INTRODUCTION: WILLIAM HOWARD TAFT, THE ORIGIN OF THE RULE OF REASON, AND THE *ACTAVIS* CHALLENGE

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The origin of the Rule of Reason can be traced to the notable decision of United States v. Addyston Pipe & Steel Co. *(1898), which was written by William Howard Taft during his tenure on the Sixth Circuit Court of Appeals. There, Judge Taft distinguished between restraints that were mainly or entirely designed to restrain trade and those that are ancillary to a procompetitive main purpose. That fundamental distinction, drawn at the dawn of Sherman Act jurisprudence, forms the basis of the Rule of Reason that currently informs antitrust case law.*

This Article describes the context in which the Rule of Reason was debated and defended both in public discourse by President and Professor Taft and in the landmark Supreme Court decisions of Standard Oil Co. of New Jersey v. United States *(1911) and* United States v. American Tobacco Co. *(1911). This Article then follows the development of the Rule of Reason through* Board of Trade of City of Chicago v. United States *(1918) to the modern era of antitrust jurisprudence.*

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Finally, this Article describes the application of the Rule of Reason to reverse-payment settlements in the pharmaceutical sector, one of the most challenging contemporary antitrust issues. It does so through a discussion of the Supreme Court case FTC v. Actavis *(2013) and the Third Circuit's application of Actavis in* In re Wellbutrin Xl Antitrust Litig. Indirect Purchaser Class *(2017).*

This Article provided the foundation for, and introduction to, the remarks of Professor Michael A. Carrier and Mr. Saul Morgenstern that were delivered at the New York State Bar Association Antitrust Law Section's William Howard Taft Lecture on September 28, 2017. Those remarks are reprinted in article form in this volume of the Columbia Business Law Review.

I. INTRODUCTION

William Howard Taft is perhaps best known for being the only person to serve both as President of the United States and Chief Justice of the Supreme Court. Some associate him with antitrust law as an enforcer. Indeed, his administration prosecuted twice as many antitrust cases as that of Theodore

Roosevelt.[1] Several seminal antitrust cases, which will be discussed below, were decided during his Presidency.

Less known among the general population is the role that Taft played in the early history of the Sherman Antitrust Act and the formation of the Rule of Reason. Before his election to the Presidency and his later ascent to the Supreme Court, Judge Taft of the Sixth Circuit Court of Appeals developed a framework for antitrust cases that continues to inform the structure of the Rule of Reason today.

In Taft's era, key questions surrounding the Sherman Act revolved around its constitutionality, its relationship to the common law jurisprudence on restraints of trade, and the extent to which the Act would constrain business conduct.[2] Today, a major issue confronting courts and commentators is the interplay of the Sherman Act, its Rule of Reason, and the Hatch-Waxman regulatory scheme governing brand-name and generic drugs. The extent to which the Sherman Act should constrain business conduct—here in the pharmaceutical industry—still predominates the debate within antitrust and business circles and centers upon the proper understanding and application of the Rule of Reason.

II. TAFT AND THE RULE OF REASON

In *The Antitrust Paradox*, Robert H. Bork opined that, "given the time at which it was written, [Taft's opinion in *United States v. Addyston Pipe & Steel*] must rank as one of the greatest, if not the greatest, antitrust opinions in the history of the law."[3] He described *Addyston Pipe* as an opinion "of almost unparalleled suggestiveness," albeit one whose "potentialities . . . remain almost entirely unexploited."[4] While

[1] *William Howard Taft*, ENCYCLOPEDIA BRITANNICA [hereinafter Taft Encyclopedia Entry], https://www.britannica.com/biography/William-Howard-Taft (last updated Jan. 25, 2018).

[2] *See e.g.*, United States v. Trans-Missouri Freight Ass'n, 166 U.S. 290 (1897); Standard Oil Co. of N.J. v. United States, 221 U.S. 1 (1911).

[3] ROBERT H. BORK, THE ANTITRUST PARADOX 26 (2nd ed. 1993) [hereinafter ANTITRUST PARADOX].

[4] *Id.*

the case had several facets, including a question of "whether the trade restrained by the combination of the defendants was interstate trade,"[5] Taft's discussion of the reasonableness of restraints of trade causes the opinion, issued near the turn of the twentieth century, to remain relevant, and indeed prescient, today.

