Antitrust Analysis After Actavis: Applying the Rule of Reason to Reverse Payments

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Abstract

In *F.T.C. v. Actavis, Inc.* the Supreme Court resolved a circuit split regarding the proper evaluation of reverse payment settlements under federal antitrust law, holding that they must be evaluated under a rule of reason analysis. However, the Court simultaneously created significant uncertainty by declaring that the lower courts were responsible for structuring the analysis. While a few cases are currently in the pre-trial phase, the only decisions relating to reverse payments since *Actavis* have been rulings on pre-trial motions—there have been no decisions on the merits. Given the intricate intersection between antitrust and intellectual property principles in these cases, the issue of how courts will structure the analysis is an area of substantial interest and uncertainty. This Article examines the minimal guidance provided by the Supreme Court in *Actavis* and traditional factors considered in other rule of reason cases to identify what elements courts should consider. Lower courts should analyze certain traditional factors, such as the market power of the settling parties, whether there are less restrictive alternatives, and any proffered pro-competitive justifications. After analyzing the relevance of each of these factors, this Article discusses how that factor weighs for or against the permissibility of a reverse payment. This Article further finds that courts must also analyze two additional factors that are closely related to reverse payments: (1) the patent’s validity and (2) the size of the settlement payment. Without a valid patent, the parties’ agreement not to compete would be subject to per se antitrust condemnation. Therefore, this Article finds that courts should examine the validity of the underlying patent in a truncated proceeding. In addition, the size of the payment must be examined in light of the services that the parties claim are to be provided in return for the payment. However, given the unusual nature of reverse payment settlements, traditional antitrust price tests are inadequate to evaluate the anticompetitive nature of the payment. This Article thus proposes a novel test comparing the size of the payment that represents identifiable “services rendered” to the total payment and allows for a range of pro-competitive values. Only after weighing and balancing all of these factors can a trial court come to a determination whether a challenged settlement as a whole has a pro- or anti-competitive effect.

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The health care industry has recently seen substantial turmoil and change. Alongside contentions related to the Affordable Care Act’s mandate requiring all Americans to have health insurance, there has been a widespread concern about the rapidly rising cost of health care. This explosion in costs is especially true in the area of pharmaceutical drugs.

The field of pharmaceutical drugs has experienced important changes in recent years. One increasingly important area, and the subject of this Article, is that of reverse payment settlements (also known as “pay-for-delay” settlements), which are used to settle a patent

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3 See NAT’L CTR. FOR HEALTH STATISTICS, HEALTH, UNITED STATES, 2012: WITH SPECIAL FEATURE ON EMERGENCY CARE Table 111 (2013), available at http://www.cdc.gov/nchs/data/hus/hus12.pdf#111 (finding that as a percentage of GDP, national health expenditures rose from 16.1% in 2005 to 17.9% in 2010).
4 See M. Howard Morse, Settlement of Intellectual Property Disputes in the Pharmaceutical and Medical Device Industries: Antitrust Rules, 10 GEO. MASON L. REV 359, 363 (2002) (“[P]harmaceutical costs make up an ever-growing portion of the country’s healthcare expenditures . . . . Health Care Financing Administration data show[s] that prescription drug spending has risen at rates of 12–19% annually.”); Brenna E. Jenny, Information Costs and Reverse Payment Settlements: Bridging the Gap Between the Courts and the Antitrust Agencies, 30 SANTA CLARA HIGH TECH L.J. 231, 233 (2014) (“Maximizing the use of generic drugs . . . promises to be a critical component in the fight for an affordable price tag on healthcare.”).
infringement lawsuit stemming from proposed generic entry into the market for a particular drug. The basic feature of such settlements is a payment made by a brand-name manufacturer to a generic manufacturer, for the purpose of persuading the generic manufacturer to refrain from competing in the market for a particular pharmaceutical drug. This settlement effectively provides the brand-name manufacturer with an exclusive market. While the payment of cash to settle a lawsuit is not unusual, payment by the plaintiff to the defendant for this purpose is unusual.

A critical theoretical conflict arises from these settlements because they lie at the intersection of intellectual property law and antitrust law. The intellectual property perspective is that a patent holder has a statutorily granted right of market exclusivity over the subject of its patent in order to reward it for its innovation. Contrarily, the antitrust perspective is that such a

5 A generic drug has been defined by the Supreme Court as “a product that contains the same active ingredients but not necessarily the same [inactive substances] as a so-called ‘pioneer drug’ that is marketed under a brand name.” United States v. Generix Drug Corp., 460 U.S. 453, 454–55 (1983). The Court went on to note that generic drugs “are usually marketed at relatively low prices because their manufacturers do not incur the research, development, and promotional costs normally associated with the creation and marketing of an original product.” Id. at n.1. As this definition indicates, a brand-name producer is usually the manufacturer who initially patents, produces, and markets a particular drug.

6 See generally F.T.C. v. Actavis, Inc., 133 S.Ct. 2223 (2013) (resolving a circuit split, holding that reverse payment settlements should be evaluated under the rule of reason analysis).


9 See Khatibifar, supra note 7, at 1354.

10 E.g., Hovenkamp, supra note 8, at 1720 (“[S]ettlements of IP disputes naturally raise antitrust concerns.”).

11 See U.S. DEP’T OF JUSTICE AND THE FED. TRADE COMM’N, ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING INNOVATION AND COMPETITION 1 (2007) (“Intellectual property law creates exclusive rights that provide incentives for innovation by establishing enforceable property rights for the creators of new and useful products . . . by allowing intellectual property owners to prevent others from appropriating much of the value
settlement violates long-standing antitrust laws because an agreement to preserve market exclusivity harms consumers. How to balance these competing perspectives is the crux of this debate.

Prior to June 2013, a circuit split existed in the United States federal courts system over the proper balance of these two perspectives in the reverse payment context. In *F.T.C. v. Actavis, Inc.*, the Supreme Court addressed this split. In *Actavis*, the Court held that reverse payment settlements should be evaluated under antitrust law’s rule of reason analysis. However, the Court left much of the issue of how to apply the analysis to be determined through subsequent litigation. As is discussed herein, the rule of reason analysis is a full-bodied, multifaceted analysis, in which no single factor is determinative.

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14 See infra note 81.


16 See id. at 2230 (“The FTC sought certiorari. Because different courts have reached different conclusions about the application of the antitrust laws to Hatch-Waxman-related patent settlement, we granted the FTC’s petition.”).

17 See id. at 2237.

18 See id. at 2238 (“[T]rial courts can structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated 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 . . . . We therefore leave to the lower courts the structuring of the present rule-of-reason antitrust litigation.”).

19 See infra Part II.B.
This Article fills in the gaps left by the Supreme Court by analyzing what factors should become the most important considerations for lower courts conducting a rule of reason analysis. Part II of this Article lays out the necessary background for understanding reverse payments and their antitrust implications, including a discussion of the Hatch-Waxman Act, the statute which provides the basis for reverse payments. This Part also describes the antitrust framework surrounding the rule of reason and its application and provides an overview of how reverse payments fit within this framework. Part III describes the five most important factors for courts to consider while conducting a reverse payment rule of reason analysis—market power, the availability of less restrictive alternatives, patent validity, size of the payment, and pro-competitive justifications.

Each of these factors is included on the basis of the Supreme Court’s discussion in *Actavis* and traditional antitrust considerations. Similar to many other antitrust analyses, a finding of market power is important because it indicates that the settling manufacturers have the ability to have an adverse effect on consumers and competition. Second, the availability of less restrictive alternatives that have the same pro-competitive benefits as a reverse payment favors a finding of anticompetitive effect. Next, this article examines the arguments and policies for and against analyzing patent validity, and concludes that analyzing patent validity is necessary in the context of reverse payments. However, this analysis should not be as full an analysis as would occur in an infringement lawsuit. Rather, it should be truncated, and a few possibilities for doing so are discussed below. The size of the payment is also a significant factor; this Article argues that existing antitrust price tests are not sufficient for analyzing reverse payments and instead proposes a new test for determining the anticompetitive nature of the price based upon the principles and considerations referenced in the *Actavis* decision. This test compares the amount
of payment for identifiable beneficial services to be performed by the generic manufacturer with
the total amount of the payment and provides for a range of permissible settlement values in
excess of the value of identifiable services rendered. Lastly, this Article discusses pro-
competitive justifications of reverse payments, which, if cognizable, favor a finding of pro-
competitive effect. Consistent with the general approach of the rule of the reason analysis, all the
factors discussed in Part III could be found to have either a pro- or anti-competitive effect; the
final determination in any case will depend upon its particular facts and circumstances. A central
aspect of the rule of reason analysis is that no one factor is determinative.

As this Article is being written, there are multiple reverse payment cases awaiting
disposition on the merits under a rule of reason analysis, including Actavis on remand to the
Northern District of Georgia.20 The proper structure of the rule of reason as applied to reverse
payment settlements has been a topic of extensive debate among antitrust practitioners and
academics, and any decision related to the legality of these arrangements will have a drastic
impact on antitrust jurisprudence. The outcome of these cases will also have monumental

20 See In re Androgel Antitrust Litig. (No. II), No. 1:09-MD-2084-TWT (N.D. Ga. Apr. 21,
2014) (denying Defendant’s motion to dismiss for Noerr-Pennington Immunity and holding that
the case needs to be decided under the rule of reason); In re Lipitor Antitrust Litig., No. 3:12-
CV-2389 (PGS) (D.N.J. Sept. 5, 2013) (granting Plaintiff’s motion for leave to amend their
complaint as related to the reverse payment claims). There are also multiple cases at the motion
to dismiss stage. See In re Effexor XR Antitrust Litig., No. 11-CV-5590 (D.N.J.) (currently
awaiting decision on motion to dismiss); King Drug Co. of Florence, Inc. v. Cephalon, Inc., No.
estoppel of patent validity, but delaying a decision on the motions to dismiss related to the
reverse payment antitrust claim for a separate opinion). One case, In re Nexium (Esomeprazole)
Antitrust Litig., No. 12-MD-02409-WGY (D. Mass. Feb. 12 2014), was administratively closed
on the eve of trial pending a full written opinion. In re Lamictal Direct Purchaser Antitrust
Litig., No. 12-CV-995 (WHM), 2014 WL 282755 (D.N.J. Jan. 24, 2014), was also recently
dismissed. There are also multiple cases in the early stages of trial proceedings. See, e.g., In re
Aggrenox Antitrust Litig., No. 14-MD-2516 (D.Conn. filed Dec. 13, 2013) (class action case
consolidated in the District of Connecticut April 3, 2014); In re Loestrin 24 FE Antitrust Litig.,
consequences on one of the largest industries in the American economy. How courts come to address the issue of reverse payments will provide necessary clarity to pharmaceutical companies in determining what is permissible and what is prohibited. Just as important, if not more so, is the impact that these cases will have on consumers of pharmaceutical drugs. This Article has already noted the importance of drug costs in relation to the rapidly rising costs of medical services in general, and there is notable debate on how a decision will impact pharmaceutical firms’ incentive to innovate and discover new medicines. And one scholar has argued, for many, “the benefits to be gained are better health, freedom from pain, and in some cases, the chance to live.”

