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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.*

I. INTRODUCTION

The health care industry has recently seen substantial turmoil and change.[1] Alongside contentions related to the Affordable Care Act's mandate requiring all Americans to have health insurance,[2] there have been widespread concerns about the rapidly rising cost of health care.[3] This explosion in costs is especially true in the area of pharmaceutical drugs.[4]

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 infringement lawsuit stemming from proposed generic[5] entry into the market of a particular drug.[6] The basic feature of such settlements is a payment made by a brand-name manufacturer to a

[1] *See generally* Keith J. Shapiro, Nancy A. Peterman & David Y. Wolnerman, *Turmoil in the Healthcare Industry: What About the Patients?*, *in* THE AMERICAS RESTRUCTURING AND INSOLVENCY GUIDE 2008/2009 100, 100 (Price, Waterhouse, Coopers, L.L.C, 2008).

[2] *See* Alicia Ouellette, *Health Reform and the Supreme Court: The ACA Survives the Battle of the Broccoli and Fortifies Itself Against Future Fatal Attack*, 76 ALB. L. REV. 87, 87 (2013).

[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) (arguing that "pharmaceutical 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) (stating that "[m]aximizing the use of generic drugs . . . promises to be a critical component in the fight for an affordable price tag on healthcare.").

[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).

generic manufacturer, for the purpose of persuading the generic manufacturer to refrain from competing in the market of a particular pharmaceutical drug.[7] This settlement effectively provides the brand-name manufacturer with an exclusive market.[8] While the payment of cash to settle a lawsuit is not unusual, payment by the plaintiff to the defendant for this purpose is unusual.[9]

A critical theoretical conflict arises from these settlements because they lie at the intersection of intellectual property law and antitrust law.[10] The intellectual property perspective is that a statute has granted the patent holder the right of market exclusivity over the subject of his patent in order to reward the holder for his innovation.[11] Contrarily, the antitrust perspective is that such a settlement violates longstanding antitrust laws because an agreement to preserve market exclusivity harms consumers.[12] How to balance these competing perspectives is the crux of this debate.[13]

Prior to June 2013, a circuit split existed in the United States federal court system over the proper balance of these two perspectives

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[7] *See* Tania Khatibifar, Note, *The Need for a Patent-Centric Standard of Antitrust Review to Evaluate Reverse Payment Settlements*, 23 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1351, 1354 (2013). *See also infra* notes 36–37.

[8] *See* Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1722 (2003).

[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 & THE FED. TRADE COMM'N, ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING INNOVATION AND COMPETITION 1 (2007) (stating that "[i]ntellectual 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 derived from their inventions.") (internal quotation marks omitted) [hereinafter PROMOTING INNOVATION].

[12] *See* Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 71–72 (2009) (discussing the harm to competition as similar to traditional market allocation, but done through time rather than location, while also noting that "the anticompetitive harm at issue has human consequences.").

[13] *See* Schering-Plough Corp. v. F.T.C., 402 F.3d 1056, 1067 (11th Cir. 2005) (arguing that "a delicate balance must be drawn between the two regulatory schemes."); Henry N. Butler & Jeffrey Paul Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 IOWA L. REV. 57, 79 (2010) (stating that the "balance between patent and antitrust law is at the center of the reverse-payment debate.").

in the reverse payment context.[14] In *F.T.C. v. Actavis, Inc.*[15], the Supreme Court addressed this split.[16] In *Actavis*, the Court held that reverse payment settlements should be evaluated under antitrust law's rule of reason analysis.[17] However, the Court left much of the issue of how to apply the analysis to be determined through subsequent litigation.[18] As discussed herein, the rule of reason analysis is a full-bodied, multi-faceted analysis, in which no single factor is determinative.[19]

This Article fills in the gaps left by the Supreme Court by analyzing what factors should become the most important considerations for lower courts when 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. Part II 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 the courts to consider while conducting a reverse payment rule of reason analysis: (1) market power; (2) the availability of less restrictive alternatives; (3) patent validity; (4) size of the payment: and (5) pro-competitive justifications.

Each of these factors is included based on the Supreme Court's discussion in *Actavis*, as well as 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

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[14] *See infra* note 81.

[15] 133 S.Ct. 2223 (2013), *rev'g* F.T.C. v. Watson Pharms., Inc., 677 F.3d 1298 (11th Cir. 2012).

[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.

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 of the publication of this article, there are multiple reverse payment cases recently disposed of or 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