Addyston Pipe involved "manufacturers and vendors of cast-iron pipe" that "entered into a combination to raise the prices for pipe for all the states west and south of New York, Pennsylvania, and Virginia."[6] The defendants argued that the Sherman Act "was not intended to reach any agreements that were not void and unenforceable at common law" and that defendants' agreement would not violate the common law and was therefore beyond antitrust scrutiny.[7]

As Taft noted in *Addyston Pipe*, however, a then-recent Supreme Court case, *United States v. Trans-Missouri Freight Ass'n*, "held that contracts in restraint of interstate transportation were within the statute, whether the restraints would be regarded as reasonable at common law or not."[8] *Trans-Missouri* specified that the Sherman Antitrust Act "render[ed] illegal all agreements which are in restraint of trade or commerce."[9] Bork styles Justice Peckham's opinion in *Trans-Missouri* as a rejection of the "reasonable-price standard" utilized by the lower court and incorporated into Justice White's *Trans-Missouri* dissent.[10] As Bork summarizes, "[s]ince the restriction in this case operated upon prices, this test proposed to judge the 'reasonableness' of the prices set by cartel agreement."[11]

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5 United States v. Addyston Pipe & Steel Co., 85 F. 271, 294 (6th Cir. 1898), *aff'd* 175 U.S. 211 (1899).

6 *Id.* at 291.

7 *Id.* at 278.

8 *Id.*

9 United States v. Trans-Missouri Freight Ass'n, 166 U.S. 290, 341 (1897).

10 ANTITRUST PARADOX, *supra* note 3, at 22–23.

11 *Id.* at 22.

The *Addyston Pipe* defendants sought to distinguish *Trans-Missouri* by arguing that "a less stringent rule of construction applies to contracts restricting parties in sales of merchandise, which is purely a private business," than the rule applied in *Trans-Missouri*, which involved "a quasi public employment necessarily under public control."[12] Taft sidestepped the question of "[w]hether or not there is substance in such a distinction" and argued that the agreement at issue in *Trans-Missouri* would have been prohibited under the common law.[13]

Taft reviewed cases from the United States at the federal and state level, and from the United Kingdom and Canada, to distill a rule that:

> [N]o conventional restraint of trade can be enforced unless the covenant embodying it is merely ancillary to the main purpose of a lawful contract, and necessary to protect the covenantee in the full enjoyment of the legitimate fruits of the contract, or to protect him from the dangers of an unjust use of those fruits by the other party.[14]

Taft styled this rule as one dictated by the common law. Bork, however, notes that Taft "chose his common law cases carefully . . . and imposed upon them his own ideas. What emerged was not the restatement it pretended to be so much as a new structure."[15] That structure would distinguish between "ancillary" restraints and ones that were designed solely to restrain competition. The former were permissible while the latter were prohibited.

Judge Taft directly addressed the "reasonable-price" approach proposed by Justice White in the dissent in *Trans-Missouri* and delivered a stinging rebuke. Courts that used that standard, Taft wrote, had "set sail on a sea of doubt, and have assumed the power to say, in respect to contracts which

12 *Addyston Pipe*, 85 F. at 278.

13 *Id.* at 278–79, 291.

14 *Id.* at 282.

15 ANTITRUST PARADOX, *supra* note 3, at 27.

have no other purpose . . . than the mutual restraint of the parties, how much restraint of competition is in the public interest, and how much is not."[16] He added that the "manifest danger in the administration of justice according to so shifting, vague, and indeterminate a standard would seem to be a strong reason against adopting it."[17]

By contrast, Taft's "doctrine of naked and ancillary restraints," according to Bork, "offered the Sherman Act a sophisticated rule of reason, a method of preserving socially valuable transactions by defining the scope of an exception for efficiency-creating agreements within an otherwise inflexible per se rule."[18]

While Taft would soon leave the Sixth Circuit, he would again opine on the Sherman Act, though then as President of the United States and later as Professor of Law at Yale Law School.

III. TAFT ON ANTITRUST AFTER *STANDARD OIL* AND *AMERICAN TOBACCO*

During Taft's presidency, the Supreme Court decided two of the most important cases in Sherman Act jurisprudence, *Standard Oil Co. of New Jersey v. United States*,[19] and *United States v. American Tobacco*.[20] The *Standard Oil* Court examined the agglomeration that had become the company by that name under both Sections 1 and 2 of the Sherman Act, though without articulating different criteria for judgment under each.[21] The *Standard Oil* Court declared "that the criteria [under the Sherman Act] to be resorted to in any given case for the purpose of ascertaining whether violations of the section have been committed is the *rule of reason* guided by

16 *Addyston Pipe*, 85 F. at 283–84.

17 *Id.* at 284.

