might own patents on several discrete inventions.⁶⁸ These usually include the product's active ingredient.⁶⁹ They might include the

65. 21 U.S.C. § 355(b)(3)(E)(ii) (2018) (applicable to 505(b)(2) applications); *id.* § 355(j)(5)(F)(ii) (applicable to ANDAs).

66. 21 U.S.C. §§ 355(b)(3)(E)(iii)–(iv), 355(j)(5)(F)(iii)–(iv) (2018); *see also* Letter from Sharon Hertz, Dir. Div. of Anesthesiology, Addiction Med. & Pain Med., to Mike Derkacz, President & CEO, Braeburn, Inc., Re: NDA 210136 (Nov. 6, 2019), <https://www.lassmanfdalaw.com/wp-content/uploads/sites/217/2019/11/FDA-Remand-Decision-11-7-2019.pdf> [<https://perma.cc/3HW2-5FBZ>] (describing FDA's interpretation of 3-year exclusivity). Bioavailability studies measure the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of action in the body. 21 U.S.C. § 355(j)(8)(A)(ii) (2018).

67. 35 U.S.C. §§ 101, 102, 103 (2018). Various other conditions must be satisfied for a patent to issue. *E.g.*, 35 U.S.C. § 112 (2018) (written description requirement).

68. *See generally* John R. Thomas, PHARMACEUTICAL PATENT LAW 46–64 (3d ed. 2015) (listing various types of pharmaceutical patent claims). Drug products are not unique in this regard. *E.g.*, Masataka Kai, *Science and Engineering Technology Behind Bridgestone Tour Gold Balls*, 1 SPORTS TECH. 57, 58 (2008) (noting “twenty-five or more patents” relevant to the Bridgestone Tour B330 golf ball).

69. *See* Thomas, *supra* note 68, at 47. A study of “new molecular entities” approved between 1988 and 2005 found, however, that only 64% had chemical compound patents. Amy Kapczynski et al., *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of “Secondary” Pharmaceutical Patents*, 7 PLOS ONLINE 12, Dec. 5, 2012, at 4. A “new molecular entity” is an active

product's formulation, or a dosage form and dosage of the active ingredient (or formulation).⁷⁰ Other possibilities include a method of using or administering the product, the manufacturing process, and a metabolite of the active ingredient.⁷¹ A patent lasts for 20 years from its application date,⁷² and generally an innovator files its active ingredient patent first, making it the first to expire.⁷³ Other inventions (formulation, dosage form, and so on) may emerge later, during premarket development. If the resulting patent applications refer to the active ingredient patent, the patents will expire when the active ingredient patent expires, but if not, they will expire later.⁷⁴

The drug statute links the timing of FDA approval of an abbreviated application to the patents claiming the reference listed drug, as follows.

In its new drug application, the innovator lists the patents that claim its ingredient, product (formulation and composition), and methods of use for which it seeks approval.⁷⁵ Once FDA approves its product, the innovator finalizes the list, and FDA publishes the patents and their expiry dates in the ORANGE BOOK.⁷⁶ If any patents issuing after this time also satisfy the listing standard (by claiming the drug or an approved method of using the drug), the innovator has 30 days to notify FDA, which adds them to the ORANGE BOOK.⁷⁷

Whether it files an ANDA or a 505(b)(2) application, a generic company must address these patents in its application.⁷⁸ For each unexpired patent listed in the ORANGE BOOK for the specific drug on

ingredient that contains no active moiety approved before or previously marketed in the United States. See FDA, *NDA Classification Codes*, MAPP 5018.2 (Nov. 4, 2016).

70. See Thomas, *supra* note 68, at 47–48; see also 21 C.F.R. § 314.53(b) (2020).

71. Thomas, *supra* note 68, at 48–50, 53–55; 21 C.F.R. § 314.53(b) (2020).

72. 35 U.S.C. § 154(a)(2) (2018). If the patent relates to an earlier-filed patent, it lasts for 20 years from the earlier patent's application date. *Id.*

73. Morris, *Myth*, *supra* note 19, at 273–74.

74. 35 U.S.C. § 154(a)(2) (2018).

75. The statute requires the innovator to file any patent that claims “the drug . . . or a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” 21 U.S.C. § 355(b)(1) (2018); see 21 C.F.R. § 314.53(b) (2020) (defining this to mean patents claiming the active ingredient, product, and method of use, but not method of manufacturing); see also 54 Fed. Reg. 28872, 28918 (July 19, 1989).

76. *Patent and Exclusivity Information Addendum*, ORANGE BOOK, *supra* note 43, at AD1–AD277.

77. 21 U.S.C. § 355(c)(2) (2018).

78. *Id.* §§ 355(b)(2)(A), 355(j)(2)(A)(vii). Technically, the generic company must address every patent that claims the reference drug or a use for which it seeks approval, whether or not the patent is listed in the ORANGE BOOK. This is why one option, for the generic company, is to say that the patent information “has not been filed” by the innovator. *Id.* § 355(j)(2)(A)(vii)(I).

which it relies, the generic company has two choices. Its selection dictates the timing of FDA approval as far as that patent is concerned, as follows.

First, the generic company may state the date on which the patent will expire, signifying that it does not plan to market its drug before patent expiry.⁷⁹ This is called a "paragraph III" certification after the statutory provision that describes it. FDA reviews the submitted application, but even if the drug approval standard is satisfied, FDA cannot grant final approval until patent expiry.⁸⁰ *Second*, the generic company may assert that the patent is invalid or will not be infringed by its drug, in which case it must notify the innovator of its position.⁸¹ This is called a "paragraph IV" certification after the statutory provision that describes it. FDA may grant final approval immediately if the approval standard is met, unless the innovator sues within 45 days of receiving notice from the generic company.⁸² If the innovator sues within 45 days, the statute stays final approval of the abbreviated application for 30 months.⁸³ The stay applies only if the innovator had listed the patent before the generic company submitted its abbreviated application.⁸⁴ At the end of the 30 months, FDA must approve the abbreviated application if the approval standard is met, even if the patent litigation is ongoing.⁸⁵ If the generic company launches at this point, it does so at the risk of losing when the litigation concludes and, in that scenario, possibly owing damages to the innovator.

79. *Id.* §§ 355(b)(2)(A)(iii), 355(j)(2)(A)(vii)(III).

80. *Id.* §§ 355(c)(3)(B), 355(j)(5)(B)(ii).

81. *Id.* §§ 355(b)(3)(A), 355(j)(2)(B)(i).

82. *Id.* §§ 355(c)(3)(C), 355(j)(5)(B)(iii).

83. *Id.* §§ 355(c)(3)(C), 355(j)(5)(B)(iii). If the generic company submitted its application during the fourth year of the innovator's five-year new-chemical-entity exclusivity term, though, the 30-month stay is extended so that it expires 7.5 years after approval of the innovator's application. *Id.* §§ 355(c)(3)(E)(ii), 355(j)(5)(F)(ii) (2018).

84. *Id.* §§ 355(c)(3)(C) (2018) (applying certification only if the patent was listed "before the date on which the" abbreviated application was submitted); *id.* § 355(j)(5)(B)(iii) (same). This was not always the case. Before December 8, 2003, a new paragraph IV certification after ANDA submission triggered a new 45-day notice window, and any resulting litigation triggered a new 30-month stay. Congress changed the law in 2003. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Title XI, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

85. There are some exceptions. A statutory exclusivity term (such as seven-year orphan exclusivity) associated with initial approval of the innovator's drug might still be running at the end of the 30-month stay and delay approval until its expiry. And the first generic company to submit a paragraph IV certification in an ANDA citing the listed drug is eligible for 180-day exclusivity, which—if awarded—blocks approval of subsequent ANDAs also containing paragraph IV certifications. 21 U.S.C. § 355(j)(5)(B)(iv) (2020). Thus, when a 30-month stay of ANDA approval expires, FDA will not approve the ANDA if another company is eligible for 180-day exclusivity and the exclusivity has not concluded (or been forfeit). *See generally* Erika Lietzan & Julia Post, *The Law of 180-Day Exclusivity*, 71 FOOD & DRUG L.J. 327 (2016).

In the end, the court's ruling will control. If the generic company wins in trial court while the stay is in place (if it establishes that its product is non-infringing or that the patent is invalid), FDA must approve its application on the day the court enters judgment (assuming the application is otherwise ready for approval).⁸⁶ If the generic company loses in the trial court but wins in the court of appeals while the stay is in place, FDA must approve the application on the date of the appellate court decision (again assuming the application is otherwise approvable).⁸⁷ In these cases, the stay evaporates. In contrast, if the generic company loses in the trial court and fails to appeal, or it loses in the trial court and again in the court of appeals, the court must order the effective date of final approval to be no sooner than patent expiry.⁸⁸ If FDA has already approved the generic drug because the stay has expired, FDA will rescind the approval.⁸⁹

Every listed patent plays a role in determining the timing of approval. If the innovator lists four patents in the ORANGE BOOK, for example, the generic company must address each, and FDA considers each. If the generic company defeats three patents (proving that one is invalid, for instance, and that it does not infringe the other two) but filed a paragraph III certification to the fourth patent, FDA cannot approve its abbreviated application until expiry of the fourth patent. If the generic company defeats two patents and is found to infringe two patents, FDA cannot approve its application until the infringed patents expire.

3. A Generic Company's Options

If a generic company believes it would infringe a patent, or if it fears it will lose the patent infringement suit brought by the innovator, it may

86. 21 U.S.C. §§ 355(c)(3)(C)(i), 355(j)(5)(B)(iii)(I) (2018). *But see* authorities cited *supra* note 85 and accompanying text for exceptions.

87. 21 U.S.C. §§ 355(c)(3)(C)(ii)(I), 355(j)(5)(B)(iii)(II)(aa) (2018). *But see* authorities cited *supra* note 85 and accompanying text for exceptions.

88. 21 U.S.C. §§ 355(c)(3)(C)(ii)(II), 355(j)(5)(B)(iii)(II)(bb) (2018) (cross referencing 35 U.S.C. § 271(e)(4)(A)). The court may also enjoin the generic company from commercial manufacture, sale, and use of the product. 35 U.S.C. § 271(e)(4)(B) (2018). But this is a formality, because the company's drug is not approved and cannot be marketed anyway. 21 U.S.C. § 355(a) (2018). Separately, FDA requires the generic company to convert its paragraph IV certification to a paragraph III certification. 21 C.F.R. § 314.94(a)(12)(viii)(A) (2020). Once the paragraph III certification is in place, approval of the abbreviated application may not take effect until the patent expires. 21 U.S.C. §§ 355(c)(3)(B), 355(j)(5)(B)(ii) (2018).

89. *E.g.*, Kathryn Phelps, *FDA Rescinds Zofran ODT ANDA Approval*, PINK SHEET (Nov. 29, 2005), <https://medtech.pharmaintelligence.informa.com/PS061322/FDA-Rescinds-Zofran-ODT-ANDA-Approval> [<https://perma.cc/EP8H-4DQN>] (“The agency revoked the ANDA Nov. 29 in light of an earlier district court decision that the generic ondansetron orally disintegrating tablets infringe an unexpired GSK patent.”).

seek a license. Settlements of paragraph IV litigation usually include a license allowing the generic company to bring its product to market earlier than the date of patent expiry.⁹⁰ But there are other options as well.

First, although the paragraph III and paragraph IV certifications are the primary options available to a generic company, the company has a third option if the patent claims a method of using the listed drug. It may decline to seek approval of the use.⁹¹ For example, if FDA has approved the innovator's drug for two uses (such as breast cancer and stomach cancer) but the innovator holds only a patent claiming use of the drug for one (breast cancer), the generic company may seek approval of its drug for the other (stomach cancer). Although federal law requires a generic drug to have the same labeling as its reference drug, FDA will usually permit a generic company to omit descriptions of uses protected by patents (or statutory exclusivity).⁹² A generic company submitting a 505(b)(2) application has the same option to omit a patented use from its labeling,⁹³ but it does not have to worry about getting permission to do so because the statute does not require its product to have the same labeling in the first case.

Second, a generic company could file a suitability petition and, upon approval of that petition, an ANDA proposing a difference that allows it to avoid patent infringement. Through this mechanism, it may be able to avoid a patent on the route of administration, dosage form, or strength of the listed drug. In this case, it would include a paragraph IV certification asserting non-infringement. It may also file a 505(b)(2) application for a product with more significant differences (including changes to the active ingredient) that need supporting safety and effectiveness data. Here too, the company would assert non-infringement. In both cases, the innovator might not sue if the generic company clearly avoided its patents.

90. Keith M. Drake & Thomas G. McGuire, *Generic Entry Before the Agreed-Upon Date in Pharmaceutical Patent Settlements* 1 (July 8, 2019), <https://ssrn.com/abstract=3416632> [<https://perma.cc/HXF8-WEHE>] ("It is also common for these patent disputes to settle on terms that license the generic manufacturer to sell prior to the date of expiry of the disputed patent(s).").

91. 21 U.S.C. §§ 355(j)(2)(A)(vii)(III)–(IV) (2018).

92. There is one exception. FDA will not permit the omission if the generic drug would be less safe and effective than the reference listed drug for its remaining labeled uses. 21 C.F.R. § 314.127(a)(7) (2020). In these cases, the generic company must include labeling that describes the infringing use, which in turn requires it to challenge the patent or wait for patent expiry. *See id.* But FDA rarely makes this finding. Erika Lietzan, *Paper Promises for Drug Innovation*, 25 GEO. MASON L. REV. 168, 186 n.91 (2018).

93. 21 U.S.C. § 355(b)(2)(B) (2018).

4. Other Statutory Exclusivity

Two other statutory exclusivities bear mentioning. *First*, federal law offers exclusivity for drugs intended to treat rare diseases, also known as “orphan drugs.”⁹⁴ An orphan drug receives seven years of orphan drug exclusivity.⁹⁵ This exclusivity prevents approval of *full* applications (supported by their own data) as well as abbreviated applications. Also, like three-year exclusivity, orphan exclusivity can protect a new use of an already approved drug. *Second*, the statute provides six months of “pediatric exclusivity” if an innovator performs pediatric studies in response to a written request from FDA.⁹⁶ Pediatric exclusivity protects every approved product containing the active moiety studied.⁹⁷ It operates by extending other applicable exclusivity periods.⁹⁸ For example, five-year new-chemical-entity exclusivity will last for five and a half years, and seven-year orphan exclusivity will last for seven and a half years. A paragraph III certification, which would ordinarily delay FDA approval until patent expiry, will delay FDA approval another six months past patent expiry.

C. Marketing, Prescribing, and Dispensing of Medicines

FDA limits virtually every new medicine to dispensing only by prescription.⁹⁹ The prescription must be written by a practitioner licensed under state law to administer the drug.¹⁰⁰ State laws govern the licensure of prescribers and pharmacists, and they take differing approaches with respect to who may prescribe and the information to be included on a

94. An orphan drug is one intended to treat a disease that affects fewer than 200,000 persons in this country. It is also one that the innovator does not expect will produce sales allowing recovery of the costs of its own research and development. *Id.* §§ 360bb(a)(1)–(2).

95. *Id.* § 360cc(a).

96. *Id.* § 355a. The innovator does not have to apply for approval of a pediatric formulation or use to qualify for exclusivity; the award is tied to performing research requested by FDA. *See* FDA, *Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act: Frequently Asked Questions on Pediatric Exclusivity (505A)*, at Q8, <https://www.fda.gov/drugs/development-resources/qualifying-pediatric-exclusivity-under-section-505a-federal-food-drug-and-cosmetic-act-frequently> [https://perma.cc/EA7X-BUZ4]. Certain other conditions must also be met.

97. FDA, *supra* note 96, at Q9.

98. *Id.* at Q9; In 2012, Congress added another exclusivity provision to the statute that operates the same way. Section 505E of the statute provides a five-year extension of statutory exclusivity periods for “qualified infectious disease products,” which are new antibiotic and antifungal products intended to address serious or life-threatening infections. 21 U.S.C. § 355f (2018).

99. Lars Noah, *Reversal of Fortune: Moving Pharmaceuticals from Over-the-Counter to Prescription Status?*, 63 VILL. L. REV. 355, 359 (2018).

100. 21 U.S.C. § 353(b)(1)(B) (2018).

prescription form.¹⁰¹ Prescribers may specify either branded drugs or generic drugs. A doctor could write the brand name, for instance, or identify a particular generic company's drug containing a particular active ingredient. Or the doctor could simply identify the active ingredient, which will usually lead the pharmacist to dispense one of the available generic drugs.

Innovators promote their drugs to doctors, payers, and patients. Generic companies rarely promote generic drugs to doctors and patients.¹⁰² They do, however, promote these drugs to payers, identifying the reference listed drugs they have copied and the lower prices they offer.¹⁰³ Some generic companies that file abbreviated applications under § 505(b)(2) brand these products and promote them to doctors and patients based on their distinguishing features and clinical profiles.¹⁰⁴ Others—such as those who used § 505(b)(2) to avoid a patent but want to position their products as near-duplicates of more expensive branded alternatives—might focus on price promotion. FDA's rules governing

101. Patricia Zettler, *Toward Coherent Federal Oversight of Medicine*, 52 SAN DIEGO L. REV. 427, 434–37 (2015) (discussing traditional authority of states over practice of medicine); Patricia Zettler, *Pharmaceutical Federalism*, 92 IND. L.J. 845, 849 and 849 n.15 (2017) (discussing state authority over practice of pharmacy).

102. Association for Accessible Medicines (AAM), *Generic Medicines*, <https://accessiblemeds.org/generic-medicines> [<https://perma.cc/43JJ-MGEM>] (stating that “generic manufacturers rarely spend money on advertising and marketing”). AAM is the trade association representing manufacturers of generic and biosimilar medicines. Sometimes generic companies *do* promote their generic drugs, however, as a review of FDA's enforcement actions makes clear. *E.g.*, Letter from Andrew S.T. Haffer, Div. Dir. Office of Prescription Drug Promotion, to Samuel D. Waksal, Ph.D., Chairman & Chief Exec. Officer of Kadmon Pharms., Inc. (Nov. 18, 2013), [http://www.natap.org/2013/HCV/RibasphereWarningLetter\(1\).pdf](http://www.natap.org/2013/HCV/RibasphereWarningLetter(1).pdf) [<https://perma.cc/ZSZ2-5AVU>] (citing a generic company for promotion for a new use, by describing a broader patient population); Letter from Jessica N. Cleck Derenick, Team Leader Office of Prescription Drug Promotion, to Carol Childers, Dir. Teva Neuroscience, Inc., <https://www.pharmamedtechbi.com/~media/Supporting%20Documents/The%20Pink%20Sheet%20DAILY/2013/April/Teva%20clozapine%20untitled%20letter%20040813.pdf> [<https://perma.cc/88SZ-CYYB>] (citing a generic company for unsubstantiated superiority claims, omission of material facts, and minimization of risks).

103. The author has reviewed product catalogues distributed by generic drug companies.

104. *E.g.*, Brian Marson, *Upsher-Smith Launches Osteoporosis Therapy Fortical in U.S.*, PINK SHEET (Aug. 15, 2005), <https://pink.pharmaintelligence.informa.com/PS062726/UpsherSmith-Launches-Osteoporosis-Therapy-Fortical-In-US> [<https://perma.cc/S6XR-BA6U>] (noting that manufacturer of Fortical (calcitonin-salmon)—approved through a 505(b)(2) application—planned to “begin aggressively promoting to physicians through sales force detailing, national conventions, professional advertising and other promotion” and would focus on the “unique aspects of nasal calcitonin” and positioning its product as an “economical alternative to existing osteoporosis therapies”).

prescription drug advertising and promotion apply to both innovators and generic companies.¹⁰⁵

Once launched, generic drugs quickly take over the market.¹⁰⁶ Conventional wisdom holds that “therapeutic equivalence” evaluations assigned by FDA to generic drugs drive this market penetration.¹⁰⁷ If FDA designates two drugs as therapeutically equivalent, this means that the products can be “substituted”—that either can be dispensed instead of the other—with the full expectation that the substituted product can be expected to have the same clinical effect and safety profile as the prescribed product” when administered to patients under the conditions specified in its labeling.¹⁰⁸ Generic drugs approved through conventional (not petitioned) ANDAs are usually deemed “therapeutically equivalent” to their reference drugs.¹⁰⁹ Every state either permits or requires pharmacists to dispense a therapeutically equivalent generic drug when a doctor prescribes an innovator’s drug by its brand name, unless the doctor has said not to.¹¹⁰

105. See generally Kathleen Sanzo & Stephen Paul Mahinka, *Prescription Drug Promotion and Marketing*, in FOOD AND DRUG LAW AND REGULATION (Adams et al. eds., 3d ed. 2015) (describing FDA’s rules governing prescription drug advertising and promotion).