[20] *See In re* Androgel Antitrust Litig. (No. II), No. 1:09-MD-2084-TWT, 2014 WL 1600331, at *9 (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). A number of cases recently have been resolved or are pending at the motion to dismiss stage. *See, e.g.*, *In re* Effexor XR Antitrust Litig., No. 11–5479, 2014 WL 4988410 (D.N.J. Oct. 6, 2014) (granting in part and denying in part a motion to dismiss); *In re* Lipitor Antitrust Litig., No. 3:12-CV-2389 (PGS), 2014 WL 4543502 (D.N.J. Sept. 12, 2014); *In re* Loestrin 24 FE Antitrust Litig., No. 1:13-MD-2472, 2014 WL 4368924 (D.R.I. Sept. 4, 2014); King Drug Co. of Florence, Inc. v. Cephalon, Inc., No. 2:06-CV-1797, 2014 WL 982848, at * 5 (E.D. Pa. Mar. 13, 2014) (deciding four motions to dismiss related to collateral estoppel of patent validity, but delaying a decision on the motions to dismiss related to the reverse payment antitrust claim for a separate opinion); *In re* Lamictal Direct Purchaser Antitrust Litig., 18 F. Supp. 3d 560 (D.N.J. 2014). One case, *In re* Nexium (Esomeprazole) Antitrust Litig., No. 12-MD-02409-WGY, 2014 WL 585827, at *3 (D. Mass. Feb. 12 2014), *aff'd mem.*, 2014 WL 4370333 (D. Mass. Sept. 4, 2014), was administratively closed on the eve of trial pending a full written opinion. Another case, *In re* Aggrenox Antitrust Litig., 11 F. Supp. 3d 1342 (J.P.M.L. 2014) (centralizing and consolidating eleven related antitrust cases in the District of Connecticut), is in the early stage of trial proceedings.

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 consequences on one of the largest industries in the American economy.[21] 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.[22] 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,[23] and there is notable debate on how a decision will impact pharmaceutical firms' incentive to innovate and discover new medicines.[24] And, as 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."[25]

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.[26] The procedure 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).[27] Prior to the Hatch-Waxman Act, generic producers were required to go through the exact same process as the original, brand-name applicant;[28] however, after its passage, generic producers are able to "rely on the safety and effectiveness tests conducted by a [brand-name] drug manufacturer so long as the generic

[21] *See supra* notes 3–4.

[22] *See* Jenny, *supra* note 4, at 299.

[23] *See supra* notes 1–4.

[24] *See generally infra* Parts III. C–D (discussing in multiple contexts the importance and necessity of preserving pharmaceutical companies' incentive to innovate).

[25] Alicia I. Hogges-Thomas, *Winning the War on Drug Prices: Analyzing Reverse Payment Settlements Through the Lens of* Trinko, 64 HASTINGS L.J. 1421, 1446 (2013).

[26] Morse, *supra* note 4, at 383.

[27] *See id.*

[28] *See id.*

applicant . . . demonstrate[s] that its drug is bio-equivalent to the approved [brand-name] drug."[29] This process is referred to as the Abbreviated New Drug Application process, or ANDA.[30]

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.[31] The Hatch-Waxman Act allows this assurance to be offered in four different ways.[32] 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."[33] 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."[34] Paragraph IV litigation is the general class of lawsuit that results in reverse payment settlements, including the settlement at bar in *Actavis*.[35]

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.[36] 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."[37] The central concern of these settlements arises at the point where intellectual property law and antitrust law conflict, and asks "whether such an agreement can

[29] *Id.* at 383–84.

[30] *E.g.*, *id.* at 383.

[31] *See* 21 U.S.C. § 355(b)(1)(G) (2012).

[32] *See* 21 U.S.C. § 355(j)(2)(A)(vii) (2012).

[33] *See* 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)–(IV) (2012).

[34] F.T.C. v. Actavis, Inc., 133 S.Ct. 2223, 2228 (2013) (internal quotation marks omitted).

[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.").

[36] *See Actavis*, 133 S.Ct. at 2227.

[37] *Id.*

sometimes unreasonably diminish competition in violation of the antitrust laws."[38]

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."[39] The Supreme Court initially held that this language should be read literally and should "not [be] limited to that kind of contract alone which is in unreasonable restraint of trade, but [that] all contracts are included."[40] However, a little over a decade later, the Supreme Court reversed course and held that only unreasonable restraints should be declared illegal.[41] The Court believed that the key concern should ultimately be whether the restraint under consideration promotes or destroys competition.[42] In answering this question, courts were directed to consider the purpose, nature, and effects of the restraint.[43] This analysis is also applied to other federal antitrust provisions, including Section 5 of the Federal Trade Commission Act.[44]

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.[45] The enforcement agencies have warned that they will not limit their consideration to any pre-determined factors, but will

[38] *Id.*

[39] 15 U.S.C. § 1 (2012).

[40] United States v. Trans-Mo. Freight Ass'n, 166 U.S. 290, 328 (1897).

[41] *See* Standard Oil Co. of N.J. v. United States, 221 U.S. 1, 60 (1911). A "reasonableness" criteria was imposed because the Court found that "every agreement concerning trade . . . restrains" and if such a reasonableness standard was not imposed than any and all business arrangements would be deemed illegal. Bd. of Trade of Chi. v. United States, 246 U.S. 231, 238–3939 (1918). The Supreme Court saw this reading of the Sherman Act as necessary in order to properly incorporate the common law origins of the Act. *See* ANDREW I. GAVIL, WILLIAM E. KOVACIC & JONATHAN B. BAKER, ANTITRUST LAW IN PERSPECTIVE: CASES, CONCEPTS & PROBLEMS IN COMPETITION POLICY 90 (2d ed. 2008).

[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 (2012); *See e.g.*, Cal. Dental Ass'n v. F.T.C., 526 U.S. 756, 759 (1999) (holding that a rule of reason analysis should have been used to evaluate the FTC's Section 5 complaint).