18 ANTITRUST PARADOX, *supra* note 3, at 30.

19 Standard Oil Co. of N.J. v. United States, 221 U.S. 1 (1911).

20 United States v. Am. Tobacco Co., 221 U.S. 106 (1911).

21 *Standard Oil*, 221 U.S. at 72–74.

the established law and by the plain duty to enforce the prohibitions of the act."[22]

The government had proposed that "the language of the statute embraces every contract, combination, etc., in restraint of trade, and hence its text leaves no room for the exercise of judgment, but simply imposes the plain duty of applying its prohibitions to every case within its literal language."[23] The Court rejected that proposed rule, and held:

> The merely generic enumeration which the statute makes of the acts to which it refers, and the absence of any definition of restraint of trade as used in the statute, leaves room for but one conclusion, which is, that it was expressly designed not to unduly limit the application of the act by precise definition, but, while clearly fixing a standard, that is, by defining the ulterior boundaries which could not be transgressed with impunity, *to leave it to be determined by the light of reason, guided by the principles of law and the duty to apply and enforce the public policy embodied in the statute, in every given case whether any particular act or contract was within the contemplation of the statute*.[24]

Later in the opinion, the Court invoked the term that has assumed center stage in contemporary antitrust jurisprudence:

> [T]he construction which we have deduced from the history of the act and the analysis of its text is simply that in every case where it is claimed that an act or acts are in violation of the statute, the *rule of reason*, in the light of the principles of law and the public policy which the act embodies, must be applied.[25]

A few weeks after the *Standard Oil* decision, the Supreme Court issued its opinion in *United States v. American Tobacco*,

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22 *Id.* at 62 (emphasis added).

23 *Id.* at 63.

24 *Id.* at 63–64 (emphasis added).

25 *Id.* at 66 (emphasis added).

which also dealt with Sections 1 and 2 of the Sherman Act and concerned alleged anticompetitive conduct in the tobacco industry.[26] The opinion offered additional gloss on the *Standard Oil* ruling and again invoked the nomenclature with which we are familiar today:

> Applying the *rule of reason* to the construction of the statute, it was held in the Standard Oil Case that, as the words 'restraint of trade' at common law and in the law of this country at the time of the adoption of the anti-trust act only embraced acts or contracts or agreements or combinations which operated to the prejudice of the public interests by unduly restricting competition, or unduly obstructing the due course of trade, or which, either because of their inherent nature or effect, or because of the evident purpose of the acts, etc., injuriously restrained trade, that the words as used in the statute were designed to have and did have but a like significance.[27]

The *American Tobacco* Court found that the record before it demonstrated the soundness of the *Standard Oil* Court's adoption of the "rule of reason" and therefore "unequivocal[ly]" "re-express[ed] and reaffirm[ed]" that rule:

> [T]he plain demonstration which this record gives . . . serves to strengthen our conviction as to the correctness of the rule of construction—the *rule of reason*—which was applied in the *Standard Oil* Case, the application of which rule to the statute we now, in the most unequivocal terms, re-express and reaffirm.[28]

The *Standard Oil* and *American Tobacco* decisions were of such importance to Taft that they were the first topics he discussed in his 1911 State of the Union remarks.[29] According

[26] United States v. Am. Tobacco Co., 221 U.S. 106, 142 (1911).

[27] *Id.* at 179.

[28] *Id.* at 180.

[29] At the time, the State of the Union was not a live address, but rather consisted of written remarks that the President sent to Congress.

to Taft, the "epoch-making" decisions "serve[d] to advise the business world authoritatively of the scope and operation of the anti-trust act of 1890."[30] Taft mentioned prior Supreme Court opinions where "the court said that the statute should be given a reasonable construction and refused to include within its inhibition, certain contractual restraints of trade which it denominated as incidental or as indirect."[31]

Although Taft did not cite specific cases, and while he connected his reasoning to earlier "Supreme Court opinions," the rule he described primarily echoed the rule that Taft himself had formulated in *Addyston Pipe*. *Standard Oil* and *American Tobacco*, he argued, "adopted the tests of the common law, and in defining exceptions to the literal application of the statute, only substituted for the test of being incidental or indirect, that of being reasonable, and this, without varying in the slightest the actual scope and effect of the statute."[32]

Taft defended the recent decisions against two lines of criticism: (1) that the opinions had limited the scope of the statute and "emasculated it," and (2) that the cases "committed to the court the undefined and unlimited discretion to determine whether a case of restraint of trade is within the terms of the statute."[33] Against the former line of criticism, Taft insisted that, through the Supreme Court's "judgment[,] every contract and combination in restraint of interstate trade made with the purpose or necessary effect of controlling prices by stifling competition, or of establishing in whole or in part a monopoly of such trade, is condemned by the statute."[34] Taft asserted that "[t]he most extreme critics can not instance a case that ought to be condemned under the

30 President William Howard Taft, Third Annual Message to Congress (Dec. 5, 1911) *in* AMERICAN PRESIDENCY PROJECT (Gerhard Peters & John T. Woolley eds., 2017), http://www.presidency.ucsb.edu/ws/index.php?pid=29552 [perma.cc/ZK4K-EHB6].