106. Henry Grabowski et al., *Recent trends in brand-name and generic drug competition*, 17 J. MED. ECON. 207, 212 (Fig. 4) (2013) (showing that approval of a generic drug leads to a roughly 70 percent market share loss for innovators in situations where it leads to substitution); Murray L. Aitken et al., *The Regulation of Prescription Drug Competition and Market Responses: Patterns in Prices and Sales Following Loss of Exclusivity* 243, 250–51 (Nat’l Bureau of Econ. Research Working Paper No. 19487, 2013), <https://www.nber.org/chapters/c13094.pdf> [<https://perma.cc/R44L-8UUT>] (finding that six drugs that lost exclusivity between 2009 and 2013 lost 60% of their market share within (on average) three months of generic entry); Ralf Boscheck, *Intellectual Property Rights and the Evergreening of Pharmaceuticals*, 50 INTERECONOMICS REV. EUROPEAN ECON. POL’Y 221, 224 (2015) (“As patents expire, the first generic competitor typically enters the market with a 20 to 30 per cent discount relative to the branded product, capturing about 44 to 80 per cent of total sales within the first full year after launch.”).

107. E.g., *New York ex rel. Scheiderman v. Actavis PLC*, 787 F.3d 638, 642–43 (2d Cir. 2015) (stating that “generic competition depends heavily on state drug substitution”); *id.* at 649 (noting district court’s finding that innovator’s explicit purpose in introducing an extended release version of its product “was to impede generic competition and to avoid the patent cliff—which occurs at the end of a drug’s exclusivity period when generics gain market share through state substitution laws”).

108. ORANGE BOOK, *supra* note 43, at vii.

109. Lietzan, *Paper Promises*, *supra* note 92, at 187. With rare exceptions, products approved under § 505(b)(2) are not deemed therapeutically equivalent to their reference products. See Kurt Karst, *Citizen Petition Requests Rulemaking Process for 505(b)(2) NDA Therapeutic Equivalence Rating Decisions*, MARTINDALE (Sept. 12, 2011), https://www.martindale.com/health-care-law/article_Hyman-Phelps-McNamara-PC_1341198.htm [<https://perma.cc/7EB8-RV8B>] (listing exceptions).

110. See Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 175 (2016) (“States have also made it easier for generics to reach the market through their enactment of drug product selection (DPS) laws. Such laws, in effect in all fifty states today, . . . allow (and in some cases require) pharmacists—absent a doctor’s contrary

Although it is tempting to assume that generic companies depend on automatic substitution for market share, the reality may be a bit more nuanced. Only 15 states expressly require substitution.¹¹¹ In these states, pharmacy law will require the pharmacist to substitute the generic drug for the prescribed brand drug, even if the payer is agnostic. But most states have permissive laws. Of these, 32 states expressly permit it,¹¹² 2 permit it indirectly by statute,¹¹³ and 1 permits it indirectly through the structure

instructions—to fill prescriptions for brand-name drugs with generic versions.”); *Scheidman*, 787 F.3d at 645 (stating that every state either “permit[s] or require[s] pharmacists to dispense a therapeutically equivalent, lower-cost generic drug in place of a brand drug absent express direction from the prescribing physician that the prescription must be dispensed as written”); *see also* Federal Trade Commission’s Brief as *Amicus Curiae* at 6, *Mylan Pharmaceuticals v. Warner Chilcott Pub. Ltd. Co.*, No. 12-3821, 2015 WL 1736957 (E.D. Penn. Apr. 16, 2015) (“Today, all states facilitate competition through laws that allow a pharmacist to substitute an AB-rated generic drug when presented with a prescription for its brand equivalent, unless a physician directs or the patient requests otherwise.”).

111. FLA. STAT. § 465.025(2) (2019); HAW. REV. STAT. § 328-92(a) (2019); KY. REV. STAT. ANN. § 217.822(1) (2019); ME. REV. STAT. ANN. tit. 32 § 13781 (2019); MINN. STAT. ANN. § 151.21 (West 2019); MINN. R. 9505.0340(H) (2020); NEV. REV. STAT. ANN. § 639.2583(1)(a) (West 2019); N.J. STAT. ANN. § 24:6E-7 (West 2016); N.Y. EDUC. LAW § 6816-a (McKinney 2019); 35 PA. STAT. AND CONS. STAT. ANN. § 960.3(a) (West 2019); 5 R.I. GEN. LAWS ANN. § 5-19.1-19 (West 2019); VT. STAT. ANN. tit. 18, § 405 (West 2019); 20-4 VT. CODE R. § 1400:10.19 (2020); VA. CODE ANN. § 65.2-603.1(B) (2019); W. VA. CODE § 30-5-12b(b) (2019); WIS. STAT. § 450.13(1s) (2018). Michigan requires substitution “when a purchaser requests a lower cost generically equivalent drug product.” MICH. COMP. LAWS § 333.17755 (2019).

112. ALA. CODE § 34-23-8(1) (2019); ALASKA STAT. ANN. § 08.80.295(a) (West 2019); ARIZ. REV. STAT. ANN. § 32-1963.01(A) (2019); ARK. CODE ANN. § 17-92-503(a)(1) (2019); CAL. BUS. & PROF. CIV. CODE § 4073(a) (West 2019); COLO. REV. STAT. ANN. § 12-42.5-122(1)(a) (2019); CONN. GEN. STAT. § 20-619(b) (2019); 24 DEL. CODE ANN. tit. 24, § 2549(a) (2020); GA. CODE ANN. § 26-4-81(a) (2019); IDAHO CODE § 54-1768 (2019); 225 ILL. COMP. STAT. § 85/25 (2019); IND. CODE § 16-42-22 (2019); IOWA CODE § 155A.32 (2020); KAN. STAT. ANN. § 65-1637(g)(1) (2019); MD. CODE ANN., HEALTH OCC. § 12-504 (d) (West 2019); MASS. GEN. LAWS ANN. ch. 112, § 12D (West 2019); MICH. COMP. LAWS ANN. § 333.17755 (West 2020); MISS. CODE ANN. § 73-21-117 (2019); MO. REV. STAT. § 338.056(1) (2019); MONT. CODE ANN. § 37-7-505(1) (2019); NEB. REV. STAT. ANN. § 38-28,111 (West 2019); N.H. REV. STAT. ANN. § 318:47-d (2019); N.M. STAT. ANN. § 26-3-3 (2019); N.C. GEN. ANN. STAT. § 90-85.28(a) (West 2019); N.D. CENT. CODE ANN. § 19-02.1-14.1(3) (West 2011); OHIO REV. CODE ANN. § 4729.38(B) (West 2020); OR. REV. STAT. § 689.515(2) (2019); S.C. CODE ANN. § 39-24-30(A) (2019); S.D. CODIFIED LAWS § 58-29E-8 (2020); TENN. CODE ANN. § 53-10-202 (2020); TEX. OCC. CODE ANN. § 562.008(b) (West 2019); UTAH CODE ANN. § 58-17b-605(b) (West 2019); WYO. STAT. ANN. § 33-24-147(b) (2019).

113. Louisiana prohibits improper substitution. LA. STAT. ANN. § 37:1241(17) (2019) (prohibiting substituting against a prescriber’s or purchaser’s consent). Oklahoma prohibits pharmacists from substituting, “without authority of the prescriber or purchaser, any like drug, medicine, chemical or pharmaceutical preparation.” OKLA. STAT. ANN. tit. 59, § 353.24(B)(4) (West 2019) (“No pharmacist being requested to sell, furnish or compound any drug, medicine, chemical or other pharmaceutical preparation, by prescription or otherwise, shall substitute or cause to be substituted for it, without authority of the prescriber or purchaser, any like drug, medicine, chemical or pharmaceutical preparation.”).

of the approved prescription form.¹¹⁴ In these states, if a generic drug is therapeutically equivalent to the prescribed drug and the payer requires its use, the permissive state pharmacy law makes it possible for a pharmacist to substitute, in accordance with the patient's insurance, without consulting the physician. In these cases, the patient's insurance drives the drug selection. State law just makes it possible to comply with the insurance without contacting the doctor.¹¹⁵

Payers may also adopt strategies to steer doctors and patients to less expensive drugs that are not therapeutically equivalent.¹¹⁶ These alternative drugs can include generic copies of older innovative drugs, as well as therapeutically similar (rather than equivalent) drugs, such as those approved through the § 505(b)(2) mechanism.¹¹⁷ Thus, even if a doctor specifies a branded product, the patient's insurance might prompt a conversation among the doctor, pharmacist, and patient, leading to the dispensing of a less expensive alternative made by a generic company. Whether FDA has designated that drug as therapeutically equivalent to the doctor's initial choice of branded product may not matter.¹¹⁸

III. USE OF “EVERGREENING” IN THE LITERATURE

Writers who use the term “evergreening” focus on a combination of circumstances within the framework just described. Subpart A catalogues

114. Washington's prescription form contains a section where the prescriber must note “whether or not a therapeutically equivalent generic drug . . . may be substituted[.]” WASH. REV. CODE § 69.41.120(1) (2019). When filling Washington prescriptions specifying substitution is allowed or filling out-of-state prescriptions where no explicit instruction is noted, Washington pharmacists “may substitute a therapeutically equivalent generic drug . . .” *Id.*

115. Many insurers require their insured to use therapeutically equivalent generic drugs. *E.g.*, BOSTON MEDICAL CENTER HEALTHNET PLAN, *Pharmacy Programs*, <https://www.bmchp.org/I-Am-A/Provider/Pharmacy/Pharmacy-Programs> [<https://perma.cc/H436-APNQ>] (stating that once FDA has granted an A rating to the generic drug, the plan will cover the brand product only if the patient has an allergy to an inactive ingredient in the generic drug or the patient has not responded adequately to at least two other covered drugs in the same class).

116. *See* Dana P. Goldman et al., Prescription drug cost sharing: associations with medication and medical utilization and spending and health, 298 J. AM. MED. ASS'N 61, 61 (2007) (considering role of prior authorization, step therapy, closed formularies, and reference pricing—along with mandatory generic substitution—in driving the selection of lower cost alternatives).

117. *See* Joanna Shepherd, *Deterring Innovation: NY v. Actavis and the Duty to Subsidize Competitors' Market Entry*, 17 MINN. J.L., SCI. & TECH. 663, 688–92 (2016).

118. *See also* Jennifer N. Howard et al., *Influencers of generic drug utilization: A systematic review*, 14 RES. SOC. & ADMIN. PHARM. 619, 624 (2018) (noting that “formulary management” and “cost containment measures” have their “intended effect of increasing generic drug use” and that “federal and state health insurance policies” are a “major factor influencing broad changes in generic drug use by encouraging generic drug use in the Medicare and Medicaid programs”).

the definitions in the literature.¹¹⁹ Subpart B sorts the roughly three dozen examples that scholars put forward as illustrations of the concept. Subpart C describes the empirical studies that some say support "evergreening" allegations. Although this Article focuses on usage in the scholarly literature, similar usage of the metaphor appears in the popular press,¹²⁰ court decisions and filings,¹²¹ and policy writing.¹²²

119. Some use the term "evergreening" without explaining it, apparently assuming their audiences will understand the term from context. *E.g.*, Faisal I. Chaudhry, *Intellectual Property and the Global Crisis of Non-Communicable Disease*, 19 N.C. J.L. & TECH. 175 (2017) (using the term several times without definition); Rochelle Cooper Dreyfuss, *Nonobviousness: A Comment on Three Learned Papers*, 12 LEWIS & CLARK L. REV. 431, 437 (2008) ("Chemical cases have their own standard (which involves a different use of hindsight), and for pharmaceuticals, the court is more likely to uphold a patent on a new therapeutic agent than to allow the patentee to engage in 'evergreening.'") (citing Rebecca S. Eisenberg, *Pharma's Nonobvious Problem*, 12 LEWIS & CLARK L. REV. 375 (2008) but not explaining the term); Sam F. Halabi, *International Intellectual Property Shelters*, 90 TUL. L. REV. 903, 920 (2016) ("The text of TPP states that patentability must be permitted for 'new uses of a known product, new methods of using a known product, or new processes of a known product,' suggesting it would include products that did not improve the known product and that could encompass, in part, evergreening strategies by pharmaceutical firms.") (not defining the term); Yaniv Heled, *Why Primary Patents Covering Biologics Should Be Unenforceable Against Generic Applicants Under the Biologics Price Competition and Innovation Act*, 21 ANNALS HEALTH L. 211, 220 (2011) (proposing to make certain patents unenforceable against biosimilar products, but permitting enforcement of "secondary patents covering inventions stemming from" continued research, though adding that this might lead to "litigation involving secondary patents (with all of its risks of evergreening and patent abuse)") (not defining the term); Lisa Larrimore Ouellette, *Patent Experimentalism*, 101 VA. L. REV. 65, 122 (2015) (stating that the Indian Supreme Court "recently affirmed the high bar for obtaining 'evergreening' patents" and—in footnote 238—noting that the decision involved "a patent on a cancer drug with enhanced stability and bioavailability," but not defining the term). Some writers describe circumstances that, they say, *others* call "evergreening." *E.g.*, Cynthia M. Ho, *A Collision Course Between TRIPS Flexibilities and Investor-State Proceedings*, 6 U.C. IRVINE L. REV. 395, 442 (2016) (stating "industry has a practice of sequentially patenting minor modifications or different uses of a drug after first obtaining a patent on the basic chemical compound in an attempt to maximize revenue," which "public health advocates" and "some governments including not only India, but also the EU, consider" to be "an inappropriate way of 'evergreening' patent profits").

120. *E.g.*, Rumman Ahmed & Amol Sharma, *Corporate News: Novartis in Fight for Cancer Pill*, WALL STREET J., Aug. 20, 2012, at B3; Editorial Board, *India's Novartis Decision*, N.Y. TIMES, Apr. 5, 2013, at A22; Melissa Healy, *Alzheimer's drug draws sharp criticism; Two experts call Aricept 23 mg's march to market 'perplexing' and 'depressing.'* L.A. TIMES, Mar. 23, 2012, at A12.

121. *E.g.*, AstraZeneca Pharm. LP v. Food & Drug Admin., 872 F. Supp. 2d 60, 89 (D.D.C. 2012) ("As the FDA notes, AstraZeneca's interpretation would result in an 'unwarranted evergreening of exclusivity.'").

122. And it has crept into policy writing. *E.g.*, Graham Dutfield, *Healthcare innovation and patent law's "pharmaceutical privilege": is there a pharmaceutical privilege? And if so, should we remove it?*, 12 HEALTH ECON. POL'Y & L. 453, 466 (2017); Tahir Amin & Aaron Kesselheim, *Secondary Patenting Of Branded Pharmaceuticals: A Case Study Of How Patents On Two HIV Drugs Could Be Extended For Decades*, 31 HEALTH AFF. 2286, 2286 (2012); *see generally* Thomas A. Faunce & Joel Lexchin, *'Linkage' pharmaceutical evergreening in Canada and Australia*, 4 AUSTRAL. & N.Z. HEALTH POL'Y 8, June 1, 2007.

A. *Definitions Offered*

Definitions of “evergreening” in the academic literature fall in three categories.¹²³ Some definitions focus only on actions of concern taken by innovators; most also mention extension of something; and a minority also talk about an objective or result relating to pricing or competition in the market. They disagree about what has been “evergreened” in the situations they describe: an invention,¹²⁴ a drug or product,¹²⁵ the drug’s price,¹²⁶ the drug’s patent or patent life,¹²⁷ the drug’s exclusivity,¹²⁸ the company’s profits¹²⁹ or monopoly,¹³⁰ or something else.¹³¹ But no matter which definition is in play, and what exactly has been “evergreened,” the scholarship consistently treats “evergreening” as bad. Almost without exception, scholars using the term “evergreening” criticize the actions.

123. For simplicity this Article uses the term “definition” even though some writers may feel they were offering something less formal, perhaps more of a description. Most definitions in the text derive from legal scholarship written by academic scholars. The footnotes cast a wider net.

124. *E.g.*, Ron A. Bouchard, *Qualifying Intellectual Property II: A New Innovation Index for Pharmaceutical Patents & Products*, 28 SANTA CLARA COMPUTER & HIGH TECH. L.J. 287, 402 (2012) (discussing a patentee that “evergreens an invention via successive patents”).

125. *E.g.*, Ron A. Bouchard et al., *Structure-Function Analysis of Global Pharmaceutical Linkage Regulations*, 12 MINN. J.L. SCI. & TECH. 391, 430 (2011) (“evergreening older products”); Andrew Hitchings et al., *Making Medicines Evergreen*, 345 BMJ, December 8, 2012, at 18, 20 (“evergreen medicine”).

126. *E.g.*, Robin Feldman, *May your drug price be evergreen*, 5 J.L. & BIOSCIENCES 590, 590 (2018).

127. *E.g.*, Steven Adamson, *Pharmaceutical Patent Wars, Reverse-Payment Settlements, and Their Anticompetitive Effects for Consumers*, 30 LOY. CONSUMER L. REV. 241, 250 (2018) (“patent evergreening”); Brook K. Baker & Katrina Geddes, *Corporate Power Unbound: Investorstate Arbitration of IP Monopolies on Medicines—Eli Lilly v. Canada and the Trans-Pacific Partnership Agreement*, 23 J. INTEL. PROP. L. 1, 26 (2015) (“evergreening patent”).

128. *E.g.*, Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT’L L. 317, 350 n.241 (2005) (evergreening of “marketing exclusivity”); Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J.L. & MED. 303, 306 (2008) (evergreening of “data exclusivity”).

129. *E.g.*, Ho, *Collision Course*, *supra* note 119 at 442 (evergreening “patent profits”); Cynthia M. Ho, *Reexamining Eli Lilly v. Canada: A Human Rights Approach to Investor-State Disputes?*, 21 VAND. J. ENT. & TECH. L. 437, 464 (2018) (“profits will continue (be ‘ever green’)”).

130. *E.g.*, Brook K. Baker, *International Collaboration on IP/Access to Medicines: Birth of South Africa’s Fix the Patent Laws Campaign*, 60 N.Y.L. SCH. L. REV. 297, 319 (2016) (“evergreen their patent monopolies”); Sean M. Flynn et al., *The U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement*, 28 AM. U. INT’L L. REV. 105, 156 (2012) (each new patent leads to a new patent term, thereby “‘evergreening’ monopoly rights on the underlying medical product”).

131. *E.g.*, Christopher M. Holman, *Biotechnology’s Prescription for Patent Reform*, 5 J. MARSHALL REV. INTEL. PROP. L. 318, 332 (2006) (companies evergreening “their proprietary position”); Lisa Larrimore Ouellette, Note, *How Many Patents Does It Take to Make A Drug- Follow-on Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMM. & TECH. L. REV. 299, 320 (2010) (evergreening the drug’s “patent protection”).

Some label it an "abuse" of patent law or "gaming" of the law.¹³² Many call the changes "trivial" or "frivolous."¹³³ Some call the innovators "unscrupulous."¹³⁴ Some call evergreening "problematic."¹³⁵ Some write

132. *E.g.*, Yaniv Heled, *Regulatory Competitive Shelters*, 76 OHIO ST. L.J. 299, 341 (2015) ("abuse . . . through such infamous practices as 'evergreening'"); Holman, *Biotechnology's Prescription*, *supra* note 131, at 332 (stating that patent applicants can "abuse" the patent prosecution process "by filing divisional patent applications incorporating new or revised claims to obtain multiple patents that all cover essentially the same invention," a "tactic referred to as 'evergreening' that has become especially associated with pharmaceutical inventions"); Yahong Li, *Intellectual Property and Public Health: Two Sides of the Same Coin*, 6 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 389, 397 (2011) ("'evergreening patents' are generally perceived as patent abuse"); Bryan Mercurio, *The Impact of the Australia-United States Free Trade Agreement on the Provision of Health Services in Australia*, 26 WHITTIER L. REV. 1051, 1092 n.115 (May 2005) (writing that the 30-month stay provisions in the United States "led to abuse of the patent system through evergreening tactics that delay the introduction of generic drugs"); Andrew F. Christie et al., *Patents Associated with High-Cost Drugs in Australia*, 8 PLOS ONE 4, April 2013, at 1, 1 (referring to "longstanding concerns about the misuse of patents by pharmaceutical companies to inappropriately extend their monopoly position"); Dutfield, *supra* note 122, at 466 ("incremental inventions may be regarded as examples of gaming the system by acquiring extended or new patent monopolies not justified by the minor level of inventive contribution or the possibly negligible added benefit to the public" and they are "commonly referred to as 'evergreening'"); William J. Bennett, Note, *Indian Pharmaceutical Patent Law and the Effects of Novartis AG v. Union of India*, 13 WASH. U. GLOBAL STUD. L. REV. 535, 544 (2014) (noting that "critics" call evergreening a "common abusive patenting practice").