[45] THE FED. TRADE COMM'N & THE U.S. DEP'T OF JUSTICE, ANTITRUST GUIDELINES FOR COLLABORATION AMONG COMPETITORS § 1.2, at 4 (2000) [hereinafter COLLABORATION GUIDELINES].

consider any factor that is necessary to a full and proper analysis of the restraint's competitive effect.[46] Each alleged restraint is evaluated separately to determine its pro- or anti-competitive effect.[47] 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."[48] Notably, "[n]o one factor is dispositive" in a rule of reason analysis.[49]

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 should be readily condemned as illegal without the need for a detailed economic analysis.[50] However, according to the Supreme Court, such "[p]er se rules of illegality are appropriate only when they relate to conduct that is manifestly anticompetitive."[51] 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.[52] Many courts and litigants favor per se rules because they provide clarity as to what conduct is

[46] *See id.* at § 3.3, at 10.

[47] *See* Edward D. Cavanagh, *The Rule of Reason Re-Examined*, 67 BUS. LAW. 435, 442–43 (2012).

[48] L.A. Mem'l Coliseum Comm'n v. N.F.L., 726 F.2d 1381, 1391 (9th Cir. 1984) (quoting Northrop Corp. v. McDonnell Douglas Corp., 705 F.2d 1030, 1050 (9th Cir. 1983)); *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 weighs 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, § 3.3, at 10.

[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.*, 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); 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); 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); 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) [hereinafter *BMI*]; 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).

unlawful, have predictability of consequences, streamline the management of evidence and burdens of proof, and promote efficiency in litigation.[53]

Nevertheless, in the 1960's and 1970's, courts began to turn away from per se illegality.[54] This was due in large part to a shift in how economists thought about antitrust law, namely the introduction of concepts related to anticompetitive effects, market power, efficiencies, and conditions of entry.[55] 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 exercise.[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.[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.[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."[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.[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.[61]

Courts have recently found occasion to recognize the continued applicability of all three of the methods of analysis described above.[62]

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[53] *See* Cavanagh, *supra* note 47, 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 decisions since the 1970s).

[56] *See BMI*, 441 U.S. at 13.

[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.'").

[58] *See* GAVIL, *supra* note 41, at 185.

[59] *See* Cal. Dental Ass'n v. F.T.C., 526 U.S. 756, 770 (1999).

[60] *See* Polygram Holding, Inc. v. F.T.C., 416 F.3d 29, 33 (D.C. Cir. 2005).

[61] The justifications can be attacked in one of two ways: (1) by explaining "why [the Commission] 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.

[62] *E.g.*, Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 551 U.S. 877, 907

continued . . .

The Supreme Court has noted that there is no bright line in determining which approach to follow, rather, there exists a sliding scale, such that the quality of proof required (and thus the analytical method to be used) varies with the particular circumstances of each case.[63] In essence, the analysis should be an "enquiry meet for the case, looking to the circumstances, details, and logic of the restraint."[64] Nevertheless, the Supreme Court has stated that the rule of reason is the default antitrust analysis.[65] Deviation from the rule of reason to a per se analysis is warranted only where the questioned conduct is manifestly anticompetitive;[66] 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.[67]

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."[68] Although the "Act does not expressly prohibit settlements in a patent infringement suit"[69] and the U.S. legal system encourages out-of-court settlement,[70] reverse payment settlements have received substantial antitrust scrutiny in recent years.[71] A prominent antitrust concern is that these settlements

(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 (1990) (holding that per se rule applies to group boycott that restricts supply).

[63] *See Cal. Dental*, 526 U.S. at 779–80.

[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.

[68] H.R. REP. NO. 98-857(I), at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48.

[69] Khatibifar, *supra* note 7, at 1390.

[70] *See* Hovenkamp, *supra* note 8, at 1721.

[71] Press Release, *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*, FTC.GOV (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

continued . . .

operate as horizontal collusive agreements[72] and create monopolies,[73] both of which generally receive scrutiny under U.S. antitrust laws.[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[75] and the enhanced ability of producers to realize returns on their investments, which encourages increased innovation.[76] Thus, reverse payments are one example of conduct that has notable benefits, but can also have clear anticompetitive consequences.[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.[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 *Actavis* extended this reasoning to reverse payment settlements.[79]

Actavis reached the Supreme Court after the United States 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

problem of pay-for-delay is getting worse, not better . . . [m]ore and more brand and generic drug companies are engaging in these sweetheart deals, and consumers continue to pay the price.").

[72] *See* Khatibifar, *supra* note 7, at 1375–76.

[73] *See In re* K-Dur Antitrust Litig., 686 F.3d 197, 216 (3rd Cir. 2012).

[74] Sherman Act, 15 U.S.C. § 1 (2012), prohibits combinations and agreements between firms that restrain competition. Sherman Act, 15 U.S.C. § 2 (2012), prohibits the formation of monopolies and engaging in monopolistic behavior that harms competition.

[75] *See* Hovenkamp, *supra* note 8, at 1723; *see also* 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). *See* discussion *infra* Part III.C.2.

[76] *See* Morse, *supra* note 4, at 367 ("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.").