31 *Id.*

32 *Id.*

33 *Id.*

34 *Id.*

statute which is not brought within its terms as thus construed."[35]

Against the argument that the Rule of Reason left courts with "undefined and unlimited discretion," Taft insisted that:

> A reasonable restraint of trade at common law is well understood and is clearly defined. It does not rest in the discretion of the court. It must be limited to accomplish the purpose of a lawful main contract to which, in order that it shall be enforceable at all, it must be incidental. If it exceeds the needs of that contract, it is void.[36]

In his 1911 State of the Union address, therefore, Taft essentially equated the test formulated by the Supreme Court to the one he developed over a decade prior in the Sixth Circuit's *Addyston Pipe* decision. In Taft's view, the Rule of Reason did not introduce uncertainty into antitrust law. Rather, it provided a principle by which contracts were to be judged. Taft acknowledged that certain additional legislation delineating specific violations may be useful. Still, he remained steadfast that "the discussions which have been brought out in recent days . . . have produced nothing but glittering generalities and have offered no line of distinction or rule of action as definite and as clear as that which the Supreme Court itself lays down in enforcing the statute."[37]

After concluding his term as President and before assuming his seat on the Supreme Court, Taft served as Professor of Law at Yale Law School, where he continued to contribute to the subject of antitrust law through his scholarship (Bork was similarly a professor at Yale when he published *The Antitrust Paradox*). Taft authored a book entitled *The Anti-trust Act and the Supreme Court* to address the ongoing discussion of an amendment to the Sherman

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35 *Id.*
36 *Id.*
37 *Id.*

Act.[38] Taft feared that "[t]he decisions of the Supreme Court interpreting the statute have not been clearly understood by many of those who have taken part in that discussion."[39]

After providing a history of crucial opinions interpreting the Sherman Act, Taft recalled his challenge to opponents of the *Standard Oil* and *American Tobacco* opinions, stating that he "invited the gentlemen who were most stentorian in condemnation of the interpretation given to the statute by the Supreme Court to mention and describe a case in which they would have the statute apply to which it would not apply under the reasoning of the court."[40] According to Taft, his challenge was never answered.[41]

Taft also challenged the other criticism of the Supreme Court's antitrust opinions—that "business men [could not] live under the anti-trust law because nobody can tell what it means."[42] Taft countered with a ringing endorsement of the Supreme Court's antitrust jurisprudence, which he declared to be "a valuable asset for the public."[43] According to Taft:

> No man who reads this series of decisions need be doubtful whether, when he is making a business arrangement, he is violating the law or not. He can search his own heart and he can tell what his purpose is and what the effect of his act is going to be.[44]

Taft's opinion in *Addyston*, his post-*Addyston* thoughts and writings, and the debate to which they were addressed foreshadow the full range of contemporary Rule of Reason commentary and jurisprudence. Following Taft's example, courts examine the pertinent agreement, determine whether the challenged restraint was incidental to the legitimate

38 WILLIAM HOWARD TAFT, THE ANTI-TRUST ACT AND THE SUPREME COURT (1914).

39 *Id.* at 1.

40 *Id.* at 94–95.

41 *Id.* at 95.

42 *Id.*

43 *Id.* at 96.

44 *Id.* (emphasis added).

purpose of the agreement, and determine whether the restraint was reasonably necessary to accomplish that purpose.[45] Assessing the actual effect of the agreement and the challenged restraint on competition would come at the next stage of the development of the Rule of Reason.

Although the Rule of Reason has evolved since Taft's day, especially with respect to an emphasis on assessing effects, one can argue that the fundamental conceptual structure of the Rule of Reason remains as outlined by Judge Taft in *Addyston Pipe* and adopted by the Supreme Court in *Standard Oil* and *American Tobacco*.

IV. THE RULE OF REASON AND A NEW EMPHASIS ON EFFECT

The next significant articulation of the Rule of Reason occurred in *Board of Trade of City of Chicago v. United States* ("*Chicago Board of Trade*") under the authorship of Justice Brandeis.[46] The decision held that "[t]he true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition."[47] Applying that test, according to Justice Brandeis, requires consideration of "the facts peculiar to the business to which the restraint is applied; *its condition before and after the restraint was imposed*; the nature of the restraint *and its effect, actual or probable*."[48]

In *Chicago Board of Trade*, members of Chicago's Board of Trade were prohibited from purchasing "wheat, corn, oats or rye" above a price set at the end of "the 'call,'" a special session of the Board.[49] Examining the effects of the rule, the Court found that:

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45 *See, e.g.*, Eichorn v. AT&T Corp., 248 F.3d 131, 145–47 (3d Cir. 2001).