133. *E.g.*, Mark A. Lemley, *Expecting the Unexpected*, 92 NOTRE DAME L. REV. 1369, 1393 (2017) ("pharmaceutical companies often obtain follow-on patents on trivial variants of their basic chemical once the initial patent is about to expire"); Daryl Lim, *Self-Replicating Technologies and the Challenge for the Patent and Antitrust Laws*, 32 CARDOZO ARTS & ENT. L.J. 131, 218 (2013) ("trivial changes are made to the drugs"); Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for A Public Goods Approach*, 13 MARQ. INTELL. PROP. L. REV. 1, 38–39 (2009) (discussing "minor improvements" made to an existing patent as "an excuse to prolong or 'evergreen' that same patented product," which he describes as having "low public health utility"); Tatum Anderson, *Rejected Novartis Cases Leave India's TRIPS Compliance Unchallenged*, INTELL. PROP. WATCH (Aug. 7, 2007), <https://www.ip-watch.org/2007/08/07/rejected-novartis-cases-leave-indias-trips-compliance-unchallenged/> [<https://perma.cc/U5C9-3D89>] ("[Section 3(d) of India's Patent Act] was drafted with the prevention of a particular practice in mind: evergreening, where pharmaceutical companies patent frivolous changes to their drugs in order to extend patent protection, thereby preventing generic companies from manufacturing cheaper drugs the poor can better afford.").

134. *E.g.*, Michael H. Davis, *Excluding Patentability of Therapeutic Methods, Including Methods Using Pharmaceuticals, for the Treatment of Humans Under Trade Related Aspects of Intellectual Property Rights Article 27(3)(a)*, 43 HOFSTRA L. REV. 185, 194 (2014) (defining "evergreening" as a process "by which unscrupulous pharmaceutical manufacturers file additional uses for drugs whose patents are immediately expiring—thus triggering an additional twenty-year period for each use, extending the effective patent term of the underlying drug"); *see also* Adamson, *supra* note 127, at 257–58 (describing "product hopping," which "makes use of patent evergreening" and is an "obstructionist" strategy).

135. *E.g.*, Janet Freilich, *The Paradox of Legal Equivalents and Scientific Equivalence: Reconciling Patent Law's Doctrine of Equivalents with the FDA's Bioequivalence Requirement*, 66 SMU L. REV. 59, 105 (2013) (stating that evergreening is "widely considered a negative behavior" and "an example of pharmaceutical companies exploiting loopholes in legislation to achieve a longer patent term than otherwise entitled" and adding that it is "problematic" because it "delays the market

of the need to prevent it or propose changes in the law to do so.¹³⁶ Critical language has crept into the popular press¹³⁷ as well as policymaking discussions.¹³⁸

1. Focus on Actions

First, some writers focus on actions taken by innovators: securing patents other than active ingredient patents, for instance, or introducing and patenting new products. Some also focus on listing new patents in the ORANGE BOOK, some focus on promotion of the new products, and some equate the term to “product hopping,” which they define in various ways.

entry of low-cost generic drugs”); Baker, *International Collaboration*, *supra* note 130, at 319 (“Extensive academic commentary suggests that such evergreening is a major problem.”); Timothy Bazzle, Note, *Pharmacy of the Developing World: Reconciling Intellectual Property Rights in India with the Right to Health: Trips, India’s Patent System and Essential Medicines*, 42 GEO. J. INT’L L. 785, 802 (2011) (“pernicious practice”); Lev D. Gabrilovich, *Motivating the Person of Ordinary Skill in the Art: Eli Lilly and Co. et al. v. Teva Parenteral Med., Inc. and the Federal Circuit’s Interpretation of the “Teaching, Suggestion, or Motivation” Test in Obviousness-Type Double Patenting*, 14 N.C. J.L. & TECH. ONLINE 271, 272 (2013) (“The pharmaceutical industry is plagued with evergreening.”).

136. *E.g.*, Srividhya Ragavan, *The (Re)newed Barrier to Access to Medication: Data Exclusivity*, 51 AKRON L. REV. 1163, 1183 (2018) (recommending that developing countries should start data exclusivity as soon as a chemical entity is the subject of a marketing application anywhere in the world, to “prevent evergreening of the data”); Roberto Romandini, *Flexibilities Under Trips: An Analysis of the Proposal for Reforming Brazilian Patent Law*, 15 J. MARSHALL REV. INTELL. PROP. L. 150, *passim* (2016) (discussing various ways to “prevent” evergreening); Sean B. Seymore, *Reinvention*, 92 NOTRE DAME L. REV. 1031, 1056–70, 1068 n.317 (2017) (proposing a new novelty paradigm and noting that it would “prevent evergreening”); *see also* Josef Drexl, *Real Knowledge Is to Know the Extent of One’s Own Ignorance: On the Consumer Harm Approach in Innovation-Related Competition Cases*, 76 ANTITRUST L.J. 677, 695 n.66 (2010) (stating that the PTO once “widely” granted “evergreening” patents, but “now such applications are subject to challenge under a more stringent non-obviousness test”).

137. *E.g.*, Editorial Board, *Have drug prices gotten too high? Combat games drugmakers play with patent laws*, NEWS PRESS (Fort Myers), July 21 2019, at A3 (“The pharmaceutical industry has shown contempt for this attempt at balance through a range of abusive tactics. . . . Evergreening involves making small alterations to a drug—a slight change to its chemical composition, say, or an external change as minor as adding a stripe to a pill—and then filing a new patent application.”).

138. *E.g.*, *Recent Developments Which May Impact Consumer Access to, and Demand for, Pharmaceuticals: Hearing Before the Subcomm. on Health of the Comm. on Energy & Commerce in the H. Comm. on Energy and Commerce*, 107th Cong. 139 (June 13, 2001) (statement of the National Association of Chain Drug Stores) (“We are also concerned with certain brand-name manufacturer ‘evergreening’ strategies”); *Insulin Access and Affordability: Hearing Before the S. Sp. Aging Comm.*, 116th Cong. 8 (statement of Jeremy A. Greene, Professor of Medicine and History of Medicine, Johns Hopkins University) (May 8, 2018) (“Several pharmaceutical industry analysts have described a repatenting tactic called evergreening”); *Hearing on President Trump’s Drug Pricing Plan Before the S. HELP Comm.*, 116th Cong. 16 (June 12, 2018) (statement of Sen. Collins) (“I’m also very concerned about the problems of gaming the patent system through strategies such as patent thickets and evergreening.”).

Securing multiple patents. Several write that “evergreening” is “obtaining multiple patents covering the same product.”¹³⁹ Some describe “evergreening” as “the securing of additional patents that expire after the expiration of the original patent for an invention.”¹⁴⁰ Another scholar, writing a report for Congress, states that “‘evergreening’ generally consists of obtaining multiple patents that cover different aspects of the same product” and is also known as “stockpiling” or “layering.”¹⁴¹

Making and patenting changes. Scholars say “evergreening” occurs “when pharmaceutical companies take existing drugs, alter them slightly, and get them approved.”¹⁴² Or they say “evergreening” is “used to label practices where a small change is made to an existing product and claimed as a new invention.”¹⁴³ Some say “evergreening” is the same as “patent stacking” and involves “introduc[ing]—and seek[ing] additional patent protection for—sustained release formulations that require less frequent dosing or a slightly modified form of the active ingredient with purportedly greater safety or effectiveness.”¹⁴⁴ One says “‘evergreening’ [is] a common practice used by drug companies to obtain additional patents for small improvements to previously patented compounds.”¹⁴⁵ Another writes that a company “evergreens” its “patents by filing patent applications with marginally different applications or modalities from the protected patents.”¹⁴⁶ Another says “evergreening” is a “strategy” by which patent holders apply “for patents for slight variations of the first pharmaceutical patent, for instance, with regard to the specific new uses of the compound, production methods, different crystalline forms,

139. Mark A. Lemley, *What Ifs and Other Alternative Intellectual Property and Cyberlaw Story: Ignoring Patents*, 2008 MICH. ST. L. REV. 19, 30 (2008); see also Randy Berholtz et al., *Where to File: A Framework for Pharmaceutical and Biotechnology Companies to Develop an International Patent Filing Strategy*, 37 T. JEFFERSON L. REV. 225, 276 (2015) (“multiple patents on the same drug”).

140. Lee Petherbridge & Jason Rantanen, *The Pseudo-Elimination of Best Mode: Worst Possible Choice?*, 59 UCLA L. REV. DISC. 170, 176 (2012); see also Justine Amy Park, Note, *Product Hopping: Antitrust Liability and A Per Se Rule*, 35 CARDOZO ARTS & ENT. L.J. 745, 755 n.85 (2017) (equating “evergreening” and “stacking patents”).

141. JOHN R. THOMAS, CONG. RESEARCH SERV. R40917, PATENT “EVERGREENING”: ISSUES IN INNOVATION AND COMPETITION 1 (2009).

142. Ryan Abbott, *Balancing Access and Innovation in India’s Shifting IP Regime*, 35 WHITTIER L. REV. 341, 344 (2014).

143. Ryan Abbott, *Of Evergreening and Efficacy: The Glivec Patent Case*, GESPAM, 3 (April 29, 2013), <https://ssrn.com/abstract=2258904> [<https://perma.cc/SQB4-A5G8>].

144. Lars Noah, *Product Hopping 2.0: Getting the FDA to Yank Your Original License Beats Stacking Patents*, 19 MARQ. INTELL. PROP. L. REV. 161, 166 (2015).

145. Cynthia M. Ho, *A New World Order for Addressing Patent Rights and Public Health*, 82 CHI.-KENT L. REV. 1469, 1512 (2007).

146. Sam F. Halabi, *Multipolarity, Intellectual Property, and the Internationalization of Public Health Law*, 35 MICH. J. INT’L L. 715, 757 (2014).

combinations with other drugs, the dosage regime or reformulations, at the end of the first patent term.”¹⁴⁷

And listing the patents. One scholar (now in practice) writes that “evergreening” refers to the “process” whereby “brand name manufacturers obtain secondary patents on incremental improvements to their products and then add those patents to the ORANGE BOOK listing for their licensed drugs.”¹⁴⁸ Others state that “‘evergreening’ [is] the process by which pharmaceutical companies file a number of patents on minor improvements to their drugs and then list those patents in the ORANGE BOOK.”¹⁴⁹

And taking steps to “shift” customers to the new product. One writes that “evergreening” occurs when drug companies “patent a closely related compound when the original patented compound is set to expire and devote a significant marketing campaign to shift the consumers to the new patented drug.”¹⁵⁰ Others describe “evergreening” as involving two steps: “(1) reformulating the product in a way that makes a generic version of the original not substitutable; and (2) encouraging doctors to write prescriptions for the reformulated, rather than the original, product.”¹⁵¹

Which is sometimes also described as “product hopping.” Several say “evergreening” is the same as “product hopping” and “line extension,” and “refers to a drug company’s reformulation of its product.”¹⁵² According to another, “ever-greening” or “product hopping” is a “trick” in which “a company produces a ‘me too’ drug that copies its *own* successful drug when its patent is set to expire.”¹⁵³ Another says “evergreening” is the same as “product hopping” and occurs when a company obtains “a series of patents all relating to the same drug, with

147. Josef Drexler, *Real Knowledge Is to Know the Extent of One’s Own Ignorance: On the Consumer Harm Approach in Innovation-Related Competition Cases*, 76 ANTITRUST L.J. 677, 695 n.66 (2010).

148. Anna B. Laakmann, *The Hatch-Waxman Act’s Side Effects: Precautions for Biosimilars*, 47 LOY. L.A. L. REV. 917, 928 (2014).

149. Freilich, *Paradox*, *supra* note 135, at 74–75; see also Ron A. Bouchard et al., *Empirical Analysis of Drug Approval-Drug Patenting Linkage for High Value Pharmaceuticals*, 8 NW. J. TECH. & INTELL. PROP. 174, 181 n.45 (2010) (referring to comparable provisions in Canadian law when defining “evergreening” as “undue extension of the statutory monopoly attached to drug product by means of listing on the patent register multiple patents with obvious or uninventive modifications”).

150. Xuan-Thao Nguyen, *Zombie Patents and Zombie Companies with Patents*, 69 FLA. L. REV. 1147, 1154 (2017).

151. Carrier & Shadowen, *supra* note 110, at 171.

152. Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1016 (2010); see also Carrier & Shadowen, *supra* note 110, at 171.

153. Eugene McCarthy, *The Pharma Barons: Corporate Law’s Dangerous New Race to the Bottom in the Pharmaceutical Industry*, 8 MICH. BUS. & ENTREPRENEURIAL L. REV. 29, 53 (2018).

the later patents claiming merely minor variations in dosage and packing."¹⁵⁴ "Patent evergreening" includes "strategic product hopping."¹⁵⁵ Evergreening is the same as "product hopping," a recent article claims, and it refers to "shifting market demand to a new formulation of a drug."¹⁵⁶ Two scholars write that "product hopping" is a "variant of evergreening" that involves making a "small change" to an approved drug "right as its patents or regulatory exclusivities are about to expire, and introduc[ing] the new formulation as an entirely new drug. . . . generally protected by new patents," after which the company "forces a market shift away from the old drug—just as it is approaching its patent cliff."¹⁵⁷

2. Focus on "Extension" of Something

Second, most writers define "evergreening" as trying to "extend" something or doing so—a drug's patent coverage, its effective patent life, its exclusivity, the company's monopoly power, or even patents themselves. Some use verbs such as "prolonging," "refreshing," or "maintaining"—rather than "extending"—but the idea is the same.

Extension. One writer says that "evergreening" is an "extension tactic" in which "pharmaceutical companies succeed in patenting new formulations and applications of a drug."¹⁵⁸

Extending patents themselves. Two others write that a company seeks to "evergreen" patents if it seeks to "extend [its] patents on weak grounds."¹⁵⁹

Refreshing a drug's patents. One scholar has used the concept of "refreshing" patents in several papers, writing, for instance, that "evergreening" refers to "patent holders' attempts to refresh their patents by patenting updated versions, alternative delivery methods, or other variations of the original product."¹⁶⁰ In a subsequent paper, she writes that "evergreening" is the "practice of attempting to refresh one's patents by patenting extended release versions, alternative delivery methods, or

154. Thomas F. Cotter, *Patents, Antitrust, and the High Cost of Health Care*, 13 ANTITRUST SOURCE 1, 3–4 (2014).

155. Dmitry Karshedt, *The More Things Change: Improvement Patents, Drug Modifications and the FDA*, 104 IOWA L. REV. 1129, 1141 n.64 (2019) (quoting Thomas, *supra* note 141).

156. Jordan Paradise, *Regulatory Silence at the FDA*, 102 MINN. L. REV. 2383, 2398 (2018).

157. Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 499, 527 (2016).

158. Sarah Harding, *Perpetual Property*, 61 FLA. L. REV. 285, 305 (2009).

159. Anupam Chander & Madhavi Sunder, *The Battle to Define Asia's Intellectual Property Law: From TPP to RCEP*, 8 U.C. IRVINE L. REV. 331, 346 (2018).

160. Robin Feldman, *Rethinking Rights in Biospace*, 79 S. CAL. L. REV. 1, 30 (2005).

other variations of the original product.”¹⁶¹ Others have picked up the word “refresh,” for instance, writing that “evergreening” means the “attempt by patentees to refresh their expiring patents with new ones by making minor modifications to subject matter that should go to the public domain.”¹⁶²

Extending a drug’s patent coverage, patent protection, or intellectual property protection. One scholar says that “evergreening” refers to “filing for improvement patents,” which means that “patent coverage” will be “extended.”¹⁶³ Another claims that “evergreening” is the “strategy adopted by patentees who seek to extend their period of patent protection by applying for secondary patents over related or derivative technologies.”¹⁶⁴ One scholar asserts that companies adopt “‘evergreening’ strategies that add new patents to their quivers as old ones expire” to “prolong their effective periods of patent protection.”¹⁶⁵ “Evergreening,” according to another, means “maintaining patent protection on a therapeutic compound for multiple patent terms,” which companies can accomplish “by devising new methods for using the compound to treat disease, by creating new dosage forms, or by incorporating the compound into new dosage media (such as slow-release capsules or a patch).”¹⁶⁶ Another article defines “‘evergreening’ [as] the practice of obtaining new patents on minor variations of, or improvements to, an existing pharmaceutical, principally to extend a manufacturer’s

161. Robin Feldman et al., *Empirical Evidence of Drug Pricing Games—A Citizen’s Pathway Gone Astray*, 20 STAN. TECH. L. REV. 39, 50 n.39 (2017) (citing Robin Feldman, *RETHINKING PATENT LAW* 170–77 (2012)).

162. Seymore, *Reinvention*, *supra* note 136, at 1069 n.317.

163. Karl F. Jorda, *Patent and Trade Secret Complementariness: An Unsuspected Synergy*, 48 WASHBURN L.J. 1, 24 (2008).

164. Dipika Jain, *Gene-Patenting and Access to Healthcare: Achieving Precision*, 36 HOUS. J. INT’L L. 101, 135 n.243 (2014) (citing Robert Chalmers, *Evergreen or Deciduous? Australia Trends in Relation to the ‘Evergreening’ of Patents*, 30 MELB. U. L. REV. 29, 29 (2006)); *see also* Rajarshi Banarjee, Note, *The Success of, and Response to, India’s Law Against Patent Layering*, 54 HARV. INT’L L.J. ONLINE 204, 207 (2013) (“evergreening” refers to the various “practices” used by drug companies “to extend the period of patent protection available to their products”); Lisa Cosgrove et al., *Digital aripiprazole or digital evergreening? A systematic review of the evidence and its dissemination in the scientific literature and in the media*, 24 BMJ EVID.-BASED MED. 231, 236 (2019) (defining “evergreening” as “a strategy used by industry to effectively extend patent protection by making small changes to existing products, changes that have almost no added benefit to the patient”).

165. Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 354 (2007); *see also* Ouellette, *How Many Patents*, *supra* note 131, at 305 (adopting Eisenberg definition).

166. Rochelle C. Dreyfuss, *Creative Lawmaking: A Comment on Lionel Bently*, Copyright, Translations, and Relations Between Britain and India in the Nineteenth and Early Twentieth Centuries, 82 CHI.-KENT L. REV. 1243, 1247 (2007).

claims of patent protection indefinitely."¹⁶⁷ And another says "evergreening" means the "legal process of extending intellectual property protection by patenting 'multiple aspects of, or incremental improvements to a single drug, so that the last patent expires well after the first.'"¹⁶⁸

Extending a drug's patent life or patent term (singular noun). One scholar describes "evergreening" as "artificially extending the life of a patent or other exclusivity by obtaining additional protections to extend the monopoly period."¹⁶⁹ According to another, "'evergreening' strategies . . . artificially extend the date a medication officially goes off-patent."¹⁷⁰ Two others write that "evergreening" is "making trivial and needless modifications to patented medicines in order to extend the term of patent protection or exclusivity."¹⁷¹

Or "effectively" doing so. One article says that "'evergreening' refers to attempts by owners of pharmaceutical product patents to effectively extend the term of those patents by obtaining related patents on modified forms of the same drug, new delivery systems for the drug, new uses of the drug, and the like."¹⁷² According to another,

167. Glynn S. Lunney, Jr., *FTC v. Actavis: The Patent-Antitrust Intersection Revisited*, 93 N.C. L. REV. 375, 420 n.198 (2015).

168. Adamson, *supra* note 127, at 250 n.37; *id.* at 258 ("patent evergreening" involves making "minor variations to existing drugs to extend their patent coverage"); *see also* Jonathan D.M. Atkinson & Rachel S. Moodie, *Legitimate Patent Extension or Patent System Abuse?*, 2 PHARM. PAT. ANALYST 317, 318 (2013) ("The term 'evergreening' is used to describe a variety of legal and business strategies by which patent proprietor extend their patent rights.").

169. Feldman, *May Your Drug Price*, *supra* note 126, at 596; *see also* Mrudula Bele & Amar Latif, *Exploring the Provisions for Precluding Patent Evergreening: Path Forward after the Glivec Saga* 5 n.5 (WIPO Academy, University of Turin and ITC-ILO - Master of Laws in IP - Research Papers Collection, 2014), <https://ssrn.com/abstract=2856909> [<https://perma.cc/845C-LT9U>] (defining evergreening as "a variety of legal and business strategies used by which the life of the patents which are about to expire is extended").

170. Christine D. Galbraith, *Dying to Know: A Demand for Genuine Public Access to Clinical Trial Results Data*, 78 MISS. L.J. 705, 759 (2009).