[77] *See* F.T.C. v. Actavis, Inc., 133 S.Ct. 2223, 2237 (2013).

[78] *See e.g.*, 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 Cont'l T.V., Inc. v. GTE Sylvania, Inc., 433 U.S. 36, 58–59 (1977)).

[79] *See Actavis*, 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.").

fall within the scope of the exclusionary potential of the patent."[80] The Supreme Court's decision resolved a circuit split over the proper antitrust analysis for reverse payments.[81] 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.[82] As the Supreme Court in *Actavis* recognized, while there are multiple considerations that make reverse payment settlements harmful to competition,[83] there are also multiple considerations that indicate that such settlements may be pro-competitive.[84] 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 conduct being challenged.[85] Significantly, the antitrust enforcement agencies see no one factor as dispositive in the overall antitrust analysis.[86]

Henceforth, this Article discusses what factors courts should consider in their analysis, describes why each particular factor is a

[80] *Id.* at 2227 (quoting F.T.C. v. Watson Pharms., 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).

[81] Some courts relied on the "scope of the patent" test. *See supra* note 80. The Sixth Circuit categorized the settlements as per se illegal. *See In re* Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003). The Third Circuit relied on a "quick look" analysis. *See In re* K-Dur Antitrust Litig., 686 F.3d 197 (3d Cir. 2012); *Cf. Tamoxifen*, 466 F.3d 187, 221 (2d Cir. 2006) (Pooler, J., dissenting).

[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).

[85] *See* COLLABORATION GUIDELINES, *supra* note 45.

[86] *See* COLLABORATION GUIDELINES, *supra* note 45, § 3.3, at 10.

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."[87] Market power is the ability of a firm to increase price or decrease output,[88] which is essentially the ability to exclude competition.[89] A firm that has a high degree of market power is considered to have monopoly power.[90] "Without market power, there is no evidence that the reverse-payment settlement could have any adverse effects on consumer welfare."[91] 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,[92] and the federal antitrust enforcement agencies agree.[93] Thus, market power is a preliminary and vital factor.

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; for example, in the pharmaceutical industry, sales occur on a national (or even

[87] *In re* Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 387 (D. Mass. 2013).

[88] *See* BLACK'S LAW DICTIONARY 1116 (10th ed. 2014).

[89] *See* United States v. E. I. Du Pont de Nemours & Co., 351 U.S. 377, 391 (1956).

[90] *See* Richard G. Price, *Market Power and Monopoly Power in Antitrust Analysis*, 75 CORNELL L. REV. 190, 195 (1989).

[91] Butler & Jarosch, *supra* note 13, at 116.

[92] *See* Copperweld Corp. v. Indep. 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 11–12.

[94] *See* Tim McCarthy, *Refining Product Market Definition in the Antitrust Analysis of Bank Mergers*, 46 DUKE L.J. 865, 867 (1997).

[95] *Id.* at 867.

international) scale, and therefore the geographic market is defined broadly to include at least the entire United States.[96]

The key to 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,"[98] an analysis performed by considering the "cross-elasticity of demand for the product."[99] This definition effectively means that if a product does not have any potential substitutes, 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 . . . ."[100]

The market power of a brand-name manufacturer for a particular pharmaceutical drug, either 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 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 supra-competitive market price that generally prevails indicate the presence of market power.[101] 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."[102] 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.[103] "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

[96] Maryan M. Chirayath, Note, *Oh Canada!: Antitrust Geographic Market Definition and the Reimportation of Prescription Drugs*, 46 B.C. L. REV. 1027, 1030 (2005).

[97] United States v. E. I. Du Pont de Nemours & Co., 351 U.S. 377, 396 (1956).

[98] In re Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 387–88 (D. Mass. 2013) (quoting United States v. E. I. Du Pont de Nemours & Co., 351 U.S. 377, 395 (1956)).

[99] *Id.* at 388 (quoting George R. Whitten, Jr., Inc. v. Paddock Pool Builders, Inc., 508 F.2d 547, 552 (1st Cir. 1974)).

[100] *Id.* at 388.

[101] *See id.* at 389.

[102] F.T.C. v. Actavis, Inc., 133 S.Ct. 2223, 2236 (2013).

[103] *See* Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 11 (2004).

insulate consumers from drug costs . . . ."[104] Furthermore, the pharmaceutical industry possesses certain structural characteristics generally associated with the possession and maintenance of market power, such as high barriers to entry.[105] 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.[106]

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,[107] 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 balancing anticompetitive harms and pro-competitive benefits[108]—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

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[104] *Id*.

[105] *See* Mark R. Patterson, *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. *See e.g.*, Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 39 (1984) (stating that where monopoly arrangement creates barriers to entry, the arrangement "remains suspect") (O'Connor, J., concurring), *abrogated by* Ill. Tool Works Inc., v. Indep. Ink, Inc., 547 U.S. 28, 28 (2006) (holding that "mere fact that a tying product is patented does not support a presumption of market power"); *BMI*, 441 U.S. 1, 37 (1979) (stating that in horizontal collusion case "arrangement that produces . . . significant barriers to entry unreasonably restrains trade").