46 Bd. of Trade of City of Chi. v. United States, 246 U.S. 231 (1918).

47 *Id.* at 238.

48 *Id.* (emphasis added).

49 *Id.* at 236–37.

> As it applies to only a small part of the grain shipped to Chicago and to that only during a part of the business day and does not apply at all to grain shipped to other markets, *the rule had no appreciable effect on general market prices; nor did it materially affect the total volume of grain coming to Chicago. But within the narrow limits of its operation the rule helped to improve market conditions*.[50]

The *Chicago Board of Trade* Court reached its conclusion, therefore, based primarily on a finding regarding the competitive effect of the restraint. The Court's emphasis thus progressed from assessing only (or primarily) the relationship between the restraint and the productive component of the agreement to the additional element of the actual impact of the agreement on competitive conditions in the marketplace. The doctrine of ancillary restraints remained a necessary condition for the application of the Rule of Reason (and, if the restraint were not ancillary, it would likely be condemned under the *per se* rule). But the Court, consistent with the Progressive Era's focus on empirical analysis, undertook to assess the actual impact of the agreement on competitive conditions in the market. The implicit basis of comparison was the market without the agreement or restraint—i.e., "the condition before and after the restraint was imposed."[51]

In the decades following *Chicago Board of Trade*, the Rule of Reason declined in fashion. According to Professor Thomas C. Arthur of Emory Law School, "[u]ntil the late 1970s, the rule of reason had been almost completely replaced by a comprehensive network of per se rules."[52] However, beginning in the late 1970s and early 1980s, "the [Supreme] Court transformed antitrust by restricting the reach of the per se rules and expanding the scope of the rule of reason."[53] All the

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50 *Id.* at 240 (emphasis added).

51 *Id.* at 238.

52 Thomas C. Arthur, *A Workable Rule of Reason: A Less Ambitious Antitrust Role for the Federal Courts*, 68 ANTITRUST L.J. 337, 337 (2000).

53 *Id.*

while, however, the Court's focus development of the Rule of Reason has focused squarely on effect.

The Court has also recognized that the structure and application of the Rule of Reason must be flexible and "meet for the case," in some instances "quick," in others "sedulous,"[54] but in all cases fixed on effect:

> [T]here is generally no categorical line to be drawn between restraints that give rise to an intuitively obvious inference of anticompetitive effect and those that call for more detailed treatment. What is required, rather, is an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint. The object is to see whether the experience of the market has been so clear, or necessarily will be, that a confident conclusion about the principal tendency of a restriction will follow from a quick (or at least quicker) look, in place of a more sedulous one.[55]

The "principal tendency" in question is the *effect* of the agreement—whether "the arrangements in question would have *an anticompetitive effect on customers and markets*."[56] In the same case, the Court held that, before the burden is shifted to the defendant "to show empirical evidence of procompetitive effects," a court must identify "the theoretical basis for the anticompetitive effects and consider[] whether the effects actually are anticompetitive."[57] And the Court has acknowledged that short-form Rule of Reason analyses can be used to acquit challenged restraints as well as to condemn them.[58]

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[54] Cal. Dental Ass'n v. FTC, 526 U.S. 756, 780–81 (1999).

[55] *Id.*

[56] *Id.* at 770 (emphasis added).

[57] *Id.* at 775 n.12.

[58] *See, e.g.*, Am. Needle Inc. v. Nat'l Football League, 560 U.S. 183, 203 (2010) (suggesting that agreements that "are essential if the product is to be available at all" are "likely to survive the Rule of Reason") (internal quotations and citation omitted); *see also id.* (further noting that "the Rule of Reason . . . can sometimes be applied in the twinkling of an eye") (internal quotations and citation omitted); Vogel v. Am. Soc'y of Appraisers, 744 F.2d

The most recent challenge in applying the Rule of Reason was issued by the Supreme Court in 2014 in the pharmaceutical context. In *FTC v. Actavis*, the Supreme Court invoked the Rule of Reason to assess "reverse payment" settlements that resolve bona-fide patent-infringement litigation under the Hatch-Waxman statutory framework.[59]

V. THE *ACTAVIS* CHALLENGE: ADAPTING THE RULE OF REASON TO THE SETTLEMENT CONTEXT

The progeny of *FTC v. Actavis,* which is still well under development, has attempted to adapt the Rule of Reason, at the direction of the Supreme Court, to restraints contained in the settlement of genuine patent disputes as to which both sides, by assumption, had an objectively "realistic[] expect[ation of] success on the merits."[60] The restraint typically relates to the date on which the settlement agreement provides for the issuance of a license by the patent holder to the generic manufacturer for entry into the relevant market. The date of entry is usually within the life of the patent but later than the date of the settlement. The claim is typically that the date of entry was delayed in return for some form of compensation (the "reverse payment") transmitted by the patent holder to the putative generic entrant.