171. Shannon Gibson & Barbara von Tigerstrom, *Orphan drug incentives in the pharmacogenomic context: policy responses in the US and Canada*, 2 J.L. & BIOSCIENCES 263, 278 (2015); *see also* Mohammed El-Said, *The Morning After: TRIPS-Plus, FTAs, and WikiLeaks: Fresh Insights on the Implementation and Enforcement of IP Protection in Developing Countries*, 28 AM. U. INT'L L. REV. 71, 90 (2012) (defining "evergreening" as securing patent protection on a new use of an already known and approved drug, "thereby extending the patent protection term substantially").

172. Janice M. Mueller & Donald S. Chisum, *Enabling Patent Law's Inherent Anticipation Doctrine*, 45 HOUS. L. REV. 1101, 1106 (2008); *see also* Daniel Gervais, *The Patent Option*, 20 N.C. J.L. & TECH. 357, 378 n.82 (2019) (quoting this definition); Inderjit Bansal et al., *Evergreening—A Controversial Issue in Pharma Milieu*, 14 J. INTELL. PROP. RTS. 299, 299 (2009) ("evergreening" as "protecting a large number of inventive aspects over the basic invention" while "avoiding any imminent double patent rejection," thus "leading to extension of patent terms to a further 20 year term for a single drug product").

“evergreening” is a process by which companies “file additional uses for drugs whose patents are immediately expiring—thus triggering an additional twenty-year period for each use, extending the effective patent term of the underlying drug.”¹⁷³ “Evergreening practices” adopted by companies, writes one legal scholar, are “various practices to extend the effective term of patent protection on their drugs.”¹⁷⁴ Elsewhere he writes that “‘evergreening’ [is] a set of tactics used by firms to extend effective patent protection on a drug.”¹⁷⁵ And in a third piece, he writes that “‘evergreening’ means trying to ‘extend the effective patent protection on a product by acquiring ancillary patents that cover the commercial product, methods of use, or other aspects other than the product itself.’”¹⁷⁶ Others say “‘evergreening’ [is] the practice of extending the effective life of drugs by successively patenting minor variants of them.”¹⁷⁷ Another similarly writes that “‘evergreening of patents’ means the ‘patenting of slight modifications that, in effect, extend the life of the original patent.’”¹⁷⁸

Extending a drug’s exclusivity period or a company’s period of exclusive or proprietary control. According to one scholar, “evergreening” occurs when companies “attempt to extend the effective period of exclusivity of existing patents by patenting minor variations.”¹⁷⁹ Another claims that the term “refers generally to strategies that brand companies use to maintain exclusivities for their products.”¹⁸⁰ Another writes that “evergreening” refers to “a wide range of pharmaceutical firm strategies for extending the exclusive market for a drug including . . .

173. Davis, *Excluding Patentability*, *supra* note 134, at 194.

174. W. Nicholson Price II, *The Cost of Novelty*, 119 COLUM. L. REV. 1, 40 (forthcoming 2020); *see also* Kristen C. Buteau, Note, *Deuterated Drugs: Unexpectedly Nonobvious?*, 10 J. HIGH TECH. L. 22, 66–67 n.269 (2009) (“‘Evergreening’ is a strategy whereby patentees try to prolong the effective market life of a pharmaceutical by filing for ‘secondary’ or ‘follow-on’ patents.”) (citing Michael Enzo Furrow, *Pharmaceutical Patent Life-Cycle Management After KSR v. Teleflex*, 63 FOOD & DRUG L.J. 275, 277 (2008)).

175. W. Nicholson Price II, *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, 55 B.C. L. REV. 491, 522 (2014).

176. W. Nicholson Price II, *Regulating Secrecy*, 91 WASH. L. REV. 1769, 1777 n.43 (2016).

177. Rochelle Dreyfuss & Esteban Donoso, *On Aiding Technological Development: The Max Planck Declaration on Patent Protection*, 6 U.C. IRVINE L. REV. 321, 325 (2016).

178. Rudolf V. Van Puymbroeck, *Beyond Sex: Legal Reform for HIV/AIDS and Poverty Reduction*, 15 GEO. J. ON POVERTY L. & POL’Y 781, 815 (2008).

179. Peter Lee, *Reconceptualizing the Role of Intellectual Property Rights in Shaping Industry Structure*, 72 VAND. L. REV. 1197, 1221 (2019); *see also* Jennifer D. Cieluch, *The FTC Has A Dog in the Patent Monopoly Fight: Will Antitrust’s Bite Kill Generic Challenges?*, 14 DUKE L. & TECH. REV. 1, 19 (2015) (stating that innovators “attempt to extend the patent exclusivity of their drugs” through “evergreening”—or “filing secondary patents”).

180. Dmitry Karshedt, *The More Things Change: Improvement Patents, Drug Modifications and the FDA*, 104 IOWA L. REV. 1129, 1215 n.491 (2019).

patenting peripheral aspects of drugs, like their coating or normal metabolites, in order to extend market exclusivity.”¹⁸¹ “Market exclusivity extensions,” writes one scholar, can “occur via a process called ‘patent evergreening.’”¹⁸² Two others define “evergreening” as “extending the basic pharmaceutical protection with less innovative modifications that keep the drug under proprietary control for a longer period of time.”¹⁸³ And another maintains that “evergreening” occurs when “companies secure successive patents to extend the effective period of their exclusive control over a drug.”¹⁸⁴

3. Focus on the Market

Third, some writers also tie the term to objectives or results relating to power, pricing, revenue, or competition in the market.

Market power. One scholar writes that “evergreening” refers to companies “extending their market power over drugs by filing newer patents covering related subject matter.”¹⁸⁵ Another asserts that company “evergreening” strategies are “primarily designed merely to maintain their market dominance.”¹⁸⁶ Another uses the term “evergreening” to refer to “practices aimed at prolonging an original product’s market power.”¹⁸⁷

Monopoly. According to one scholar, “evergreening” strategies are “efforts to extend the period of patent protections through incremental modifications” to a product, and they “may help maintain monopolies.”¹⁸⁸ Another defines “evergreening” as “the practice of taking out new patents

181. Sam F. Halabi, *The Drug Repurposing Ecosystem: Intellectual Property Incentives, Market Exclusivity, and the Future of “New” Medicines*, 20 YALE J.L. & TECH. 1, 43 (2018); see also Saby Ghoshray, *3(d) View of India’s Patent Law: Social Justice Aspiration Meets Property Rights in Novartis v. Union of India & Others*, 13 J. MARSHALL REV. INTELL. PROP. L. 719, 722 n.2 (2014) (defining “evergreening” as “the slew of business strategies and legal maneuverings to extend market exclusivity of products, and in the process continuing to extract monopoly rent-seeking practices”).

182. Aaron S. Kesselheim, *Think Globally, Prescribe Locally: How Rational Pharmaceutical Policy in the U.S. Can Improve Global Access to Essential Medicines*, 34 AM. J.L. & MED. 125, 129 (2008).

183. Robert C. Bird & Daniel R. Cahoy, *The Emerging BRIC Economies: Lessons from Intellectual Property Negotiation and Enforcement*, 5 NW. J. TECH. & INTELL. PROP. 400, 417 (2007).

184. Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India’s Pharmaceutical Sector*, 97 CAL. L. REV. 1571, 1590–91 (2009).

185. Brian J. Love, *An Empirical Study of Patent Litigation Timing: Could A Patent Term Reduction Decimate Trolls Without Harming Innovators?*, 161 U. PA. L. REV. 1309, 1351–52 (2013).

186. Thomas Faunce et al., *New Forms of Evergreening in Australia: Misleading Advertising, Enantiomers and Data Exclusivity: Apotex vs. Servier and Alphapharm vs. Lundbeck*, 12 J.L. & MED. 220, 226 (2008).

187. Yaniv Heled, *Follow-on Biologics Are Set Up to Fail*, 2018 U. ILL. L. REV. ONLINE 113, 132 n.103 (2018).

188. Baker, *Ending Drug Registration Apartheid*, *supra* note 128, at 304.

on existing medicines in order to maintain monopolies.”¹⁸⁹ Another paper describes “evergreening” as a “phenomenon . . . in which a company tries to refresh its market monopoly by making slight modifications to the delivery mechanism, dosage, or other characteristics” of its drug “to make the drug eligible for additional patents or exclusivity.”¹⁹⁰ Another describes it as “the strategic small improvements made by producers of small molecule drugs in an attempt to extend their market monopoly.”¹⁹¹ One article reports that “evergreening” is “trying to refresh one’s monopoly protection on a drug.”¹⁹² A group of scholars claim in their article that “evergreening” is “extending the market monopoly on a drug facing originating patent expiration through listing of further relevant patents on the patent register for minor modifications to the marketed drug.”¹⁹³ Another scholar says that “evergreening” is companies “making relatively minor changes to existing products in order to restart their monopoly protection clocks.”¹⁹⁴ And another defines “evergreening” as “patenting an incremental aspect of a preexisting technology to unduly extend the monopoly lifetime of the underlying technology.”¹⁹⁵

Monopoly privileges. According to one article, “evergreening” is “best understood as a social idea used to refer to the myriad ways in which pharmaceutical patent owners utilize the law and related regulatory processes to extend their high rent-earning intellectual monopoly privileges, particularly over highly profitable (either in total sales volume or price per unit) ‘blockbuster’ drugs.”¹⁹⁶ Another says “evergreening” refers to the “numerous strategies whereby owners of pharmaceutical

189. Lisa Forman, *The Inadequate Global Policy Response to Trade-Related Intellectual Property Rights: Impact on Access to Medicines in Low- and Middle-Income Countries*, 31 MD. J. INT’L L. 8, 13 (2016).

190. Feldman & Frondorf, *supra* note 157, at 527.

191. Janet Freilich, *Patent Infringement in the Context of Follow-on Biologics*, 16 STAN. TECH. L. REV. 9, 23 (2012).

192. Feldman, *May Your Drug Price*, *supra* note 126, at 601.

193. Ron A. Bouchard, Jamil Sawani, Chris McLelland, Monika Sawicka & Richard W. Hawkins, *The Pas De Deux of Pharmaceutical Regulation and Innovation: Who’s Leading Whom?*, 24 BERKELEY TECH. L.J. 1461, 1501 (2009) (discussing “evergreening” in Canada).

194. Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419, 462 n.198 (2012) (quoting definition in Laurence J. Kotlikoff, *Clearing the Way to Low-Cost Biogenerics*, BOSTON GLOBE, Oct. 26, 2008).

195. David Orozco, *Administrative Patent Levers*, 117 PENN ST. L. REV. 1, 15 (2012); *see also* David Orozco, *Legal Knowledge as an Intellectual Property Management Resource*, 47 AM. BUS. L.J. 687, 724 (2010) (stating that some drug companies have “extended the lifetime monopoly of their patented compounds by engaging in ‘evergreening’ practices, including patenting minor variants of the compound or delivery processes that extend the lifetime of the original compound”).

196. Faunce & Lexchin, *supra* note 122, at 1.

products use patent laws and minor drug modifications to extend their monopoly privileges on the drug.”¹⁹⁷

High pricing and revenue. Some scholars say “evergreening” refers to the “strategic methods by which an originator company protects the royalties flowing from an original patent over an active pharmaceutical substance.”¹⁹⁸ One explains that “evergreening” entails “adding ‘bells and whistles’ to existing products on which older new-chemical-entity patents have since expired, thus allowing for continued monopoly pricing.”¹⁹⁹ Two write that “evergreening” refers to patenting “very similar compounds to extend the patent period so that” a company “can continue charging high prices beyond the initial patent period.”²⁰⁰ According to another, “evergreening” “typically refer[s] to a variety of practices of brand-name pharmaceutical manufacturers aimed at extending exclusivity periods for their products to maintain their revenue streams.”²⁰¹ And another declares that “evergreening” is “[t]he process of patenting subtle improvements on a drug,” and “[i]t helps drug makers ensure a continued stream of revenue when the patents on their drugs expire.”²⁰²

A period without generic competition. One scholar says that “patent evergreening” occurs when “manufacturers seek and receive patents on peripheral features of drug products, including a pill’s coating or a naturally-occurring metabolite of a drug, that can serve to block others from producing generic versions of the underlying active ingredient.”²⁰³ Another describes “evergreening” as “making minor modifications to existing drug patents in order to avoid facing generic competition as the basic patent on a drug expires.”²⁰⁴ With a coauthor, this same scholar also describes “evergreening” as using the continuation process to obtain “multiple patents covering obvious variants of the same drug” and then

197. Ali Alkhafaji et al., *Impact of evergreening on patients and health insurance: a meta analysis and reimbursement cost analysis of citalopram/escitalopram antidepressants*, 10 BMC MED. 142, November 20, 2012, at 1 (2012); see also Molly F.M. Chen, Note, *Reconsidering the U.S. Patent System: Lessons from Generics*, 45 VAND. J. TRANSNAT’L. L. 1249, 1252 (2012) (“The United States, by supporting ‘follow-on’ patents and evergreening practices, has allowed pharmaceutical giants to effectively extend their monopolies on brand-name drugs.”).

198. Faunce, *New Forms of Evergreening*, *supra* note 186, at 222.

199. Ron A. Bouchard, *Balancing Public and Private Interests in the Commercialization of Publicly Funded Medical Research: Is There A Role for Compulsory Government Royalty Fees?*, 13 B.U. J. SCI. & TECH. L. 120, 178 (2007).

200. James Gathii & Cynthia Ho, *Regime Shifting of IP Lawmaking and Enforcement from the WTO to the International Investment Regime*, 18 MINN. J.L. SCI. & TECH. 427, 461–62 (2017).

201. Heled, *Regulatory Competitive Shelters*, *supra* note 132, at 341 n.177.

202. Mason Marks, *Psychedelic Medicine for Mental Illness and Substance Use Disorders: Overcoming Social and Legal Obstacles*, 21 N.Y.U. J. LEGIS. & PUB. POL’Y 69, 106 (2018).

203. Kesselheim, *Think Globally*, *supra* note 182, at 129.

204. Lemley, *Expecting the Unexpected*, *supra* note 133, at 1393.

listing the patents in the ORANGE BOOK at “different times,” thus obtaining “many sequential thirty-month stays” of generic approval.²⁰⁵ Two scholars maintain that “evergreening” is “the use of multiple patents to delay the appearance of a generic product on the market and accordingly prolong the brand’s patent monopoly.”²⁰⁶ A group defines “[e]vergreening” [as] a strategy wherein an innovative pharmaceutical firm introduces an upgrade of its current product when the product on this patent expires,” and “[t]he upgrade is introduced with a new patent and is designed to counter competition from generic manufacturers that seek to imitate the firm’s existing product.”²⁰⁷ And finally, another article describes “evergreening [as] a process whereby the holder of the patents for a biologic drug, using incremental changes to its original product, is able to shift the market to a newer product so as to limit a generic competitor’s market opportunity.”²⁰⁸

B. Examples Offered

Legal scholars cite roughly three dozen examples of what they call “evergreening” in the United States since the enactment of the generic drug approval provisions in 1984.²⁰⁹ A review of the facts underlying

205. Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 82 (2004). The law permitted sequential stays when Profs. Lemley and Moore wrote this article, but Congress amended the statute in December 2003. See authorities cited *supra* note 84 and accompanying text. See also Stephanie Plamondon Bair, *Adjustments, Extensions, Disclaimers, and Continuations: When Do Patent Term Adjustments Make Sense?*, 41 CAP. U.L. REV. 445 (2013) (using “evergreening” to mean the practice of securing sequential 30-month stays but noting that the practice effectively ended with the legislative amendments of 2003).

206. Emir Aly Crowne & Cristina Mihalceanu, *Innovators and Generics: Proposals for Balancing Pharmaceutical Patent Protection and Public Access to Cheaper Medicines in Canada (or, Don’t NOC the Players, Hate the Regulations)*, 51 IDEA 693, 707 (2011).

207. Ram Bala, et al., *Evergreening and Operational Risk Under Price Competition* 1, 36 (Jan. 9, 2012), <https://ssrn.com/abstract=2354125> [<https://perma.cc/RHQ9-PXG7>]; see also Alexandra E. Blasi, *An Ethical Dilemma: Patents & Profits v. Access & Affordability*, 33 J. LEG. MED. 115, 119 (2012) (evergreening is an “art form of getting, protecting, keeping, and extending their patents” that “substantially delays the entry of generic drugs into the market”); John Altin, *Pharmacogenomics: A New Frontier for the Evergreening of Pharmaceutical Drugs* 5 (ANU College of Law Research Paper No. 08-04, Oct. 2007), <https://ssrn.com/abstract=1129064> [<https://perma.cc/L7GN-SBZT>] (defining evergreening as “the various strategies that originators use to extend the period for which their blockbuster drugs remain free from generic competition beyond the expiration of their base patents”).

208. Heled, *Patents vs. Statutory Exclusivities*, *supra* note 194, at 462 n.198 (quoting definition offered in Alex M. Brill, *Proper Duration of Data Exclusivity for Generic Biologics: A Critique* 11 (2008) (unpublished manuscript) (on file with author)).

209. The medical, scientific, and economic literature adds examples, but for brevity’s sake this Article focuses mainly on examples offered by legal scholars in law journals and their equivalent. And much of the literature is global in focus and includes examples irrelevant in the United States, which this Article excludes. *E.g.*, Sandeep Rathod, *Ever-Greening: A Status Check in Selected*

these examples indicates many involve an innovator introducing a new medicine, patenting another innovation, introducing a new product that corresponds to the innovation, and perhaps discontinuing its older product. It is rare to see a discussion of the full factual and legal landscape in which an example arises, however. For instance, the literature generally will not describe the kinds of products containing the active ingredient that a generic company *could* have sought to market (its room to operate), whether any generic companies *actually* marketed copies (or variations) of the innovator's first approved product, whether and why doctors chose (or did not choose) the innovator's newer product, and whether and how payers responded to the innovator's new product.

1. New Products

New dosage forms. Many scholars offer, as examples of "evergreening," instances in which an innovator introduced a new dosage form (a capsule after a tablet, for example, or an extended release product after an immediate release product).²¹⁰ They most often cite Asacol (mesalamine) (delayed release tablets, then delayed release capsules),²¹¹

Countries, 7 J. GENERIC MED. 227, 229 n.7 (2010) (discussing Lunesta (eszopiclone), an enantiomer of zopiclone, though FDA never approved a product containing zopiclone, and discussing a patent claiming crystalline forms of atorvastatin, marketed in the United States as Lipitor, though FDA never approved a product containing the crystalline form).

This Article also excludes two examples in the literature that do not correspond to actual approved products. *First*, many articles discuss Gleevec (imatinib mesylate), a salt of imatinib, presumably because Indian authorities rejected a patent on the salt due to the earlier patenting of imatinib. *E.g.*, Abbott, *Balancing Access*, *supra* note 142, at 343–45; Halabi, *Multipolarity*, *supra* note 146, at 757. But FDA never approved an application for a product containing imatinib (nor did the Indian authorities). *Second*, another article mentions the development of torcetrapib on the heels of Lipitor (atorvastatin), perhaps because Pfizer was considering the introduction of a fixed-dose-combination of the two active ingredients together. The active ingredients were unrelated, however, and torcetrapib failed in clinical trials. Faunce & Lexchin, *supra* note 122, at 188. *See also* Bala, *supra* note 207, at 2 (characterizing torcetrapib as an "upgrade" to atorvastatin that failed due to its toxicity).

210. Many call the latter "reformulation," but FDA classifies them as new dosage forms. ORANGE BOOK, *supra* note 43, at Appendix C. This matters because FDA often requires a separate marketing application for a new dosage form. *See infra* Part IV.B.

211. Feldman & Frondorf, *supra* note 157, at 530. FDA approved Asacol, which were delayed release tablets, in 1992. Approval dates in this Part of the Article are taken from Drugs@FDA. Asacol was not the first approved drug containing mesalamine; FDA had approved another company's Rowasa (mesalamine) in 1987. In 2013, the company selling Asacol launched Delzicol (mesalamine), which were delayed release capsules. FDA did not approve the first generic tablets until 2017, 25 years after approval of Asacol, in part due to uncertainty about how generic companies would show bioequivalence to Asacol. *FDA Reverses Stance on Bioequivalence Standards for Mesalamine*, PINK SHEET (Aug. 30, 2010), <https://pink.pharmaintelligence.informa.com/PS052561/FDA-Reverses-Stance-On-Bioequivalence-Standards-For-Mesalamine> [<https://perma.cc/YV63-RK2T>]. By then, though, FDA had approved generic copies of Rowasa (2004) and another innovator's delayed release mesalamine tablets (2007).