[106] *See* Michael A. Sanzo, *Antitrust Law and Patent Misconduct in the Proprietary Drug Industry*, 39 VILL. L. REV. 1209, 1256 (1994).

[107] *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.") (noting that joint venture that forbid member banks from issuing competing credit cards found illegal); Law v. NCAA, 134 F.3d 1010, 1019 (10th Cir. 1998) ("[T]he plaintiff then must prove that the challenged conduct is not reasonably necessary . . . or that those objectives can be achieved in a substantially less restrictive manner.") (holding that 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.

[108] *See supra* Part II.B.

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."[109] 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.[110]

One generally non-controversial settlement option is for the brand-name manufacturer to enter into a licensing agreement with the generic manufacturer.[111] The ability to negotiate, through sale or license, is one of the privileges associated with the ownership of intellectual property rights.[112] Importantly, "[t]he granting of a non-exclusive license itself almost never harms competition, regardless of the presence or absence of any IP dispute."[113] 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.[114] 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.[115] 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.[116] The use of non-exclusive licenses to resolve patent infringement suits remains viable, so long as the license agreements do not possess

[109] Hogges-Thomas, *supra* note 25, at 1429 (citing a 2010 Federal Trade Commission study).

[110] *See generally* Hovenkamp, *supra* note 8, at 1739–40 (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 these arrangements that are more commonly seen in regard to intellectual property ("IP")-based restraints.

[111] *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).

[112] *See* Ramon A. Klitzke, *Patents and Monopolization: The Role of Patents Under Section Two of the Sherman Act*, 68 MARQ. L. REV. 557, 567 (1985).

[113] Hovenkamp, *supra* note 8, at 1739.

[114] *See id.* at 1739–40.

[115] *See supra* note 4.

[116] *See* Hovenkamp, *supra* note 8, at 1740.

anticompetitive effects of their own, such as improper territorial allocations[117] or price restrictions.[118]

Brand-name and generic manufacturers may also create patent-pooling groups. Patent pooling, "if properly structured, has potentially strong pro-competitive benefits."[119] Patent pooling enables multiple manufacturers to use the patent.[120] 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.[121] 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.[122]

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 alternative is dependent upon whether that alternative "could achieve similar efficiencies" in light of the market context and business realities;[123] 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

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[117] *See id.*; *see also* Klitzke, *supra* note 112, at 570; *cf.* Palmer v. BRG of Ga., Inc., 498 U.S. 46 (1990) (holding that market allocation agreement between competitors at the same level of commerce violated the Sherman Act).

[118] *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 id.*

[119] Daniel Lin, *Research Versus Development: Patent Pooling, Innovation and Standardization in the Software Industry*, 1 J. MARSHALL REV. INTELL. PROP. L. 274, 274 (2002).

[120] *See id.* at 298.

[121] *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 Mfrs.' Ass'n v. United States, 268 U.S. 563 (1925).

[122] *See* Lin, *supra* note 119, at 298–99.

[123] COLLABORATION GUIDELINES, *supra* note 45, at § 3.36(b), at 24.

under a rule of reason to have notable pro-competitive benefits.[124] 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."[125]

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.

1. The Reason Patent Validity Should Be A Factor

The Supreme Court has previously held that "[a]ntitrust analysis must sensitively recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies." [126] According to one authority, "[a] particular regulatory regime sets the boundaries of feasible anticompetitive conduct [and at] the same time, it embodies a specific congressional judgment about the proper balance between competition and innovation in an industry."[127] 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,[128] it seems implicit that whether or not a valid

[124] *See generally supra* Part II.B.

[125] Daniel A. Crane, *Ease over Accuracy in Assessing Patent Settlements*, 87 MINN. L. REV. 698, 708 (2004).

[126] Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 411 (2004) (citing Town of Concord, Mass. v. Boston Edison Co., 915 F.2d 17, 22 (1st.Cir. 1990)); *see also* Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc., 555 U.S. 438 (2009).

[127] C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as A Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1557 (2006).

[128] *See supra* Part II.A.

patent exists and is being infringed upon should be a necessary factor.[129]

Two additional considerations demonstrate the necessity of considering patent validity: the per se anticompetitive nature of the agreement, if there were no IP right involved;[130] and the Hatch-Waxman Act's goal of increasing generic competition.[131] A reverse payment settlement is, in effect, an agreement between two competitors to allocate a market;[132] such horizontal collusive agreements between competitors have been definitively placed into the per se category of antitrust illegality.[133] 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.[134] 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.[135] Under antitrust theory, without this cognizable defense, the manufacturers entering into a reverse payment settlement would have difficulty in justifying their agreement as anything other than anticompetitive, and would become subject to per se condemnation.[136]

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[129] 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, it is not necessary that the consideration of patent validity undergo the same procedure as would exist in traditional infringement litigation. *See infra* Part III.C.2.

[130] *See* Hovenkamp, *supra* note 8, at 1725–28.

[131] *See generally* H.R. REP. NO. 98-857 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647.

[132] *See supra* Part II.A.

[133] *See generally* Palmer v. BRG of Ga., 498 U.S. 46 (1990) (holding that a market allocation agreement between competitors is per se illegal).