II. Background

A. The Hatch-Waxman Act and Reverse Payment Settlements

Under the Federal Food, Drug, and Cosmetic Act (FDCA), initially passed in 1938, any individual or company wishing to produce and market a new pharmaceutical drug must first obtain the approval of the U.S. Food and Drug Administration by filing what is known as an NDA—a New Drug Application. The process for completing the approval process was streamlined for generic producers in the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the Hatch-Waxman Act). Prior to the Hatch-Waxman Act, generic producers were required to go through the exact same process as the original, brand-
name applicant; however, after its passage, subsequent generic producers are able to “rely on the safety and effectiveness tests conducted by a [brand-name] drug manufacturer so long as the generic applicant . . . demonstrate[s] that its drug is bio-equivalent to the approved [brand-name] drug.” This process is referred to as the Abbreviated New Drug Application process, or ANDA.

One requirement of an ANDA filing is an assertion by the generic manufacturer that its drug will not infringe upon any patents held by the brand-name manufacturer. The Hatch-Waxman Act allows this assurance to be offered in four different ways. The generic manufacturer can show “(I) that such patent information has not been filed, (II) that such patent has expired, (III) . . . the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug.” Proceeding via the last option—claiming that the brand-name manufacturer’s patent, if valid, will not be infringed—is known as the “paragraph IV route” and “automatically counts as patent infringement . . . and often means provoking litigation.” Paragraph IV litigation is the general class of lawsuit that results in reverse payment settlements, including the settlement at bar in Actavis.

28 See id.
29 Id. at 383–84.
30 E.g., id. at 383.
35 See id. at 2229 (2013) (“Solvay initiated paragraph IV patent litigation against Actavis and Paddock . . . but, in 2006, the patent-litigation parties all settled.”); In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1328 (Fed. Cir. 2008) (“[Barr’s] ANDA included a Paragraph IV certification . . . [then] Bayer sued Barr for patent infringement . . . [but before trial the parties entered] agreements.”); Schering-Plough Corp. v. F.T.C., 402 F.3d 1056, 1059–60 (11th Cir. 2005) (“Schering sued for patent infringement . . . [but] the day before the patent trial was to begin, Schering and Upsher concluded the settlement.”).
A reverse payment settlement is a payment by a brand-name manufacturer (the plaintiff in the patent infringement lawsuit) to a generic producer (the defendant in the patent infringement lawsuit) for the purpose of settling the infringement dispute and terminating the patent litigation.\footnote{See Actavis, 133 S.Ct. at 2227.} The basic structure of the settlement is that the alleged infringer agrees “not to produce the patented product until the patent’s term expires” and the patent holder in return will “pay [the defendant] many millions of dollars.”\footnote{Id.} The central concern of these settlements arises where intellectual property law and antitrust law conflict, and asks “whether such an agreement can sometimes unreasonably diminish competition in violation of the antitrust laws.”\footnote{Id.} 

**B. Antitrust Background—The Evolution of the Rule of Reason**

When Congress passed the Sherman Act in 1890, it outlawed “every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce.”\footnote{15 U.S.C. § 1 (2012).} The Supreme Court initially held that this language should be read literally and “not [be] limited to that kind of contract alone which is in unreasonable restraint of trade, but [that] all contracts are included.”\footnote{United States v. Trans-Missouri Freight Ass’n, 166 U.S. 290, 328 (1897).} However, a little over a decade later, the Supreme Court reversed course and held that only unreasonable restraints should be declared illegal.\footnote{See Standard Oil Co. of N.J. v. United States, 221 U.S. 1, 60 (1911).} The Court believed that the key concern should ultimately be whether the restraint under consideration promotes or destroys...
competition. In answering this question, courts were directed to consider the purpose, nature, and effects of the restraint. This analysis is also applied to other federal antitrust provisions, including Section 5 of the Federal Trade Commission Act.

The “rule of reason analysis focuses on the state of competition with, as compared to without, the relevant agreement,” which is essentially a consideration of how the restraint impacts a particular market. The enforcement agencies have warned that they will not limit their consideration to any pre-determined factors, but will consider any factor that is necessary to a full and proper analysis of the restraint’s competitive effect. Each alleged restraint is evaluated separately to determine its pro- or anti-competitive effect. The analysis is in effect a “thorough investigation of the industry at issue and a balancing of the arrangement’s positive and negative effects on competition.”

Notably, “[n]o one factor is dispositive” in a rule of reason analysis.

As the 20th century progressed, courts began to realize that certain classes of restraints were so harmful to competition that they were wholly devoid of any economic benefit, and thus

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42 See Bd. of Trade of Chi., 246 U.S. at 239.
43 See id. (“[T]he court must ordinarily consider 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.”).
44 15 U.S.C. § 5; See e.g., Cal. Dental Ass’n v. F.T.C., 526 U.S. 756 (1999) (holding that a rule of reason analysis should have been used to evaluate the FTC’s Section 5 complaint).
46 See id., at § 3.3, at 10.
48 L.A. Mem’l Coliseum Comm’n v. N.F.L., 726 F.2d 1381, 1391 (9th Cir. 1984); see also Cont’l T.V., Inc. v. GTE Sylvania, Inc., 433 U.S. 36, 49 (1977) (“Under this rule [of reason], the fact-finder weights all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition.”).
49 Collaboration Guidelines, supra note 45, at § 3.3, at 10.
should be readily condemned as illegal without the need for a detailed economic analysis.  

However, such “per se rules of illegality are appropriate only when they relate to conduct that is manifestly anticompetitive.”  

One of the more common arrangements subject to per se condemnation is price-fixing, an anticompetitive restraint addressed in multiple Supreme Court cases, whereby competitors agree to set the market price of the product or service that they compete to provide.  

Many courts and litigants favor per se rules because they provide clarity as to what conduct is unlawful, have predictability of consequences, streamline the management of evidence and burdens of proof, and promote efficiency in litigation.

Nevertheless, in the 1960s and 1970s, courts began to turn away from per se illegality.  

This was due in large part to a shift in economic thinking related to antitrust law, namely concepts related to anticompetitive effects, market power, efficiencies, and conditions of entry.

Courts began to recognize that certain conduct, while seemingly illegal per se, was also likely to have socially redeeming benefits and that an evaluation of those benefits would not be a futile

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50 See Cavanagh, supra note 47, at 443–44.
51 GTE Sylvania, 433 U.S. at 50.
52 The Supreme Court has considered the legality of price fixing in many contexts. E.g., United States v. Socony-Vacuum Oil Co., 310 U.S. 150 (1940) (holding that price fixing arrangements between two competitors in the same market is the kind of arrangement that is a per se violation of the antitrust laws such that illegality is established without regard to economic analysis); Broad. Music, Inc. v. Columbia Broad. Sys., Inc., 441 U.S. 1 (1979) (holding that before condemning the conduct as per se illegal price-fixing, the court must first determine if the activity is the kind of price fixing which the antitrust laws were created to condemn) (individual firms independently setting the market price for blanket licenses for copyrighted music) (“BMI”); Texaco, Inc. v. Dagher, 547 U.S. 1 (2006) (holding that a joint venture to sell gasoline at an agreed price is not a per se illegal price fixing arrangement); Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 551 U.S. 887 (2007) (holding that per se illegality does not apply to vertical retail price maintenance agreements); see also Catalano, Inc. v. Target Sales, Inc., 446 U.S. 643 (1980) (collective refusal to compete on credit terms indistinguishable from traditional price-fixing agreement since credit terms are an input of total price).
53 See Cavanagh, supra note 47, at 445.
54 See id. at 454.
55 See GAVIL, supra note 41, at 202–04 (discussing the core economic concepts that have impacted Supreme Court decision since the 1970s).
exercise.\textsuperscript{56} During this era, the Supreme Court developed the “characterization” principle, whereby courts were directed initially to determine whether the restraint at issue in fact clearly lacked redeeming value before applying per se condemnation.\textsuperscript{57}

As a balance between the two extremes—a full-blown rule of reason analysis and a categorical per se illegality standard—courts developed the “quick look” analysis.\textsuperscript{58} A quick look analysis is appropriate where the alleged conduct is not a type of per se violation, but there is still a “great likelihood of anticompetitive effects.”\textsuperscript{59} Under a quick look analysis, if the plaintiff shows that the questioned conduct is inherently suspect as to its anticompetitive effect, then the burden shifts to the defendant to come forward with pro-competitive justifications for its conduct.\textsuperscript{60} If such justifications are provided, and the court finds them to be legitimate and cognizable, then the burden shifts back to the plaintiff to address and counter the justifications.\textsuperscript{61}

Courts have recently found occasion to recognize the continued applicability of all three of the methods of analysis described above.\textsuperscript{62} The Supreme Court has noted that there is no bright line in determining which approach to follow but rather there exists a sliding scale, such that the quality of proof required (and thus the analytical method to be used) varies with the

\textsuperscript{56} See BMI, 441 U.S. at 13.

\textsuperscript{57} See id. at 9 ([I]t is necessary to characterize the challenged conduct as falling within or without that category of behavior to which we apply the label ‘per se price fixing’.”).

\textsuperscript{58} See GAVIL, supra note 41, at 185.


\textsuperscript{60} See Polygram Holding, Inc. v. F.T.C., 416 F.3d 29, 33 (D.C. Cir. 2005).

\textsuperscript{61} The justifications can be attacked in one of two ways: (1) by explaining “why it can confidently conclude, without adducing evidence, that the restraint very likely harmed consumers;” or (2) by providing “sufficient evidence to show that anticompetitive effects are in fact likely.” Id. at 36.

\textsuperscript{62} E.g., Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 551 U.S. 877, 907 (2007) (holding that vertical minimum retail price maintenance should be evaluated under the rule of reason); Polygram, 416 F.3d at 36 (holding that the quick look should be applied to determine the legality of a joint marketing campaign); F.T.C. v. Superior Court Trial Lawyers Ass’n, 493 U.S. 411, 436 (holding that per se rule applies to group boycott that restricts supply).
particular circumstances of each case. In essence, the analysis should be an “enquiry meet for the case, looking to the circumstances, details, and logic of the restraint.” Nevertheless, the Supreme Court has stated that the rule of reason is the default antitrust analysis. Deviation from the rule of reason to a per se analysis is warranted only where the questioned conduct is manifestly anticompetitive, and deviation to a quick look analysis is warranted only where the questioned conduct is not a type of per se violation but there is still a high likelihood of anticompetitive effect.