Buspar (buspirone hydrochloride) (tablets, then capsules),²¹² Doryx (doxycycline hyclate) (tablets, then capsules, and scoring lines on tablets),²¹³ Glucophage (metformin hydrochloride) (immediate release, then extended release),²¹⁴ Loestrin (ethinyl estradiol and norethindrone acetate) (tablets, then chewable tablets),²¹⁵ Namenda (memantine hydrochloride) (immediate release, then extended release),²¹⁶ Oxycontin (oxycodone hydrochloride) (extended release tablets, then new extended release tablets that were more abuse resistant),²¹⁷ Prozac (fluoxetine

212. Carrier, *Real-World Analysis*, *supra* note 152, at 1016. FDA approved Buspar (buspirone hydrochloride) oral tablets in 1986. FDA approved a capsule dosage form in 2000.

213. Feldman, *May Your Drug Price*, *supra* note 126, at 608 n.87 (focusing on the adding of scoring lines on the tablet); Jorge Lemus & Olga Ozkul, *Product Hopping and Innovation Incentives* (March 20, 2019), <https://ssrn.com/abstract=3275815> [<https://perma.cc/6FLA-VADE>] (referring to a switch “from tablet to capsules”). Immediate release doxycycline had been available since the 1960s, when Mayne launched Doryx—extended release capsules—in 1985. Twenty years later, in 2005, Warner Chilcott (which had an arrangement with Mayne) launched delayed release tablets, and in 2008 it launched a scored tablet—a tablet with a groove down the middle, which makes it easier for patients to split the dose in half. Eventually the company introduced tablets with multiple scores that could be split in half or in thirds. *See generally* Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd., Civ. No. 12-3824, 2015 WL 1736957, *2–*5 (E.D. Penn. Apr. 15, 2015) (describing the history), *aff’d*, 838 F.3d 421, 441–42 (3d Cir. 2016).

214. Halabi, *The Drug Repurposing Ecosystem*, *supra* note 181, at 49 (creating “improved formulations”); *see also* Joli Patel, Comment, *India’s Crack Down on the Practice of Pharmaceutical Evergreening: The 2013 Novartis Decision*, 85 UMKC L. REV. 503, 506 (2017) (sustained release). FDA approved Glucophage immediate release oral tablets in March 1995. It approved Glucophage XR extended release tablets in October 2000.

215. Erik Hovenkamp & Jorge Lemus, *Delayed Entry Settlements at the Patent Office*, 54 INT’L REV. L. & ECON. 30, 45 (2018) (“switching over to the chewable form”). The first ethinyl estradiol marketing application took effect in the 1940s, and the first application for a combination of ethinyl estradiol and norethindrone acetate took effect in 1961. FDA approved Loestrin in 1972. In 2013, FDA approved an application from the same company for a chewable tablet formulation, which the company markets as Minastrin.

216. Feldman & Frondorf, *supra* note 157, at 531–32 (introduction of extended release dosage form); Feldman, *May Your Drug Price*, *supra* note 126, at 602–03 (same); Cynthia M. Ho, *Should All Drugs Be Patentable?: A Comparative Perspective*, 17 VAND. J. ENT. & TECH. L. 295, 320 (2015); Lemus & Ozkul, *supra* note 213 (same); Price, *The Cost of Novelty*, *supra* note 174, at 41 (same); *see also* Gregory Jones, Michael Carrier, Richard Silver & Hagop Kantarjian, *Strategies that delay or prevent the timely availability of affordable generic drugs in the United States*, 127 BLOOD 1398 (2016) (same). FDA approved Namenda immediate release tablets in 2003 and Namenda XR extended release capsules in 2010.

217. Lemus & Ozkul, *supra* note 213. *See also* Jaime F. Cárdenas-Navia, *Thirty Years of Flawed Incentives: An Empirical and Economic Analysis of Hatch-Waxman Patent-Term Restoration*, 29 BERKELEY TECH. L.J. 1301, 1339 (2014). In November 2007, Purdue Pharma applied for approval of reformulated controlled release tablets that would be less easily compromised by tampering than its earlier marketed formulation. *See* FDA, APPLICATION NUMBER: 22-272 SUMMARY REVIEW (Apr. 5, 2010), https://accessdata.fda.gov/drugsatfda_docs/nda/2010/0222272s000SumR.pdf [<https://perma.cc/BE58-Q8AJ>]. When FDA approved the new “Oxycontin OP” tablets, it determined that, for safety reasons, it would not accept or approve ANDAs relying on the older and less abuse-resistant products the innovator had marketed before. *See* FDA, *FDA Actions*

hydrochloride) (capsules, then tablets, then extended release),²¹⁸ Suboxone (buprenorphine hydrochloride and naloxone hydrochloride) (sublingual tablets, then sublingual film),²¹⁹ and Tricor (fenofibrate) (capsules, then tablets).²²⁰ One article mentions Ambien (zolpidem tartrate) (immediate release tablets, then extended release tablets) when discussing "evergreening" in another country, but the same products were introduced here.²²¹

New active ingredients. Some articles cite new products containing active ingredients that relate to the active ingredient in the innovator's first product. Several cite subsequent products containing metabolites: Claritin (loratadine) and Clarinex (desloratadine),²²² as well as Effexor (venlafaxine hydrochloride) and Pristiq (desvenlafaxine succinate).²²³ Others mention the introduction of a left-handed or right-handed molecule (enantiomer) after the marketing of an active ingredient containing a mixture of both (racemate). The examples offered are: Celexa

on *OxyContin Products* (Apr. 16, 2013), <https://www.fda.gov/drugs/information-drug-class/fda-actions-oxycotin-products-4162013> [<https://perma.cc/6ZWH-YYKZ>].

218. Carrier, *Real-World Analysis*, *supra* note 152, at 1017 (capsule to tablet); *see also* Patel, *India's Crack Down*, *supra* note 214, at 506 (sustained release). FDA approved Prozac capsules first in 1987; it approved tablets in 1999; and it approved oral delayed release pellets in 2001.

219. Feldman, *May Your Drug Price*, *supra* note 126, at 608 n.87 ("new film version"); Lemus & Ozkul, *supra* note 213 (sublingual film). Although each active ingredient had been marketed previously, FDA approved the new fixed dose combination product in 2002. FDA, Ever Approved Drug List (on file with author). The company's initial product was a sublingual tablet. In 2010, FDA approved a sublingual film.

220. Carrier, *Real-World Analysis*, *supra* note 152, at 1017 (tablet); Mohammed K. El-Said, *TRIPS-Plus, Public Health and Performance-Based Rewards Schemes Options and Supplements for Policy Formation in Developing and Least Developed Countries*, 31 AM. U. INT'L L. REV. 373, 395–97 (2016); Feldman, *May Your Drug Price*, *supra* note 126, at 608 n.87; Ho, *Should All Drugs*, *supra* note 216, at 320; Lemus & Ozkul, *supra* note 213, at 3; Lim, *Self-Replicating Technologies*, *supra* note 133, at 218. For a discussion of the sequence of introduced fenofibrate products, *see* Nicholas S. Downing et al., *How Abbott's Fenofibrate Franchise Avoided Generic Competition*, 172 ARCH. INTERN. MED. 724, 276 (2012).

221. Nathalie Vernaz et al., *Patented Drug Extension Strategies on Healthcare Spending: A Cost-Evaluation Analysis*, 10 PLOS MED. 6, June 2013, at 2. FDA approved Ambien in 1992 and Ambien CR in 2005.

222. Carrier, *Real-World Analysis*, *supra* note 152, at 1017; Noah, *Product Hopping*, *supra* note 144, at 166 n.5. *See also* Bansal, *supra* note 172, at 300. FDA approved Claritin in 1992 and Clarinex in 2001.

223. Price, *The Cost of Novelty*, *supra* note 174, at 40; *see also* Lehman & Wojnowicz, *infra* note 224, at 387; Hazel Moir, *Exploring evergreening: Insights from two medicines*, 49 AUS. ECON. REV. 413, 420–24 (2016). FDA approved Effexor in 1993 and Pristiq in 2008. Pristiq tablets are an extended release formulation of the major active metabolite of Effexor. FDA, APPLICATION NUMBER: 21-992 MEDICAL REVIEW(S) 2 (Feb. 5, 2008), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2008/021992s000_MedR_P1.pdf [<https://perma.cc/2MH6-GLQS>].

(citalopram) and Lexapro (escitalopram),²²⁴ Prevacid (lansoprazole) and Dexilant (dexlansoprazole),²²⁵ Prilosec (omeprazole) and Nexium (esomeprazole),²²⁶ Provigil (modafinil) and Nuvigil (armodafinil),²²⁷ Ritalin (methylphenidate hydrochloride) and Focalin (dexmethylphenidate hydrochloride),²²⁸ and Zyrtec (cetirizine) and Xyzal (levocetirizine).²²⁹ Finally, some cite Neurontin (gabapentin) and Lyrica (pregabalin), which are structurally similar because both relate to a human neurotransmitter, though they are not directly related to each other.²³⁰

New Fixed-Dose Combination Products. A few scholars refer to fixed dose combination products. They cite Azor (amlodipine besylate and olmesartan medoxomil),²³¹ Caduet (amlodipine besylate and

224. Carrier, *Real-World Analysis*, *supra* note 152, at 1017; Marks, *Psychedelic Medicine*, *supra* note 202, at 106; *see also* David F. Lehman & Sarabeth Wojnowicz, *The Evergreening of Biopharmaceuticals: Time to Defoliate*, 56 J. CLIN. PHARM. 383, 384 (2015). FDA approved Celexa in 1998 and Lexapro in 2002. Escitalopram is an enantiomer of citalopram.

225. *E.g.*, Carrier, *Real-World Analysis*, *supra* note 152, at 1017 (referring to Prevacid and “Kapidex,” which was the original name for Dexilant); *see also* Lehman & Wojnowicz, *supra* note 224, at 386. FDA approved Prevacid in 1995 and Dexilant in 2009. Dexlansoprazole is an enantiomer of lansoprazole.

226. Adamson, *supra* note 127, at 259; Bouchard, *The Pas De Deux*, *supra* note 193, at 1502; Price, *The Cost of Novelty*, *supra* note 174, at 40; McCarthy, *Pharma Barons*, *supra* note 153, at 53; *see also* Dutfield, *supra* note 122, at 466; Bansal, *supra* note 172, at 302. FDA approved Prilosec in 1989 and Nexium in 2001. Esomeprazole is an enantiomer of omeprazole.

227. Jones, *supra* note 216, at 1400; *see also* Rathod, *supra* note 209. FDA approved Provigil in 1998 and Nuvigil in 2007. Armodafinil is an enantiomer of modafinil.

228. *E.g.*, Sean Dickson, *Effect of Evergreened Reformulations on Medicaid Expenditures and Patient Access from 2008 to 2016*, 25 J. MANAG. CARE SPEC. PHARM. 780, 785 (2019). Methylphenidate is a racemic mixture and has been marketed for decades by various companies under various brand names, including Ritalin, Concerta, and Metadate. FDA, APPLICATION NUMBER: 21-278 ADMINISTRATIVE DOCUMENTS 23 (2001), https://accessdata.fda.gov/drugsatfda_docs/nda/2001/21-278_Focalin_admindocs.pdf [<https://perma.cc/ER4L-P2AV>]. FDA approved Focalin (dexmethylphenidate) in 2001. Dexmethylphenidate is an enantiomer of methylphenidate.

229. Lehman & Wojnowicz, *supra* note 224, at 387; *see also* Vernaz, *supra* note 221, at *2 (discussing these examples in Geneva). FDA approved Zyrtec in 1995 and Xyzal in 2007. Levocetirizine is an enantiomer of cetirizine.

230. Jeremy A. Greene & Kevin Riggs, *Why Is There No Generic Insulin? Historical Origins of a Modern Problem*, 372 NEW ENG. J. MED. 1171, 1173 (2015) (“after Pfizer lost patent exclusivity on the antiepileptic agent gabapentin (Neurontin) in 2004, it retained a healthy share of the market through patents on a metabolic cognate, pregabalin (Lyrica)”); *see also* Vernaz, *supra* note 221, at 2 (discussing gabapentin and pregabalin in Geneva). FDA approved Neurontin in 1993 and Lyrica in 2004. The active ingredients are gabapentinoids. *See generally* H. Brockbrader et al., *A comparison of the pharmacokinetics and pharmacodynamics of pregabalin and gabapentin*, 49 CLIN. PHARMACOKINETICS 661 (2010).

231. Carrier, *Real-World Analysis*, *supra* note 152, at 1017.

atorvastatin calcium),²³² Exforge (amlodipine besylate and valsartan),²³³ Treximet (naproxen sodium and sumatriptan succinate),²³⁴ and Ultracet (acetaminophen and tramadol hydrochloride).²³⁵ In each case, the active ingredients had been marketed separately before being offered in a combination product.

2. Other Examples

The preceding examples involve new products that are usually (though perhaps not in every case) protected by new patents and perhaps new statutory exclusivity. And, as noted, many scholars define "evergreening" as just that.²³⁶ But the remaining examples are harder to categorize.

A few articles cite patents claiming new methods of using approved drugs.²³⁷ One points to a patent that claimed a new method of using gemcitabine (the active ingredient of Gemzar) in the treatment of cancer.²³⁸ Another article points to a patent claiming "pharmacokinetic/therapeutic parameters" associated with venlafaxine (the active ingredient of Effexor).²³⁹ That article also states that "evergreening" occurs through patents claiming impurities or substantially pure compounds, adding that a patent claiming lamotrigine (the active ingredient of Lamictal) fell into the latter category.²⁴⁰ Others consider the

232. Hazel Moir & Luigi Palombi, *Patents and Trademarks: Empirical Evidence on "Evergreening" from Australia* 33 (December 7, 2013), <https://ssrn.com/abstract=2365786> [<https://perma.cc/R93N-ULN7>]. The authors refer to the introduction of Caduet in Australia, but the same combination was also introduced in the United States.

233. Carrier, *Real-World Analysis*, *supra* note 152, at 1017.

234. *Id.*

235. Kevin Outterson, *Death from the Public Domain?*, 87 TEX. L. REV. SEE ALSO 45, 50 (2009) ("Ultracet could be characterized as an attempt to evergreen 50 mg Ultram by reducing the dose to 37.5 mg and combining it with 325mg of acetaminophen.").

236. *See supra* Part III.A.1.

237. Some examples relate to the *first* use that FDA approved, however. One article points to the patent claiming use of sildenafil (the active ingredient of Viagra) for treatment of erectile dysfunction, even though this was the first use for which the drug was approved. Rathod, *supra* note 209, at 229 n.11. It also points to a patent claiming treatment of a "segmented patient population" with BiDil (isosorbide dinitrate and hydralazine hydrochloride), though the drug was proven safe and effective in, and approved only for, that patient subpopulation. *Id.* at 229 n.229.

238. Noah, *Product Hopping*, *supra* note 144, at 166 n.5.

239. Rathod, *supra* note 209, at 229 n.12.

240. *Id.* at 229 n.10.

patent claiming the coating of omeprazole to be an instance of evergreening.²⁴¹

A few other examples offered by scholars are difficult to interpret. One article points to the fact that the manufacturers of Claritin (loratadine) and Glucophage (metformin) “petitioned Congress for extended market exclusivity based on” the “marketing exclusivity regimes administered by FDA.”²⁴² The author does not elaborate. The reference to Glucophage may reflect a debate about the relationship between pediatric exclusivity and three-year condition of approval exclusivity.²⁴³ The reference to Claritin probably reflects Schering-Plough’s efforts to persuade Congress that the U.S. Patent and Trademark Office (PTO) should extend patents for a small group of drugs that experienced unusual delays during FDA reviews of their marketing applications.²⁴⁴ In describing “evergreening,” that article also refers to a “legal technicality” that gave Zantac (ranitidine hydrochloride) “seven more years of market protection,” which appears to refer to a Federal Circuit ruling that rejected an invalidity challenge.²⁴⁵

241. Amin & Kesselheim, *supra* note 122, at 2287; Moir & Palombi, *supra* note 232, at 46–47. Although this patent—U.S. Patent No. 4,786,505—issued and expired later than the active ingredient patent, it covered the *first* approved omeprazole product.

242. Halabi, *The Drug Repurposing Ecosystem*, *supra* note 181, at 43.

243. Bristol Myers-Squibb submitted a supplemental application for use of metformin by teenagers, which FDA approved in December 2000. The company had earned three-year exclusivity under the 1984 statute and assumed it was also entitled to a six-month extension (to that three years) under the pediatric exclusivity provisions. When Congress reauthorized pediatric exclusivity in 2001, however, it added a provision—largely understood as targeting Glucophage—that (1) allowed approval of a generic drug when the innovator has received a new pediatric indication protected by patent or exclusivity, (2) authorized omission of the pediatric indication, and (3) authorized special labeling that alerts doctors to the off-label pediatric use and provides information needed for safe prescribing. 21 U.S.C. § 355a(o). *See generally* *Glucophage Provision in HR 2887 Could Be Breach of Contract—Bristol*, PINK SHEET (Nov. 19, 2001), <https://pink.pharmaintelligence.informa.com/PS038862/Glucophage-Provision-In-HR-2887-Could-Be-Breach-Of-Contract—Bristol> [<https://perma.cc/CE8J-9WFU>]; *Pediatric Exclusivity Bill Passes; CBO Scoring Flawed, Rep. Tauzin Says*, PINK SHEET (Nov. 26, 2001), <https://pink.pharmaintelligence.informa.com/PS093315/Pediatric-Exclusivity-Bill-Passes-CBO-Scoring-Flawed-Rep-Tauzin-Says> [<https://perma.cc/BRE6-BTFG>]; *Glucophage Exclusivity Compromise Could Resolve Pediatric Bill Delay*, PINK SHEET (Dec. 3, 2001), <https://pink.pharmaintelligence.informa.com/PS038930/Glucophage-Exclusivity-Compromise-Could-Resolve-Pediatric-Bill-Delay> [<https://perma.cc/LS4Z-QHYI>]; *Glucophage Provision Likely to Remain in Final Pediatric Exclusivity Bill*, PINK SHEET (Dec. 10, 2001), <https://pink.pharmaintelligence.informa.com/PS038966/Glucophage-Provision-Likely-To-Remain-In-Final-Pediatric-Exclusivity-Bill> [<https://perma.cc/7EQS-Y56N>].

244. *See Claritin Extension Should Be Debated as Product-Specific Bill—Barr CEO*, PINK SHEET (May 25, 1998), <https://pink.pharmaintelligence.informa.com/pS032218/Claritin-Extension-Should-Be-Debated-As-Product-Specific-Bill—Barr-CEO> [<https://perma.cc/4WHK-FAY2>].

245. Halabi, *The Drug Repurposing Ecosystem*, *supra* note 181, at 43 (citing *Glaxo Patent on Zantac Gets Extension*, N.Y. TIMES (Apr. 22, 1995), <https://nytimes.com/1995/04/22/business/glaxo-patent-on-zantac-gets-extension.html> [<https://perma.cc/YQ66-PC3Z>] (noting that the Federal Circuit

Finally, some examples offered by scholars reflect law that has since changed. For example, some articles discuss the patents listed in the ORANGE BOOK for Paxil (paroxetine).²⁴⁶ Several issued while generic applications were pending before FDA. A generic company must address any patent that issues while its application is under review, even if there is already a 30-month stay of approval in place.²⁴⁷ At the time, if a generic company submitted a paragraph IV certification, a new patent infringement suit led to a new 30-month stay. Here, there were five overlapping stays. Congress amended the statute nearly two decades ago, however, making it unlikely that approval will be stayed more than once.²⁴⁸

rejected Novopharm's argument that the Zantac patent was invalid). See *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043 (Fed. Cir. 1995) (rejecting anticipation, best mode, and inequitable conduct arguments). The patent at issue—U.S. Patent No. 4,521,431—issued in June 1985 on an application filed in August 1982. It was slated to expire in 2002. This led the *New York Times* to write in 1995 that the court's ruling protected Zantac "for seven more years." But, to be clear, the court's ruling simply meant that the patent would expire as scheduled, after an ordinary 20-year term, seven years after the reporter was writing.

246. E.g., Michael A. Carrier & Carl J. Minniti III, *Biologics: The New Antitrust Frontier*, 2018 U. ILL. L. REV. 1, 34 (2018); Halabi, *The Drug Repurposing Ecosystem*, *supra* note 181, at 43; C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 959 (2011); see also Bansal, *supra* note 172, at 304–05.

247. 21 C.F.R. § 314.94(a)(12)(viii)(C)(1)(ii) (2020).