[134] *See supra* Part II.B; *BMI*, 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); *see also* COLLABORATION GUIDELINES, *supra* note 45, at § 3.2.

[135] *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.").

[136] 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)

continued . . .

Essentially, it is only the presence of a patent that saves such agreements from per se antitrust condemnation by providing a characterization defense;[137] this threshold function of patents necessitates that the validity of the patent be evaluated.

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.[138] The elimination of invalid patents removes a substantial barrier to entry in the pharmaceutical drug industry; additionally, it increases competition by removing unjustifiable monopolies and opening the door for competition.[139] Since 40% to 50% of challenged patents are held to be invalid,[140] 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.[141] "[P]atent monopolies [should] exist . . . only to the extent that the public is given a novel and useful invention . . . ."[142]

To achieve this end, a consideration of patent validity cannot rest on a blind presumption of validity. Neither *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

(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).

[137] *See* Crane, *supra* note 118, at 753.

[138] Brief of Amici Curiae Representative Henry A. Waxman in Supporting of Petitioner at 3, F.T.C. v. Actavis, Inc., 133 S.Ct. 2223 (2013) (No. 12-416). For an in-depth discussion of the purposes of the Act, see generally H.R. REP. No. 98-857(I) (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647.

[139] *See* Peter Picht, *New Law on Reverse Payment Settlements—The Agenda for Courts and the Legislature After the Supreme Court's* Actavis *Ruling*, 16 TUL. J. TECH. & INTELL. PROP. 105, 122 (2013); MICHAEL CLANCY ET AL., REVERSE-PAYMENT PATENT SETTLEMENTS IN THE PHARMACEUTICAL INDUSTRY: AN ANALYSIS OF US ANTITRUST AND EU COMPETITION LAW 6 (2014), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2345851.

[140] *See* Picht, *supra* note 139, at 119.

[141] *See* Hovenkamp, *supra* note 8, at 1735.

[142] *See Actavis*, 133 S.Ct. at 2232.

the Court could easily have made and which it has expressly made in prior patent lawsuits.[143] Nor did the Court in *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 of literal patent infringement cases, and has been further limited to apply only to decisions on the merits of such cases.[144]

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 *Actavis* decision that antitrust theory predominates over patent policy,[145] 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.[146] 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.[147]

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,"[148] 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."[149] An analysis

[143] *See 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).

[144] *See* Butler & Jarosch, *supra* note 13, at 83–84. As the article discusses, the Federal Circuit has abided by these constraints on the presumption of patent validity. *See* Nutrition 21 v. United States, 930 F.2d 867, 869 (Fed. Cir. 1991) (denying use of the presumption at the preliminary injunction phase); In re Etter, 756 F.2d 852, 858 (Fed. Cir. 1985) (refusing to apply the presumption to a patent reexamination proceeding).

[145] *See Actavis*, 133 S.Ct. at 2234 (holding that the "patent-related factor should not determine the result here [but] [r]ather, five sets of considerations lead [the Court] to conclude that the FTC should have been given the opportunity to prove its antitrust claim").

[146] 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. *See supra* Part II.B.

[147] *See infra* Part III.C.3.

[148] *Actavis*, 133 S.Ct. at 2238.

[149] Crane, *supra* note 125, at 699.

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.[150] 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.[151]

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.[152] Patent litigation also has "[b]road discovery rules [that] require the production of documents and sensitive competitive information for which protective orders fail to provide [an] adequate assurance of confidentiality"[153] 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."[154] The exchange of this sort of information is precisely what antitrust law typically aims to prevent.[155] 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."[156] An extended period of litigation not only results

[150] *See, e.g.*, Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 455–56 (1993); United States v. Socony-Vacuum Oil Co., 310 U.S. 150, 218 (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 1118-21 (5th Cir. 1984).

[151] *See generally* Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on* Hovenkamp, Janis & Lemley, 87 MINN. L. REV. 1789, 1811 (2003).

[152] 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 one and one half years, regardless of the success of the challenge).

[153] Crane, *supra* note 125, at 704.

[154] Crane, *supra* note 118, at 757–58.

[155] *See id.* at 758.

[156] Crane, *supra* note 125, at 706; *see also* Xiang Yu & Anjan Chatterji, *Why Brand Pharmaceutical Companies Choose to Pay Generics in Settling Patent Disputes: A Systematic Evaluation of the Asymmetric Risks in Litigation*, 10 NW. J. TECH & INTELL. PROP. 19, 19 (2011).

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.[157] 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. 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 *Actavis* opinion concluding that it may not be necessary to litigate the patent validity question.[158] 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.

The Supreme Court statement in *Actavis* that an analysis of patent validity may not always be necessary is not 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.[159] 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."[160] 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[161]—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

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[157] *See* Crane, *supra* note 125, 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.").

[158] *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. . . .").

[159] *See id.* at 2236–37.

[160] *Id.* (emphasis added).

[161] *See id.* at 2236.

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.[162] These statements by the Court in *Actavis*, when coupled with other Supreme Court precedent requiring that antitrust analyses reflect the particulars of the industry at issue,[163] show that the Supreme Court in *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.[164] While this is a valid concern that has been substantiated by some studies,[165] 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.[166] The first such period is a thirty-month stay of the generic manufacturer's approval to market its version of the pharmaceutical drug,[167] which is automatically imposed when the generic manufacturer notifies the brand-name manufacturer of its ANDA

[162] *See id.* at 2238.

