

Big Pharma, Big Problems: COVID-19 Heightens Patent-Antitrust Tension Caused by Reverse Payments

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ABSTRACT

In the wake of COVID-19, pharmaceutical companies rushed to produce vaccinations and continue to work on developing treatments, while the tension caused by reverse payments intensifies between patent and antitrust law. Lawmakers must address this tension, and the current pandemic should serve as a catalyst to prompt reform at the legislative level. By amending the Hatch-Waxman Act, lawmakers can ease the increasing strain between patent and antitrust policy concerns. In 2013, the U.S. Supreme Court attempted to resolve this tension in its landmark decision, *F.T.C. v. Actavis*, but the tension remains as lower courts struggle to produce a uniform standard when applying *Actavis* to reverse payment settlements arising as a result of the current Hatch-Waxman Act provisions. Much scholarship exists explaining and addressing the lingering issues surrounding reverse payment settlements. However, no better time exists to address this heightened problem in the pharmaceutical context than now—amidst the COVID-19 pandemic devastating the United States. Lawmakers must act now to shield consumers from big pharma barring public access to affordable medications through reverse payment settlements.

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INTRODUCTION

The fundamental goal of antitrust law “is to prevent or eliminate practices that interfere with free competition.”¹ Antitrust laws “are designed to promote a vigorous and competitive economy in which each business enterprise has a full opportunity to compete on the basis of price, quality, and service.”² Patents, however, are the exception to the rule. In the big pharma³ context,⁴ a patent gives the pharmaceutical company developing a new drug a “legal monopoly over the production—and profit—of that drug.”⁵ In granting patents for drugs to pharmaceutical companies, the United States government seeks to protect innovation and reward investment.⁶ While antitrust law aims to prevent monopolies, patent law permits limited monopolies.⁷ And just as the patent exception

1. Phillip A. Proger, *Antitrust Primer*, in 2010 AM. HEALTH L. ASS’N SEMINAR PAPERS 1, 1 (2010).

2. *Id.*

3. “Big pharma” is defined as “large pharmaceutical companies considered especially as a politically influential group.” *Big Pharma*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/Big%20Pharma> [<https://perma.cc/ZT7L-XYRH>].

4. Although I mention the pharmaceutical context specifically, patents grant limited monopolies to a broad range of companies. See Audra J. Passinault, Note, *A Prescription for the Future: Reverse-Payment Settlements in the Wake of FTC v. Actavis Pharmaceuticals*, 29 NOTRE DAME J.L. ETHICS & PUB. POL’Y 549, 549 (2015).

5. *Id.*

6. *Id.*

7. *The Antitrust Laws*, FED. TRADE COMM’N, <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws> [<https://perma.cc/P9Y9-KA5Q>]; Passinault, *supra* note 4, at 549.

to antitrust law appears utilitarian, this exception also has an exception: the Hatch-Waxman Act.⁸

The Hatch-Waxman Act allows generic drug companies to enter the pharmaceutical market sooner by using a brand-name pharmaceutical company's approval efforts—so long as the generic drugs comprise the same active ingredients and are bioequivalent.⁹ This exception is unique because it allows the generic drug company to obtain Food and Drug Administration (FDA) approval for a generic equivalent without having to submit extensive safety and efficacy data typically required to submit a New Drug Application (NDA).¹⁰ Therefore, generic drug companies may gain the right to distribute drugs with essentially the same ingredients as the patent holders' drugs before the patent term, or limited monopoly, expires.

To achieve its goal, the “Hatch–Waxman Act sets forth special procedures for identifying, and resolving, related patent disputes.”¹¹ Principally, in order to piggyback on brand-name drug manufacturers' work, generic drug manufacturers must “‘assure the FDA’ that the generic drugs ‘will not infringe’ the brand-name’s patents.”¹² If the generic drug manufacturer can demonstrate to the FDA that any listed, relevant patent is invalid or will not be infringed, the Hatch-Waxman Act provides that such demonstration automatically shows patent infringement, meaning the generic company may enter the market before the brand-name manufacturer's patent expires.¹³ The most common way for the generic drug manufacturer to provide the FDA such assurance is for the generic drug company to “certify that any listed, relevant patent ‘is invalid or will not be infringed by the manufacture, use, or sale’ of the drug described in the [generic drug company's] Abbreviated New Drug Application [ANDA].”¹⁴ However, “[i]f the brand-name patentee brings an infringement suit within 45 days, the FDA then must withhold approving the generic . . . while the parties litigate patent validity (or infringement) in court.”¹⁵ As a result, the arrangement of the Hatch-Waxman Act provides the public with access to the generic, more affordable version

8. 21 U.S.C. § 355(j).

9. Daryl Lim, *The Defense Docket: Intellectual Property Litigation: Intellectual Property and Antitrust: Practical Insights*, 13 IN-HOUSE DEF. Q. 7, Winter 2018, at 1 [hereinafter *The Defense Docket*].

10. 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv); HATCH-WAXMAN ACT FUNDAMENTALS, Lexis (practice note updated July 28, 2018).

11. *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 143 (2013).

12. *Id.* (quoting *Caraco Pharm. Laboratories, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 406 (2012)).

13. *Id.*

14. *Id.*

15. *Id.*

of a medication sooner than patent law would typically allow. In theory, the Hatch-Waxman Act exception to the patent law limited monopoly satisfies the goals of antitrust law by restricting limited monopolies in the pharmaceutical context. In actuality, however, this realization is not the case.¹⁶

Big pharma circumvents the Hatch-Waxman Act requirements through agreements known as “pay-for-delay settlements,” “reverse payments,” or “reverse payment settlements,”¹⁷ where brand-name drug companies pay generic drug companies large sums of money or something of high value to settle patent litigation claims and “maximize their own profits.”¹⁸ Such reverse payments have the effect of postponing more affordable, generic medications entering the market and thus benefitting consumers.¹⁹ Further, these settlements can even restrict generic medications from entering the market for a longer period of time than patent law intended by extending the brand-name company’s limited monopoly.²⁰ Not only can these “payments . . . produce significant anticompetitive effects” and harm consumers,²¹ but also these payments serve as a “surrogate for [the] patent’s weakness.”²² The U.S. Supreme Court undertook to resolve this conflict in its landmark decision, *F.T.C. v. Actavis*, but the patent-antitrust law relationship remains strained because of the confusion amongst lower courts about how to reconcile antitrust and patent law policy concerns while adhering to the Supreme Court’s decision.²³

This Note addresses the lingering unresolved tension in this post-*Actavis* era between patent and antitrust law over pay-for-delay settlements and proposes ways to relieve this tension. It also recommends that Congress confront this unresolved tension because big pharma will continue to deny citizens access to affordable medications absent a clear

16. See *The Defense Docket*, *supra* note 9, at 1.

17. Passinault, *supra* note 4, at 549.

18. Michele M. Kang, Note, *ANDA Reverse Payments and Post-Actavis Landscape*, 8 HASTINGS SCI. & TECH. L.J. 73, 75 (2016); Passinault, *supra* note 4, at 550.

19. Passinault, *supra* note 4, at 549, 555.

20. See Mariana Mazzucato, *Big Pharma Is Hurting Drug Innovation*, WASH. POST (Oct. 17, 2018), <https://www.washingtonpost.com/news/theworldpost/wp/2018/10/17/pharmaceutical/> [<https://perma.cc/D6LX-N7CM>] (noting “pharmaceuticals [ab]use the patent system . . . [to] extend existing patents beyond the initial 20-year protection set by the United States”). Additionally, Chief Justice Roberts addresses this concern in his dissent in *Actavis*. See *Actavis*, 570 U.S. at 162 (“If its actions go beyond the monopoly powers conferred by the patent, we have held that such actions are subject to antitrust scrutiny.”).

21. *In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d 180, 189 (D.R.I. 2014). “We rely on pharmaceutical companies to develop and bring to market the medical advances that keep us healthy.” *Id.* at 183.

22. *Actavis*, 570 U.S. at 158.

23. *Id.* at 136.

legal standard that addresses both antitrust and patent policy concerns. Finally, this Note asks lawmakers to seriously consider the future ramifications of having a system that lacks uniformity in an area of law that severely impacts citizens' access to medications, which is especially crucial during the current state of the COVID-19 pandemic.

Part I of this Note provides background information on patent infringement claims in the pharmaceutical context, the Hatch-Waxman Act, and reverse payments. Part II of this Note explains the U.S. Supreme Court's opinion in *Actavis*, while Part III highlights the problems remaining under the post-*Actavis* regime. Lastly, Part IV of this Note concludes with a proposal that suggests possible legislative and common law solutions.

I. BACKGROUND

A. Patent Infringement Claims

The U.S. Constitution established patent protection by providing Congress the power “[t]o promote the progress of [s]cience and useful [a]rts, by securing for limited [t]imes to [a]uthors and [i]nventors the exclusive [r]ight to their respective [w]ritings and [d]iscoveries.”²⁴ Patent law “gives patentees a limited exclusionary power.”²⁵ Under the U.S. Patent Act, 35 U.S.C. §§ 1–301, “[a] patent grants the patent holder the exclusive right to exclude others from making, using, importing, and selling the patented innovation for a limited period of time.”²⁶ The idea behind this legislation is to “encourage the investment of time and resources into the development of new and useful discoveries” by granting these “exclusive rights” to the inventor.²⁷ In the pharmaceutical context, this right applies to the “exclusive right to sell [a] drug.”²⁸

The patent holder is also said to have “limited monopoly” power because the patent allows the holder to gain financial rewards for their patented work.²⁹ However, the patented work enters the public domain after the patent term expires.³⁰ The “term begin[s] on the date on which the patent issues and end[s] 20 years from the date on which the application for the patent [is] filed in the United States.”³¹

24. U.S. CONST. art. I, § 8, cl. 8.

25. See *Impression Prods., Inc. v. Lexmark Int’l, Inc.*, 137 S. Ct. 1523, 1531–32 (2017).

26. *Patent*, CORNELL L. SCH., <https://www.law.cornell.edu/wex/patent> [<https://perma.cc/7DVK-3PQJ>].