C. Basic Antitrust Principles as Applied to Reverse Payment Legality

The Hatch-Waxman Act was passed to “make available more low cost generic drugs . . . [and] to create a new incentive for increased expenditures for research and development.” Although the “Act does not expressly prohibit settlements in a patent infringement suit” and the U.S. legal system encourages out-of-court settlement, reverse payment settlements have received substantial antitrust scrutiny in recent years. A prominent

64 Polygram, 416 F.3d at 35.
65 See Leegin, 551 U.S. at 887 (“[D]eparture from the rule-of-reason must be based upon demonstrable economic effect.”) (quoting Cont’l T.V., Inc. v. GTE Sylvania, Inc., 433 U.S. 36, 58–59 (1977)).
66 See GTE Sylvania, 433 U.S. at 49–50.
67 See Cal. Dental, 526 U.S. at 770.
69 Khatibifar, supra note 7, at 1390.
70 See Hovenkamp, supra note 8, at 1721.
71 Press Release, Fed. Trade Comm’n, FTC Study: In FY 2012, Branded Drug Firms Significantly Increased the Use of Potential Pay-for-Delay Settlements to Keep Generic Competitors off the Market (Jan. 17, 2013), available at http://www.ftc.gov/news-events/press-releases/2013/01/ftc-study-fy-2012-branded-drug-firms-significantly-increased (“Sadly, this year’s report makes it clear that the problem of pay-for-delay is getting worse, not better . . . . More and more brand and generic drug companies are engaging in these sweetheart deals, and consumers continue to pay the price.”).
antitrust concern is that these settlements operate as horizontal collusive agreements\textsuperscript{72} and create monopolies,\textsuperscript{73} both of which generally receive scrutiny under U.S. antitrust laws.\textsuperscript{74} At the same time, reverse payments can have substantial benefits to both producers and consumers, including the cost efficiency and certainty of settlement over litigation\textsuperscript{75} and the enhanced ability of producers to realize returns on their investments, which encourages increased innovation.\textsuperscript{76} Thus, reverse payments are one example of conduct that has notable benefits, but can also have clear anticompetitive consequences.\textsuperscript{77} As discussed above, the Supreme Court has generally held that where an economic action possesses characteristics that are not clearly anticompetitive, a rule of reason analysis should apply.\textsuperscript{78} By holding that the rule of reason is to be used in evaluating the competitive effect of reverse payment settlements, the Supreme Court’s decision in \textit{Actavis} extended this reasoning to reverse payment settlements.\textsuperscript{79}

\textsuperscript{72}See \textit{Khatibifar, supra} note 7, 1375–76.

\textsuperscript{73}See \textit{In re K-Dur Antitrust Litig.}, 686 F.3d 197, 216 (3rd Cir. 2012).

\textsuperscript{74}Sherman Act Section 1, 15 U.S.C. § 1, prohibits combinations and agreements between firms that restrain competition. Sherman Act Section 2, 15 U.S.C. § 2, prohibits the formation of monopolies and engaging in monopolistic behavior that harms competition.

\textsuperscript{75}See \textit{Hovenkamp, supra} note 8, at 1723; \textit{see also} \textit{Khatibifar, supra} note 7, at 1375 (stating that a successful brand-name manufacturer has spent notable sums of money and is in no better position if it wins the infringement suit, while losing the suit results in a substantial loss of its market share, and finding that “these exceedingly asymmetric litigation risks [help] to explain the unconventional reverse flow of consideration” from the plaintiff to the defendant) (internal quotation marks omitted). For further discussion on this asymmetry \textit{see Part III.C.2, infra.}

\textsuperscript{76}See \textit{Morse, supra} note 4, at 366 (“When enforcing the antitrust laws [in the pharmaceutical and medical device] industries, such [price] savings must of course be balanced against maintaining incentives for firms to invest in innovation as societal benefits from technological progress quickly swamp short-term price effects.”).

\textsuperscript{77}See \textit{F.T.C. v. Actavis, Inc.}, 133 S.Ct. 2223, 2237 (2013).

\textsuperscript{78}See \textit{e.g.}, \textit{Leegin Creative Leather Prods. v. PSKS, Inc.}, 551 U.S. 877, 887 (2007) (“[D]eparture from the rule-of-reason must be based upon demonstrable economic effect.”) (quoting \textit{Cont’l T.V., Inc. v. GTE Sylvania, Inc.}, 433 U.S. 36, 58–59 (1977)).

\textsuperscript{79}See 133 S.Ct. at 2237 (“These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases.”).
Actavis reached the Supreme Court after the Court of Appeals for the Eleventh Circuit dismissed a Federal Trade Commission complaint, holding that 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.” The Supreme Court’s decision resolved a circuit split over the proper antitrust analysis for reverse payments. Yet, numerous questions about reverse payments remain unanswered, including the one addressed by this Article: what are the antitrust considerations on which lower courts should rely when determining their competitive effect?

III. Analysis—What Factors Should the Courts Consider?

The rule of reason analysis dictates a full consideration of the pro- and anti-competitive aspects of an agreement or transaction, weighing all relevant circumstances. As the Supreme Court in Actavis recognized, while there are multiple considerations that make reverse payment settlements harmful to competition, there are also multiple considerations that indicate that such settlements may be pro-competitive. The analysis of each case under the rule of reason will be different—depending on the position of the firms within an industry and the exact

80 Id. at 2227 (quoting F.T.C. v. Watson Pharm., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012)). The “scope of the patent” test was also adopted by the Second Circuit—In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006) and Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. 2010) (holding that Tamoxifen is controlling, but that there may be reason to revisit the decision)—and by the Federal Circuit—In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008).


82 See supra notes 45–48.

83 See Actavis, 133 S.Ct. at 2235 (“[A] reverse payment settlement . . . removes from consideration the most motivated challenger, and the one closest to introducing competition.”) (internal quotation marks omitted).

84 See id. at 2237 (holding that reverse payment settlements are not obviously anticompetitive in every context); see also Morse, supra note 4, at 366 (recognizing the benefits of innovation and that exclusivity is a necessary prerequisite to such innovation).
conduct being challenged. Significantly, the antitrust enforcement agencies see no one factor as dispositive in the overall antitrust analysis.

Henceforth, this Article discusses what factors courts should consider in their analysis, describes why each particular factor is a pertinent consideration, and how that particular factor should be weighed in the overall rule of reason analysis.

A. Market Power is an Indicator of Anticompetitive Effect

“The first rule-of-reason criterion to address is whether the Defendants exercised market power in the relevant market.” Market power is the ability of a firm to increase price or decrease output, which is essentially the ability to exclude competition; a firm that has a high degree of market power is considered to have monopoly power. “Without market power, there is no evidence that the reverse-payment settlement could have any adverse effects on consumer welfare.” The Supreme Court has equated the rule of reason to an analysis of market power in cases where there is a potential for pro-competitive benefit, indicating that courts should look to the firms’ market power as a preliminary matter, and the federal antitrust enforcement agencies agree. Thus market power is a preliminary and vital factor.

85 See COLLABORATION GUIDELINES, supra note 45, at § 1.2, at 4.
86 See supra note 49.
88 See BLACK’S LAW DICTIONARY 476 (4th pocket ed. 2011) (based on the 9th unabridged ed.).
91 Butler, supra note 13, at 116.
92 See Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752, 768 (1984) (“[Some] combinations . . . hold the promise of increasing a firm’s efficiency and enabling it to compete more effectively. Accordingly, such combinations are judged under a rule of reason, an inquiry into market power and market structure designed to assess the combination’s actual effect.”).
93 See COLLABORATION GUIDELINES, supra note 45, at § 3.3, at 11.
Defining the relevant market over which a firm would possess market power has two parts—geographic market and product market.94 “The relevant geographic market is the area in which a hypothetical monopolist could impose an increase in the price of its products” without risking market entry by competitors that would force a decrease in prices.95 Essentially, this is the physical area where the manufacturer distributes its product. In the pharmaceutical industry, in which sales occur on a national (or even international) scale, the geographic market is defined broadly to include at least the entire United States.96

The key in determining the relevant product market “is the use or uses to which the commodity is put,” not the price of the commodity.97 This definition looks to which products are “reasonably interchangeable by consumers for the same purposes,” an analysis performed by considering the “cross-elasticity of demand for a product.”98 This definition effectively means that if a product does not have any potential substitutes, then that product comprises its own market. “The Supreme Court has held that a properly constituted market may indeed be comprised of a single product . . . and lower courts across the country have on numerous occasions ruled that both a brand-name drug and its generic analogs can fall within the bounds of a relevant market . . . .”99

The market power of a brand-name manufacturer for a particular pharmaceutical drug, independently or when combined with the market power of the generic manufacturers which have received ANDA approval, will generally prove to be large enough—if not constituting the

94 See Tim McCarthy, Note, Refining Product Market Definitions in the Antitrust Analysis of Bank Mergers, 46 DUKE L.J. 865, 867 (1997); see also GAVIL, supra note 41, at 489.
95 McCarthy, supra note 94, at 867.
99 Id. at 388.
entire market—to establish sufficient market power to achieve an anticompetitive outcome. The small number of firms in the market for a pharmaceutical drug, and the relative market shares of those firms, coupled with the supracompetitive market price that generally prevails indicate the presence of market power.\footnote{100 \textit{Id.} at 388–89.} The Supreme Court has held, and studies have substantiated, that “reverse payment agreements are associated with the presence of higher-than-competitive profits—a strong indication of market power.”\footnote{101 F.T.C. v. Actavis, Inc., 133 S.Ct. 2223, 2236 (2013).} The presence of substantial market power is supported by the high degree of product differentiation and the low elasticity of demand prevalent in the pharmaceutical drug industry.\footnote{102 \textit{See} Herbert Hovenkamp, \textit{Sensible Antitrust Rules for Pharmaceutical Competition}, 39 U.S.F. L. REV. 11, 11 (2004).} “Consumers often need drugs badly and are willing to pay a great deal to have them . . . [and] employee-paid health insurance and other third party payors tend to insulate consumers from drug costs.”\footnote{103 \textit{Id.}} Further, the pharmaceutical industry possesses certain structural characteristics generally associated with the possession and maintenance of market power, such as high barriers to entry.\footnote{104 \textit{See} Mark R. Patterson, \textit{The Market Power Requirement in Antitrust Rule of Reason Cases: A Rhetorical History}, 37 SAN DIEGO L. REV. 1, 43 (2000). Barriers to entry have been equated with the ability of a firm or group of firms to achieve and retain market power. \textit{See e.g.}, Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 38 (1984) (where monopoly arrangement creates barriers to entry, the arrangement “remains suspect”); Broad. Music, Inc. v. Columbia Broad. Sys., Inc., 441 U.S. 1, 37 (1979) (stating that in horizontal collusion case “arrangement that produces . . . significant barriers to entry unreasonably restrains trade”) (“\textit{BMI}”).} These barriers are due to the high costs required to develop and market a new drug, and the existence of statutorily conferred intellectual property rights.\footnote{105 \textit{See} Michael A. Sanzo, \textit{Antitrust Law and Patent Misconduct in the Proprietary Drug Industry}, 39 VILL. L. REV. 1209, Part II.B (1994).}
A determination of market power is an important factor for a finding of anticompetitive effect in rule of reason cases; however, it will usually be found to exist without a great deal of contention in reverse payment settlements.

B. The Availability of Less Restrictive Alternatives

The requirement that there be no “less restrictive alternatives” to the contested restraint has been applied in an array of rule of reason cases, and the existence of such alternatives is a factor that weighs toward a finding of anticompetitive effect in a reverse payment analysis. The rule of reason analysis—ultimately being a balancing of anticompetitive harms and pro-competitive benefits—indicates that a goal of antitrust law should be to minimize the anticompetitive harm of an activity without losing its social benefits. “[B]etween 2004 and 2009, seventy percent of Hatch-Waxman settlements did not contain reverse payments . . . [which] suggest[s] that reverse payment settlements are not necessary to settle patent infringement cases in the pharmaceutical context.” In the realm of intellectual property, there are various alternatives that brand-name and generic manufacturers can pursue in settling their dispute in a potentially less anticompetitive manner.