The underlying patent litigation occurs under the Hatch-Waxman statute. Generic drug manufacturers hoping to compete with a brand-name drug can submit an "Abbreviated New Drug Application ['ANDA'] specifying that the generic

598, 603 (7th Cir. 1984) ("Moreover, there is no evidence that the Society has any power in the market for appraising gems, or any other market, and an absence of market power is a reason against inferring that a business practice is monopolistic."); *compare Cal. Dental*, 526 U.S. at 780–81, *with* Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Okla., 468 U.S. 85, 109 n.39 (1984) ("[T]he rule of reason can sometimes be applied in the twinkling of an eye.") (internal quotation marks and citation omitted).

59 FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013).

60 *See* Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60 (1993).

has the same active ingredients as, and is biologically equivalent to, the already-approved brand-name drug."[61]

Such generics can avoid the costly studies and long waits for approval that new drugs undergo. The purpose of this process is procompetitive, as it allows the generic to "piggy-back on the pioneer's approval efforts," which "speed[s] the introduction of low-cost generic drugs to market."[62] The statute provides an incentive for the first generic to file an ANDA; from its "first commercial marketing of its drug," it will have a 180-day exclusivity period where no other generic can market its version, and its only competition is the brand-name drug or its authorized generic.[63]

To gain approval, the generic must "assure the FDA that the generic will not infringe the brand-name's patents."[64] Per the statute, the generic can do so in four ways:

> It can certify that the brand-name manufacturer has not listed any relevant patents. It can certify that any relevant patents have expired. It can request approval to market beginning when any still-in-force patents expire. Or, it can 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 Abbreviated New Drug Application . . . . Taking this last-mentioned route (called the "paragraph IV" route), automatically counts as patent infringement . . . and often means provoking litigation.[65]

FTC v. Acatvis stemmed from the conclusion of one such litigation. Solvay Pharmaceuticals held a patent to a drug known as AndroGel.[66] A number of generics either filed ANDAs or joined in litigation with a generic filer.[67] At the conclusion of the litigation, the party that filed the first

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61 *Actavis*, 133 S. Ct. at 2228 (internal citation and quotations omitted).

62 *Id.* (internal citation and quotations omitted).

63 *Id.* at 2228–29.

64 *Id.* at 2228 (internal citation and quotations omitted).

65 *Id.* (internal citations and quotations omitted).

66 *Id.* at 2229.

67 *Id.*

ANDA, Actavis, Inc., agreed to delay marketing its generic until August 31, 2015, more than five years before the patent's expiration, and it agreed "to promote AndroGel to urologists."[68] According to the Supreme Court, "[t]he other generic manufacturers made roughly similar promises."[69]

Solvay, for its part, "agreed to pay millions of dollars to each generic."[70] Actavis, for example, was to receive "an estimated $19–30 million annually, for nine years."[71] The settling parties described the payments as "compensation for other services the generics promised to perform, but the FTC contend[ed] the other services had little value."[72] However, "[a]ccording to the FTC[,] the true point of the payments was to compensate the generics for agreeing not to compete against AndroGel until 2015."[73]

In *Actavis*, the FTC appealed from a defeat in the Eleventh Circuit.[74] The Eleventh Circuit reasoned that, while paying a competitor not to enter a market is generally an antitrust violation, "'reverse payment settlements of patent litigation presen[t] atypical cases because one of the parties owns a patent,'" and patents allow the holder to exclude competitors from the market.[75] The Eleventh Circuit applied what could be viewed as a quick-look analysis to acquit the agreement: "'[A]bsent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.'"[76] Under *PRE*, "litigation cannot be . . . sham unless the litigation is

68 *Id.*

69 *Id.*

70 *Id.*

71 *Id.*

72 *Id.*

73 *Id.*

74 *Id.* at 2230.

75 *Id.* (citing FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1307, 1310 (11th Cir. 2012)).

76 *Id.* (citing *Watson*, 677 F.3d at 1312).

objectively baseless[,]" which occurs only if "no reasonable litigant could realistically expect success on the merits."[77]

While the Eleventh Circuit "recognized that, if the parties to this sort of case do not settle, a court might declare the patent invalid," it held that "in light of the public policy favoring settlement of disputes (among other considerations)[,] . . . the courts could not require the parties to continue to litigate in order to avoid antitrust liability."[78] The Eleventh Circuit opinion provided an example of the "scope of the patent" rule that was the majority position among circuit courts before *Actavis.*[79]

The Supreme Court, in a 5-3 decision authored by Justice Breyer,[80] reversed the Eleventh Circuit. The Court noted that, while a valid patent permits the holder to exclude others from the market and to charge higher prices than those found in a competitive market, an "*invalidated* patent carries with it no such right. And even a valid patent confers no right to exclude products or processes that do not actually infringe."[81]

The Court pointed out that "[t]he paragraph IV litigation in this case put the patent's validity at issue, as well as its actual preclusive scope. The parties' settlement ended that litigation."[82] Justice Breyer concluded that settlements of the type at issue, where "the plaintiff agreed to pay the defendants many millions of 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 . . . tend to have significant adverse effects on competition."[83]

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77 Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 51, 60 (1993).