27. *Id.*

28. Kang, *supra* note 18, at 74.

29. *Lexmark*, 137 S. Ct. at 1532.

30. *Patent*, *supra* note 26.

31. 35 U.S.C. § 154(a)(2).

Although “encourag[ing] the investment of time and resources into the development of new and useful discoveries” is imperative to society, the Hatch-Waxman Act created a significant exception for the pharmaceutical industry in order to increase consumers’ access to affordable medications.³²

B. The Hatch-Waxman Act

The 1984 Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act, was created to address antitrust policy concerns arising from the limited monopolies granted by patent law in the pharmaceutical context.³³ Primarily, the Act addressed antitrust concerns of brand-name companies sustaining monopolies in the market and cutting off citizens’ access to cheaper, generic medications.³⁴ Congress’s purpose in passing the Hatch-Waxman Act was “to increase generic competition while balancing the resulting cost savings with sufficient incentives to encourage continued medical innovation through the development of new drugs.”³⁵ The intent behind the Hatch-Waxman Act was to allow more competition in the market and provide the public access to generic (less expensive) medications before the expiration of the brand-name manufacturers’ patents.³⁶

To achieve its goal, the Hatch-Waxman Act changed the nature of patent infringement disputes in the pharmaceutical context. “Prior to the enactment of the Hatch-Waxman Act, generic drug manufacturers could only obtain approval by the FDA if they submitted the same sort of data supporting the drug’s safety and efficacy that brand-name drug manufacturers were required to submit.”³⁷ Typically, “a drug manufacturer[] wishing to market a new prescription drug, must submit a New Drug Application [(NDA)] to the federal Food and Drug Administration (FDA) and undergo a long, comprehensive, and costly

32. *Patent*, *supra* note 26. “[G]eneric drugs save consumers an estimated eight to ten billion dollars a year at retail pharmacies, and even billions more when used by hospitals.” Kang, *supra* note 18, at 74.

33. “The Hatch-Waxman Act, which brought about the abbreviated pathway for generic drug approval, spurred the growth of the current generic drug industry in the United States.” Kang, *supra* note 18, at 76.

34. “[G]eneric drug[s] . . . provide a safe, effective, and low-cost alternative to the American public.” *Id.* at 75.

35. *Id.* at 82.

36. PRAC. L. ANTITRUST, REVERSE PAYMENT SETTLEMENT AGREEMENTS, Westlaw Note 0-577-4285 (practice notes continually maintained); *see also* Kang, *supra* note 18, at 75.

37. Jennifer E. Sturiale, *Hatch-Waxman Patent Litigation and Inter Partes Review: A New Sort of Competition*, 69 ALA. L. REV. 59, 69 (2017); *see also* Bruce N. Kuhlik, *The Assault on Pharmaceutical Intellectual Property*, 71 U. CHI. L. REV. 93, 98 (2004). *See generally* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ch. 9.

testing process, after which, if successful, the manufacturer will receive marketing approval from the FDA.”³⁸

However, the Hatch-Waxman Act created “a framework to allow generic-drug manufacturers to obtain FDA approval more quickly.”³⁹ “[O]nce the FDA has approved a brand-name drug for marketing,”⁴⁰ the Hatch-Waxman Act allows generic drug manufacturers to “submit an [A]bbreviated [N]ew [D]rug [A]pplication (ANDA).”⁴¹ The legislation explicitly states that “[a]ny person may file . . . an [ANDA] for the approval of a new drug.”⁴² An ANDA is an “abbreviated route to FDA approval of a generic drug” because, “[i]nstead of filing a full [(NDA)], the generic drug company need only demonstrate in an ANDA that the generic product is bioequivalent to the reference-listed drug,” which cuts out the time-consuming testing processes required by an NDA.⁴³ The generic drug manufacturer in the ANDA must specify “that the generic has the ‘same active ingredients as,’ and is ‘biologically equivalent’ to the already-approved brand-name drug.”⁴⁴ Essentially, the Hatch-Waxman Act allows the generic drug companies to “piggy-back” on the brand-name company’s “approval efforts,” which in turn, accelerates the introduction of the low-cost generic medications into the market.⁴⁵

Also inherent in the Hatch-Waxman Act is a “special patent litigation scheme that enables patent infringement and validity issues to be determined before the generic drug is launched on the market.”⁴⁶ The Hatch-Waxman Act sets forth specific procedures for “identifying, and resolving, related patent disputes.”⁴⁷ Specifically, the Hatch-Waxman Act “requires the pioneer brand-name manufacturer to list in its [NDA] the ‘number and the expiration date’ of any relevant patent,” and “it requires the generic manufacturer in its [ANDA] to ‘assure the FDA’ that the generic ‘will not infringe’ the brand-name’s patents.”⁴⁸ The Act provides four ways in which the generic drug manufacturer can assure that it will not infringe the brand-name manufacturer’s patent: (1) by certifying “that

38. *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 142 (2013); *see also* 21 U.S.C. § 355(b)(1).

39. *PRAC. L. ANTITRUST*, *supra* note 36, at 4.

40. *Actavis*, 570 U.S. at 142; *see also Caraco Pharm. Laboratories, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 403 (2012).

41. *Hatch-Waxman Letters*, U.S. FOOD & DRUG ADMIN. (July 19, 2018), <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/hatch-waxman-letters> [<https://perma.cc/8PG8-SEHE>]; 21 U.S.C. § 355(j).

42. 21 U.S.C. § 355(j)(1).

43. JANET B. LINN, *HATCH-WAXMAN PRE-SUIT CONSIDERATIONS FROM THE GENERIC PERSPECTIVE* (practice note updated July 30, 2020), Lexis.

44. *Actavis*, 570 U.S. at 142 (quoting *Caraco Pharm. Laboratories*, 566 U.S. at 403).

45. *Id.*; *see also Caraco Pharm. Laboratories*, 566 U.S. at 403.

46. LINN, *supra* note 43, at 1.

47. *Actavis*, 570 U.S. at 143; 21 U.S.C. § 355(b)(1).

48. *Actavis*, 570 U.S. at 143 (quoting *Caraco Pharm. Laboratories*, 566 U.S. at 403).

the brand-name manufacturer has not listed any relevant patents;” (2) by certifying “that any relevant patents have expired;” (3) by requesting “approval to market beginning when any still-in-force patents expire;” or (4) by certifying “that any listed, relevant patent ‘is invalid or will not be infringed by the manufacture, use, or sale’ of the drug described in the [ANDA].”⁴⁹

The fourth option is most common and is often referred to as “the paragraph IV route” or “paragraph IV certification.”⁵⁰ The paragraph IV route is the preferred avenue for Hatch-Waxman Act litigation because the Hatch-Waxman Act “provides a special incentive” for the first generic manufacturer to file an ANDA “taking the paragraph IV route[,]” where the first generic “applicant will enjoy a period of 180 days of exclusivity.”⁵¹ This provision is important because the first generic applicant enjoys “an exclusive right to sell a generic version of the brand-name product,”⁵² where no other generic manufacturer can enter the market for that drug during the 180 days.⁵³

In regard to patent litigation, one of the goals “of creating the [p]aragraph IV challenge process was to provide a mechanism through which generic manufacturers could challenge weak patents.”⁵⁴ Technically, the paragraph IV route “automatically counts as patent infringement” and triggers patent litigation.⁵⁵ This route “serves as a statutorily defined act of infringement,” meaning that “in making a [p]aragraph IV certification, a generic drug manufacturer infringes a listed drug’s patent claims as a matter of law, not as a matter of fact,” which

49. *Id.* (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(IV)).

50. *Id.*; see also 21 U.S.C. § 355(j)(5)(B)(iv); *In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d 180, 184 (D.R.I. 2014).

51. *Actavis*, 570 U.S. at 143; see also LINN, *supra* note 43, at 2; 21 U.S.C. § 355(j)(5)(B)(iv). This provision of the Hatch-Waxman Act also demonstrates the policy motives underlying the Act. The Act aims to encourage generic drugs to enter into the market more quickly, especially because “[i]f the first-to-file generic manufacturer can overcome any patent obstacle and bring the generic to market, this 180-day period of exclusivity can prove valuable” to the generic drug company by making the company more profitable as other generic drug companies will be prevented from diluting the market for 180 days. *Actavis*, 570 U.S. at 144; see also 21 U.S.C. § 355(j)(5)(D). “[T]he Hatch-Waxman Act serves to incentivize generic manufacturers that incur the cost and risk stemming from [p]aragraph IV certification litigation . . . [and] encourage generic competition” by affording this exclusivity. *In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d at 185. For more on this subject, see generally C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006) (article written prior to *Actavis*).

52. *Actavis*, 570 U.S. at 155; see also *id.* at 144 (noting the value of such exclusivity: “this 180-day period of exclusivity can prove valuable, possibly ‘worth several hundred million dollars’” (quoting Hemphill, *supra* note 51, at 1579)).

53. See *Actavis*, 570 U.S. at 155.

54. Laura A. Gregory, Note, *Cashing Out: How Big Pharma Continues to Capitalize on the Antitrust Loophole Created in FTC v. Actavis*, 18 N.C. J.L. & TECH. 107, 127 (2016).

55. *Actavis*, 570 U.S. at 143; see also 35 U.S.C. § 271(e)(2)(A).

“then enables the patent owner to bring suit against the ANDA filer for patent infringement.”⁵⁶ The brand-name manufacturer has forty-five days to bring an infringement suit, after which the FDA “must withhold approving the generic, usually for a 30-month period, while the parties litigate patent validity (or infringement) in court.”⁵⁷ “If the courts decide the matter within that period, the FDA follows that determination,”⁵⁸ meaning, if the court decides that the patent is invalid or not infringed, the approval will be made effective on the date of the judgment or settlement.⁵⁹ If, alternatively, the court determines that the patent has been infringed and the case is not successfully appealed, the approval will be made effective no earlier than the expiration of the patent.⁶⁰ Lastly, if the court does not decide the matter within that period, then “the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of . . . notice”⁶¹ and “the FDA may go forward and give approval to market the generic product.”⁶²

C. Reverse Payments

A generic drug manufacturer’s journey to speedy market approval via paragraph IV of the Hatch-Waxman Act almost always ends in a

56. Sturiale, *supra* note 37, at 71. “An ANDA filer that relies on a [p]aragraph IV certification will almost certainly be sued by the brand manufacturer.” In re *Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d at 184–85.