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106 See, e.g., United States v. Visa U.S.A., Inc., 344 F.3d 229, 238 (2d Cir. 2003) (“For the government to prevail in a rule of reason case . . . the government must prove either that the challenged restraint is not reasonably necessary . . . [or] that [the defendant’s] objectives may be achieved in a manner less restrictive of free competition.”) (joint venture that forbid member banks from issuing competing credit cards found illegal); Law v. NCAA, 134 F.3d 1010, 1019 (10th Cir. 1998) (It is the plaintiff’s burden to “prove that the challenged conduct is not reasonably necessary . . . or that those objectives can be achieved in a substantially less restrictive manner.”) (holding compensation limit for college basketball coaches to be unlawful). Note that in each case it is the plaintiff’s burden to establish both the existence and plausibility of less restrictive alternatives.

107 See supra Part II.B.


109 See generally Hovenkamp, supra note 8, at Part IV (discussing in particular non-exclusive licensing and cross-licensing; purely vertical arrangements; patent pooling; and price-, output-, or territory-restricted licenses). In the interest of brevity, this Article only discusses a few of
One generally non-controversial settlement option is for the brand-name manufacturer to enter into a licensing agreement with the generic manufacturer.\textsuperscript{110} The ability to negotiate, through sale or license, is one of the privileges associated with the ownership of intellectual property rights.\textsuperscript{111} Importantly, “the granting of a non-exclusive license itself almost never harms competition, regardless of the presence or absence of any IP dispute.”\textsuperscript{112} A major benefit of non-exclusive licensing is that it allows the brand-name manufacturer to continue producing the pharmaceutical drug on its own, while also ensuring that there is at least one producer in the market in addition to the brand-name manufacturer; it also does not restrict the patentee’s ability to license the patent to others.\textsuperscript{113} This market entry works to alleviate a main anticompetitive concern of reverse payment settlements—the maintenance of high prices as a result of a monopoly.\textsuperscript{114} Additionally, in return for granting the use of its patent, brand-name manufacturers receive compensation from the generic manufacturers, such as in the form of royalty payments, which serves to preserve the brand-name manufacturer’s incentive to innovate.\textsuperscript{115} The use of non-exclusive licenses to resolve patent infringement suits remains viable, so long as the license

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\textsuperscript{110} See id. at 1739–40; cf. White Motor Co. v. United States, 372 U.S. 253, 271–272 (1963) (recommending use of franchising—an undertaking similar to licensing—as a less anticompetitive alternative to territorial allocations).


\textsuperscript{112} Hovenkamp, supra note 8, at 1739.

\textsuperscript{113} See id. at 1740.

\textsuperscript{114} See supra note 4.

\textsuperscript{115} See Hovenkamp, supra note 8, at 1740.
agreements do not possess anticompetitive effects of their own, such as improper territorial allocations \(^{116}\) or price restrictions.\(^ {117}\)

Brand-name and generic manufacturers may also create patent-pooling groups. Patent pooling, “if properly structured, has potentially strong pro-competitive benefits.”\(^ {118}\) Patent pooling enables multiple manufacturers to use the patent.\(^ {119}\) The opportunity for market entry and participation created by these arrangements helps alleviate the anticompetitive concerns that arise from reverse payment settlements. In addition, patent pools have substantial pro-competitive characteristics, such as providing a non-litigation platform for settling patent disputes and facilitating the exchange of information in order to reduce redundancies.\(^ {120}\) Similar to non-exclusive licensing, patent pools distribute royalties to their members in relation to the use of each member’s patents in the pool, which works to preserve a brand-name manufacturer’s incentive to innovate.\(^ {121}\)

However, the mere mention of a potential alternative does not automatically equate to that alternative being considered a “less restrictive alternative.” The viability of using that

\(^{116}\) See id.; Klitzke, supra note 111, at 570; cf. Palmer v. BRG of Ga., 498 U.S. 46 (1990) (market allocation agreement between competitors at the same level of commerce violated the Sherman Act).

\(^{117}\) See Daniel A. Crane, Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications, 54 U. Fla. L. Rev. 747, 765–66 (2002). The settlement at issue in In re Tamoxifen Citrate Antitrust Litig. involved a non-exclusive license, whereby the generic tamoxifen “sold at retail for just five percent less than the [brand-name] version,” rather than the usual drop of 30% to 80% seen in a “truly competitive market.” 466 F.3d 187, 216 (2d Cir. 2006). However, the Second Circuit ultimately found the restraint not to violate the antitrust laws because it was not outside the scope of the patent. See Tamoxifen, 466 F.3d at 216.


\(^{119}\) See id. at 298.

\(^{120}\) See id. at 299–300. Antitrust law does not automatically condemn all information exchange between competitors. Compare Amer. Column & Lumber Co. v. United States, 257 U.S. 377 (1921), with Maple Flooring Mfr.’s Ass’n v. United States, 268 U.S. 563 (1925).

\(^{121}\) See Lin, supra note 118, at 299.
alternative is dependent upon whether that alternative “could achieve similar efficiencies,” in light of the market context and business realities; in effect, the alternative needs to be evaluated in light of the pro-competitive benefits of the challenged restraint. This is especially important when conducting a full rule of reason analysis because of the acknowledged ability of an economic restraint being analyzed under a rule of reason to have notable pro-competitive benefits. For instance, a licensing agreement may prove in some cases not to be less restrictive because it results in free-riding “on the patentee’s promotional efforts or dilute[s] the value of the patent through poor production or marketing of the patented product.”

If a challenged restraint possesses substantial pro-competitive benefits, an analysis of the anticompetitive impact of that restraint should be careful not to destroy those benefits in cases where an alternative arrangement may seem more benign in competitive terms, but may not possess the notable pro-consumer aspects of the challenged restraint. The existence of legitimate, less restrictive alternative settlement methods, which do not detract from the cognizable, pro-competitive benefits of the particular reverse payment at issue, is a factor leaning towards a finding of anticompetitive effect.

C. Patent Validity is a Fundamental Consideration

A consideration of patent validity is a necessary factor in a reverse payment rule of reason analysis, but it should assume a truncated form.

122 COLLABORATION GUIDELINES, supra note 45, at § 3.36(b), at 24.
123 See generally supra Part II.B.
1. The Reason Patent Validity Should be a Factor

The Supreme Court has previously held that “antitrust analysis must sensitively recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies.”125 “A particular regulatory regime sets the boundaries of feasible anticompetitive conduct [and a]t the same time, it embodies a specific congressional judgment about the proper balance between competition and innovation in an industry.”126 In the context of reverse payment settlements, that regulatory regime centers on the Hatch-Waxman Act and traditional patent policy. Since patent validity and infringement is the central issue raised by a paragraph IV ANDA certification,127 it seems implicit that whether or not a valid patent exists and is being infringed should be a necessary factor.128

Two additional considerations demonstrate the necessity of considering patent validity: the per se anticompetitive nature of the agreement if there were no IP right involved129 and the Hatch-Waxman Act’s goal of increasing generic competition.130 A reverse payment settlement is in effect an agreement between two competitors to allocate a market;131 such horizontal collusive agreements between competitors have been definitively placed into the per se category of

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127 See supra Part II.A.
128 One particularly notable tenet of patent policy for the rule of reason is “that patents never become incontestable.” Rochelle Cooper Dreyfuss & Lawrence S. Pope, Dethroning Lear?: Incentives to Innovate After Medimmune, 24 BERKELEY TECH. L.J. 971, 997 (2009). However, as developed more fully in Part III.C.2, infra, it is not necessary that the consideration of patent validity undergo the same procedure as would exist in traditional infringement litigation.
131 See supra Part II.A.
antitrust illegality. However, classification as a per se violation is subject to “characterization,” whereby an alleged violator is given the opportunity to argue that its activity is not the type of horizontal agreement the antitrust laws seek to condemn. This is essentially what the presence of IP rights in a reverse payment settlement provides: a cognizable argument that the settlement is not actually an illegal horizontal agreement because the patent grants a legally defensible degree of market control to the patent owner. Under antitrust theory, lacking this cognizable defense, the manufacturers entering into a reverse payment settlement would have difficulty justifying their agreement as anything other than anticompetitive, and would become subject to per se condemnation. Essentially, it is only the presence of a patent that saves such agreements from per se antitrust condemnation by providing a characterization defense; this threshold function of patents necessitates that the validity of the patent be evaluated.

132 See generally Palmer v. BRG of Ga., 498 U.S. 46 (1990) (holding that a market allocation agreement between competitors is per se illegal).
133 See supra Part II.B; Broad. Music, Inc. v. Columbia Broad. Sys., Inc., 441 U.S. 1, 19–20 (1979) (holding that blanket licensing agreements for musical compositions did not “threaten the proper operation of our predominantly free-market economy” but rather promoted the use of the product (“BMI”); see also COLLABORATION GUIDELINES, supra note 45, at § 3.2.
134 See Hovenkamp, supra note 8, at 1730 (“[T]he question is whether this particular price-fixing agreement is one contemplated by the IP laws as part of the supracompetitive incentive those laws give to innovation.”).
135 The Supreme Court seems to have created a high bar to what it considers to be allowable defenses to per se condemnation of competitor agreements. See generally F.T.C. v. Superior Court Trial Lawyers Ass’n, 493 U.S. 411 (1990) (holding that neither the argument that defendant did not have sufficient market power nor that the prices set through the agreement were reasonable are cognizable defenses); NCAA v. Bd. of Regents of the Univ. of Okla., 468 U.S. 85 (1984) (holding that the argument that the restraint against one set of products actually promoted competition by allowing new products to enter the market and viably compete is not a cognizable defense); Nat’l Soc’y of Prof’l Eng’rs v. United States, 435 U.S. 679 (1978) (holding that the argument that price competition in an advanced industry was destructive because of its negative impact on engineering quality is not a cognizable defense to escape per se condemnation).
136 See Crane, supra note 117, at 753.
Second, an analysis of patent validity is necessary to achieve one of the central purposes of the Hatch-Waxman Act: increasing competition in the pharmaceutical drug industry by removing bad patents. An examination of the legislative history of the Act and statements by Representative Henry Waxman himself show that the promotion of generic competition is key to furthering the purpose of the Act, and that reverse payment settlements are an “unintended consequence” that may undermine this goal.\textsuperscript{137} The elimination of invalid patents removes a substantial barrier to entry in the pharmaceutical drug industry and increases competition by removing unjustifiable monopolies and opening the door for competition.\textsuperscript{138} Since 40\% to 50\% of challenged patents are held invalid,\textsuperscript{139} the potential benefit to competition that arises from analyzing the validity of patents is substantial. It has also been stated that questioning patent validity is pro-competitive because it encourages settling parties to consider less anticompetitive alternatives.\textsuperscript{140} “[P]atent monopolies [should] exist . . . only to the extent that the public is given a novel and useful invention.”\textsuperscript{141}

To achieve this end, a consideration of patent validity cannot rest on a blind presumption of validity. Neither \textit{Actavis} as a whole nor the Court’s statement that it may not be necessary to litigate patent validity establishes that patent validity is presumed, a statement that the Court


\textsuperscript{139} See Picht, \textit{supra} note 138, at 119.