78 *Actavis*, 133 S. Ct. at 2225, 2230.

79 *See* Henry N. Butler & Jeffrey Paul Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation,* 96 IOWA L. REV. 57, 66–76 (2010).

80 Justice Alito did not participate in the decision. *See Actavis*, 133 S. Ct. at 2223.

81 *Id.* at 2231 (emphasis in original).

82 *Id.*

83 *Id.*

The Court acknowledged that, on some occasions, the reverse payment could be justified by "traditional settlement considerations, such as avoided litigation costs or fair value for services . . . In such cases, the parties may have provided for a reverse payment without having sought or brought about the anticompetitive consequences . . . mentioned above."[84] However, the Court found that this concern did not "justify dismissing the FTC's complaint," since "[a]n antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason."[85]

The Court also found that "it is normally not necessary to litigate patent validity to answer the antitrust question."[86] The Court stated:

> An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness.[87]

Justice Breyer's opinion acknowledged that "[t]he owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment."[88] The Court, however, continued: "[B]e that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm."[89] Justice

84 *Id.* at 2236.

85 *Id.*

86 *Id.*

87 *Id.*

88 *Id.*

89 *Id.* (emphasis added); *see also* King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 403–04 (3d Cir. 2015)

Breyer concluded that "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness."[90]

Some have argued that the Court was suggesting a procedural mechanism by which a court should infer an anticompetitive effect from an "unexplained large reverse payment" from the brand name to the generic.[91] That suggestion, however, would seem to contradict the Court's decision to decline the FTC's invitation to adopt presumptions of illegality or to subject reverse payment agreements to "quick look" condemnation. Instead, the Court required the application of the full Rule of Reason scrutiny,[92] stating:

> [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. The existence and degree of any anticompetitive consequence may also vary as among industries. These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases.[93]

The Court then enlisted the lower courts to:

> [S]tructure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated

(characterizing *Actavis* as holding that "reverse payments are problematic because of their potential to negatively impact consumer welfare by preventing the risk of competition, which arises from expected litigation outcomes").

[90] *Actavis*, 133 S. Ct. at 2236–37. In *King Drug*, the Third Circuit extended this reasoning to cases where the generic receives some type of consideration other than a monetary payment, such as the brand-name agreeing to delay its own "authorized generic" of the drug. 791 F.3d at 393, 403.

[91] Brief for 58 Law, Economics, and Business Professors as Amici Curiae Supporting Appellants at 6–7, *In re* Wellbutrin XL Antitrust Litig., No. 15-2875 (3d Cir. Sept. 7, 2017) [hereinafter *Wellbutrin* Amicus Brief].

[92] *Actavis*, 133 S. Ct. at 2237.

[93] *Id.*

> to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences.[94]

The Court thus seemed to limit its decision to holding that the FTC's pleading against Actavis (and similar such pleadings) was legally sufficient and was to be assessed under the full Rule of Reason. Although, as noted above, the Court suggested that "litigating patent validity" should be "normally not necessary,"[95] the Court expressly "[left] to the lower courts the structuring of the present rule-of-reason antitrust litigation,"[96] and, with it, the competitive assessment of the reverse payment settlement.

VI. *WELLBUTRIN* AND ASSESSING ANTICOMPETITIVE CONSEQUENCES

Just how that competitive assessment should be structured continues to be a controversial topic. In the recent *Wellbutrin* decision by the Third Circuit Court of Appeals, the court held that "[a]ppellants must show that the harm they say they experienced—increased drug prices for Wellbutrin XL (and its generic equivalents)—was caused by the settlement they are complaining about."[97] The Third Circuit reviewed appellants' showing of harm in the context of an assessment of appellants' antitrust standing, rather than in the context of an application of the Rule of Reason.[98] Given that the appellants were direct and indirect purchasers,

94 *Id.* at 2238.

95 *Id.* at 2236.

96 *Id.* at 2238.

97 *In re* Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132, 164–65 (3d Cir. 2017).