57. *Actavis*, 570 U.S. at 143. If the applicant used the paragraph IV route to make a certification, “the approval may be made effective immediately unless, before the expiration of 45 days after the date on which the notice . . . is received, an action is brought for infringement of the patent that is the subject of the certification.” 21 U.S.C. § 355(j)(5)(B)(iii).

58. *Actavis*, 570 U.S. at 143. “If such an action is brought before the expiration of [the 45] days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice . . .” 21 U.S.C. § 355(j)(5)(B)(iii).

59. 21 U.S.C. § 355(j)(5)(B)(iii)(I) (“If the court “decides that the patent is invalid or not infringed . . . the approval shall be made effective” either on “the date on which the court enters judgment . . . or [on] the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed.”).

60. *Id.*

61. 21 U.S.C. § 355(j)(5)(B)(iii). “Notice” is “notice of opinion that [the] patent is invalid or will not be infringed.” *Id.* § 355(j)(2)(B).

62. *Actavis*, 570 U.S. at 143; *see* 21 U.S.C. § 355(j)(5)(B)(iii). In essence, the filing of an ANDA taking the paragraph IV route is an “artificial act” of patent infringement, meaning that it does not necessarily equate to a finding of patent infringement. *Caraco Pharm. Laboratories, Ltd. v. Forest Laboratories, Inc.*, 527 F.3d 1278, 1283 (2008); *see also* *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 677–78 (1990) (discussing the Hatch-Waxman Act and ANDA process in detail); HATCH-WAXMAN ACT FUNDAMENTALS, *supra* note 10, at 4 (noting that the infringement is “artificial”). Rather, the purpose of the exception is to establish jurisdiction over a complaint for patent infringement based on the ANDA in the federal courts. HATCH-WAXMAN ACT FUNDAMENTALS, *supra* note 10, at 2.

reverse payment.⁶³ These reverse payments may also be referred to as “pay-for-delay settlements” or “reverse payment settlements.” The Supreme Court noted that “most . . . reverse payment settlement agreements arise in the context of pharmaceutical drug regulation, and specifically in the context of suits brought under [the Hatch-Waxman Act, challenging] the validity of a patent owned by an already-approved brand-name drug owner.”⁶⁴ It is nearly unheard of outside of the pharmaceutical context for a party that owns a patent “to pay an accused infringer to settle the lawsuit.”⁶⁵

To understand what a reverse payment settlement is, it is important to understand why a patent infringement lawsuit (which leads to the reverse payment settlement) arises in the pharmaceutical context in the first place. Reverse payments occur under this framework because brand-name companies ideally want to settle paragraph IV patent litigation.⁶⁶ The reason for this desire to settle appears to be, at least on its face, to avoid the high costs of the patent litigation. However, brand-name companies may also settle to avoid patent litigation because they know that their patent is invalid, and the generic company would likely gain entry into the market sooner than the expiration of that patent.

In these types of patent disputes, companies typically settle under terms that require: (1) the generic drug manufacturer, or “the claimed infringer, not to produce” the generic drug for an amount of time agreed upon by the parties; and (2) the brand-name manufacturer, or the patentee, to pay the generic drug manufacturer something of high value.⁶⁷ “Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a ‘reverse payment’ settlement agreement.”⁶⁸ Stated concisely by the U.S. Supreme Court, the typical reverse payment settlement takes the form of: “Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent’s term expires, and (2) Company A, the patentee, to pay B many millions of dollars.”⁶⁹ In other words, “[t]he patent holder eventually settles the suit by providing cash or something else of value, referred to as a reverse

63. *Actavis*, 570 U.S. at 141; see also Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 24 (2004) [hereinafter *Sensible Antitrust Rules*].

64. *Actavis*, 570 U.S. at 141; see also *Sensible Antitrust Rules*, *supra* note 63, at 24.

65. *Actavis*, 570 U.S. at 155; *In re Liptor Antitrust Litig.*, 46 F. Supp. 3d 523, 535 (D.N.J. 2014).

66. PRAC. L. ANTITRUST, *supra* note 36, at 3.

67. See *Actavis*, 570 U.S. at 140–41.

68. *Id.*

69. *Id.*

payment, to the generic [drug manufacturer].”⁷⁰ A brand-name drug manufacturer may “ultimately enter into reverse payment settlements with several generic firms relating to a single branded drug.”⁷¹

Additionally, reverse payments substantially affect the market. These agreements prevent generic medications from entering the market as the Hatch-Waxman Act intended: before the brand-name company’s patent term expires. These agreements may also extend the patent holder’s limited monopoly where the brand-name company pays the generic company to stay out of the market even after the expiration of its patent term.⁷²

Even though reverse payments may look like a way for brand-name and generic pharmaceutical companies to settle patent disputes without diving into costly litigation, these settlements raise very significant and pressing policy concerns. In regard to patent law, a reverse payment may mean that a weak patent remains unchallenged.⁷³ Reverse payments create a significant loophole. Since pharmaceutical companies know that paragraph IV certification automatically triggers an infringement dispute, brand-name pharmaceutical companies can hold weak patents because they know they can settle without ever needing to defend the validity of their patents.

In regard to antitrust law, reverse payments “allow brand-name drugs to hold onto their control of the market.”⁷⁴ Furthermore, these potentially “weak patents . . . enable their holders to charge supracompetitive prices,” which “prevent[] generic drugs from entering the market and competing with the brand-name drug manufacturer.”⁷⁵ As a result, “supracompetitive prices persist and follow-on innovation is [impeded, and these] settlement[s] . . . [have] consequences inconsistent with the objectives of the Hatch-Waxman Act and [that are] harmful to consumers.”⁷⁶ This lack of competition creates and allows brand-name drug companies to hold monopolies in the market, which have detrimental effects on consumers’ access to affordable medications.⁷⁷

Supporters of reverse payments argue that brand-name drug companies need to recoup the high costs of creating new drugs to increase

70. PRACTICAL LAW ANTITRUST, *supra* note 36, at 3.

71. *Id.* at 1.

72. See Mazzucato, *supra* note 20 (recognizing extension of patents beyond the initial twenty-year protection); *Actavis*, 570 U.S. at 162 (Chief Justice Roberts, in dissent, addressing “actions [that] go beyond the monopoly powers conferred by the patent”).

73. Sturiale, *supra* note 37, at 80.

74. Kang, *supra* note 18, at 78.

75. Sturiale, *supra* note 37, at 80.

76. *Id.*

77. See *Actavis*, 570 U.S. at 148.

innovation, and reverse payments protect the exclusive patent rights afforded to the inventors of those drugs.⁷⁸ However, this reasoning does not warrant anticompetitive reverse payments for three reasons. First, the Hatch-Waxman Act's goal of increasing access to affordable medication cannot be disregarded in the name of capitalism.⁷⁹ Second, reverse payment settlements may extend the life of a brand-name company's patent even longer than its original term.⁸⁰ Third, scholars suggest that the monetary value associated with reverse payment settlements does not correlate with the amount needed to recoup the costs of invention.⁸¹

Generic manufacturers' failure to release their products into the market via the Hatch-Waxman exception leads to a lack of competition in the market, which means that consumers are forced to pay the prices set by the brand-name drug manufacturers.⁸² Brand-name drug manufacturers often set exceedingly high prices, barring citizens from accessing affordable medications, many of which might be vital to a person's life.

78. See Amber N. Sanges, Comment, *Earth to Congress—The Pharmaceutical Patent System Is Broken—Pharma Patents Need Their Own Set of Rules*, 41 S. ILL. U. L.J. 93, 112 (2016); see also Herbert Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision*, 15 MINN. J.L. SCI. & TECH. 3, 8 (2014) [hereinafter *Anticompetitive Patent Settlements*] (“A pay-for-delay settlement preserves the exclusive right created by the patent but requires the patentee to share the profits with the first generic filer.”) However, Hovenkamp further noted that “[t]he arrangement is thus similar to a situation in which two firms cartelize their market but one of them shuts down its plant altogether while the other compensates it out of its monopoly profits.” *Id.*

79. “The Federal Trade Commission (‘FTC’) estimated that these deals cost American consumers \$3.5 billion a year.” Kang, *supra* note 18, at 78. Hovenkamp noted: “In the Hatch-Waxman pay-for-delay setting . . . what is being placed at risk is both the investment of the pioneer and the welfare of consumers, and these two interests pull in opposite directions.” *Anticompetitive Patent Settlements*, *supra* note 78, at 11. “[C]onsumers . . . stand to lose the benefits of competition that would otherwise have occurred.” *Id.*

80. See Mazzucato, *supra* note 20; Valerie Bauman, *Pharma Pay-For-Delay Deals Called ‘Cost of Doing Business,’* BLOOMBERG L. (Feb. 10, 2020), <https://news.bloomberglaw.com/pharma-and-life-sciences/pharma-pay-for-delay-settlements-cost-of-doing-business> [<https://perma.cc/5VH6-T3H3>] (noting that brand-name company AbbVie's settlements with generic companies have granted AbbVie “an additional four-plus years of market exclusivity”). A generic manufacturer may even agree to “cancel the launch of its authorized generic” drug altogether. Kang, *supra* note 18, at 78.

81. “The size of the payment [may] signal[] the degree of doubt about the underlying patent dispute” even though the “likelihood of a pay-for-delay settlement is not driven by the likelihood that the patent will be found invalid, . . . the size of the settlement will be.” *Anticompetitive Patent Settlements*, *supra* note 78, at 10, 12. Although Hovenkamp mentions that “[t]he generic's calculus depends on the size of anticipated profits under entry as opposed to the value of the settlement,” he does not mention that the brand-name company's calculus depends on size of anticipated profits to recoup innovation costs. *Id.* at 12. Further, “it may still be more valuable for the generic to share the monopoly returns with the pioneer patentee for the duration of the settlement agreement, rather than produce in competition with the pioneer,” signaling that the brand-name company may pay the generic more to settle than what competition in the market would cost the brand-name company. *Id.* at 12.