\textsuperscript{140} See Hovenkamp, \textit{supra} note 8, at 1735.

could easily have made and which it has expressly made in prior patent lawsuits.\textsuperscript{142} Nor did the Court in \textit{Actavis} mention 35 U.S.C. § 282, the federal statute that establishes a default presumption of patent validity. Additionally, the presumption of validity has been narrowly confined so that it does not apply outside literal patent infringement cases, and has been further limited to apply only to decisions on the merits of such cases.\textsuperscript{143}

\subsection*{2. The Form of a Patent Validity Analysis}

Having established that an analysis of patent validity is a necessary factor, the next question is how that analysis should be structured. Consistent with statements by the Supreme Court in the \textit{Actavis} decision that antitrust theory predominates over patent policy,\textsuperscript{144} it is not necessary that the consideration of patent validity take the identical form as an analysis in a traditional infringement lawsuit. Rather, the patent validity analysis should take an abbreviated form.\textsuperscript{145} Structuring patent validity determinations as a truncated analysis also satisfies concerns regarding the potential negative side effects of undertaking a judicial analysis of patent validity.\textsuperscript{146}

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\item See \textit{e.g.}, Microsoft Corp. v. i4i Ltd. P’ship, 131 S.Ct. 2238, 2245 (2011) (stating explicitly that in patent infringement suits a patent is presumed valid and the challenger must overcome that presumption).
\item See \textit{Butler}, supra note 13, at 83–84. As the article discusses, the Federal Circuit has abided by these constraints on the presumption of patent validity. \textit{See In re Etter}, 756 F.2d 852 (Fed. Cir. 1985) (refusing to apply the presumption to a patent reexamination proceeding); \textit{Nutrition 21 v. United States}, 930 F.2d 867 (Fed. Cir. 1991) (denying use of the presumption at the preliminary injunction phase).
\item See \textit{Actavis}, 133 S.Ct. at 2234 (holding that the “patent-related factor should not determine the result here [but] \textit{rather}, five sets of considerations lead [the Court] to conclude that the FTC should have been given the opportunity to prove its antitrust claim”).
\item The use of shortcuts in the litigation of antitrust claims is well established and their development is expected. The most notable instance of this is in regard to the development of and use of the “quick look” analysis for horizontal restraints. \textit{See supra} notes 66–67.
\item See Part III.C.3, \textit{infra}.
\end{enumerate}
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In view of the leeway granted by the Supreme Court to refrain from a “consideration of every possible fact or theory irrespective of the minimal light it may shed on the [antitrust] question,” several prominent antitrust scholars have proposed tests that use abbreviated analyses of patent validity. One proposal is to look at the “ex ante likelihood of prevailing in [the] infringement lawsuit.” An analysis following this form would take into consideration the settling parties’ views as to their belief of the validity of the patent at the time they entered into the agreement. This is comparable to a determination of the parties’ intent, a consideration that commonly appears in other antitrust cases analyzed under the rule of reason. Another potential method would be to require the plaintiff to establish only a likelihood of success in a patent validity suit, as opposed to providing a full proof of validity.

An abbreviated analysis minimizes the disruptive effects of patent validity litigation, which is a benefit of truncation in and of itself. Challenges to a patent’s validity, regardless of the chances that the patent will actually be found invalid, have been shown to weaken patents and harm innovation. Patent litigation also has “broad discovery rules [that] require the production of documents and sensitive competitive information for which protective orders fail

147 Actavis, 133 S.Ct. at 2238
148 Crane, supra note 124, at 699.
149 See, e.g., Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447 (1993) (attempted monopolization); United States v. Socony-Vacuum Oil Co., 310 U.S. 150 (1940) (finding that companies need only have intent to price fix in horizontal collusion); Broadcom Corp. v. Qualcomm, Inc., 501 F.3d 297, 320 (3rd Cir. 2007) (applying a five-factor test to determine antitrust standing, including “the intent by the defendant to cause that harm”); United States v. Am. Airlines, Inc., 743 F.2d 1114 (5th Cir. 1984) (invitation to collude).
151 Diane E. Bieri, Implications of FTC v. Actavis: A Reasonable Approach to Evaluating Reverse Payment Settlements, 15 MINN. J.L. SCI. & TECH. 135, 141–42 (2014) (citing a study that finds that Paragraph IV challenges have shortened the effective life of challenged patents by 1.5 years, regardless of the success of the challenge).
to provide [an] adequate assurance of confidentiality”\textsuperscript{152} and “increases the likelihood that competitors will gain access to one another’s trade secrets . . . such as internal research and development or manufacturing and marketing processes.”\textsuperscript{153} The exchange of this sort of information is precisely what antitrust law typically aims to prevent.\textsuperscript{154} The substantially increased discovery burden, coupled with the increased litigation time and costs that would be associated with a fully detailed patent analysis, “may also freeze inventive activity for years.”\textsuperscript{155} An extended period of litigation not only results in companies delaying innovation due to the uncertainty of litigation, but also causes the company and its employees to shift from research and development to discovery production and trial preparation.\textsuperscript{156} A truncated analysis can allow a fundamental review of patent validity to be performed with much less distraction, disruption, and cost than a full form review.

3. \textit{Arguments Against Assessing Patent Validity Do Not Withstand Analysis}

Arguments against addressing patent validity as part of a rule of reason analysis arise from statements in the \textit{Actavis} opinion that it may not be necessary to litigate the patent validity question.\textsuperscript{157} These arguments, however, are not persuasive, because they misinterpret the Court’s language and rest on a misapprehension of the side effects of Hatch-Waxman patent litigation.

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\textsuperscript{152} Crane, \textit{supra} note 124, at 704.
\textsuperscript{153} Crane, \textit{supra} note 117, at 757–58.
\textsuperscript{154} \textit{See id.} at 758.
\textsuperscript{156} \textit{See Crane, supra} note 124, at 703–04 (“Firm employees often spend as much time as their lawyers preparing the case, producing documents, working with lawyers on litigation strategy, being deposed, traveling for lawsuit-related events, testifying at trial, and observing legal proceedings.”).
\textsuperscript{157} \textit{See F.T.C. v. Actavis, Inc.}, 133 S.Ct. 2223, 2236 (2013) (stating that “it is normally not necessary to litigate patent validity to answer the antitrust question”).
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The Supreme Court statement in *Actavis* that an analysis of patent validity may not always be necessary is not as an independent holding, but was made in support of the Court’s ultimate holding that a rule of reason analysis encompassing a full range of considerations should control.  

The Court summarized this particular portion of its opinion with the statement that “unexplained reverse payment[s] can provide a workable surrogate for a patent’s weakness, all *without forcing* a court to conduct a *detailed exploration* of the validity of the patent itself.”  

This statement does not direct that patent validity is never to be analyzed, but rather suggests (1) that other factors in a rule of reason analysis may sometimes override the necessity of considering patent validity in a particular case and (2) that the manner in which validity is determined may vary from case to case. First, when discussing the necessity of analyzing patent validity, the Court did so in relation to other factors—such as the size of the payment and the parties’ intent—that other factors in a rule of reason analysis may sometimes override the necessity of considering patent validity in a particular case and (2) that the manner in which validity is determined may vary from case to case. First, when discussing the necessity of analyzing patent validity, the Court did so in relation to other factors—such as the size of the payment and the parties’ intent—indicating that a consideration of patent validity would be unnecessary only when other factors weigh so heavily in one direction that a determination of validity would be unlikely to be able to change a court’s overall decision regarding competitive effect. Second, the tempered language of the passage indicated above only notes that it will not typically be necessary to litigate the question of patent validity; it does not go so far as to instruct lower courts not to undertake a truncated analysis whatsoever. Indeed, the fact that lower courts will develop truncated analyses as part of a rule of reason analysis was explicitly recognized and sanctioned by the Supreme Court. These statements by the Court in *Actavis*, when coupled with other Supreme Court precedent requiring that antitrust analyses, reflect the particulars of the

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158 *See id.* at 2236–37.
159 *Id.* (emphasis added).
160 *See Id.* at 2236.
161 *See Id.* at 2238.
industry at issue,\textsuperscript{162} show that the Supreme Court in \textit{Actavis} did not intend to preclude the lower courts from considering patent validity in a reverse payment rule of reason analysis.

Arguments against considering patent validity also fail because they rely on faulty premises. The two main premises on which these arguments commonly rely are (1) the negative impact of patent scrutiny on innovation and (2) the burdens and costs associated with conducting a patent validity mini-trial. The first argument is that an analysis of patent validity would stifle innovation in the pharmaceutical drug industry by intruding upon a patent holder’s right to exercise its statutorily granted market exclusivity.\textsuperscript{163} While this is a valid concern that has been substantiated by some studies,\textsuperscript{164} it ultimately fails to consider the realities of exploiting pharmaceutical drug patents under the Hatch-Waxman Act; as discussed above, this concern is also mitigated through the use of a truncated analysis.

The Hatch-Waxman Act provides substantial periods of special marketing privileges—regardless of any consideration or determination of patent validity—for the brand-name manufacturer, which allows it to maintain a monopoly position and potentially receive substantial compensation to reward its innovative efforts.\textsuperscript{165} The first such period is a 30-month stay of the generic manufacturer’s approval to market its version of the pharmaceutical drug,\textsuperscript{166} which is automatically imposed when the generic manufacturer notifies the brand-name manufacturer.

\textsuperscript{162} See supra notes 125–127.
\textsuperscript{163} See \textit{Carrier}, supra note 12, at 62 (“[One] principle motivating courts is to defer to settlements so as not to harm incentives for innovation.”).
\textsuperscript{164} See supra notes 151–154.
\textsuperscript{165} “Pharmaceutical innovations enjoy longer-lasting protection than innovations in other industries.” Hemphill, supra note 126, at 1578.
manufacturer of its ANDA filing\textsuperscript{167} and the brand-name manufacturer initiates a patent infringement lawsuit.\textsuperscript{168} The 30-month stay will be curtailed only if a court finds that the patent is either invalid or not infringed.\textsuperscript{169}

The Hatch-Waxman Act also provides a second period of quasi-exclusivity if a generic manufacturer has been successful in proving a patent invalid.\textsuperscript{170} Under this provision, the first generic manufacturer that files an ANDA receives a 180 day period of exclusivity, beginning with the first day of commercial marketing of the generic version, during which only the brand-name manufacturer and the first-to-file generic manufacturer may sell the pharmaceutical drug.\textsuperscript{171} The Hatch-Waxman Act also contains a new drug exclusivity period, whereby no ANDA can be approved under paragraph IV certification for 4 years after a brand-name manufacturer receives approval to market its pharmaceutical drug, if the patented drug contains “no active ingredient . . . which has been approved in any other application.”\textsuperscript{172} Further, normal patent procedures and protections still apply, and a brand-name manufacturer that desires to enforce its patent rights will be able to bring a traditional infringement lawsuit against generic manufacturers.\textsuperscript{173} Lastly, the use of a truncated analysis that does not necessarily examine the technical aspects of the patent will not have the same negative effects on innovation as a full-blown patent validity analysis.\textsuperscript{174}

\textsuperscript{167} See 21 U.S.C. § 355(j)(2)(B)(ii)(I) (2012). If the paragraph IV certification is not included in the initial ANDA, but is included in an amendment or supplement, then notification is required at the time of filing of the amendment or supplement. See 21 U.S.C. § 355(j)(2)(B)(ii)(II) (2012).
\textsuperscript{168} See § 355(j)(5)(B)(iii).
\textsuperscript{171} See id.; see also F.T.C. v. Actavis, Inc., 133 S.Ct. 2223, 2229 (2013).
\textsuperscript{174} See supra Part III.C.2.
The *Actavis* Court briefly mentioned the second faulty premise—that the burden of conducting a patent validity mini-trial within the main antitrust trial is excessive and adds substantial complexities to the trial.\(^{175}\) On other occasions, the Supreme Court has repudiated this argument by holding that a reduction in costs or easing of administrative burdens is not a cognizable reason for circumventing a complete rule of reason analysis where such a full analysis is otherwise required.\(^{176}\) Further, while the fact that patent cases are complex and difficult cannot be ignored,\(^{177}\) it should also be recognized that lower courts have a demonstrated ability to handle large and complex cases expeditiously.\(^{178}\) This is true even for “dynamic” industries, which includes the areas of technology and intellectual property.\(^{179}\) There are also numerous tools and management techniques available to lower courts to assist in analyzing and administratively simplifying complex cases. As an initial matter, lawyers may offer bench memoranda or other informative tools to judges and provide informational, non-adversarial expert witnesses in order to help judges direct their focus to the proper considerations for a

\(^{175}\) See 133 S.Ct. at 2236–37.