248. See authorities cited *supra* note 84 and accompanying text. Most who discuss Paxil note that the law has changed. E.g., Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 711 n.111 (2009) (describing the "tactic" of sequentially listing patents in the ORANGE BOOK to trigger sequential 30-month stays and noting that Congress amended the Hatch-Waxman scheme in 2003 "to eliminate this particular form of patent evergreening"); Flynn, *supra* note 130, at 178 (stating that sequential 30-month stays under the pre-2003 Hatch-Waxman provisions were a type of evergreening, but adding that U.S. law now limits patent holders to one stay); Hemphill & Lemley, *supra* note 246, at 959–60 (discussing overlapping stays associated with patents listed for Paxil that "stretched out over sixty-five months" and adding that after 2003 changes to the statute "evergreening of this form won't work for new cases"); Herbert Hovenkamp et al., *Balancing Ease and Accuracy in Assessing Pharmaceutical Exclusion Payments*, 88 MINN. L. REV. 712, 716 n.17 (2004) (noting that FDA changed its regulations in 2003 "to permit no more than one thirty-month stay," which is correct, but Congress changed the law *after* this, and the change—which was different—superseded the regulations); Arti K. Rai, *Building A Better Innovation System: Combining Facially Neutral Patent Standards with Therapeutics Regulation*, 45 HOUS. L. REV. 1037, 1049 (2008) (noting that before 2003, drug companies could "string together sequential thirty-month stays based on multiple patents," which was an "evergreening" practice and "curtailed to some extent" by changes in the law).

Some do not. E.g., Erik Hovenkamp & Jorge Lemus, *Delayed Entry Settlements at the Patent Office*, 54 INT'L REV. L. & ECON. 30, 35 (2018) (stating that "drug companies may strategically list additional patents in the ORANGE BOOK over time, with each new addition triggering an additional 30-month stay on generic approval pending litigation—a practice known as evergreening").

Another article gives the example of the Cabilly patents, which claimed basic technologies used to artificially synthesize antibodies.²⁴⁹ Companies developing and marketing monoclonal antibodies for medical use had to pay licensing fees to the patent owner for years. The author focuses on the fact that the patent owner filed continuation applications with the PTO, and the patents issuing on those applications expired much later than the patent issued on its original application.²⁵⁰ The law governing patent terms changed in the mid-1990s, however, and continuation patents no longer expire later than their original parent patent.²⁵¹

C. *Empirical Studies Offered*

Some scholars have published empirical studies that they, or others, say support allegations of “evergreening.” Many use datasets from other countries, however, and these are governed by different drug approval frameworks, patent laws, pricing and reimbursement arrangements, and advertising and promotion laws and practices.²⁵² The empirical work considering the U.S. market falls in three categories. Some scholars count patents and exclusivities associated with drugs; some examine litigation challenging innovator patents; and some calculate spending associated with the newer products introduced by innovators.

1. Counting Patents and Exclusivities

Several articles count patents and exclusivities associated with drugs. Four articles examine patents alone. The most significant study considers the 1,304 patents listed in the ORANGE BOOK for the 528 new molecular entities approved by FDA between 1988 and 2005.²⁵³ Not all new

249. Holman, *Biotechnology's Prescription*, *supra* note 131, at 333 (discussing use of continuation practices to “evergreen protection for some of the fundamental enabling technologies of biotechnology,” citing the Cabilly patents, and calling MedImmune the “victim of this particular evergreening”).

250. *Id.*

251. See also Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y, L. & ETHICS 717, 723 n.20 (2005) (asserting that the 17-year patent term in place before 1995 permitted drug companies to prosecute patents “lethargically” in order to “defer issuance and prolong the period of patent protection” and referring to this as an “evergreening strategy”).

252. E.g., Alkhafaji, *supra* note 197 (France); Bouchard, *Empirical Analysis*, *supra* note 149 (Canada); Christie, *supra* note 132 (Australia); Hazel Moir et al., *Assessing the impact of alternative patent systems on the cost of health care: the TPPA and HIV treatment in Vietnam*, presented at 5th Asia-Pacific Innovation Conference (Nov. 2014), <https://ssrn.com/abstract=2536254> [<https://perma.cc/5PDR-EXYF>] (Vietnam); Vernaz, *supra* note 221 (Switzerland).

253. See generally Kapczynski, *Polymorphs and Prodrugs*, *supra* note 69.

molecular entities were linked to patents, but those with listed patents were more often associated with a formulation patent (81% of drugs) or a method of use patent (83%) than with a chemical compound patent (64%).²⁵⁴ Patents with no chemical compound claim expired an average of 9 to 11 years later than the five-year data exclusivity term, or 14 to 16 years after approval.²⁵⁵ They also expired on average 4 to 5 years after the chemical compound patent.²⁵⁶ Within this set, the formulation patents expired an average of 6.5 years after the compound patent, and method of use patents expired an average of 7.4 years later.²⁵⁷ For half of the new molecular entities (51%), the innovator also held a patent claiming a variant of the initial active ingredient—a polymorph, isomer, prodrug, ester, or salt.²⁵⁸ These patents tended to expire 6.3 years later than the initial compound patent.²⁵⁹

Three articles round out this collection. One author considered the patents listed in the ORANGE BOOK for the 938 new drug applications approved by FDA from 1998 to 2005.²⁶⁰ She found that 305 applications listed just one patent, 67% listed more than one patent, and the average number of patents listed was 2.97.²⁶¹ She also found that the number of patents listed for a given new drug application increased over time.²⁶² The authors of another study counted and classified patents associated with ritonavir (marketed as Norvir), lopinavir, and the combination of the two (marketed as Kaletra), finding 82 patents and 26 patent applications.²⁶³ The initial active-ingredient patents were due to expire in 2014 (ritonavir) and 2016 (lopinavir).²⁶⁴ Other patents covered innovations ranging from new formulations to polymorphs, and the last was scheduled to expire in 2028.²⁶⁵ Finally, a group of authors counted the patents listed in the ORANGE BOOK for 49 products that combined a medical device and

254. *Id.* at 6.

255. *Id.*

256. *Id.*

257. *Id.* at 7 (Table 3).

258. *Id.* at 6.

259. *Id.* at 5.

260. Ouellette, *How Many Patents*, *supra* note 131, at 311–14.

261. *Id.* at 314.

262. *Id.* at 316.

263. Amin & Kesselheim, *supra* note 122. They used the Thomson Innovation database of U.S. patent applications and granted patents, rather than the ORANGE BOOK, though they double checked their results in the latter. *Id.* at 2287. For another example of this type of patent counting, see Mike Lloyd, *Evergreening by whom? A review of secondary patents for omeprazole*, 2 PHARM. PAT. ANALYST 737 (2013) (counting and describing patents associated omeprazole).

264. Amin & Kesselheim, *supra* note 122, at 2288.

265. *Id.* at 2290.

epinephrine, insulin, or a drug for asthma or chronic obstructive pulmonary disease.²⁶⁶ They found 235 patents, 129 of which claimed the device itself.²⁶⁷ For 26 products, a device patent expired later than the active ingredient patent, and for 14 products, device patents were the only unexpired patents.²⁶⁸

Two articles examined both patents and statutory exclusivities. The more significant article examined every ORANGE BOOK listing for every approved drug listed in the publication between 2005 and 2015.²⁶⁹ The author focused on the 3,372 discrete new drug applications in her dataset.²⁷⁰ Of these, 1,322 applications (roughly 40%) were linked to a patent issued or exclusivity recognized by FDA *after* the initial application approval date.²⁷¹ Most had more than one post-approval patent or exclusivity.²⁷² And 29 applications had more than 18 patents or exclusivities added after approval.²⁷³ Roughly three-quarters of the best-selling drugs (meaning those in the top 50 of sales in any of the years studied) had a post-approval exclusivity or patent that expired later than the patents and exclusivities recorded at the time of initial approval.²⁷⁴

Another author reviewed all patents and approval-related exclusivities associated, by 2011, with applications approved by FDA from 2000 to 2010.²⁷⁵ Applications approved at the start of the window averaged more patents than applications approved at the end of the window: she recorded 4.5 per application approved in 2000 and 2.9 per application approved the year before the paper was published.²⁷⁶ She also calculated the remaining patent life (the time from approval until expiry of latest expiring patent) for the applications, finding that applications approved in 2000 averaged 17 years and drugs approved in 2010 averaged 9.2 years.²⁷⁷ Applications approved at the start of the window also averaged more statutory exclusivities (new-chemical-entity exclusivity, three-year condition-of-approval exclusivity, seven-year orphan

266. Read F. Beall et al., *Is Patent “Evergreening” Restricting Access to Medicine/Device Combination Products?*, 11 PLOS ONE 2, Feb. 24, 2016.

267. *Id.* at 3.

268. *Id.* at 6.

269. See Feldman, *May Your Drug Price*, *supra* note 126.

270. *Id.* at 607, 619 Table 1.

271. *Id.* at 619 Table 2.

272. *Id.* at 634.

273. *Id.* at 635 Table 7.

274. *Id.* at 638.

275. See Kate Gaudry, *Evergreening: A Common Practice to Protect New Drugs*, 29 NAT. BIOTECHNOLOGY 876 (2011).

276. *Id.* at 877.

277. *Id.*

exclusivity, and six-month pediatric exclusivity) than applications approved at the end of the window; she recorded 5.6 for applications approved in 2000 and 2.0 for applications approved in 2010.²⁷⁸ And applications approved at the beginning averaged 6.4 years between approval date and expiry of last-expiring exclusivity, compared to applications approved at the end (3.6 years).²⁷⁹

2. Patent Litigation

Two authors have focused on patent litigation associated with patents held by innovators, especially patents other than the active ingredient patent. *First*, these authors examined patents listed in the ORANGE BOOK for 479 "drugs" that first became eligible for generic challenge between 2000 and 2008.²⁸⁰ This appears to mean 479 active ingredients rather than finished products or marketing applications.²⁸¹ The number of patents listed per "drug" increased over time.²⁸² The "nominal patent term"—the period between application approval and expiration of the last-expiring patent—increased over time.²⁸³ A longer nominal patent term had a positive and significant effect on the likelihood of a patent challenge, meaning the likelihood that a generic company would file a paragraph IV certification stating that its product did not infringe the patent or that the patent was invalid.²⁸⁴ Having only non-active-ingredient patents had a positive and statistically significant effect on the likelihood of a challenge by a generic applicant.²⁸⁵ Sales had a large, positive, and statistically significant effect on the likelihood of challenge, meaning that larger sales volumes increased the chances of challenge.²⁸⁶ And the number of patents listed after approval had a strong, positive, and statistically significant effect on the likelihood of a challenge.²⁸⁷

278. *Id.* at 878.

279. *Id.* at 878.

280. C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 9 J. EMPIRICAL LEGAL STUD. 613, 626 (2011).

281. *See id.* at 627 (identifying several "drugs" in the sample, including Abilify (aripiprazole)—which by the time they ran their study was linked to more than one new drug application, suggesting they were counting all "aripiprazole" applications together). There is nothing wrong with this approach, to be sure; it is simply important to be clear what was counted.

282. *Id.* at 619.

283. *Id.* at 622.

284. *Id.* at 633.

285. *Id.*

286. *Id.* at 632.

287. *Id.* at 633.

In their second study, the authors examined the patents listed in the ORANGE BOOK for the 119 new molecular entities first subjected to competition from a therapeutically equivalent generic product between 2001 and 2010.²⁸⁸ Each new molecular entity (first dosage form) had 2.7 patents on average, yielding an average nominal patent term of 15.9 years.²⁸⁹ The average “effective market life”—meaning the time from FDA approval until first approval of a therapeutically equivalent generic product—was, however, 12.2 years.²⁹⁰ This effective market life ends well before the last-expiring patent and has not meaningfully increased over time.²⁹¹ Two-thirds (78) received a patent challenge, fewer than half of which targeted an active ingredient patent.²⁹² Nominal patent term increased sharply with sales, as did the likelihood of a patent challenge within five years of launch.²⁹³ Conditional on sales, the likelihood of challenge was also strongly related to nominal patent term.²⁹⁴ New molecular entities with more non-active-ingredient patents were also more likely to draw challenges.²⁹⁵ Finally, there was a strong, negative, and statistically significant relationship between patent challenges and time to generic entry, meaning that drugs facing patent challenges experience earlier generic entry.²⁹⁶

These articles contribute to a broader literature examining drug patent litigation, effective patent life, and actual exclusivity (time to generic market entry) with a new active ingredient. A full review of this literature, much of which does not use the term “evergreening,” is beyond the scope of this Article.²⁹⁷ One paper published in 2017 adds two important nuances, however.²⁹⁸ The authors assembled a dataset of new drugs approved from 1994 to 2006 and found that litigation outcomes

288. See C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327 (2012). They restricted their attention to the dosage form designated by FDA as the new molecular entity, meaning the first approved finished product (or products, if FDA approved multiple strengths at the same time). *Id.* at 329.

289. *Id.* at 330.

290. *Id.*

291. *Id.* at 329 (defining effective market life); *id.* at 330 (noting average effective market life is four years shorter than average nominal patent term); *id.* at 336 (noting that average effective market life is “essentially stable over time”).

292. *Id.* at 330.

293. *Id.* at 330–31.

294. *Id.* at 334.

295. *Id.*

296. *Id.* at 333.

297. See Henry Grabowski, et al., *Pharmaceutical Patent Challenges*, 3 AM. J. HEALTH ECON. 33, 37–38 (2017) (providing a brief literature review).

298. *Id.*

varied among the different types of non-active-ingredient patents. Generic companies prevail in 71% of the court decisions relating to formulation-only patents, but only 33% of the decisions relating to method-of-use patents.²⁹⁹

3. Healthcare Expenditures

A recent article calculated healthcare expenditures associated with certain new dosage forms listed in the ORANGE BOOK between 1982 and 2018.³⁰⁰ The author focused on "reformulations," which he defined to mean extended release, delayed release, or oral dissolving products containing the same active ingredient as a previously approved product, marketed by the same company or under the same proprietary name.³⁰¹ Out of 2,405 active ingredients in the ORANGE BOOK, he identified 73 associated with reformulation.³⁰² The new dosage forms were listed an average of 7.9 years after initial approval of the active ingredient.³⁰³ The author calculated "healthcare expenditures" associated with reformulation by assuming that every sale of the innovator's new dosage form represented a "foregone" sale for the generic company.³⁰⁴ Using the price differential between the innovator's new dosage form and generic copies of the older dosage form, he calculated that these "evergreened" reformulations "increased Medicaid expenditures" by \$9.35 billion from 2008 to 2016.³⁰⁵

IV. THE MEANING OF THE METAPHOR

The examples and empirical work tell us five things. *First*, innovators do a lot of incremental innovation—they develop new medicines that relate to and build on their initial discovery of a biologically useful molecule.³⁰⁶ They patent the innovations they can, and

299. *Id.* at 53.

300. *See generally* Dickson, *supra* note 228.

301. *Id.* at 781.

302. *Id.* at 783. This includes three that did not satisfy his definition but that he added manually because the reformulations "captured substantial market share for the group more than 2 years after the first brand product was released." *Id.* at 782.

303. Dickson, *supra* note 228, at 783.

304. *Id.* at 782–83 ("For example, if there was 90% generic uptake of initial formulation prescriptions and no generic evergreened reformulations were approved, we assumed that 90% of the evergreened reformulation prescriptions would have been generic had a generic been available.").

305. *Id.* at 784.

306. This is not surprising, nor is it unique to the pharmaceutical industry. *See, e.g.*, Albert Wertheimer et al., *Too Many Drugs? The Clinical and Economic Value of Incremental Innovations*, in 14 INVESTING IN HEALTH: THE SOCIAL AND ECONOMIC BENEFITS OF HEALTH CARE INNOVATION

they introduce new products, which usually also benefit from statutory exclusivity. *Second*, the associated patents often expire later than the initial active ingredient patent, and the associated exclusivity expire, which is also later than the data exclusivity protecting the new chemical entity. *Third*, generic companies file ANDAs as early as they can, arguing that the patents are invalid or, if applicable, not infringed. They tend to lose these arguments when the active ingredient patent is at issue, but they tend to win (one argument or the other) if a formulation patent is at issue. *Fourth*, generic challenges—claims that listed patents are invalid or not infringed—are linked to earlier market entry. *Finally*, the innovator’s newer products, protected by patents and exclusivity, are more expensive than generic copies of the innovator’s first-approved products.

The challenge comes in leaping from these unremarkable findings to the term “evergreening,” whether this means the metaphor or the definitions in the literature. Both require that something be *extended*, and the challenge lies in identifying a thing extended. Writers are inconsistent about what has been extended and often vague about how the supposed “extension” occurs, given the landscape described in Part II.³⁰⁷ The empirical scholarship does not help; the various counting exercises offer robust evidence of post-approval innovations, new product introductions, and patents and exclusivity, but locating an *extension* of a *thing* is challenging.³⁰⁸

This Part considers the definitions, examples, and empirical studies described in Part III within the context described in Part II to arrive at a proposal about what, exactly, has been *extended* in the scenarios of concern. But this Article was motivated in part by concern that use of the metaphor and imprecision in the scholarship may be leading audiences to error. So, it begins with a discussion of what has *not* been extended. As

77, 78 (I. Farquhar et al. eds., 2001) (“The process of repeated incremental improvement is the predominant mechanism of innovation and product development within most manufacturing and high-technology industries.”).

307. See *supra* Part III.A.

308. The author of the primary patent and exclusivity counting paper, for instance, writes that with these patents and exclusivity an innovator extends its “protection cliff.” Feldman, *May Your Drug Price*, *supra* note 126, at 597. But the paper does not examine the timing or effect of FDA approval of any abbreviated applications that may have cited the innovator’s active ingredient. Others may assume that more has been shown empirically. *E.g.*, Yaniv Heled et al., *Why Healthcare Companies Should Be(Come) Benefit Corporations*, 60 B.C. L. REV. 73, 102 (2019) (asserting that there is “significant controversy surrounding the purpose and legitimacy of these practices” but that “there is little dispute that they delay and sometimes even prevent competition in drug markets,” citing articles that do not provide empirical support for the latter claim); Ho, *New World Order*, *supra* note 145, at 1512 (“[E]vergreening is recognized as an issue worldwide due to its negative impact in delaying introduction of lower-cost generic drugs . . .”).

explained below, no patent has been extended. No statutory exclusivity has been extended. No generic company has been blocked from obtaining approval of its own product containing the same active ingredient through an abbreviated application that relies on the innovator's research, nor has any been blocked from enjoying sales of such a product (even sales exceeding those enjoyed by the innovator). For that matter, no generic company has been prevented from conducting its own clinical testing to secure approval for its own product.

A. *No Extension of Patent or Statutory Exclusivity*

To begin with, these situations never involve extension of patents. This would be legally impossible. In the United States, a patent expires 20 years after its application date.³⁰⁹ There are only two ways a patent's expiration date can shift later in time. *First*, when it issues a patent, the PTO adjusts the expiry date later to compensate for routine delays at the PTO.³¹⁰ *Second*, if the marketing application proposed a new active ingredient and the company asked the PTO for a patent term extension within 60 days of FDA approval, then the PTO will use a statutory formula to extend one patent claiming the product to compensate partially for the lapse of patent life during premarket testing and regulatory review.³¹¹ There is no other mechanism by which a drug patent might be extended.³¹² Legal scholars rarely suggest the impossible—extension of individual patents—though some do.³¹³ But much of the scholarship uses loose

309. 35 U.S.C. § 154(a)(2) (2018). If the patent relates to an earlier-filed patent, it lasts for 20 years from the earlier patent application date. *Id.*

310. *Id.* § 154(b).

311. *Id.* § 156. See generally Erika Lietzan and Kristina Acri, *Distorted Drug Patents*, 95 WASH. L. REV. (forthcoming 2020) (discussing how the restoration does not compensate fully for the time lost in trials).

312. To be sure, a company could seek a legislative fix, meaning a private bill extending its patent. But companies rarely seek them, and Congress almost never enacts them. See Erika Lietzan, *The History and Political Economy of the Hatch-Waxman Amendments*, 54 SETON HALL L. REV. 53, 107–11 (2018) (discussing four exceptions in the early 1980s).