82. “Typically, a company that has developed such a medication will enjoy a period of time during which it can sell it exclusively and at a supracompetitive price, thereby recovering its development costs and turning a profit.” *In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d 180, 183 (D.R.I. 2014).

II. *F.T.C. v. ACTAVIS*A. *An Attempt to Remedy Antitrust Policy Concerns*

In 2013, the Supreme Court of the United States addressed the legitimacy of reverse payment settlements and antitrust concerns in *F.T.C. v. Actavis*.⁸³ In that case, Solvay Pharmaceuticals filed an NDA “for a brand-name drug called AndroGel.”⁸⁴ Subsequently, the FDA approved the application, and Solvay obtained a patent.⁸⁵ Solvay disclosed the fact that it filed an NDA to the FDA as the Hatch-Waxman Act requires.⁸⁶ “Later the same year . . . , Actavis, Inc. (then known as Watson Pharmaceuticals), filed an [ANDA] for a generic drug modeled after AndroGel.”⁸⁷ Soon after, “Paddock Laboratories, . . . separately filed an [ANDA] for its own generic product[, and b]oth Actavis and Paddock certified under paragraph IV that Solvay’s listed patent was invalid and their drugs did not infringe it.”⁸⁸

In response to the certifications under paragraph IV, “Solvay initiated paragraph IV patent litigation against Actavis and Paddock”⁸⁹ for patent infringement. However, “the patent-litigation parties all settled.”⁹⁰ Under the terms of the settlement, Actavis agreed, amongst other things, “that it would not bring its generic [drug] to market until . . . 65 months before Solvay’s patent expired.”⁹¹ The other generic manufacturers that were involved made similar promises, and Solvay agreed to pay millions of dollars to each generic manufacturer.⁹² Further, “[t]he paragraph IV litigation in this case put the patent’s validity at issue, . . . [but t]he parties’ settlement ended that litigation.”⁹³

The FTC then filed suit against the settling parties, most importantly, Solvay, Actavis, and Paddock.⁹⁴ The FTC’s complaint alleged “that respondents violated . . . the [FTC] Act by unlawfully agreeing to abandon their patent challenges, to refrain from launching their low-cost generic drugs, and to share in Solvay’s monopoly profits.”⁹⁵ In essence, the FTC claimed that “the plaintiff agreed to pay the defendants many millions of

83. See *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 148 (2013).

84. *Id.* at 144.

85. *Id.*

86. *Id.*

87. *Id.*

88. *Id.*

89. *Id.* at 145.

90. *Id.*

91. *Id.*

92. *Id.*

93. *Id.* at 147.

94. *Id.* at 145.

95. *Id.* at 136.

dollars to stay out of its market, even though the defendants did not have any claim that the plaintiff was liable to them for damages.”⁹⁶ This case made its way up through the federal courts. “Because different courts [had] reached different conclusions about the application of the antitrust laws to Hatch-Waxman–related patent settlements,” the U.S. Supreme Court granted certiorari.⁹⁷ The Supreme Court “answered the antitrust question by considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as . . . those related to patents.”⁹⁸

The Court declined to accept the FTC’s argument that it should use the “‘quick look’ approach” and instead adopted a “‘rule of reason’” analysis.⁹⁹ The quick-look approach shifts the burden to the defendant to show “empirical evidence of procompetitive effects.”¹⁰⁰ Under a rule of reason analysis, a reverse payment settlement survives antitrust scrutiny when a court concludes that a practice is “reasonable” and does not demonstrate anticompetitive conduct.¹⁰¹ “[T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.”¹⁰² The Court concluded that “these considerations, taken together, outweigh . . . the desirability of settlements.”¹⁰³ Chief Justice Roberts pushed back on this notion in his dissent, where he rejected the rule of reason analysis to “inquire into the anticompetitive effects of such settlements” because he said this approach “is without support in any statute, and will discourage the settlement of patent litigation.”¹⁰⁴ Chief Justice Roberts underscored the important notion that the antitrust–patent scale should not tip too heavily in favor of antitrust policy considerations.

96. *Id.* at 147. Prior to *Actavis*, the courts were split as to whether to use the quick-look or scope-of-the-patent approach (which Chief Justice Roberts mentions in his dissent). See *id.* at 160 (Roberts, C.J., dissenting). In *Actavis*, the Court rejected the FTC’s quick-look approach under which “reverse payment settlement agreements are presumptively unlawful” and instead adopted rule of reason analysis. Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Activating Actavis*, 28 ANTITRUST, Fall 2013, at 16, 17 [hereinafter *Activating Actavis*].

97. *Actavis*, 570 U.S. at 146.

98. *Id.* at 149.

99. *Id.* at 159 (citing *Cal. Dental Ass’n v. F.T.C.*, 526 U.S. 756, 775 n.12 (1999) (discussing the quick-look and rule-of-reason analysis)).

100. *Id.*

101. Herbert Hovenkamp, *The Rule of Reason*, 70 FLA. L. REV. 81, 83 (2018) [hereinafter *The Rule of Reason*].

102. *Actavis*, 570 U.S. at 159.

103. *Id.* at 158.

104. *Id.* at 160–61 (Roberts, C.J., dissenting).

Finally, the *Actavis* decision established a three-part inquiry for the lower courts to use in assessing the “anticompetitive effects”¹⁰⁵ of reverse payment settlements. First, a district court asks whether a reverse payment exists.¹⁰⁶ Second, a district court asks whether that reverse payment was large and unjustified.¹⁰⁷ Third, a district court applies rule of reason analysis.¹⁰⁸ However, the Court ultimately concluded by giving the lower courts broad discretion in applying the rule of reason.¹⁰⁹

B. An Attempt to Remedy Patent Policy Concerns

The Court in *Actavis* also addressed the interplay between patent and antitrust policy concerns surrounding patent monopolies granted to brand-name pharmaceutical companies.¹¹⁰ Chief Justice Roberts, in dissent, expressed much discomfort with the idea of antitrust law overriding the limited monopolies held by pharmaceutical companies.¹¹¹ He argued, “The correct approach should[,] . . . be to ask whether the settlement gives . . . monopoly power beyond what the patent already gave it” because “[a] patent carves out an exception to the applicability of antitrust laws.”¹¹² In order to understand Chief Justice Roberts’ concerns, it is important to understand the landscape of patent law and antitrust law in reverse payment settlements before *Actavis*.

Prior to *Actavis*, the courts applied the scope-of-the-patent test to reverse payment settlements.¹¹³ Under this test, “absent sham litigation or fraud in obtaining the patent, a reverse payment settlement [was] immune from antitrust attack so long as its anticompetitive effects [fell] within the scope of the exclusionary potential of the patent.”¹¹⁴ Essentially, as long as “settlement agreements limit[ed] their breadth to the ‘scope of the patent,’”¹¹⁵ no antitrust concerns were raised and reverse payment settlements arising under the Hatch-Waxman act were upheld based on patent policy grounds.¹¹⁶ However, under the scope-of-the-patent test, “courts frequently struggled with the question of what role, if any, evidence of patent strength [played] in the analysis of an alleged payment

105. *In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d 180, 189 (D.R.I. 2014).

106. *Id.* (citing *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560, 564–66 (D.N.J. 2014)).

107. *Id.*

108. *Id.*

109. *Actavis*, 570 U.S. at 160.

110. *See generally id.*

111. *Id.* at 161 (Roberts, C.J., dissenting).

112. *Id.* at 160 (Roberts, C.J., dissenting).

113. *See id.* at 141.

114. *Id.* at 146 (quoting *F.T.C. v. Watson Pharms., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012)).

115. *F.T.C. v. AbbVie, Inc.*, 107 F. Supp. 3d 428, 435 (E.D. Pa. 2015) (citation omitted).

116. *See generally Actavis*, 570 U.S. 136.

for delay.”¹¹⁷ When pharmaceutical companies engage in reverse payment settlements, it is unclear whether the patent holder’s invalid patent or desire to extend its monopoly on the market for that drug triggers the settlement, and such convergence lent to the courts’ struggles.¹¹⁸

The majority in *Actavis* made it clear that litigating the patent is not a precursor to bringing an antitrust suit.¹¹⁹ However, the evidence used in patent litigation to demonstrate patent strength can be useful in “providing a baseline for identifying the expected amount of competition absent the settlement, which could then[,] in principle[,] be compared to the terms of the settlement.”¹²⁰ The majority’s opinion signaled that the Court was more concerned with attending to antitrust policy concerns than patent policy concerns, a perception that Chief Justice Roberts took issue with.¹²¹

Chief Justice Roberts suggested that the majority has “in mind a regime where courts ignore the patent, and simply conduct an antitrust analysis of the settlement without regard to the validity of the patent.”¹²² He argued: “[A]ntitrust law has no business prying into a patent settlement so long as that settlement confers to the patent holder no monopoly power beyond what the patent itself conferred—unless, of course, the patent was invalid, but that again is a question of patent law, not antitrust law.”¹²³ Chief Justice Roberts reasoned that “a patent holder acting within the scope of its patent does not engage in any unlawful anticompetitive behavior; it is simply exercising the monopoly rights granted to it by the Government.”¹²⁴ His dissent shows that even though the majority prioritized antitrust policy concerns over patent policy concerns, some members of the Court were still rightfully troubled about what the decision would mean for the future of Hatch-Waxman Act patent litigation.¹²⁵

C. The Rule of Reason as the Post-Actavis Standard

The rule of reason “requires the plaintiff to plead and prove that defendants with market power have engaged in anticompetitive conduct.”¹²⁶ When a court concludes that a practice is “reasonable” and does not demonstrate anticompetitive conduct, such practice survives

117. *Activating Actavis*, *supra* note 96, at 19.