[163] *See supra* Part III.C.1.

[164] *See* Carrier, *supra* note 12, at 62 ("[One] principle motivating courts is to defer to settlements so as not to harm incentives for innovation.").

[165] *See* Bieri, *supra* note 151, at 141–42; Crane, *supra* note 125, at 704; Crane, *supra* note 118, at 757–58.

[166] *See* Hemphill, *supra* note 127, at 1578. ("Pharmaceutical innovations enjoy longer-lasting protection than innovations in other industries.").

[167] *See* 21 U.S.C. § 355(j)(5)(B)(iii) (2012).

filing [168] and the brand-name manufacturer initiates a patent infringement lawsuit.[169] The thirty-month stay will be curtailed only if a court finds that the patent is either invalid or not infringed.[170]

The Hatch-Waxman Act also provides a second period of quasi-exclusivity if a generic manufacturer has been successful in proving a patent invalid.[171] 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.[172] The Hatch-Waxman Act also contains a new drug exclusivity period, whereby no ANDA can be approved under paragraph IV certification for four 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."[173] 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.[174] 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.[175]

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.[176] 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.[177] Further, while the fact that patent cases are

[168] 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 id*. at § 355(j)(2)(B)(ii)(II) (2012).

[169] *See id.* at § 355(j)(5)(B)(iii).

[170] *See id.* at § 355(j)(5)(B)(iii)(I).

[171] *See id*. at § 355(j)(5)(B)(iv).

[172] *See id.*; *see also* FTC v. Actavis, Inc., 133 S.Ct. 2223, 2229 (2013).

[173] 21 U.S.C. § 355(j)(5)(F)(ii) (2012).

[174] *See id*. at. § 355(j)(5)(B)(iii)(II).

[175] *See supra* Part III.C.2.

[176] *See Actavis*, 133 S. Ct. at 2236–37.

[177] *See* Leegin Creative Leather Prods., 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

continued . . .

complex and difficult cannot be ignored,[178] it should also be recognized that lower courts have demonstrated an ability to handle large and complex cases expeditiously.[179] This is true even for "dynamic" industries, which includes the areas of technology and intellectual property.[180] 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 patent validity case.[181] 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,[182] an option that has been endorsed by the Supreme Court.[183] 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.[184]

The Federal Rules of Civil Procedure[185] provide two additional options for easing administrative burdens—Rule 53 Masters and Rule

U.S. 36, 50 n. 16 (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. *Actavis*, 133 S. Ct. at 2237; *Leegin*, 551 U.S. at 877; *GTE Sylvania*, 433 U.S. at 37. 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.

[178] *See* Morse, *supra* note 4, at 359.

[179] *See* William E. Kovacic, *From* Microsoft *to* Google*: Intellectual Property, High Technology, and the Reorientation of U.S. Competition Policy and Practice*, 23 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 645, 648 (2013).

[180] *See, e.g.*, 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).

[181] *See* John Shepard Wiley, Jr., *Taming Patent: Six Steps for Surviving Scary Patent Cases*, 50 UCLA L. REV. 1413, 1421 (2003).

[182] *See id.* at 1425–26.

[183] *See id.* at 1426 (citing Archer-Daniels-Midland Co. v. Dellwood Farms, Inc., 537 U.S. 1188 (2003) and Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993)).

[184] *See* Wiley, Jr., *supra* note 181, at 1438.

[185] 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

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73 Magistrate Judges. Rule 53 allows a court to appoint a master to "hold trial proceedings and make or recommend findings of fact,"[186] who may utilize "all appropriate measures to perform the assigned duties."[187] 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.[188] Rule 73 authorizes the appointment of a magistrate judge to conduct a proceeding,[189] which could include a patent validity mini-trial in a broader antitrust lawsuit.[190] 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[191]—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.[192]

4. How Patent Validity Affects the Rule of Reason Balancing

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

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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(a)(1)(B).

[187] *Id.* at 53(c)(1)(B).

[188] *See* Wiley, Jr., *supra* note 181, at 1464–65.

[189] FED. R. CIV. P. 73(a).

[190] *See* HISTORY OF THE FEDERAL JUDICIARY: MAGISTRATE JUDGESHIPS, 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* Joshua P. Davis, *Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should Be Per Se Illegal*, 41 RUTGERS L.J. 255, 256 (2009).

[192] *See* Crane, *supra* notes 153–156.

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.

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.[193] It should be recalled that in *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.[194] To conclude after *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 *Actavis*, the theory of the rule of reason analysis generally, and the positive aspects of reverse payments.

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 the 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."[195] 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.[196] 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 "traditional settlement considerations, such as avoided litigation costs."[197] Therefore, looking only at the nominal size of the

[193] *See* COLLABORATION GUIDELINES, *supra* note 49 (indicating that "[n]o one factor is dispositive" in a rule of reason analysis.).

[194] *See* F.T.C. v. Actavis, Inc., 133 S.Ct. 2223, 2230, 2238 (2013).

[195] *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.

[196] *See id.* at 2235–36.