\(^{176}\) See *Leegin Creative Leather Products, Inc.* v. PSKS, Inc., 551 U.S. 877, 895 (2007) (“[A]dministrative advantages are not sufficient in themselves to justify the creation of per se rules . . . .” (quoting Cont’l T.V., Inc. v. GTE Sylvania, Inc., 433 U.S. 36, 50 (1977))). In *GTE Sylvania* and in *Leegin*, the Court overruled the use of a per se analysis in favor of a full rule of reason analysis, while in *Actavis* the Court took similar action in overturning the use of a per se, quick look, and “scope of the patent” analyses. The *Actavis* Court “recognize[d] the value of settlements and the patent litigation problem,.” but ultimately concluded that it “should not determine the result here.” *Actavis*, 133 S.Ct. at 2234.

\(^{177}\) See Morse, supra note 4, at 359.


\(^{179}\) See United States v. Microsoft Corp., 253 F.3d 34, 57 (D.C. Cir. 2001) (finding that the complexity of the industry did not affect the district court’s ability to apply the appropriate legal analysis).
patent validity case. In response to the concern that it is difficult for a party to put on a truly unbiased witness for informational purposes only, courts also have the ability to appoint an expert witness, an option that has been endorsed by the Supreme Court. Additionally, courts may appoint a technical advisor; a technical advisor is different from an expert witness in that a technical advisor is not required to testify at trial and cannot be questioned by the parties to the lawsuit, but rather serves as a private consultant to the judge providing informal, ex parte communication on complex matters.

The Federal Rules of Civil Procedure provide two additional options for easing administrative burdens—Rule 53 Masters and Rule 73 Magistrate Judges. Rule 53 allows a court to appoint a master to “hold trial proceedings and make or recommend findings of fact,” who may utilize “all appropriate measures to perform the assigned duties.” Special masters have been appointed for a wide variety of purposes, including to assist in fact-finding at the pretrial stage and to address technical issues. Rule 73 authorizes the appointment of a magistrate judge to conduct a proceeding, which could include a patent validity mini-trial in a broader antitrust

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181 See id. at 1425–26.
183 See Wiley, supra note 180, at 1438.
184 Antitrust defendants may also be prosecuted criminally; however, this is not a major concern in the reverse payment context because the FTC and private litigants only have civil authority and because the Department of Justice generally only uses criminal sanctions for cartels and clearly intentional violations. See Meghan Edwards-Ford & Matthew J. McDonald, Antitrust Violations, 44 AM. CRIM. L. REV. 241, 270 (2007).
186 FED. R. CIV. P. 53(c)(1)(B).
188 FED. R. CIV. PRO. 73(a).
lawsuit. These management techniques can assist in streamlining the trial process by isolating a technical variable for individualized determination.

Lastly, determinations of patent validity in a reverse payment lawsuit will not require deliberations on all of the issues that are generally addressed in a traditional patent validity lawsuit. One typical aspect of patent lawsuits that adds substantially to their level of intricacy is the determination of damages; however, there will not typically be a determination of patent-related damages in reverse payment lawsuits because the generic drug will not have been brought to market and thus will not have made any sales infringing upon a valid patent—meaning that there can be no damages. The use of a truncated analysis will also help to reduce the administrative burdens and costs typically associated with patent validity determinations, such as by not requiring as burdensome of a discovery process and not requiring litigants to discuss and prove all the elements of infringement.


On balance, the central role of the patent in overcoming per se illegality and in achieving the purposes of the Hatch-Waxman Act, and the repudiation of undue concerns about cost, complexity, and a chilling effect on innovation, weigh in favor of conducting a review of patent validity. Further, the Actavis decision allows that such a determination need not be a full-blown analysis as would occur in an infringement lawsuit; rather, it is permissible (and more beneficial) that an abbreviated patent analysis be performed.

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189 See History of the Federal Judiciary: Magistrate Judges, http://www.fjc.gov/history/home.nsf/page/judges_magistrate.html (last visited July 26, 2014) (“Magistrate judges may be authorized to preside in almost every type of federal trial proceeding . . . [and may] conduct all civil trials as long as the parties consented.”).


191 See supra notes 152–155.
A finding of patent invalidity is a factor strongly favoring antitrust condemnation. However—as with every factor in a rule of reason—such a finding is not sufficient alone to support a determination that a settlement is anticompetitive.\textsuperscript{192} It should be recalled that in \textit{Actavis} the Supreme Court reversed the Eleventh Circuit, which had applied the “scope of the patent” test as the sole test for determining the validity of the settlement, and instead held that a full rule of reason analysis should be conducted.\textsuperscript{193} To conclude after \textit{Actavis} that a reverse payment agreement involving an invalid patent is anticompetitive based solely on a finding of patent invalidity would ignore the central holding of \textit{Actavis}, the theory of the rule of reason analysis generally, and the positive aspects of reverse payments.

\textbf{D. Size of the Payment—A Novel Test for Reverse Payments}

The price of the payment from the brand-name manufacturer to the generic manufacturer is another essential consideration for lower courts. The necessity of considering the size of the payment is due largely to statements by the Court that for a reverse payment the “anticompetitive effects depends upon its size.”\textsuperscript{194} While the payment generally requires a generic producer to refrain from competing in the market for a drug, the Supreme Court has recognized that these payments may also reflect legitimate business considerations.\textsuperscript{195} In this sense, the payment serves as “compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item” or may reflect

\begin{itemize}
\item\textsuperscript{192} “No one factor is dispositive” in a rule of reason analysis. \textit{See supra} note 49.
\item\textsuperscript{193} \textit{See F.T.C. v. Actavis, Inc.}, 133 S.Ct. 2223, 2230, 2238 (2013).
\item\textsuperscript{194} \textit{Id.} at 2237. In different portions of the opinion, the Court discusses the size of the payment both as an independent variable and in relation to other considerations.
\item\textsuperscript{195} \textit{See id.} at 2235–36.
\end{itemize}
“traditional settlement considerations, such as avoided litigation costs.” Therefore, looking only at the nominal size of the payment—such as considering whether or not it exceeds a pre-established threshold—is not a sufficient test for this factor, because it does not include the requisite analysis of potentially cognizable business considerations. The remainder of Part III.D defines the proper price test to be used for reverse payment settlements, based upon statements in the Court’s opinion and traditional antitrust theories.

1. What the Test Cannot Be

The least burdensome price test would be to incorporate a standard from horizontal collusive agreement cases or from monopoly cases, two types of cases that have features similar to reverse payment cases. However, such tests ultimately do not satisfy the basic requirements suggested by the Supreme Court for reviewing the size of a reverse payment, since neither considers the value of services rendered. Horizontal price fixing cases provide no actual standard of review, since the structure and purpose of price discussions in such cases are so distinct from the discussions in a reverse payment case. More fundamentally, the Supreme Court has consistently held in horizontal collusion cases that when two competitors discuss price, there is

196 Id. at 2236; see also In re K-Dur Antitrust Litig., 686 F.3d 197, 218 (2012) (“[E]vidence of an unreasonable restraint of trade . . . could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.”).
197 Price tests that avoid the use of numerical thresholds have also been suggested by Daniel A. Crane, supra note 117, at 788–91, and by Henry Butler & Jeffrey Paul Jarosch, supra note 13, at 299–300; see also infra note 235 for a more detailed discussion of Butler & Jarosch’s test.
198 This price test has not been adopted by the courts, but serves as a model; the test looks to the Actavis decision and highlights features that lower courts should incorporate after that decision when establishing a price test for reverse payments.
199 As discussed previously in Part II.A, reverse payments are paid directly from one competitor to another, and the market and consumer impacts are an indirect result of the agreement; horizontal price-fixing agreements, as alluded to throughout this Article, are discussions among competitors relating to third parties—purchasers in the market—that have a direct impact on the market (the setting of the market price) but involve no exchange between the competitors. These distinctions mean that a test developed for one type of arrangement will be an inappropriate fit for the other.
no leeway for arguing that the price is reasonable or is not anticompetitive; therefore, any such discussion constitutes a per se violation of the antitrust laws.\textsuperscript{200} The use of a test that would treat an essential factor of the rule of reason test as illegal per se is contrary to the ultimate holding of \textit{Actavis} abrogating an antitrust analysis that would make any single factor determinative.\textsuperscript{201}

The prevalent monopoly-pricing standard of recoupment\textsuperscript{202} is a closer fit, but it also fails to consider the value of services rendered, as directed by the Supreme Court.\textsuperscript{203} The recoupment standard essentially asks whether a firm has or can reasonably be expected to set and maintain a monopoly price long enough to make a sufficient profit to recover the expense it incurs while previously setting prices artificially low in an effort to drive out competitors.\textsuperscript{204} As applied to reverse payments, the recoupment standard would be too simple because it effectively asks whether the brand-name manufacturer will ultimately realize profits from avoiding competition that are greater than the expense incurred in paying a generic manufacturer not to compete.

\textsuperscript{200} See F.T.C. v. Superior Court Trial Lawyers Ass’n, 493 U.S. 411, 424 (1990) (“[I]t was settled shortly after the Sherman Act was passed that it is no excuse that the prices fixed are themselves reasonable.”); Nat’l Soc’y of Prof’l Eng’rs v. United States, 435 U.S. 679, 689 (1978) (“[S]ubsequent decisions by this Court . . . unequivocally foreclose an interpretation of the Rule [of Reason] as permitting an inquiry into the reasonableness of the prices . . . .”).

\textsuperscript{201} See \textit{Actavis}, 133 S.Ct. at 2237.

\textsuperscript{202} Recoupment is the second stage of predatory pricing. “Predatory pricing is a two-step strategy for securing monopoly profits. During the first step—the predation stage—a firm charges a price below its costs in the hope of driving its competitors out of the market by forcing them to sell at a loss as well. If it succeeds, the firm can proceed to the second step—the recoupment stage. After it has the market to itself, the now-dominant firm charges a monopoly price in an effort to recoup the losses it sustained in the predation stage and to earn a steady stream of monopoly profits into the future.” Christopher R. Leslie, \textit{Predatory Pricing and Recoupment}, 113 COLUM. L. REV. 1695, 1695 (2013). If a plaintiff can prove that the monopolist has already recouped or will be able to recoup its losses, then the strategy is deemed to have violated the antitrust laws. \textit{See id.} This standard was adopted for all predatory pricing cases by the Supreme Court in \textit{Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.}, 509 U.S. 209, 226 (1993).