118. *See id.* at 16.

119. *Id.* at 19.

120. *Id.*

121. *See Actavis*, 570 U.S. at 161 (Roberts, C.J., dissenting).

122. *Id.* at 164.

123. *Id.* at 169.

124. *Id.* at 164.

125. Chief Justice Roberts was joined by Justice Scalia and Justice Thomas in his dissent. *Actavis*, 570 U.S. at 160 (Roberts, C.J., dissenting).

126. *The Rule of Reason*, *supra* note 101, at 83.

antitrust scrutiny.¹²⁷ Essentially, rule of reason analysis utilizes a “sliding scale” for determining reasonableness where the nature of the proof varies based on the circumstances.¹²⁸ The *Actavis* Court provided “five considerations” to guide district courts in applying the rule of reason to reverse payments in the pharmaceutical industry.¹²⁹ One district court summarized them accordingly:

First, [d]oes the payment have the “potential for genuine adverse effects on competition”? Second, [i]s the payment justified in some way, perhaps because it approximates “litigation expenses saved through the settlement” or compensates the patent challenger for “other services . . . such as distributing the patented item or helping to develop a market for that item”? Third, [d]oes the brand name manufacturer have the market power needed to bring about anticompetitive harm? Fourth, [d]oes the size of the settlement suggest that it is intended to maintain supracompetitive prices and serve as a “workable surrogate for a patent’s weakness”? Fifth, [c]ould the parties have settled in some way that did not involve the use of reverse payments?¹³⁰

“The Court’s rule-of-reason approach acknowledges that not all reverse payments are anticompetitive: some payments represent avoided litigation expenses; some are fair compensation for valuable services rendered by the alleged infringer; and some may have other legitimate justifications”¹³¹ However, problems with reverse payment settlements still exist. Although the Court urged lower courts to consider a patent’s potential weakness when assessing whether a reverse payment was anticompetitive, “the merits of the patent dispute [still] matter,”¹³² and a large payment does not necessarily imply that the patent litigation would have been extensive because the generic company may require a large payment for other reasons. For example, the length of time may lead the brand-name company to offer the generic company a larger settlement: “[t]he longer the Generic agrees to stay out in exchange for a payment . . . the greater the joint profits and the more the [brand-name

127. *Id.*

128. *Activating Actavis*, *supra* note 96, at 17.

129. *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560, 565 (D.N.J. 2014).

130. *Id.* (citations omitted) (citing *Actavis*, 570 U.S. at 155–58). The term “supracompetitive” refers to when a company prices its product higher than what it would be in a competitive market. See Patrick Bolton, Joseph F. Brodley & Michael H. Riordan, *Predatory Pricing: Strategic Theory and Legal Policy*, U.S. DEP’T OF JUST.: ANTITRUST DIV., <https://www.justice.gov/atr/predatory-pricing-strategic-theory-and-legal-policy> [<https://perma.cc/A6ZY-6FLV>].

131. *Activating Actavis*, *supra* note 96, at 21.

132. Rebecca S. Eisenberg & Daniel A. Crane, *Patent Punting: How FDA and Antitrust Courts Undermine the Hatch-Waxman Act to Avoid Dealing with Patents*, 21 MICH. TELECOMM. & TECH. L. REV. 197, 202 (2015).

company] must pay.”¹³³ Or, the sole fact that the generic and brand-name companies, after settling, can “split the resulting monopoly profits.”¹³⁴

III. RECONCILING THE HATCH-WAXMAN ACT, REVERSE PAYMENTS, AND *ACTAVIS*

A. *The Paradox*

Brand-name and generic drug companies “can profit by agreeing not to compete with each other, so long as they can find a way to split the extra profits” and “[t]he longer they avoid competition, the more profits they can split.”¹³⁵ Because the generic company gets a large payment while the brand-name company dominates the market for however long the companies jointly agree to, both brand-name and generic drug companies “have a joint incentive to settle the [patent] suit to avoid competition for as long as they can.”¹³⁶ The paradox is that the Hatch-Waxman Act, which aimed to bridge the gap between antitrust and patent law, sparked the need for reverse payments; however, reverse payments subject to *Actavis* scrutiny destabilize the critical policies underlying both patent law and the Hatch-Waxman Act.

Even though the *Actavis* Court addressed how a large and unjustified settlement may both indicate a patent’s weakness and have anticompetitive effects, conflating these two pieces stretches too far into the realm of ignoring patent law to address antitrust policy concerns. Following *Actavis*, the standard seemed to be that “proving that a payment is above [a certain] threshold [would create] an inference that the settlement is anticompetitive.”¹³⁷ Specifically, the Court’s acknowledgement that “the size of the unexplained reverse payment can provide a workable surrogate for a patent’s weakness” seems to address patent concerns, but this statement really only helps in antitrust litigation by lending to the “inference that the settlement is anticompetitive.”¹³⁸ Another way to view the Court’s approach is when “the net reverse payment exceeds the patentee’s avoided litigation expense . . . what can be inferred is not that the patent is weak in any absolute sense, but rather that it is *sufficiently* weak that the settlement reduces competition.”¹³⁹

133. Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Actavis and Error Costs: A Reply to Critics*, ANTITRUST SOURCE, Oct. 2014, at 1 [hereinafter *Actavis and Error Costs*].

134. *Id.* at 7.

135. *Id.* at 1.

136. *Id.*

137. *Activating Actavis*, *supra* note 96, at 17.

138. *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 158 (2013); *Activating Actavis*, *supra* note 96, at 16.

139. *Activating Actavis*, *supra* note 96, at 17.

However, even assuming that the patent is sufficiently weak may be an overreach.

When big pharma engages in reverse payment settlements, patent validity issues are rarely, if ever, resolved even though the Hatch-Waxman Act provides “an opportunity for the parties to litigate disputes about patent validity.”¹⁴⁰ “[T]he patentee’s actual views on patent strength may bear little relation to what its alleged sacrifice might suggest, and those views may further bear little relation to the actual strength of the patent.”¹⁴¹ Further, the rule of reason factors noted by the Court might only weigh in determining the power of the parties during the settlement.¹⁴² To illustrate, if the brand-name company’s patent is likely invalid, then the generic drug company “will demand a larger payment” from the brand-name drug company.¹⁴³ Reverse payment settlements make this particular kind of patent suit, in a sense, irrelevant because the brand-name company likely only brings the patent suit to reach a reverse payment settlement with the generic company. The patent infringement claim should still be taken seriously in order to prevent weak patents and prevent antitrust solutions from undermining patent law.

B. Policy Issues Left Unanswered

While the Supreme Court in *Actavis* attempted to ease tension between patent and antitrust law, the Court also left many policy issues unanswered.¹⁴⁴ One issue left unanswered is how to prevent patent validity issues from going uncontested. The *Actavis* Court conflates the idea that large reverse payment settlements may not only signal the weakness of a patent but also indicate anticompetitive effects. However, a difference exists between the two notions: some parties enter into reverse payment settlements in order to settle patent litigation and cover the costs of patent litigation (which can be very high) while others enter into reverse payment settlements in order to keep generic drugs out of the market. Such variant intentions should not be treated the same.

Chief Justice Roberts alluded to this unanswered policy concern in his dissent; his “patent-strength approach contrasts with the payment approach advanced by the *Actavis* Court.”¹⁴⁵ Eisenberg and Crane note

140. Eisenberg & Crane, *supra* note 132, at 238.

141. Bryan Gant, *Understanding Actavis: How Courts Misinterpret FTC v. Actavis, Inc., and How to Get It Right*, 22 HARV. NEGOT. L. REV. 111, 119 (2016).

142. See *Actavis and Error Costs*, *supra* note 133, at 1.

143. *Id.*

144. I want to emphasize that I believe that *Actavis* was a step in the right direction, and I would certainly not go so far as suggesting that we need to honor the strength of the limited patent monopoly in all contexts, but rather, I believe there is a way to remedy these conflicting values.

145. *Activating Actavis*, *supra* note 96, at 19.

that “[i]ncentives to recover patent-generated monopoly profits are a feature, not a bug, in the patent system, serving to motivate and reward innovators for making new inventions.”¹⁴⁶ Thus, a patent grants “the right to exclude others from profiting by the patented invention.”¹⁴⁷ Chief Justice Roberts’ analysis suggests that a patent already provides an exception to antitrust law, with the argument being: patent holders should be able to exercise their lawful patent rights without facing antitrust liability.¹⁴⁸ The problem Chief Justice Roberts acknowledges is that “a large payment may be made to eliminate [even] a small probability of losing litigation”; however, the majority would say “that is [still] enough for an antitrust violation.”¹⁴⁹

The majority in *Actavis* in large part rejected patent concerns in favor of assessing reverse payment settlements based on antitrust elements. The Court does not even leave “open the way to creative defenses [to an antitrust claim] rooted in patent policy.”¹⁵⁰ Even though Chief Justice Roberts favored a scope-of-the-patent approach, he did not provide a solution that mends “patent law policy of challenging and eliminating invalid patents”¹⁵¹ with antitrust law policy of preventing reverse payment settlements from harming consumers.¹⁵² Both the majority and the dissent seem to agree that avoiding a “patent mini-trial inside an antitrust case”¹⁵³ is significant to prevent inefficiency, but patents are not absolute and must

146. Eisenberg & Crane, *supra* note 132, at 242.

147. See *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 161 (2013); see also *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980).

148. *Actavis*, 570 U.S. at 161; see also *Dawson Chem.*, 448 U.S. at 215.

149. *Activating Actavis*, *supra* note 96, at 19.

150. *Id.* “[A] defendant might present evidence that the patent was valid and infringed” and “[s]uch evidence might be thought valuable by providing a baseline for identifying the expected amount of competition absent the settlement, which could then in principle be compared to the terms of the settlement”; however, “[s]uch a patent-strength approach contrasts with the payment approach advanced by the *Actavis* Court. *Id.*”

151. Michael A. Carrier, *A Response to Chief Justice Roberts: Why Antitrust Must Play a Role in the Analysis of Drug Patent Settlements*, 15 MINN. J.L. SCI. & TECH. 31, 33 (2014).