313. In some cases, this wording—though legally impossible—is meant to attract attention rather than to assert a factual claim. *E.g.*, Amin & Kesselheim, *supra* note 122 (referring to “how patents on two HIV drugs could be extended for decades” in their title). In others, it may be a misstatement of the law. *E.g.*, Miriam Bitton, *Examining the Trans-Pacific Partnership Agreement*, 17 J. INTERNET L. 25, 35 (2014) (defining evergreening as “drug companies making small changes to their drug and thus ‘blocking’ the patent’s expiration for another 20 years”); Chander & Sunder, *supra* note 159, at 340 n.33 (“Lower patentability standards allow for more patents and longer patents—hence the name ‘evergreen’ patent. Innovators can go for low hanging fruit—extensions on existing patents—rather than focus on breakthrough inventions with proven therapeutic benefits.”).

language about extending the patent “term” or patent “life” of a drug.³¹⁴ And other writers do suggest the impossible.³¹⁵

The explanation might be something like this: *We mean that another patent effectively precludes approval (or launch, or market penetration) of a generic copy of the innovator’s first product, so it is “as if” the innovator had extended the active ingredient patent. We are simply using words economically.*³¹⁶ The concern is that non-specialist audiences—journalists, lay readers, and policymakers—may take the language literally. And they do.³¹⁷

314. See *supra* Part III.A.2. See also McCarthy, *Pharma Barons*, *supra* note 153, at 53 (“an extended 20-year patent period for what amounts to an identical drug product produced by the same company”); William G. Adams, Note, *Combating the Anti-Trade Movement: Evaluating the Trans-Pacific Partnership’s Place in International Patent Law*, 24 J. INTELL. PROP. L. 75, 80 (2016) (“Evergreening is a popular practice for pharmaceutical companies, which extend the effective life of their patent, often well beyond the statutory period of twenty years, to prevent cheaper generic drugs from entering the market.”); Jeffrey Coleman, Note, “*Undetected, Unsuspected, and Unknown*”: *Should We Anticipate Problems for Scientific Innovation Following Schering Corp. v. Geneva Pharmaceuticals?*, 82 FORDHAM L. REV. 165, 169 n.29 (2013) (defining “evergreening” as “a strategy by which a patentee obtains, or attempts to obtain, multiple patents that cover different aspects of the same invention in an effort to extend the term of the patent and the exclusivity privileges that come with it”).

315. E.g., Katrina Grace Geddes, *Sovereign Immunity for Rent: How the Commodification of Tribal Sovereign Immunity Reflects the Failures of the U.S. Patent System*, 29 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 767, 780 (2019) (stating that pharmaceutical patentees are “notorious for their attempts to extend the duration of their patents through evergreening”); Sierra Dean, Case Note, *India’s Controversial New Patent Regime: The End of Affordable Generics?*, 40 INT’L L. 725, 731 (2006) (“Evergreening refers to renewals of expired patents by pharmaceutical companies by citing a new use for the same drug, thereby extending the patent monopoly.”); Hannah Elizabeth Jarrells, Note, *History, TRIPS, and Common Sense: Curbing the Counterfeit Drug Market in Sub-Saharan Africa*, 43 GA. J. INT’L & COMP. L. 557, 568 (2015) (stating that “slightly changing a drug’s chemical composition by combining formulas or making time-release versions . . . extends the life of the original patent”).

316. Several scholars write about the innovator *effectively* or *nominally* extending its active ingredient patent. E.g., Daniel R. Cahoy, *Patent Fences and Constitutional Fence Posts: Property Barriers to Pharmaceutical Importation*, 15 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 623, 632 (2005) (“Later-filed patents on ancillary aspects of a product may have the effect of nominally extending core patents, assuming they continue to prevent competitors from making the product.”). One explains that the term “evergreening” is used because “the patent term appears ‘evergreen’ even if the commercial exclusivity is technically achieved through different patents.” Ho, *Should All Drugs*, *supra* note 216, at 297.

317. E.g., *Federal Trade Commission Oversight, Hearing Before the S. Comm. on Commerce, Sci., & Transp.*, 114th Cong. (Sept. 27, 2016) (statement of Sen. Klobuchar) (“And the idea here is that a company will take a drug and maybe go from a tablet to a capsule or maybe to a 24-release capsule, and then that extends their patent protections. That’s why they call it ‘evergreening.’ Then another competitor or a generic can’t come in the market. So, you can just keep extending and extending, and then we have no competition at all.”); *Insulin Access and Affordability: Hearing Before the S. Spec. Comm. on Aging*, 115th Cong. (May 8, 2018) (statement of Sen. Collins) (“I have previously expressed my concern with the practice called evergreening. This means when pharmaceutical companies obtain patents based on small innovations to extend the exclusivity of a

But even the more nuanced claim is wrong. It is never “as if” the innovator had extended the active ingredient patent. Whether an innovator secures a patent on a new strength, dosage form, route of administration, formulation, or combination—and markets a new product reflecting that innovation—does not affect the term of the initial patent claiming the active ingredient.³¹⁸ Once that patent expires, a generic company can use the ingredient in its own product, and it may even rely on the research in the innovator’s initial marketing application. And *only* the active ingredient has to be the same for a generic drug. A generic company may be able to design around intellectual property claiming other aspects (such as strength and route of administration) of the innovator’s drug and *still* file an ANDA.³¹⁹ If it cannot file an ANDA, it can always file a 505(b)(2) application.³²⁰ As one scholar points out, the suggestion that the innovator has secured an “extension” of the first patent in these situations “involves a bit of analytical sleight of hand.”³²¹ Claiming that the innovator might as well have done so is similarly disingenuous.

So too with statutory exclusivity. The drug statute provides five years of new-chemical-entity data exclusivity and three years of exclusivity for new products and new conditions of approval.³²² It also provides seven years of market exclusivity for orphan drugs and orphan indications.³²³ These exclusivities are governed by different provisions, triggered in different situations, and operate in different ways. And none is extended in the scenarios of concern. The contrasting mechanism of pediatric

product after its initial patent expires. For insulin, a careful look is warranted to determine if minor modifications were used to just extend the patent protection and discourage competitors.”).

318. Cf. Daniel R. Cahoy & Leland Glenna, *Private Ordering and Public Energy Innovation Policy*, 36 FLA. ST. U.L. REV. 415, 429 (2009) (“[O]ne cannot simply extend the power of a broad patent by filing subsequent, related patents based on the original disclosure because the original claimed invention will be available to competitors once the initial right expires.”); Holman, *In Defense of Secondary Pharmaceutical Patents*, *supra* note 19, at 795 (“[N]ew patents might preclude some newly invented uses, [but] they generally do not stop a generic company from selling a competing version of the original drug for the originally approved indications.”); see also Price, *Regulating Secrecy*, *supra* note 176, at 1777 n.43 (noting that patents have a “clearly defined term of twenty years from the date of the application” and that despite the potential for adjustment and restoration for the PTO’s delay and premarket testing, respectively, they have a “distinct end,” which means that “evergreening can only do so much, and each individual patent remains a right with a defined duration”); Israel Agranat & Silvy R. Wainschein, *The Strategy of Enantiomer Patents of Drugs*, 15 DRUG DISCOV. TODAY 163, 168 (2010) (“inventing the single-enantiomer drug as a successor to the racemic drug does not ‘extend,’ ‘repatent’ or ‘evergreen’ the basic patent”).

319. See *supra* Parts I.A and I.B.3. And its formulation need not be the same. See *supra* Part II.A.

320. See *supra* Parts I.A and I.B.3.

321. Darrow, *Debunking*, *supra* note 19, at 7 (typographical error corrected).

322. See *supra* Part II.B.1.

323. See *supra* Part II.B.4.

exclusivity illustrates the point.³²⁴ Six-month pediatric exclusivity extends all applicable exclusivity periods in the drug statute. Thus, abbreviated applications may not be submitted until five *and a half* years after approval of a new chemical entity, and this period is shortened to four *and a half* years if the generic company challenges a patent.³²⁵ Exclusivity for new conditions of approval and new products that lack new chemical entities lasts for three *and a half* years, and orphan exclusivity lasts for seven *and a half* years.³²⁶ If a generic company submits a paragraph III certification agreeing not to challenge a particular patent, FDA approval of its application cannot take effect until patent expiry *plus six months*.³²⁷ This is what it means to “extend” exclusivity.³²⁸ Whatever else may be going on in the “evergreening” situations described by scholars, it is *never* the case that the duration of one of these fixed terms has been lengthened.

B. No Extension of “Exclusivity” in the Descriptive Sense

Nor has the innovator preserved its position as the only company selling products containing the active ingredient. The innovator’s actions have not blocked approval of abbreviated applications or the promotion and sale of the resulting products. The scholarship could be clearer on this point. Instead, an ambiguity inherent in FDA law—which generally goes unremarked—has led to confusing, and perhaps even sometimes confused, claims in the literature, which may mislead general audiences.

At FDA, the term “drug” has more than one meaning.³²⁹ The statute defines “drug” to mean (among other things) any article “intended for use” in the treatment of disease, any article (other than food) “intended to affect the structure or function of the body,” and any “component” of such an article.³³⁰ Depending on the statutory provision or regulation at issue, FDA may take the term to mean *only* a finished drug product, *only* an active ingredient, or *both*. For example, for years FDA interpreted the

324. See *supra* Part II.B.4.

325. 21 U.S.C. §§ 355a(b)(1)(A)(i)(I), (c)(1)(A)(i)(I) (2018).

326. *Id.* §§ 355a(b)(1)(A)(i)(II), (b)(1)(A)(ii), (c)(1)(A)(i)(II), (c)(1)(A)(ii).

327. *Id.* §§ 355a(b)(1)(B)(i), (c)(1)(B)(i).

328. A few scholars describe earning pediatric exclusivity as an act of “evergreening.” *E.g.*, El-Said, *supra* note 220, at 394 (referring to pediatric exclusivity for atorvastatin, marketing as Lipitor); see also Gervais, *The Patent Option*, *supra* note 172, at 395 n.151 (footnote implying that pediatric exclusivity is a type of evergreening); Halabi, *The Drug Repurposing Ecosystem*, *supra* note 181, at 50–51 (stating that pediatric exclusivity for glucophage represented evergreening).

329. See also Feldman, *May Your Drug Price*, *supra* note 126, at 607–09 (grappling with some of this ambiguity).

330. 21 U.S.C. § 321(g)(1) (2018).

term "drug" in the statutory provision governing five-year new-chemical-entity exclusivity to mean finished drug product. But in 2014, it switched to construing the term to mean "drug substance or active ingredient."³³¹ The statute requires FDA to publish a list of every approved "drug,"³³² and FDA lists every approved product. The pediatric exclusivity provision refers to studying use of a "new drug" and extending by six months various statutory exclusivities related to the "drug," and FDA interprets the provision to permit extension of exclusivity applicable to the drug products containing the underlying active moiety.³³³ In one part of its regulation governing the contents of a new drug application, FDA uses "drug" to mean active ingredient, reserving "drug product" for the finished product.³³⁴ In another part of the same regulation, FDA distinguishes between "drug substance" and "drug product."³³⁵

The distinction between active-ingredient-*drug* and finished-product-*drug* is important because active ingredients and finished products occupy different places in the legal framework. An example will show this. Consider the atypical antipsychotic Zyprexa (olanzapine). Zyprexa (olanzapine) is sold in tablets for oral administration; there are six strengths ranging from 2.5 mg to 20 mg. FDA considers each strength a separate drug product; FDA approved one application (#20592), but it considers the strengths as *products* 001 through 006 associated with that application.³³⁶ Lilly also sells a 10 mg vial of olanzapine for intramuscular injection. FDA generally requires a separate application for a new route of administration.³³⁷ And Lilly filed a separate application (#21253) for this product. The company also developed an orally disintegrating tablet for oral administration. FDA considers this a different dosage form,³³⁸

331. See FDA, NEW CHEMICAL ENTITY EXCLUSIVITY DETERMINATIONS FOR CERTAIN FIXED-COMBINATION DRUG PRODUCTS: GUIDANCE FOR INDUSTRY 2 (Oct. 2014) ("NCE GUIDANCE") (referring to 21 U.S.C. § 355(j)(5)(F)(ii)). FDA changed its approach so that a fixed dose combination with one new chemical entity would receive five years, instead of three years, of exclusivity, noting that these combinations were "becoming increasingly important from patient and public health perspectives" and that combination therapy was "emerging as the standard of care" in several disease settings. *Id.*

332. 21 U.S.C. § 355(j)(7) (2018).

333. See *supra* Part II.B.4.

334. *E.g.*, 21 C.F.R. § 314.50(c)(2)(ii) (2020) (requiring that each new drug application include a summary with a statement "identifying the pharmacologic class of the drug and a discussion of the scientific rationale for the drug, its intended use, and the potential clinical benefits of the drug product").

335. *E.g.*, 21 C.F.R. § 314.50(d)(1) (2020) (requiring that each new drug application describe "the composition, manufacture, and specifications of the drug substance and the drug product").

336. ORANGE BOOK, *supra* note 43, at 3-326.

337. FDA, SEPARATE APPLICATIONS GUIDANCE, *supra* note 48.

338. ORANGE BOOK, *supra* note 43, at Appendix C.

which usually needs a separate application.³³⁹ There are four strengths—four products, 001 through 004—on this marketing application (#21086).³⁴⁰ Lilly calls this product Zyprexa Zydis.³⁴¹ Finally, the company developed an extended release formulation containing olanzapine pamoate monohydrate, also for intramuscular injection.³⁴² An innovator must file a separate application for a product containing a new active ingredient, even if the underlying active moiety is the same.³⁴³ Lilly submitted a separate marketing application (#22173) and calls this product Zyprexa Relprevv.

One active moiety—olanzapine—is offered for sale in 14 discrete drug products covered by 4 new drug applications associated with 3 brand names.³⁴⁴ Because of the ambiguity in the term “drug,” one could correctly say that there are 14 drugs (discrete products), 2 drugs (two active ingredients), and perhaps even 1 drug (one active moiety). Writers and readers insufficiently attuned to the nuances of the regulatory framework might also think—incorrectly—that because there are four marketing applications, there are four drugs. Others might focus on the brand name (which is never a “drug” at FDA) and think this story involves either one drug or three drugs. Understanding that there are 14 discrete drug products is important because each product is legally distinct. When a generic company cites a “reference listed drug” in its generic application, it cites *one* product—meaning *1 of the 14*, not “Zyprexa” or olanzapine writ large.³⁴⁵ The generic company’s burden—the requirement to show sameness and bioequivalence and, critically, the obligation to address patents—is tied to the specific *one* product, alone.³⁴⁶

339. FDA, SEPARATE APPLICATIONS GUIDANCE, *supra* note 48.

340. ORANGE BOOK, *supra* note 43, at 3-327.

341. FDA might tell an innovator that it could not use the same brand name for a different but related product, if FDA was concerned about prescriber or patent confusion. And an innovator might choose a new brand name for business reasons.

342. The pamoate salt of the molecule slowly dissociates into olanzapine and pamoic acid, which means the olanzapine releases slowly into the blood stream over several weeks. J.P. Lindenmayer, *Long-acting injectable antipsychotics: focus on olanzapine pamoate*, 6 NEUROPSYCHIATRIC DISEASE & TREATMENT 261, 262 (2010).

343. From FDA’s perspective, a change in active ingredient inherently raises issues of safety and effectiveness that must be examined in clinical investigations.

344. Some articles imply that the proliferation of applications and products containing a single active ingredient reflects gamesmanship on the part of innovators, but FDA’s policies and preferences—often dictated by review considerations—typically control in these situations.

345. *See supra* Part II.A.

346. *See supra* Part II.A. If a generic company files an application under § 505(b)(2), it may reference multiple listed drugs. *E.g.*, Letter from Steven K. Galson, Acting Dir. of Ctr. for Drug Evaluation & Research, to Donald O. Beers & William F. Cavanaugh, Jr., Re: Docket No. 2004P-0386/CP1 & RC1 (Nov. 30, 2004) at 7–8 (referring to a 505(b)(2) applicant relying on listed “drug

It would therefore be a mistake for policymakers to focus on the number of "patents" associated with a "drug." A generic company does not copy a "drug" in the broad sense of the term. It copies a particular finished product—a "drug" in the narrow sense of the term. Lilly no longer holds an unexpired patent on the active ingredient, olanzapine. Suppose it developed a new Zyprexa product containing olanzapine, and suppose it listed five patents for that product. One could correctly assert that Lilly had secured approval of a new olanzapine product with patents expiring long after its active-ingredient patent expired. Someone counting patents would say that Zyprexa has five later-issued patents (on top of whatever earlier issued patents it might have had). Yet, there are approved *generic* olanzapine drugs in the market. Someone seeking to describe accurately a generic company's freedom to operate would focus on *discrete drug products* that can serve as reference listed drugs and on the number, scope, and breadth of the patent *claims* held by the innovator for *those products*. This would tell us more about the market impact of an innovator's innovation and patenting practices than the number of patents associated with a particular brand name or the number of patents associated with the many finished products containing a particular active ingredient.

The same thing is true when one counts statutory exclusivity terms.³⁴⁷ Again, a three-year exclusivity period associated with a new condition of approval delays approval only of abbreviated applications proposing products with the same active moiety for the same condition of

or drugs"). In this case, it would need to address the patents listed for each that it has chosen to cite. *Id.* at 8, 8 n.8. But regardless of the type of abbreviated application it files, a generic applicant is not required to address patents listed only for *other* products marketed by the innovator, including newer products containing the same active ingredient. *See generally id.* (rejecting petition that had asked FDA to require Reliant to certify to all patents on all later-approved products that were supported by any of the same clinical studies).

347. Although definitions of "evergreening" focus more on patents than statutory exclusivity, some legal scholars do mention statutory exclusivity. *E.g.*, Baker, *Ending Drug Registration Apartheid*, *supra* note 128, at 306 (describing "evergreening of data-exclusivity" by which "a product can obtain overlapping and successive periods of three-year exclusivity if the innovator acts strategically in seeking new indications or in introducing product variations"); Feldman, *May Your Drug Price*, *supra* note 126, at 596 (defining "evergreening" as "artificially extending the life of a patent or other exclusivity by obtaining additional protections to extend the monopoly period"); Gervais, *The Patent Option*, *supra* note 172, at 395 n.151; Halabi, *The Drug Repurposing Ecosystem*, *supra* note 181, at 43 (arguing that "evergreening strategies" are "adopted . . . in the various market exclusivity regimes administered by FDA"); *see also* Emily K. White, *Killing U.S. Slowly: Curing the Epidemic Rise of Cancer Drug Prices*, 72 *FOOD & DRUG L.J.* 189, 204 (2017) ("Although the practice of extending market protection through statutory exclusivities is not technically considered evergreening . . . , this practice also delays generic market entry, contributing to increased drug costs."). And some empirical literature counts statutory exclusivity. *See supra* Part III.C.1.

approval.³⁴⁸ Thus, if an innovator establishes its product is safe and effective for treatment of a new disease, FDA will not approve any applications for the same active moiety for treatment of that disease for three years.³⁴⁹ If the innovator establishes that its product is safe and effective for treatment of that disease through a novel route of administration, its three-year exclusivity will block only products containing that active moiety for that use through that route of administration.³⁵⁰ Orphan exclusivity operates similarly.³⁵¹ These later-arising exclusivities are, in other words, thin—leaving generic companies substantial freedom to operate.³⁵² That a particular “drug” is linked to many exclusivities earned after approval tells us that the innovator has a vigorous research and development program but precious little about the prospects for (and timing of) approval of abbreviated applications proposing products with the same active ingredient.³⁵³

For all of these reasons, it is a challenge to locate the “extension” alleged in the definitions and supposedly illustrated by the examples in the literature. FDA’s approval of a new dosage form does not prevent a generic company from copying the innovator’s old dosage form. To be sure, the new dosage form might be protected by a new patent. But a patent claiming only the *new* dosage form would not be listed in the ORANGE Book with the original marketing application, and generic companies referencing that application would not need to address it. And while the new dosage form might earn the innovator three years of statutory exclusivity, preventing approval of any other application for *that* active moiety in *that* dosage form for three years, this exclusivity would not block approval of an abbreviated application proposing a product containing the active ingredient in the *original* dosage form.

348. See *supra* Part II.B.2.

349. See *supra* Part II.B.2.

350. See *supra* Part II.B.2.

351. See *supra* Part II.B.4.

352. Failing to make this point clearly may confuse readers. *E.g.*, Baker, *Ending Drug Registration Apartheid*, *supra* note 128, at 306 (complaining of “overlapping and successive periods of three-year exclusivity” and suggesting that a second applicant cannot get approval until the final three-year term has ended).

353. The innovator’s first product could have patents claiming aspects other than its active ingredient, and these could expire later than the active ingredient patent. In these cases, the generic company will need to design around these patents, challenge them as invalid, or seek licenses, which means it will face higher entry costs than if the innovator had only one patent. Most allegations of “evergreening” relate to the introduction of newer products with their own intellectual property protection, though, rather than to the issuance of more than one patent on the innovator’s originally marketed product as introduced. See *supra* Part III.B.1.