\textsuperscript{203} See \textit{Actavis}, 133 S.Ct. at 2237 (“[T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon . . . its scale in relation to the payor’s anticipated future litigation costs . . . .”).

\textsuperscript{204} \textit{See supra} note 202.
Pharmaceutical drug companies are generally sophisticated entities that are sufficiently aware of their expenses to see a recoupment price to recover what it pays to a generic manufacturer not to produce; thus, a recoupment standard will result in always finding the size of the payment to be an anticompetitive factor, making it an effectively pointless analysis\textsuperscript{205}.

2. What the Test Should Be

The proper test should directly compare the value of the services rendered to the total value of the payment. A reverse payment can be divided into two parts—one part is directly tied to the value of the services rendered, and the remainder is in effect a payment for market exclusivity.\textsuperscript{206} If the remainder is greater than the services rendered, then the payment is, on balance, principally for the purpose of eliminating competition and automatically deemed to be an anticompetitive factor. However, if the remainder is less than the services rendered portion, then the payment is subject to a mini-reasonableness test. At this second step, if the amount paid is found to be unreasonable, then the price factor favors a finding of anticompetitive effect. Having outlined the test, the remainder of this section defines its contours.

The definition of “services rendered” should be flexible, as opposed to consisting of a tightly defined group of factors, because it potentially includes any legitimate services for which a reasonable brand-name manufacturer might pay. However, before a proffered service can be considered part of this definition, it should be subject to scrutiny by the courts to ensure that such

\textsuperscript{205} See generally Exhibit A for Plaintiff, F.T.C. v. Watson Pharm., Inc., No. 1:09-CV-0955-TWT (N.D.Ga. May 28, 2009) (consolidated as MDL-2084) (exhibit shows Solvay Pharmaceuticals’ internal analysis of their market share and profits depending on whether they win the patent infringement lawsuit, lose the lawsuit, or settle with the generic manufacturers).

\textsuperscript{206} The size of the payment can be anticompetitive dependent upon “its independence from other services for which it might represent payment.” See Actavis, 133 S.Ct. at 2237. This indicates that the Court contemplated that some portion of the payment may not be related to services rendered; otherwise it would not be possible to consider any independence from such services in a meaningful way.
service or other benefit is actually being conferred and that it is reasonably priced. At a minimum, “services rendered” includes the “payor’s anticipated future litigation costs.” The Supreme Court explicitly found in *Actavis* that the anticompetitive effects of the payment depend in part on this factor. Services rendered could also include anything from “promotion and backup manufacturing services” to a licensing fee paid to the generic manufacturer in return for exclusive use of the generic’s patent. It is important to distinguish services rendered from the pro-competitive justifications discussed in Part III.E, *infra*.

Applying a test that permits some payment to be made for market exclusivity is consistent with statements in *Actavis* that direct the lower courts to consider the size of the payment in conjunction with “its independence from other services for which it might represent payment.” This requirement allows the brand-name manufacturer to make some payment beyond the value of services rendered and implicitly recognizes the permissibility of possessing market exclusivity. Neither the text of the *Actavis* decision nor the policies that underlie it

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207 *See* Image Technical Servs., Inc. v. Eastman Kodak Co., 125 F.3d 1195, 1212 (9th Cir 1997) (“A plaintiff may rebut an asserted business justification by demonstrating either that the justification does not legitimately promote competition or that the justification is pretextual.”); Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 608 (1985) (finding that the evidence submitted by both parties contradicted defendant’s proffered justifications); *see also* NCAA v. Bd. of Regents of the Univ. of Okla., 468 U.S. 85, 113–15 (1984).

208 *Actavis*, 133 S.Ct at 2237.

209 *See id.*

210 Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Activating Actavis*, 28-FALL ANTITRUST 16, 18 (2013). These are justifications offered by the defendants in *Actavis*.

211 Picht, *supra* note 138, at 122. This justification in particular is a prime example of the need for courts to evaluate the legitimacy of the proferred services rendered; such proferred justification may itself implicate antitrust concerns.

212 While pro-competitive justifications are associated with the benefits of the economic arrangement to the public as a whole, payment for services rendered is justified based on the value thereof solely to the brand-name manufacturer.

213 *Actavis*, 133 S.Ct. at 2237.

214 *E.g.*, Edlin, *supra* note 210, at 18–19 (using the same cautionary terminology, stating that after deducting the value of considerations provided, “the resulting net payment is otherwise
prohibit reverse payments in excess of the value of services rendered. The Supreme Court in *Actavis* had the opportunity to make a definitive statement that a settlement price that exceeds the value of services rendered is automatically anticompetitive, but the Court declined to do so. Rather, the Court left open the possibility of a small or justified payment being found pro-competitive. The Court was even more direct regarding the possibility that the total settlement price need not correlate dollar-for-dollar to the price of services rendered when the Court stated that “there is always something of a sliding scale in appraising reasonableness” and that whether a reverse payment is anticompetitive depends not only upon its size but upon other factors in conjunction with its size. A black-and-white rule pursuant to which a payment exceeding the amount of services rendered is deemed to be illegal would be akin to applying a per se rule, which the Supreme Court held do not apply to reverse payments.

Furthermore, the existence of a range of potentially permissible values for exclusivity is necessary in order that two important legal policies alluded to in *Actavis* are not ignored in their entirety—the encouragement of legal settlements and of the protection of patent rights. Drawing a strict line between pro- and anti-competitive settlements at the point where the price is unexplained and, if it is a positive quantity, may be understood to be a payment for delaying entry”.

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215 See supra note 206.
216 See *Actavis*, 133 S.Ct. at 2237 (“[A] reverse payment, where large *and* unjustified, can bring with it the risk of significant anticompetitive effects . . . .” (emphasis added)). “And” is traditionally considered to mean “together with or along with; in addition to; as well as.” THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 66 (Steven R. Kleinedler et al. eds., 5th ed. 2011). This fettered language leaves open the possibility that some relatively small payment, or a very large but entirely justified payment, may escape antitrust condemnation, because such a payment would not meet both the “large” and “unjustified” prongs.
217 See *Actavis*, 133 S.Ct. at 2237.
218 Id. at 2237.
219 See id. at 2237–38.
220 See id. (noting the “desirability of settlements” but finding that “[antitrust] considerations, taken together, outweigh the single strong [settlement] consideration”).
221 See id. at 2232 (finding that there exists a “public interest in granting patent monopolies”).
exceeds the value of services rendered, thereby disallowing any amount of payment for exclusivity, would in effect turn a reverse settlement into a literal services contract, where one party is performing a specified service or set of services in return for a payment that equates to the value of those services. Such a price-cap would remove much of the incentive for a generic manufacturer to settle since its profit would be limited to that which it could generate from these incidental activities. Such a narrow standard of liability “would have too chilling an effect on the ability of the settling parties to act in their own self interest.” 222

Such a limit is also inconsistent with the realities of litigation and settlement. Litigation is costly and uncertain, and therefore litigants are commonly risk-averse, especially where one litigant has a lot to lose. 223 “While litigation may help reduce false positives (invalid patents otherwise thought to be valid), it may also lead to false negatives (valid patents held invalid).” 224 This uncertainty impacts large companies with extensive patent portfolios, which risk the threat of multiple and concurrent suits, some of which may put their most successful patents through the uncertainties of litigation; it may pose an even greater threat to smaller companies, whose entire success may depend on protecting a small number of patents that apply to the majority of the firm’s products. 225 “For these companies, the uncertainty of litigation can be untenable—

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222 Scott A. Backus, *Reversing Course on Reverse Payment Settlements in the Pharmaceutical Industry: Has Schering-Plough Created the Blueprint for Defensible Antitrust Violations?*, 60 Okla. L. Rev. 375, 416 (2007) (also finding that “[e]ach company’s risk aversion . . . [,] knowledge of other potential drugs that could be introduced to the market to compete, and the financial standing all could come into play as settlement talks progress”).

223 See Yu, supra note 155, at ¶ 38 (“[F]alse negatives are extremely costly for pharmaceutical patents, because of huge R&D spending, leading to undesired deterrence of innovation.”). Parties having asymmetric risks generally characterize reverse settlements. See id. at ¶ 2; Hemphill, supra note 126, at 1577.

224 See Yu, supra note 155, at ¶ 38.

225 See Bieri, supra note 151, at 142
even when the company has no doubt about the validity, scope, and term of its patents." Thus, “it should not be surprising—nor should it be seen as an admission of weak patents—that many pharmaceutical innovators quite reasonably choose to settle some Hatch-Waxman challenges, even on terms that include providing considerable value to a generic competitor.”

One example of such a provision of considerable value is where a brand-name manufacturer makes a large payment to a generic manufacturer that affords the brand-name manufacturer market exclusivity but permits generic entry into the market at a date prior to the patent’s expiration. A reverse payment taking this form is reasonable and beneficial to both of the settling parties, and to consumers, considering the uncertainties associated with patent litigation discussed above. The brand-name manufacturer is willing to make a large payment to the generic manufacturer in order to avoid the risk of having the patent found invalid. The generic manufacturer also benefits because it receives an earlier entry date than if the patent is found valid, as well as avoiding the costs and burdens of litigation while simultaneously receiving an influx of cash that it may use for its own research and development program. This guarantee of early market entry and boost to research and development funding also benefits consumers. Creating a strict rule whereby every dollar must be accounted for as payment for a service rendered would effectively foreclose the use of these settlements, which would run contrary to statements by the Supreme Court and scholars that reverse payments can have

\[\text{\textsuperscript{226}} \text{Id.}\]
\[\text{\textsuperscript{227}} \text{Id. at 142–43 (citing a study that finds “across all patent cases, 95% are resolved by settlement”).}\]
\[\text{\textsuperscript{228}} \text{E.g., id. at 144. The settlement at issue in Actavis allowed Actavis to “bring its generic to market . . . 65 months before Solvay’s patent expired.” F.T.C. v. Actavis, Inc., 133 S.Ct. 2223, 2229 (2013).}\]
\[\text{\textsuperscript{229}} \text{See Bieri, supra note 151, at 142.}\]
notable pro-competitive benefits for consumers and pharmaceutical companies, thus improperly deterring potentially pro-competitive behavior.

It is also necessary to allow for a range of pro-competitive values in excess of services rendered because the burden of full-blown litigation “might deter some patentees from protecting their patent rights.” While bad or invalid patents harm consumers, good or valid patents have notable benefits and thus their protection should be encouraged. Allowing some justifiable payment for exclusivity provides an additional form of protection for good patents. Prominent antitrust scholars have also suggested the viability of a pricing factor that allows for a range of pro-competitive values.