152. See Gregory, *supra* note 54, at 127 (noting “many brand and generic manufacturers abuse the system by entering into closed-door settlement negotiations that divide the market for the drug, increasing their joint profits at the expense of consumers”).

153. *Activating Actavis*, *supra* note 96, at 19.

be challenged if a reason to do so exists,¹⁵⁴ so long as these challenges are “still bound to respect antitrust laws spelled out in the Sherman Act.”¹⁵⁵

C. Lower Courts’ Struggle to Produce a Uniform Standard

The majority opinion in *Actavis* left open “to the lower courts the structuring of the present rule-of-reason antitrust litigation.”¹⁵⁶ The majority in *Actavis* gave district courts broad discretion to develop a procedure to collect and appraise this evidence.¹⁵⁷ Chief Justice Roberts even wished the district courts “[g]ood luck,”¹⁵⁸ implying what one district judge later openly acknowledged just a year later—“that the holding in *Actavis* was likely to cause district courts . . . much difficulty.”¹⁵⁹ The Chief Justice’s concerns have proven to be well-founded.¹⁶⁰ Because the Court chose “an open, case-by-case approach, instructing lower courts to analyze the potential anticompetitive effects of each settlement put before them[,]”¹⁶¹ lower courts have had “a difficult time”¹⁶² applying the *Actavis* standard with some courts simply undermining it.¹⁶³

The lower courts seem confounded because “[p]ayment from the patent holder to the claimed infringer can take many forms,” and the majority did not outline what forms of payment trigger *Actavis* analysis.¹⁶⁴

154. Patent strength policy concerns are substantial, as evidenced by: “Generic-drug manufacturers . . . us[ing] . . . ‘inter partes review’ . . . [to] overturn[] 43 percent of the patents they challenged.” Sarah Jane Tribble, *Drugmakers Play the Patent Game to Ward off Competitors*, NBC NEWS (Oct. 2, 2018), <https://www.nbcnews.com/health/health-news/drugmakers-play-patent-game-ward-competitors-n915911> [<https://perma.cc/7B7F-5XMZ>].

155. Passinault, *supra* note 4, at 569; *see also* F.T.C. v. *Actavis, Inc.*, 570 U.S. 136, 141 (2013) (noting that the Sherman Act prohibits restraints on trade or commerce and citing 15 U.S.C. § 1 (commonly known as the Sherman Act)). “The Sherman Antitrust Act of 1890 is a federal statute which prohibits activities that restrict interstate commerce and competition in the marketplace . . . The Sherman Act is codified in 15 U.S.C. §§ 1–38.” *Sherman Antitrust Act*, CORNELL L. SCH., https://www.law.cornell.edu/wex/sherman_antitrust_act [<https://perma.cc/8SBG-A64M>].

156. F.T.C. v. *Actavis, Inc.*, 570 U.S. 136, 160 (2013); *Activating Actavis, supra* note 96, at 16.

157. *Actavis*, 570 U.S. at 156–60 (providing recommendations for lower courts); *Activating Actavis, supra* note 96, at 18.

158. *Actavis*, 570 U.S. at 173 (Roberts, C.J., dissenting).

159. *In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d 180, 195 (D.R.I. 2014); *see also* Gregory, *supra* note 54, at 144–45 (stating “district courts are now faced with the difficult task of determining which non-cash settlements meet the standard of an antitrust violation without any authority from the Supreme Court to help set forth that standard”).

160. *In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d at 195.

161. Passinault, *supra* note 4, at 569.

162. Marc G. Schildkraut, *Actavis and the Burden of Proof: Antitrust Revolution, a Muddle, or Both*, 33 ANTITRUST, Spring 2019, at 56.

163. *Id.*

164. *Activating Actavis, supra* note 96, at 18. “Actavis ‘fixates on one form of consideration that was at issue in the case: cash.’” Marc G. Schildkraut, *Actavis, Authorized Generics, and the Future of*

Specifically, lower courts have different approaches in regard to what constitutes “a large and unjustified payment.”¹⁶⁵ Further, it is unclear whether showing that the payment was large and unjustified is “analyzed separately from the rule of reason, or whether it is part of the plaintiff’s initial burden under the rule of reason.”¹⁶⁶ In early 2014, a district judge held that non-monetary reverse payment settlements do not violate antitrust laws under *Actavis*.¹⁶⁷ A year later, in *King Drug Co. of Florence v. Smithkline Beecham Corp.*, the Third Circuit reversed, holding that reverse payment settlement agreements involving non-cash payments may trigger *Actavis* scrutiny and violate antitrust laws.¹⁶⁸ The U.S. District Court for the Northern District of California had already reached the same conclusion, finding that *Actavis* applies to non-cash reverse payments settlements.¹⁶⁹ The district court in *In re Loestrin 24 Fe Antitrust Litigation* held that “*Actavis* requires cash consideration in order to trigger rule of reason scrutiny,” but this decision was later vacated and remanded by the First Circuit.¹⁷⁰ Yet, “[a] majority of courts seem to take the opposite position that a reverse payment is not limited to cash payments.”¹⁷¹ Although these examples comprise a non-exhaustive survey of the lower

Antitrust Law, in 28 HEALTHCARE ANTITRUST, SETTLEMENTS, AND THE FEDERAL TRADE COMMISSION 25, 60 (James Langenfeld & Edwin Galeano eds., 2018) [hereinafter *Actavis*, *Authorized Generics*] (citing *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538 (1st Cir. 2016)).

165. *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 163 (2013); see also Karen N. Walker & Gavin R. Tisdale, *Overstating Actavis: A Muddle Perhaps, But No Revolution—A Reply to Schildkraut*, 33 ANTITRUST, Spring 2019, at 65. “The lower courts could not find a limiting principle in *Actavis* . . . [and] there are no obvious principles behind the limitations.” *Actavis*, *Authorized Generics*, *supra* note 164, at 29.

166. Walker & Tisdale, *supra* note 165.

167. *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560, 566 (D.N.J. 2014), *vacated and remanded sub nom. King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015); see also PRAC. L. ANTITRUST, DISTRICT OF NEW JERSEY HOLDS THAT *ACTAVIS* APPLIES ONLY TO MONETARY REVERSE PAYMENT SETTLEMENTS, Westlaw Note 3-555-5347 (Jan. 27, 2014).

168. *King Drug Co. of Florence*, 791 F.3d at 403; see also PRAC. L. ANTITRUST, THIRD CIRCUIT: *ACTAVIS* APPLIES TO NON-CASH PAY-FOR-DELAY AGREEMENTS, Westlaw Note 8-616-8206 (June 29, 2015).

169. *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1070 (N.D. Cal. 2014) (holding that “courts need not restrict the definition of ‘payments’ under *Actavis* to cash”); PRAC. L. ANTITRUST, ND CAL. JUDGE HOLDS THAT *ACTAVIS* APPLIES TO NON-CASH PAYMENTS, Westlaw Note 0-589-2745 (Nov. 21, 2014)

170. *In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d 180, 195 (D.R.I. 2014), *vacated and remanded*, 814 F.3d 538 (1st Cir. 2016); see also Kang, *supra* note 18, at 94.

171. Kang, *supra* note 18, at 94; see also Sophie Lawrance & Edwin Bond, ‘Reverse-Payment’ Patent Settlement Agreements: Non-Cash Value Transfers Are Not Immune from Competition Law Scrutiny, 13 J. INTELL. PROP. L. & PRAC. 552, 553 (2018) (noting that most courts adopted the view “that non-cash value transfers from originator to generic companies should be subject to the same rule-of-reason analysis as transfers of cash”). For more information on cash versus non-cash payments, see generally *Actavis*, *Authorized Generics*, *supra* note 164.

courts' methods of applying *Actavis*, such examples underscore a lack of uniformity in addressing reverse payment disputes.

Lower courts are also left with little, if any, guidance on how to address patent validity concerns. “[T]rial courts handling these antitrust cases will continue to be faced with evidence and arguments regarding patent validity or invalidity.”¹⁷² However, the majority in *Actavis* did not provide lower courts with a standard for addressing patent validity concerns arising in the context of antitrust litigation over reverse payments.

Lower courts are fiercely laboring over a solution to the unanswered questions in *Actavis* but seem to be falling down a rabbit hole, focusing too narrowly on what types of payments constitute a large and unjustified payment.¹⁷³ Regardless of cash or non-cash payment, big pharma’s drive for increased profits will lead pharmaceutical companies to find ways to settle.¹⁷⁴ Before focusing narrowly on these specific issues, lower courts need to step back and pinpoint a standard for addressing validity of the patent prior to assessing any antitrust concerns.¹⁷⁵ This patent–antitrust

172. Aaron S. Edlin, C. Scott Hemphill, Herbert J. Hovenkamp & Carl Shapiro, *The Actavis Inference: Theory and Practice*, 67 RUTGERS U. L. REV. 585, 617 (2015) [hereinafter *The Actavis Inference*]. “Perhaps the starkest instances arise in antitrust cases where, subsequent to the reverse-payment settlement in question, but prior to the resolution of the antitrust case, the relevant patent is litigated and found to be either valid or invalid.” *Id.* “A second situation arises if the antitrust court is asked to relitigate the patent case to assess its likely outcome, an unappetizing task” *Id.*

173. The FTC has even recognized that non-cash “agreements [may] raise even further antitrust concerns [more than reverse cash payments] because they embody a second, additional agreement not to compete.” Lawrance & Bond, *supra* note 171, at 553 (quoting FTC amicus brief in *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015)). Lawrance and Bond focus on a specific type of non-cash agreement, known as “no-AG agreements.” Lawrance & Bond, *supra* note 171, at 553. No-AG agreements are “a specific species of patent settlement agreement which involves a commitment by the patentee not to launch its own, or an authorized, generic version of its brand-name drug.” *Id.* at 552. For more information on no-AG agreements, see generally *King Drug*, 791 F.3d 388.