So too, if the innovator introduces a new active ingredient. The new product might be claimed in a new patent, and it might receive three years of statutory exclusivity (or even five years if the active ingredient is a new chemical entity). But the patent and exclusivity will not affect a generic company seeking to copy the innovator's original product.³⁵⁴ Nor would the innovator's combination of the active ingredient with another, in a new fixed dose combination product. The combination product might receive three years of statutory exclusivity (or five years, if the second, new active ingredient is a new chemical entity), but the exclusivity would not prevent FDA from approving a generic copy of the innovator's original single-ingredient product.³⁵⁵ And if the patents on the underlying active ingredients have expired, a generic company could also market—and doctors prescribe and payers cover—the two constituents as stand-alone drugs.³⁵⁶

Nor does approval of the innovator's drug for a new use block approval of abbreviated applications or sales of the resulting products. Even if there is only one approved innovative product to reference, a generic company may omit the use from its labeling, and FDA will usually approve its drug anyway.³⁵⁷ The generic company will even enjoy sales for the use that is omitted from its labeling.³⁵⁸ This illustrates how narrowly we should interpret the patent and exclusivity counting exercises. In the 35 years since enactment of the generic drug statute, FDA has awarded nearly 800 three-year exclusivity terms for the development and approval of a new "indication" for an already approved product.³⁵⁹ In each case, although this exclusivity prohibited generic companies from adding the indication to their labeling, it did not block approval of their generic drugs, *and* those drugs were likely to be prescribed and dispensed for that use. While one article reports that "almost 40% of all drugs available on the market created additional market barriers by having patents or exclusivities added onto them,"³⁶⁰ hundreds of three-year

354. Cf. Andrew Q. Leba, Comment, *Lowering the "Efficacy" Threshold for Section 3(d) of the Indian Patents (Amendment) Act 2005: A Case for a Broader Scope*, 28 EMORY INT'L L. REV. 649, 682–83 (2014) ("[O]meprazole works sufficiently and has been available as a generic drug to U.S. patients for almost ten years Patients do not have to take Nexium to treat their afflictions.").

355. In addition, at least in theory, a generic applicant could submit an ANDA citing the fixed dose combination product and changing one of the two active ingredients. 21 U.S.C. § 355(j)(2)(A)(ii)(III) (2018).

356. See *supra* Part II.C.

357. See *supra* Part II.A.

358. A pharmacy will usually dispense a therapeutically equivalent generic drug for a patented use that has been carved out of its labeling. Lietzan, *Paper Promises*, *supra* note 92, at 183–91.

359. ORANGE BOOK, *supra* note 43, at ADB34.

360. Feldman, *May Your Drug Price*, *supra* note 126, at 597.

exclusivity awards for new indications counted in that article did *not* serve as market barriers to generic companies. By expanding the uses for which those generic drugs were dispensed, as a practical matter, some might even have *increased* the sales that generic companies received.

Some articles acknowledge that generic companies may introduce copies of the innovator's first product but still apply the "evergreening" metaphor.³⁶¹ It may help to consider the market in these situations. The innovator's newer product creates a new choice for doctors and payers. If a doctor selects this product, pharmacists will dispense it rather than generic copies of the innovator's older product.³⁶² Doctors might shift their prescribing to this newer product for several reasons, including persuasive advertising and promotion—meaning they come to believe (based on advertising that, per FDA rules, must be truthful and not misleading) that there are benefits to the newer product.³⁶³ They might shift for other reasons, including actual experience treating patients with the two options. But generic companies may advertise and promote their products to doctors and patients, and on the basis of this advertising (or for other reasons, such as experience with the drug) a doctor might *not* select the innovator's newer product.³⁶⁴ A doctor might specify the innovator's older product (which would lead to automatic substitution, even if the innovator no longer marketed the product) or even the generic drug itself. In many cases, the payer's decision will control, and generic companies promote to payers.³⁶⁵ If a payer perceives the innovator's new product as less cost effective than available generic drugs containing the

361. These articles equate "evergreening" with "product hopping." See *supra* Part III.A.1.

362. See *supra* Part II.C.

363. For example, numerous articles cite the introduction of Lexapro (escitalopram) as an instance of evergreening. See authorities cited *supra* note 224. But several studies have found Lexapro (escitalopram) more effective than Celexa (citalopram) in treatment of severe depression, and it stands to reason that some doctors might choose to prescribe Lexapro instead. *E.g.*, Valery Yevtushenko et al., *Efficacy and tolerability of escitalopram versus citalopram in major depressive disorder: A 6-week, multicenter, prospective, randomized, double-blind, active-controlled study in adult patients*, 29 CLINICAL THERAPEUTICS 2319 (2007) (concluding from a prospective, randomized, double-blind, active-controlled study of 322 adults with major depressive disorder that escitalopram 10 mg was more effective than citalopram 10 and 20 mg at six weeks); J.M. Azorin et al., *Traitement des épisodes dépressifs sévères: escitalopram est plus efficace que citalopram*, 30 L'ENCEPHALE 158 (2004) (describing meta-analysis of three clinical trials involved 506 severely depressed patients that escitalopram was more effective than citalopram in treatment of severe depression).

364. See *supra* Part II.C; see also *Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd.*, Civ. No. 12-3824, 2015 WL 1736957 at *13 (E.D. Penn. Apr. 16, 2015) ("Spending some of its revenue on advertising would have lessened Mylan's now-increased profits. Mylan chose not to do so, relying instead on the 'promotion' provided by state automatic substitution laws. Mylan is thus a 'victim' of its own business strategy, not Defendants' 'predatory' conduct.").

365. See *supra* Part II.C.

same active ingredient, it might decline to cover the product. In brief: when an innovator introduces a new product into the market, generic companies will be able to introduce copies of the innovator's first product, and they may or may not enjoy sales, depending on the choices they make, and the choices made by others in the market. And yet, scholars still apply the "evergreening" metaphor. To be clear, the fact that generic companies may introduce their own copies of the innovator's initial product is not meant as a claim that "there is no such thing as evergreening." The point of this Article is to figure out what the term really means given these facts.

C. An "Extension" Therefore . . . of What?

The literature contains more than 100 definitions of "evergreening" and several dozen examples of what the authors view as "evergreening." The metaphor directs our attention to something *enduring*, and the definitions center on *extension*. But no patent has been extended, and no statutory exclusivity has been extended. In these scenarios, the innovator's position as the lone source of products containing the active ingredient has ended. No barriers prevent generic companies from promoting their competing product to doctors, payers, and patients. No barriers prevent payers from requiring that their insured patients use the generic company's drug. What, then, has been extended?

An example will tease out the answer. Suppose that at any given time, 1,000 patients suffer from Disease X. Consider a simple world in which the innovator is the only game in town; there are no other treatments available for the disease.

First Brand Product. Suppose that in 2010, Innovator introduces Product A (containing active ingredient α) for treatment of Disease X. Suppose that its patent on α expires in 2020.

Starting in 2010, all 1,000 patients use Product A.

Second Brand Product. Suppose that in 2018, Innovator introduces Product B for Disease X. Put aside for the moment questions about what this product entails; imagine only that it is a discrete drug product. Suppose a patent covering this product expires in 2030.

Beginning in 2018, some patients with Disease X use Product A, and some use Product B. Innovator enjoys all the sales.

Generic Products. In 2020, the patent on α expires, and suppose that two generic companies enter the market. They sell Generic A1 and Generic A2, which are much cheaper than Product A. Assume that FDA designates these generic products as therapeutically equivalent to

Product A. Thus if a doctor prescribes Product A, the pharmacist will dispense Generic A1 or Generic A2.

To conclude the example, suppose that beginning in 2020, after expiry of the patent on active ingredient α , three-quarters of the patients with Disease X (750 patients) purchase Product B from Innovator at prices that reflect its patent-based exclusivity, while one-quarter (250 patients) use Generic A1 or Generic A2 (at much lower prices). Whether the literature calls this an “evergreening” scenario depends on the nature of Product B. If Product B contains the same active ingredient (α)—for instance, it is a new extended release formulation of α —they will say the company has evergreened. If Product B contains a different active ingredient in some fashion *related* to active ingredient α —if it is an enantiomer, an active metabolite, or a prodrug, for instance—they will say that the company has evergreened. But if Product B contains an active ingredient unrelated to α , they will not apply the evergreening label.

In all three scenarios, beginning in 2020, Innovator enjoys 750 of the available 1,000 sales to patients with Disease X at prices that reflect its patent protection. But the literature generally holds that in the first two scenarios—and not the third—*something* was extended, lengthened, or prolonged in duration.³⁶⁶ Scholars cannot mean the company’s dominance in the market for treatment of Disease X has been extended because they do not label the third scenario evergreening. They cannot mean the company’s dominance in the market for the active ingredient has been extended, because the second scenario—an evergreening scenario—does not involve that active ingredient.

These “evergreening” scenarios have two things in common. *First*, there is a relationship between the initial innovation (discovery and development of active ingredient α) and the innovator’s new products. Although the relationship is hard to describe, the new products stem in some fashion from this innovation. They can be attributed in some “but for” sense to this initial innovation. *Second*, the innovator enjoys exclusive sales of these *but-for* products, perhaps at supra-competitive (patent-based and perhaps exclusivity-based) prices, even though the patent and data exclusivity on the initial innovation—active ingredient α —has expired. Taking these two points into account permits precise characterization of the extension. It seems the innovator’s ability to charge supra-competitive prices for at least some discrete products that can be traced to its discovery of active ingredient α (that it would not have been

366. *Extend*, OED, *supra* note 2, at 4a, 4b.

able to introduce if it had not discovered active ingredient α) has lasted longer than the patent on α itself.³⁶⁷

About this, two points should be made. *First*, the existing empirical work suffices to make this claim. It shows that innovators introduce new products, the result of incremental innovation, protected by patents and exclusivity that expire later than the original protections on its active ingredient.³⁶⁸ But it does not tell us more. It tells us nothing about the effect of the innovations and product introductions on the market. For instance, it does not tell us whether (and how much of) the market shifts to the newer products, nor does it tell us—if the market does shift—*why* payers (or prescribers or patients) make the shift. These empirical questions could be answered. *Second*, calling this an extension—and therefore using the “evergreen” metaphor—is inherently normative. It is normative because there is no basis in current law to state a usual or expected length of time during which a company *should* be permitted to market related products at supra-competitive prices. Patent law does not provide a basis. It provides a 20-year term for every discrete invention claimed. The 20-year term is not meant to cover *other* inventions that would not exist had it not been for the first invention, and there is no basis in patent law to deny protection for a discrete invention that meets the patenting standards simply because the inventor has already enjoyed a patent term on another invention. Nor does FDA law provide a basis for stating a usual or expected length of time.

V. CONCLUSION: A PRELUDE TO POLICYMAKING

The evergreening metaphor in intellectual property scholarship reflects a radical normative claim: a drug innovator should not enjoy supra-competitive prices for any products that can be traced to its discovery of a new active ingredient *after* expiry of the patent and data exclusivity associated with that active ingredient. But if the underlying intuition behind this body of scholarship is that after a fixed period drug innovators should simply move on—that they should not enjoy revenue

367. Some articles refer to “evergreening” of orphan exclusivity, which would occur if FDA allowed unrelated companies to receive sequential orphan-drug exclusivity terms for the same drug for the same disease. See, e.g., Shannon Gibson & Barbara von Tigerstrom, *Orphan Drug Incentives in the Pharmacogenomic Context: Policy Responses in the U.S. and Canada*, 2 J.L. & BIOSCIENCES 263 (2015). Congress amended the statute in 2017 to provide that a company cannot earn orphan-drug exclusivity if FDA has already approved the same drug for the same disease, unless its drug is clinically superior. 21 U.S.C. § 360cc(c) (2018). This effectively precludes the possibility.

368. See *supra* Part III.C.

on new products that can be traced back in some fashion to the same new chemical entity—that has to be defended.

Some scholars who use the metaphor hint at normative arguments. For instance, they talk about the “rightful” term of a patent, or the notion that the public “agreed to pay” for innovation with a 20-year patent term, or that after 20 years a “product” belongs in the “public domain.”³⁶⁹ All of these things may be true, but these arguments do not defend the claim described above. This is why the literature’s failure to grapple with the nuanced legal and factual context in which innovators and generic companies operate is so pernicious. We would all be better served if everyone acknowledged forthrightly that patents are not extended, statutory exclusivities are not extended, and generic companies may introduce, promote, and sell the active ingredient—so that we can focus together on debating the real normative claim.

Serious policy proposals should be based on rigorous evidence-based scholarship that is careful and precise about the law and the facts. Policymakers cannot make reasoned and well-informed decisions about law and policy in this area if descriptive claims are not rigorously supported and carefully assessed and if normative claims are not stated clearly and justified. This Article therefore concludes with two recommendations for further scholarship on the topic.

First, descriptive scholarship about “evergreening” should be more precise and detailed. Scholars should describe the relevant regulatory,

369. E.g., Ron A. Bouchard, *I’m Still Your Baby: Canada’s Continuing Support of U.S. Linkage Regulations for Pharmaceuticals*, 15 MARQ. INTELL. PROP. L. REV. 71, 117 (2011) (discussing prolongation of monopoly “beyond what the public has agreed to pay”); Rebecca S. Eisenberg, *Pharma’s Nonobvious Problem*, 12 LEWIS & CLARK L. REV. 375, 420 (2008) (suggesting that Pfizer’s patent on amlodipine besylate, which expired after the patent on amlodipine, “may have seemed like improper patent ‘evergreening’ of a product that had already enjoyed a healthy term of patent protection and belonged in the public domain”); Geddes, *Sovereign Immunity*, *supra* note 315, at 780 (arguing that patentees seek to “extend their statutory monopolies beyond their rightful term”); Seymore, *Reinvention*, *supra* note 136, at 1068 n.317 (discussing “evergreening” as “an attempt by patentees to refresh their expiring patents with new ones by making minor modifications to subject matter that should go to the public domain”); Joel Lexchin, *Canada’s Patented Medicine Notice of Compliance Regulations: Balancing the Scales or Tipping Them?*, 11 BMC HEALTH SERVS. RES. 64, Mar. 24, 2011, at 2 (describes “evergreening” as “attempts to unfairly extend patent life in order to prevent generic competition”); *see also* Bansal, *supra* note 172, at 306 (“Enhanced IP scrutiny may remove the curse of these unfair practices which are widely followed by the innovator companies to create a roadblock for generic companies that are trying hard to provide safe and efficacious medicines to the masses at cost effective prices.”); *see also* Jennifer Robichaux Carter, Comment, *Hedge Funds Should Be Able to Challenge Patent Validity Using Inter Partes Review Despite Mixed Motives*, 54 HOUS. L. REV. 1315, 1330 n.125 (2017) (mentioning evergreening in a footnote, when discussing the proposition that “non-novel patents upset the quid pro quo exchange between the public and patent owner and consequently, fail to add any social value”).

intellectual property, and state laws thoroughly and precisely.³⁷⁰ We should be clear that the various sources of exclusive rights that an innovator might enjoy are legally distinct, derive from different bodies of law, and have differing scopes and standards. We should be candid about what the law currently does and does not require of innovators and generic companies. We should be careful when using the term "drug," given its inherent ambiguity, and we should distinguish clearly among approved products, describing accurately the scope of approvals as well as the scope of associated patents and exclusivity. We should also avoid creating inferences that are legally impossible. For instance, we should ensure our readers do not infer that a patent claiming a particular innovative modification to an earlier approved product claims more than it does. We should not refer to patent "extension" unless discussing the extension of a particular patent's term through patent term adjustment (35 U.S.C. § 154) or patent term restoration (35 U.S.C. § 156). And we should be careful when writing that the PTO issues patents for "uninventive" modifications, that it allows multiple patents on the same invention, or that it issues patents that are weak, bogus, or inappropriate.³⁷¹ The problem is that non-expert readers may

370. Related to this point, we should distinguish carefully between non-biological drugs (those approved under the Food, Drug, and Cosmetic Act and discussed in this article) and biological drugs, which are licensed under the Public Health Service Act. The regulatory, intellectual property, and state law frameworks governing innovative biological medicines and the "biosimilar" and "interchangeable" versions marketed on the basis of abbreviated applications differ from the frameworks governing non-biological drugs and their generic copies. Policymakers will need to distinguish between the two, and scholars should do the same. *See generally* Erika Lietzan, *The Uncharted Waters of Competition and Innovation in Biological Medicines*, 44 FLA. ST. L. REV. 1 (2017) (arguing that the scientific, legal, and real world framework in which biologics innovators and biosimilar producers will compete differs fundamentally from the framework applicable to small molecule drug innovators and their generic competitors); Carrier & Minniti, *The New Antitrust Frontier*, *supra* note 246 (arguing that various anticompetitive actions will be taken by biologics innovators or their biosimilar competitors); Erika Lietzan, *A Solution in Search of a Problem at the Biologics Frontier*, 2018 U. ILL. L. REV. ONLINE 19 (responding to Carrier and Minniti, *The New Antitrust Frontier*, *supra* note 246).

371. *E.g.*, Bouchard, *Empirical Analysis*, *supra* note 149, at 182 n.45 ("uninventive" modifications); Altin, *supra* note 207, at 9 ("the filing of 'secondary patents', covering related (but typically non-innovative) technologies, late in a drug's base patent life"); Moir, *Exploring evergreening: Insights*, *supra* note 223, at 424 ("relatively un inventive patents"); Kesselheim, *Think Globally*, *supra* note 182, at 136 ("Loose interpretation of patents laws has permitted evergreening, where overly broad or otherwise inappropriate patents have been granted on peripheral aspects of pharmaceutical products, leading to extensions in market exclusivity."); Gaurav Dwivedi et al., *Evergreening: A deceptive device in patent rights*, 32 TECH. SOC. 324, 326 (2010) (describing "evergreening strategies" such as "listing bogus patents in the Orange Book"); Chander & Sunder, *supra* note 159, at 346 (evergreening is "where drug companies seek to extend their patents on weak grounds"). In contrast, consider claims that "evergreening" results from mistakes or failures at the PTO; these claims can be debated, but they are not legally impossible. *E.g.*, Lemley, *Expecting the*

misunderstand these as undisputed descriptions of fact or of patent law, when instead they are argument.³⁷²

Second, we should engage in a robust conversation about the ultimate normative claim. Scholars need to own their claim that an innovator should not enjoy supra-competitive prices for any products that can be traced to its discovery of a new active ingredient *after* expiry of the patent and data exclusivity associated with that active ingredient.³⁷³ It is conceivable that social welfare is best served by policies that discourage drug innovators from introducing more than one finished product containing each novel active ingredient and from developing variants of that active ingredient. But this normative conversation will be difficult. And it should be difficult. It must consider the many subsequent products that could be traceable to an initial innovation, the situations in which those subsequent products may provide meaningful benefits (clinical or otherwise) to patients, whether those products would be developed without the protections available after expiry of the initial active ingredient patent and data exclusivity, the role we think that consumer and physician choice ought to play, and what we think of the information and leverage that payers have. And it must grapple with whether drug innovators are exceptional (and why) or whether, instead, this rule should apply to all inventors.

Use of the term “evergreening” in scholarship is problematic.³⁷⁴ It is a sloppy metaphor that conceals not only descriptive failures but also a failure to own and defend a radical—and important—normative claim. Serious writers about this topic should avoid the shorthand and focus on

Unexpected, *supra* note 133, at 1393 (“While patent law theoretically prohibits ‘double patenting’—obtaining more than one patent on the same invention—in practice pharmaceutical companies often obtain follow-on patents on trivial variants of their basic chemical once the initial patent is about to expire.”).

372. Indeed, the Director of the PTO recently testified, in responses to questions about “evergreening,” that the PTO applies the same rigorous standards and process to every patent application, regardless of the field of technology. Ryan Davis, *Iancu Tells Congress One Drug Can Deserve Many Patents*, LAW360 (May 9, 2019), <https://www.law360.com/articles/1156731/iancu-tells-congress-one-drug-can-deserve-many-patents> [<https://perma.cc/U959-DHAZ>].

373. Professor Feldman makes the claim by proposing a solution, which she calls “one-and-done.” See Feldman, *May Your Drug Price*, *supra* note 126, at 640–43; see also Robin Feldman, “One-and-done” for new drugs could cut patent thickets and boost generic competition, STAT (Feb. 11, 2019), <https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/>, [<https://perma.cc/86T5-PZZQ>] (arguing that “one period of protection should be enough” and thus “a drug” should “receive just one period of exclusivity, and no more”).

374. Some scholars criticize the term, though they still criticize the underlying scenario. *E.g.*, Chaudhry, *supra* note 119, at 206 n.97 (“There is much dissatisfaction with the term ‘evergreening.’ However, it should not be mistaken for clarity as to patent extension being of no importance.”).

what matters: an actual description of the law and facts in play and the real normative claim being made. The term's meaninglessness makes it impossible for audiences to distinguish among situations that may be different, as a legal, theoretical, or normative matter, and that may call for differing policy solutions. Using the metaphor does a disservice to policymakers and therefore the public.