98 *Id.* at 163–170, 170 n.64 ("Having concluded that the Appellants lack antitrust standing, we do not need to consider the District Court's application of the rule of reason. We note, however, that the rule of reason inquiry is fact intensive and is not easy to resolve at the summary judgment stage.").

however, the question arises as to whether appellants' failure to demonstrate antitrust injury is equivalent to their failure to demonstrate consumer injury, or a cognizable anticompetitive effect—i.e., an injury to competition—under the Rule of Reason.

In attempting to establish an antitrust injury, appellants purported to show that, absent the settlement, the generic company would have launched its drug earlier.[99] As the Third Circuit found, however, to make that argument, the appellants would have also had to show that the generic launch would have been legal and not been blocked by a patent.[100]

After rejecting an argument that the generic might have been able to license the patent,[101] the Third Circuit turned to the question of whether the generic could have prevailed in the underlying patent litigation. It held that the size of the reverse payment itself was "far from dispositive" of the outcome of the underlying litigation.[102] The Third Circuit found that the size of the payment was especially limited in serving as a proxy for "how confident a litigant is in the strength of its case" in instances, like the case it was considering, where "the settlement is complex and multi-faceted" and the patent holder is risk-averse.[103] The court also examined the merits of the litigants' positions in the underlying patent suit and concluded that "no reasonable jury could conclude that the [potential infringer] would have been more likely than not to prevail."[104]

Appellants sought rehearing or rehearing *en banc*. A group of fifty-eight professors, led by Distinguished Professor of Law Michael A. Carrier, submitted an *amicus* brief in support of the petition. The brief argued, in part, that, by placing too little weight on the size of the reverse payment and by

99 *Id.* at 165.

100 *Id.*

101 *See id.* at 166–67.

102 *Id.* at 168.

103 *Id.*

104 *Id.* at 169.

apparently making an exception for "complex and multi-faceted settlements," the Third Circuit panel disregarded the instructions of the Supreme Court in *Actavis* as well as precedent from within the Third Circuit.[105] The professors further argued that the *Actavis* Court specified that "a large unexplained payment can serve as a proxy for a patent's weakness" and that the Third Circuit erred in looking beyond that payment to examine the strength of the underlying litigation positions.[106] The Third Circuit denied Appellants' petition for rehearing or rehearing *en banc*.

Wellbutrin, as part of the progeny of *Actavi*s, is just one among numerous lower courts trying to adapt the Rule of Reason, without indulging presumptions of illegality, to assess the competitive consequences of reverse payment settlements. Just how courts should compare output and price in the relevant market with the settlement agreement to those in the relevant market without the settlement agreement, without invoking the legal presumptions that *Actavis* explicitly rejected, remains to be clarified.

VII. CONCLUSION

Without using the term "Rule of Reason," Judge William Howard Taft's opinion in the Sixth Circuit case of *United States v. Addyston Pipe & Steel Co.* has served as the foundation for the primary mode of Sherman Act analysis. Taft believed that the doctrine of naked and ancillary restraints of trade would provide clarity and certainty to business actors. Taft endorsed the Rule of Reason that was further developed in *Standard Oil* and *American Tobacco*, claiming first as President and then as a Professor of Law that the rule provided the clarity and certainty that he prized.

Since the twilight of the Progressive Era, the Rule of Reason has focused on *both* the relationship between the restraint and the procompetitive aspect of the agreement of which it is a part *and* the competitive effects of the restraint.

105 *See Wellbutrin* Amicus Brief, *supra* note 91, at 1–11.

106 *Id.* at 7.

Courts have also adopted variations on the Rule of Reason that are "meet for the case," though they have maintained their sights on the relationship between the restraint and both the procompetitive purpose of the agreement and the economic impact of the restraint and the agreement.

The Supreme Court's decision in *FTC v. Actavis* raised a new issue in Rule of Reason jurisprudence. The Court rejected what had become the majority approach to reverse payment settlements among the circuits, which evaluated the restraint in light of the patent's scope, in favor of a full-scale Rule of Reason review. The primary challenge has been assessing the competitive effect of settlement agreements that resolve bona-fide litigation, include "reverse" consideration, and permit generic entry before the expiration of the patent in dispute.

A recent Third Circuit opinion, and a subsequent petition for rehearing, squarely presented the question of how that competitive assessment should be undertaken: In considering the counterfactual (the relevant market without the subject agreement), should courts view a large reverse payment as dispositive, or at least presumptive, evidence of an outcome of the underlying patent litigation in favor of the generic entrant? Or should courts consider such explanations of the payment as risk aversion by the patent holder to a small but still plausible possibility of loss in the underlying patent litigation as sufficient to justify the payment as a legitimate means of resolving that litigation?

Those and similar questions may remain unresolved until the Supreme Court decides another reverse payment case.