174. “Pharmaceutical companies are profit-making entities, after all, that face pressure from their shareholders to produce ever-better results.” 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/BT28-DV6N>]. Hovenkamp remarks on big pharma’s drive for high profit margins: “of course” pharmaceutical companies “want larger profits.” Erik Hovenkamp, *Antitrust Law and Patent Settlement Design*, 32 HARV. J.L. & TECH. 417, 423 (2019). Generic companies are “willing to be restrained excessively” in settling “to accept a disproportionately long delay period, or a disproportionately high royalty—in exchange for the opportunity to face a smaller competitive field upon entering the market.” *Id.* at 461. Further, “a reduction in competition will be reflected by both an increase in total profits and a reduction in consumer welfare.” *Id.* at 432.

175. See *The Actavis Inference*, *supra* note 172, at 617 (“A subsequent finding of patent invalidity does not imply that there was an antitrust violation, regardless of the presence or size of a reverse payment. Nor does a subsequent finding of patent infringement imply there was no antitrust violation despite a large and unexplained reverse payment.”).

tension should be addressed through legislative reform rather than placing the heavy burden on lower courts to grasp at creating uniformity.

IV. HOW TO AID LOWER COURTS IN ADDRESSING UNANSWERED POLICY CONCERNS

A successful solution should both provide consumers with access to affordable medication and promote innovation.¹⁷⁶ As Hovenkamp, a renowned antitrust scholar,¹⁷⁷ noted: “antitrust must always step lightly” because “pharmaceutical markets are characterized by a high degree of innovation[,]” so “[a]ntitrust remedies that unnecessarily deprive [brand-name companies] of patent rights or . . . reduce the value of prospective patenting are likely to do more harm than good to the long run performance of the industry.”¹⁷⁸ However, of paramount importance to the consumer is the timing of generic medication entry into the market, which brings competition and lower prices.¹⁷⁹

In the wake of COVID-19, as big pharma swiftly produced vaccinations and continually work to develop medications and treatments to stop the pandemic, now is the time to alleviate the growing tension between patent and antitrust law. First, this Note calls on legislators to amend the Hatch-Waxman Act to incorporate the following changes: a tiered approach to ANDA filings; the choice of either an *inter partes* review¹⁸⁰ or standard federal court patent litigation for resolving patent disputes; and subjecting all forms of reverse payments to *Actavis* rule of reason analysis. Although legislative reform is no small task,¹⁸¹ this legislative reform most succinctly addresses patent and antitrust policy concerns. However, because legislative reform is such a sizeable goal,

176. See *Sensible Antitrust Rules*, *supra* note 63, at 11–12.

177. Herbert Hovenkamp is recognized for his “lifetime contributions to antitrust law.” *Herbert Hovenkamp*, UNIV. OF PENN. CAREY L. SCH., <https://www.law.upenn.edu/cf/faculty/hhovenka/> [<https://perma.cc/852N-ZGVZ>].

178. See *Sensible Antitrust Rules*, *supra* note 63, at 12.

179. Eisenberg & Crane, *supra* note 132, at 239.

180. An *inter partes* review is a procedural method to challenge patent validity. See *infra* Part IV.A. Also note the statistics regarding *inter partes* review. See Tribble, *supra* note 154.

181. I do not want to be naïve to the political aspects of this suggestion. I understand that a legislative effort would not only encounter procedural hurdles but may also raise significant political concerns. Given that big pharma lobbying efforts can influence, I recognize that people may have valid concerns about proposing a legislative solution. To support this notion, see Lim’s acknowledgement that “[s]elf-interest drives incumbents to entrench their dominance and thwart challenge.” Daryl Lim, *Biologics as the New Antitrust Frontier: Reflections, Riposte, and Recommendations*, 2018 U. ILL. L. REV. 209, 209 (2018). However, viewed separately and categorically, antitrust and patent ideals do not congregate on one end of the political spectrum. There are key players on either side of the debate because both brand-name and generic companies comprise big pharma, which plays a large role in influencing politics as a whole. Therefore, even in light of political concerns, I believe that legislative reform would be the most effective pathway to appease parties on both sides.

reform should be made through common law, where federal courts would work to create a uniform standard in approaching pay-for-delay settlement litigation arising out of the Hatch-Waxman Act.

Lawmakers should act now—tensions are too high between patent and antitrust law to continue in this COVID-19 pandemic absent a uniform standard for addressing reverse payments.

A. Legislative Approach

First, legislators should amend the Hatch-Waxman Act to create a tiered approach to ANDA filing. Such a tiered approach to ANDA filling could encompass the following aspects. Similar to the current structure of the Hatch-Waxman Act, the first generic drug manufacturer to file an ANDA would enjoy a period of exclusivity in the market. Because the Hatch-Waxman Act already incentivizes generic drug companies to pay the costs of litigation through its exclusivity period, this exclusivity granted under paragraph IV should remain. However, the Act should be amended to extend this period of exclusivity from 180 days to five years, granting the first generic drug manufacturer to file an ANDA five years of exclusivity in the generic drug market. The exclusivity period should also apply to the next generic drug manufacturer to file an ANDA, where, after the first generic drug manufacturer's five-year exclusivity period ends, the next generic drug manufacturers would begin, and that company would enjoy five years of exclusivity in the market (with the brand-name and first generic manufacturer), and so on. This process would continue until the brand-name company's patent term expires, after which all generic manufacturers would gain access to the market.

By carving out a way for generic drug companies to enter into the market sooner, the Hatch-Waxman Act paved the way for reverse payment settlements and undermined antitrust issues the Act aimed to resolve. This proposed legislative change addresses antitrust and patent policy concerns by allowing generic medications to enter the market sooner than a typical, permitted patent term. Additionally, this change would allow the brand-name company the ability to not only recoup its innovation costs, but also turn a profit because the market size for the particular drug is reduced to a limited number of pharmaceutical companies for the duration of the patent term.¹⁸² Having only two drugs on the market for five years

182. By extending the exclusivity for five years and only allowing one generic drug to enter the market during that time, data shows that the brand-name company can still recoup costs of innovation and turn a profit. See *In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d 180, 183 (D.R.I. 2014). “[W]here there is a single generic competitor, the generic tends to be priced approximately 25% lower than the brand name counterpart. And, where there are multiple generic alternatives, the price of the generics typically falls to 50% to 80% below the brand name product.” *Id.*

(one brand-name and one generic), then three drugs on the market for five years (one brand-name and two generics), and so on, allows for competition, but less competition than if all generic manufacturers to file ANDAs flooded the market at once.

Second, the Hatch-Waxman Act should be amended to give companies the option of either an *inter partes* review with the U.S. Patent and Trademark Office's Patent Trial and Appeal Board (PTAB) or foregoing the standard federal litigation to assess the validity of the patent.¹⁸³ Regardless of *inter partes* review or federal court litigation, the remaining process under the Hatch-Waxman Act apply would still apply. The paragraph IV route still "automatically counts as patent infringement" and would trigger patent litigation.¹⁸⁴ If the court were to determine that the brand-name company's patent is not infringed, then the generic drug would be approved and the generic drug company would enjoy five-year exclusivity.¹⁸⁵ If, on the other hand, the court were to determine that the brand-name company's patent has been infringed and the case is not successfully appealed, then the approval would be made effective no earlier than the expiration of the patent.¹⁸⁶

Amending the Hatch-Waxman Act to specifically allow for *inter partes* review addresses one of the driving factors behind reverse payment settlements: costly patent litigation. *Inter partes* review "provide[s] a specialized forum to resolve complex, scientific issues associated with an invention."¹⁸⁷ *Inter partes* review also alleviates costly patent litigation in federal court¹⁸⁸ and "is statutorily required to be complete within one year of institution, except that the time may be extended up to six

183. This suggestion aligns with the recent trend in pharmaceutical litigation: "pharmaceutical companies have been simultaneously settling federal court litigation and a proceeding before the U.S. Patent and Trademark Office's Patent Trial and Appeal Board (PTAB)" in *inter partes* review. Jamie Towey & Brad Albert, *Then, Now, and Down the Road: Trends in Pharmaceutical Patent Settlements After FTC v. Actavis*, FED. TRADE COMM'N: BLOG (May 28, 2019), <https://www.ftc.gov/news-events/blogs/competition-matters/2019/05/then-now-down-road-trends-pharmaceutical-patent> [https://perma.cc/WUQ5-BT7M].

184. F.T.C. v. Actavis, Inc., 570 U.S. 136, 143 (2013); see also 35 U.S.C. § 271(e)(2)(A).

185. See 21 U.S.C. § 355(j)(5)(B)(iii). Further, if the court "decides that the patent is invalid or not infringed . . . the approval shall be made effective" either on "the date on which the court enters judgment . . . or [on] the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed." *Id.* § 355(j)(5)(B)(iii)(I).

186. *Id.* § 355(j)(5)(B)(iii)(I).

187. Francisco Javier Espinosa, *Big Pharma Versus Inter Partes Review: Why the Pharmaceutical Industry Should Seek Logical Hatch-Waxman Reform over Inter Partes Review Exemption*, 50 J. MARSHALL L. REV. 337, 352 (2017).

188. *Inter partes* review or "IPR was designed to be less expensive and less time consuming than district court proceedings." *Id.*

months for good cause.”¹⁸⁹ *Inter partes* review would drastically reduce the amount of time and money the parties would spend litigating the validity of a patent.¹⁹⁰

Lastly, legislators should amend the Hatch-Waxman Act to make all forms of reverse payment subject to the *Actavis* rule of reason analysis. This proposition is intended to disincentivize big pharma from engaging in reverse payments because almost all reverse payments delay generic medication entry into the market in some way.¹⁹¹ Further, while the *Actavis* Court played an important role in untangling the reverse payment chaos, at this point, legislative change is imperative. Although critics argue that reverse payments are becoming less prominent, the FTC noted that “[c]ompanies are settling more cases on more pharmaceutical products than before the *Actavis* decision.”¹⁹² The problem is that even though the kinds of reverse payments that currently trigger antitrust scrutiny have declined, “companies [have] found other ways to settle.”¹⁹³ And while companies use reverse payments that the courts have deemed acceptable,¹⁹⁴ the definition of a “large and unjustified payment” has narrowed substantially.¹⁹⁵ Regardless of that fact, “pay-for-delay is most certainly still happening[.]”¹⁹⁶ Amending the Act to subject all forms of

189. *America Invents Act (AIA) Frequently Asked Questions: How Long Will an Inter Partes Review Take?*, U.S. PATENT & TRADEMARK OFF. (Mar. 6, 2019), <https://www.uspto.gov/patent/laws-and-regulations/america-invents-act-aia/america-invents-act-aia-frequently-asked#type-inter-partes-review> [<https://perma.cc/3W3X-ZTMB>].