An immediate criticism of this justification is that the settling parties could pursue a less anticompetitive alternative to protect their interest. While pursuit of a less anticompetitive alternative should always be considered, such consideration should not impact the structuring of a price test because consideration of less restrictive alternatives receives separate analysis under the rule of reason. Further, as discussed in Part III.B, a less anticompetitive alternative is better

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230 See, e.g., Actavis, 133 S.Ct. at 2237 (finding that diversion from the rule of reason is only appropriate where there is an obvious anticompetitive effect, but holding that reverse payments do not meet that criterion); Backus, supra note 222, at 416 (discussing prominent antitrust scholars who agree that “reverse payment settlement[s] could be beneficial to consumers.”).
231 For a discussion of the pro-competitive benefits of reverse payment settlements see Part III.E, infra; for a discussion of the benefits of avoiding prolonged litigation see Part III.C.2, supra.
233 See Actavis, 133 S.Ct. at 2232 (“[T]he public interest in granting monopolies exists only to the extent that the public is given a novel and useful invention . . . .”).
234 The benefits associated with allowing settlement to protect patents and innovation is discussed in more detail in Part III.C.2, supra.
235 See Butler, supra note 13, at 91–94 (creating a range of permissible settlement values based on a comparison of the parties’ expected gain or loss from competition, the parties’ respective estimation of success, and the time of market entry).
described as the presence of a less anticompetitive alternative that achieves similar pro-competitive benefits.\textsuperscript{236}

The next consideration concerns the point at which, during step two of the price test, a payment crosses from being pro-competitive to being anticompetitive. A crucial input into the reasonableness of the settlement value is the intent of the settling parties, namely who initiated the settlement and for what purpose. Intent is a factor that appears as a consideration in numerous antitrust contexts.\textsuperscript{237} “Evidence of intent can be highly probative . . . because knowledge of intent may help the court to interpret facts and to predict consequences.”\textsuperscript{238} It is well established that courts may consider a party’s bad intentions to assist in understanding how an action will affect markets and consumers.\textsuperscript{239} Intent becomes most beneficial in close-call cases, where the activity under consideration could easily be either anticompetitive or pro-competitive.\textsuperscript{240} Reverse payment settlements are an example of such close-call cases;\textsuperscript{241} when the Supreme Court decided that the validity of reverse payment settlements should be considered under the rule of reason it acknowledged that the anticompetitive effect of a particular agreement is not easily established.\textsuperscript{242} Intent has also been used to determine the legality of competitor agreements in other intellectual property antitrust contexts.\textsuperscript{243}

\textsuperscript{236} See supra Part III.B.
\textsuperscript{237} See supra note 149 (citing an array of cases where intent was an important consideration).
\textsuperscript{238} Graphic Prods. Dists., Inc. v. ITEK Corp., 717 F.2d 1560, 1573 (11th Cir. 1983) (quoting Bd. of Trade of Chi. v. United States, 246 U.S. 231, 238 (1918)).
\textsuperscript{239} See Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 586 (1985) (“The question of intent is relevant . . . in determining whether the challenged conduct is fairly characterized as ‘exclusionary,’ ‘anticompetitive,’ or ‘predatory.’”); see also Graphic Prods., 717 F.2d at 1573.
\textsuperscript{240} See Cal. Dental Ass’n v. F.T.C., 224 F.3d 942, 948 (9th Cir. 2000).
\textsuperscript{241} See supra Part II.C.
\textsuperscript{242} See Morse, supra note 4, at 368.
\textsuperscript{243} For example in the trademark context, courts have allowed agreements between competitors that allocate the markets in which a company may use its trademark when the agreement is a
Intent can be found in direct evidence or may be inferred from conduct.\textsuperscript{244} The existence of a smoking gun—for instance, when high-level documents exist stating that the sole purpose of the settlement is to increase market share—can directly demonstrate an anticompetitive intent.\textsuperscript{245} Circumstantial evidence of bad intent could be shown through the presentation of evidence suggesting that the brand-name manufacturer never intended to litigate the validity of the patent at issue, but rather only brought suit to attain an additional period of market exclusivity for a patent it knew would be deemed invalid.\textsuperscript{246}

Another item that should impact a court’s determination of the reasonableness of the price is when there are other price-based variables that do not fit neatly into the definition of “services rendered,” but which nevertheless have an impact on the settling parties’ determination of the value of their settlement. One example of this is when a settlement includes a waiver or a payment of unpaid damages relating to a previous dispute.\textsuperscript{247} An evaluation of a pharmaceutical firm’s desire to protect its trade secrets may impact this consideration as well.\textsuperscript{248} For instance, a company may study its patent portfolio and financial statements and realize that pursuing litigation will result in the disclosure of trade secrets and other proprietary information that would impact its business by a certain dollar amount; increasing the settlement value by a

\textsuperscript{244}See\ Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447 (1993) (specific intent to monopolize can be inferred from conduct); see also Aspen Skiing, 472 U.S. at 610–11 (holding that a monopolist’s choice to change its pattern of conduct even though it meant decreased sales was sufficient to infer an abuse of dominance).


\textsuperscript{246}See\ Picht, \textit{supra} note 138, at 111–112. In order to receive the 30 months of market exclusivity the brand-name manufacturer must initiate an infringement lawsuit against the generic manufacturer.

\textsuperscript{247}See\ Picht, \textit{supra} note 138, at 120.

\textsuperscript{248}See\ Yu, \textit{supra} note 155, at ¶ 35.
proportional amount to protect against this risk would be a rational undertaking. Indirect litigation costs, such as the amount that litigation “drains away from firm resources by requiring managers and other employees to focus time and attention on the litigation, instead of ordinary firm business, may also help to justify the larger payment size.”

In summation, where a court finds that the value of the remainder portion of a settlement is not in excess of the portion paid for services rendered, the price becomes subject to a reasonableness evaluation in light of the circumstances of the settlement. If that value is deemed unreasonable then the size of the payment factor weighs in favor of finding the reverse payment to be anticompetitive; a determination of reasonableness favors a pro-competitive finding. If the remainder exceeds the value of services rendered, then the price becomes an anticompetitive factor without considering reasonableness.

E. Pro-Competitive Justifications

One of the principal advantages of a rule of reason analysis is that it allows a consideration of pro-competitive benefits, which increase consumer welfare. There are numerous benefits that can accrue from reverse payments that could justify their use; however, any claimed pro-competitive justification must be proven by the defendants to be actual and

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249 See Crane, supra note 117, at 757.

250 Recall that these justifications are distinct from the services rendered, discussed in Part III.D.2, supra. While pro-competitive justifications are associated with the benefits of the economic arrangement to the public as a whole, payment for services rendered is justified based on the value thereof solely to the brand-name manufacturer.


cognizable.\textsuperscript{253} It is the courts’ role to determine which proffered justifications are real and which are merely pretext. Legitimate justifications favor a finding that a particular settlement is pro-competitive.

One possible justification of reverse payments is that they afford a manufacturer the ability to provide valuable information and services to consumers that may not be available unless the manufacturer receives higher profits than it can obtain through free-market competition, in order to cover the cost of these services.\textsuperscript{254} Valuable services associated with the existence of guaranteed profits include efficient quality control\textsuperscript{255} and higher marketing expenditures, which increase overall consumption.\textsuperscript{256} Decreases in brand marketing lead to a loss of “non-price competition benefits” such as “continuing professional education and patient awareness for under-diagnosed diseases as well as preventative care.”\textsuperscript{257} Further, payment in exchange for a generic manufacturer’s assistance with continued clinical testing and analysis could be deemed a cognizable justification.\textsuperscript{258}

\textsuperscript{253} See supra note 207 (discussing how courts require pro-competitive justifications be proven cognizable).
\textsuperscript{255} See Dresnick, \textit{supra} note 251, at 251.
\textsuperscript{256} See Butler, \textit{supra} note 13, at 99–100 (“Vigorous marketing may increase consumption of the drug more than any increase in consumption due to cheaper prices when a generic drug enters the market. Because brand-name drug manufacturers face lower prices and lose a significant portion of their market share upon generic entry, they also lose much of their incentive to market the drug.”).
\textsuperscript{257} Yu, \textit{supra} note 155, at ¶ 36.
\textsuperscript{258} See Andrew D. Regan & Charles E. Miller, \textit{Hatch-Waxman Litigation Post-Actavis: Crafting a Pro-Competitive Settlement Agreement}, 6 NO. 1 LANDSLIDE 52, 53 (2013) (“By having the brand name exchange payment for services such as research, clinical testing, manufacturing, sales, marketing, or other services, and receiving an abatement of the generic's patent challenge in return, the underlying interests of all parties can be addressed.”).
In certain contexts, reverse payments may ultimately increase competition. If the company that received the initial FDA approval is a new or small company, market exclusivity may provide it with additional profits that are necessary to allow the company to grow and to finance and better equip its own research and development program, which will ultimately enable it to compete more effectively in the markets for other pharmaceutical drugs.259 “[A] modest cash payment [may] enable . . . a cash-starved generic manufacturer to avoid bankruptcy and begin manufacturing” a generic version of that drug after the exclusivity period ends.260 Guaranteed profit can also help facilitate and incentivize new market entry.261

Perhaps the most commonly cited pro-competitive effect of reverse payments is that “settlements increase the value of the underlying patent to the patent holder” and thus a manufacturer’s incentive to innovate.262 If these settlements were not allowed, the increase in patent litigation would cause increased uncertainty about a manufacturer’s intellectual property rights and thus delay innovation.263

These pro-competitive justifications do not comprise an exhaustive list and are only a small handful of the potential justifications that exist for allowing reverse payments. “The Court left open the possibility for other defenses that justify [a] reverse payment.”264 Courts should be open to the possibility of other justifications, and evaluate them with attention towards increased

259 See Butler, supra note 13, at 90; see also Christine A. Varney, A Post-Leegin Approach to Resale Price Maintenance Using a Structured Rule of Reason, 24-FALL ANTITRUST 22, 23 (2009).
260 Hogges-Thomas, supra note 25, at 1442.
261 See Dresnick, supra note 251, at 245.
262 See Butler, supra note 13, at 90. This issue was previously discussed in Part III.C.2.
263 See Carrier, supra note 12, at 62 (citing Schering-Plough Corp. v. F.T.C., 402 F.3d 1056, 1075 (11th Cir. 2005), Valley Drug Co. v. Geneva Pharmas., Inc., 344 F.3d 1294, 1308 (11th Cir. 2003), and In re Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 256 (E.D.N.Y. 2003)).
264 See Edlin, supra note 210, at 20.
competition and consumer benefit. The existence of cognizable and substantial justifications favors a finding that the reverse payment at issue is pro-competitive.

IV. Conclusion

In its decision in F.T.C. v. Actavis, Inc., the Supreme Court resolved a circuit split and held that reverse payment settlements are subject to antitrust scrutiny under a rule of reason analysis. While this decision removed one level of uncertainty, it created another, which it left unanswered—what are the important factors to consider in applying the rule of reason analysis? The disparate outcomes and rationales of the few preliminary motions in reverse payment cases since the Actavis decision indicate the need for lower courts to adopt a standardized analysis with consistent factors that will guide settling parties and courts in their evaluation of reverse payment settlements.

This Article has laid out a list of key factors for courts to analyze—based on the Actavis decision and traditional antitrust theories—on which courts should come to rely. When faced with an antitrust challenge to a reverse payment settlement, courts need to examine the market power of the settling parties, the availability of less anticompetitive alternatives that do not eliminate the pro-competitive benefits of the agreement, whether the patent at issue is valid (using a truncated analysis), the size of the payment as related to the claimed services rendered, and any cognizable pro-competitive justifications. No single factor is determinative. The

266 See id.
determination of the competitive effects of any particular reverse payment will ultimately depend on the precise facts of the case.