190. I understand that the mechanics behind incorporating *inter partes* review into reverse payment settlement litigation would also need to be addressed with regard to patent legislation. However, I will only briefly provide my thoughts on this matter. Although *inter partes* review is typically “used by anyone who is not the owner of a patent who wants to challenge a patent’s validity[.]” the PTAB should automatically grant an *inter partes* review in the context of paragraph IV litigation so long as the brand-name company wishes to resolve the patent dispute via *inter partes* review because paragraph IV certification automatically counts as patent infringement. Espinosa, *supra* note 187, at 352. Further because “[t]he petitioner [in an *inter partes* review proceeding] must demonstrate that there is a reasonable likelihood that he/she would prevail as to at least one of the claims challenged to trigger an *inter partes* review[.]” I also suggest that the brand-name company’s petition for an *inter partes* review automatically count as “reasonable likelihood.” See *America Invents Act (AIA) Frequently Asked Questions: What Is the Standard for Instituting an Inter Partes Review and Who Will Decide Whether the Standard Is Met?*, U.S. PATENT & TRADEMARK OFF., <https://www.uspto.gov/patent/laws-and-regulations/america-invents-act-aia/america-invents-act-aia-frequently-asked#type-inter-partes-review> [<https://perma.cc/3W3X-ZTMB>].

191. “If we want to change the system, we must change the incentives driving the system.” Feldman, *supra* note 174.

192. Towey & Albert, *supra* note 183.

193. *Id.*

194. *Id.*

195. See Bauman, *supra* note 80.

196. *Id.*

reverse payments to *Actavis* rule of reason scrutiny would disincentivize anticompetitive settlements.¹⁹⁷

Further, one of the goals “of creating the [p]aragraph IV challenge process was to provide a mechanism through which generic manufacturers could challenge weak patents.”¹⁹⁸ Subjecting all reverse payments to antitrust scrutiny would pigeonhole pharmaceutical companies into concluding patent disputes rather than settling without determining the validity of a patent. This notion is especially important given that “[p]harmaceutical companies have become adept at maneuvering through the system of patent and non-patent rights to create mountains of rights that can be applied, one after another.”¹⁹⁹ Disincentivizing pay-for-delay settlements so that pharmaceutical companies will engage in patent litigation may also discourage brand-name companies from obtaining new patents on minor tweaks to medications²⁰⁰ because the brand-name companies will not want to spend money to resolve numerous patent claims.

Amending the Hatch-Waxman Act to incorporate a tiered approach to ANDA filing eases generic medications into the market, allowing brand-name companies the entirety of their patent term to profit with restricted competition while still granting the public access to affordable medication. Amending the Act to specifically allow parties an *inter partes* review to resolve patent disputes addresses the issue of parties engaging in reverse payments in lieu of traditional, expensive patent litigation. Amending the Act to render all forms of reverse payments subject to rule of reason analysis disincentivizes big pharma from engaging in reverse payments that delay entry of generic medications into the market.

B. Common Law Approach

Aside from legislative reform, courts can create a uniform standard at the judicial level by hearing evidence of patent validity or invalidity prior to resolving antitrust claims. Adopting some elements of patent litigation can also help rebut claims of anticompetitive reverse payments. Although the *Actavis* Court warned against patent trials within antitrust

197. This is because “antitrust scrutiny of a reverse payment agreement” may “require the parties to engage in time-consuming, complex, and expensive litigation to demonstrate what would have happened to competition absent the settlement.” *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 137 (2013). California has already adopted a strict approach to reverse payments: “California’s Assembly Bill 824 . . . declares that any reverse payment is ‘presumed to have anticompetitive effects’ under the state’s Cartwright Act.” Bauman, *supra* note 80.

198. Gregory, *supra* note 54, at 127.

199. Feldman, *supra* note 174.

200. *See* Feldman, *supra* note 174. “This behavior lets drug companies keep competitors out of the market and beat them back when they get there.” *Id.*

trials, permitting evidence imperative to the patent dispute would help ensure that the pharmaceutical patent in question is not weak. However, such a showing of patent strength need not be extensive.

Tangentially, courts should also hold all reverse payments that extend a brand-name pharmaceutical company's limited monopoly beyond the twenty-year term a per se violation of antitrust law.²⁰¹ These settlements grossly "undermine the regulatory framework of the Hatch-Waxman Act, which was intended to speed the entry of generic drugs and stimulate innovation by research-based pharmaceutical companies."²⁰²

Because *Actavis* already allows the lower courts leeway in applying the rule of reason, federal courts should subject all reverse payments to *Actavis* rule of reason scrutiny but should require a pre-trial hearing with limited discovery to assess patent claims. Payments larger than those that "would be expected from the outcome of the patent case" "look[] suspiciously like payment to avoid more competition" and essentially "create[] an inference that the settlement is anticompetitive,"²⁰³ thus ignoring the issue of patent validity. A pre-trial hearing addressing patent validity would not only resolve this issue, but also uncover a more accurate estimate of the avoided patent litigation costs, a factor that may lead the court to determine that no further antitrust analysis is necessary. Further, if the pre-trial hearing reveals that the brand-name company's patent is valid and infringed, then the generic company would not gain entry into the market.

This suggestion is also efficient. Because the Court in *Actavis* was concerned with the efficiency of "a patent mini-trial inside an antitrust case[,]"²⁰⁴ one proposal is for courts to remand these antitrust cases to the lower courts to resolve patent disputes prior to moving forward with the antitrust litigation. However, this proposal is inefficient because it halts antitrust litigation to resolve patent claims that should have been resolved at the onset of paragraph IV litigation as intended by the Hatch-Waxman Act. Conversely, a pre-trial hearing assessing any patent issues would allow patent claims and antitrust claims to be resolved as one matter. This proposed structure would allow for the patent dispute to be resolved (to some extent) without the need for a whole separate, lengthy patent trial

201. See Mazzucato *supra* note 20; *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 162 (2013) (Roberts, C.J., dissenting) (arguing against "actions [that] go beyond the monopoly powers conferred by the patent").

202. Jamie Towey, *Quo Vadis Post-Actavis?*, FED. TRADE COMM'N (Mar. 30, 2016), <https://www.ftc.gov/news-events/blogs/competition-matters/2016/03/quo-vadis-post-actavis> [<https://perma.cc/6ZXC-A46P>].

203. *Activating Actavis*, *supra* note 96, at 16–17. "Unless there is another explanation for the payment, that inference should stand." *Id.* at 17.

204. *Id.* at 19.

within the antitrust trial. Nonetheless, a common law approach would only move forward with antitrust litigation where the patent is found to be invalid or not infringed, in which the patent evidence from the pre-trial hearing can be used to disprove anticompetitive effects of the reverse payment in dispute. Upon resolution of the patent dispute, the courts would still assess the reverse payment using the rule of reason analysis from *Actavis*.

Although legislative reform is preferred, because legislative reform is such a sizeable goal, courts should work to adopt a uniform standard in approaching pay-for-delay settlements. Further, such common law reform may spark change at the legislative level by showing Congress that change is necessary.

CONCLUSION

When considering reform, it is important to strike a balance between providing the public access to affordable medication, on the one hand, and promoting pharmaceutical innovation, on the other hand. Amending the Hatch-Waxman Act strikes such a balance. The legislative changes alleviate tension between antitrust and patent law by facilitating delivery of generic medication to the public while protecting innovation and allowing brand-name companies to turn a profit. Further, federal courts should work to adopt a uniform common law standard, assessing patent validity before addressing antitrust concerns.

Regardless, antitrust and patent policy concerns must be considered in conjunction, especially given that big pharma suited for battle against COVID-19. Lawmakers should seriously consider the future ramifications of our current system which lacks uniformity in an area of law that so severely impacts the lives of United States citizens.²⁰⁵ No better time exists to address this tension in the pharmaceutical context than now, in light of the rush to develop treatments and medications aimed at preventing illness

205. Although a slightly different context, the pharmaceutical company Gilead Sciences was recently granted a limited monopoly for a medication being tested to treat COVID-19. Although Gilead ended up giving up the limited monopoly, such power over the market still raises future concerns. For more information, see Ed Silverman, *Under Intense Criticism, Gilead Forsakes Monopoly Status for Its Experimental Covid-19 Drug*, STAT (Mar. 25, 2020), <https://www.statnews.com/pharmalot/2020/03/25/gilead-covid19-coronavirus-orphan-drug/> [https://perma.cc/A5N3-EZEU]; Lee Fang & Sharon Lerner, *Coronavirus Treatment Developed By Gilead Sciences Granted "Rare Disease" Status, Potentially Limiting Affordability*, THE INTERCEPT (Mar. 23, 2020), <https://theintercept.com/2020/03/23/gilead-sciences-coronavirus-treatment-orphan-drug-status/> [https://perma.cc/QGJ2-D8XB]; Jonathan Gardner, *In Rare Move, Gilead Gives Up 'Orphan' Status for Experimental Coronavirus Drug*, BIOPHARMA DIVE (Mar. 25, 2020), <https://www.biopharmadive.com/news/coronavirus-gilead-remdesivir-orphan-drug/574882/> [https://perma.cc/5XNT-K2SQ].

and death caused by the COVID-19 pandemic. Lawmakers must step up to battle against the pharmaceutical companies that are blocking consumers' access to affordable medications through reverse payment settlement agreements.