[197] *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.").

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.[198] 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.[199]

1. What the Test Cannot Be

The price test that would prove to be the least burdensome would be one that incorporates a standard from either horizontal collusive agreement cases or from monopoly cases, two types of cases that have features similar to reverse payment cases. However, as is discussed below, 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 do not provide an 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.[200] More fundamentally, the Supreme Court has consistently held in horizontal collusion cases that when two competitors discuss price, there is 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.[201] The use of a test that would treat an

[198] Price tests that avoid the use of numerical thresholds have also been suggested by Daniel A. Crane, *supra* note 118, at 788–91, and by Henry Butler & Jeffrey Paul Jarosch, *supra* note 13, at 299–300; *see also infra* note 236 for a more detailed discussion of Butler & Jarosch's test.

[199] 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.

[200] 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.

[201] *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 . . . . ").

essential factor of the rule of reason test as illegal per se is contrary to the ultimate holding of *Actavis* abrogating an antitrust analysis that would make any single factor determinative.[202]

The prevalent monopoly-pricing standard of recoupment[203] is a closer fit, but it also fails to consider the value of services rendered, as directed by the Supreme Court.[204] 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.[205] 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. Pharmaceutical drug companies are generally sophisticated entities, and are therefore 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.[206]

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[202] *See Actavis*, 133 S.Ct. at 2237.

[203] Recoupment is the second stage of predatory pricing. Christopher R. Leslie, *Predatory Pricing and Recoupment*, 113 COLUM. L. REV. 1695, 1695 (2013) ("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."). 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. *See id*. This standard was adopted for all predatory pricing cases by the Supreme Court in *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 226 (1993).

[204] *See 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 . . . .").

[205] *See supra* note 203.

[206] *See generally* Joint Appendix at 103–16, F.T.C. v. Watson Pharm., Inc., 133 S.Ct. at 787 (2013), *available at* http://www.ftc.gov/system/files/documents/cases/130122watsonappendix2.pdf. (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).

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 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.[207] If the remainder is greater than the services rendered, then the payment is, on balance, principally for the purpose of eliminating completion 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 flexile, 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 service or other benefit is actually being conferred and that it is reasonably priced.[208] At a minimum, "services rendered" includes the "payor's anticipated future litigation costs."[209] The Supreme Court explicitly found in *Actavis* that the anticompetitive effects of the payment depend in part on this factor.[210] Services rendered could also include anything from "promotion and backup manufacturing services"[211] to a licensing fee paid to the generic manufacturer in return for exclusive use of the

[207] 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.

[208] *See* 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); 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."); *see also* NCAA v. Bd. of Regents of the Univ. of Okla., 468 U.S. 85, 113–15 (1984).

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

[210] *See id.*

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

generic's patent.[212] It is important to distinguish services rendered from the pro-competitive justifications discussed in Part III.E.[213]

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."[214] 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.[215] Neither the text of the *Actavis* decision nor the policies that underlie it prohibit reverse payments in excess of the value of services rendered.[216] 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.[217] Rather, the Court left open the possibility of a small or justified payment being found pro-competitive.[218] 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.[219] A black-and-white rule pursuant to which a payment exceeding the amount of services rendered is deemed

[212] Picht, *supra* note 139, at 122. This justification in particular is a prime example of the need for courts to evaluate the legitimacy of the proffered services rendered; such proffered justification may itself implicate antitrust concerns.

[213] 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.

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

[215] *See, e.g.*, Edlin, *supra* note 211, at 18–19 (using the same cautionary terminology, stating that after deducting the value of considerations provided, "the resulting net payment is otherwise unexplained and, if it is a positive quantity, may be understood to be a payment for delaying entry").

[216] *See supra* note 207.

[217] *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.

[218] *See Actavis*, 133 S.Ct. at 2237.

[219] *Id.* at 2237.

to be illegal would be akin to applying a per se rule, which the Supreme Court held do not apply to reverse payments.[220]

Furthermore, the existence of a range of potentially permissible values for exclusivity is necessary in order to prevent the two important legal policies alluded to in *Actavis* from being ignored in their entirety—the encouragement of legal settlements[221] and of the protection of patent rights.[222] Drawing a strict line between pro- and anti-competitive settlements at the point where the price 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."[223]

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.[224] "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)."[225] 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

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[220] *See id.* at 2237–38.

[221] *See id.* at 2237 (noting the "desirability of settlements" but finding that "[antitrust] considerations, taken together, outweigh the single strong [settlement] consideration").

[222] *See id.* at 2232 (finding that there exists a "public interest in granting patent monopolies").

[223] 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) (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").

[224] *See* Yu, *supra* note 156, at ¶ 38 ("[F]alse negatives are extremely costly for pharmaceutical patents, because of huge R&D spending, leading to undesired deterrence of innovation."); *see also id.* at ¶ 2 (explaining that parties having asymmetric risks generally characterize reverse settlements); Hemphill, *supra* note 127, at 1577.

[225] *See* Yu, *supra* note 156, at ¶ 38.

depend on protecting a small number of patents that apply to the majority of the firm's products.[226] "For these companies, the uncertainty of litigation can be untenable—even when the company has no doubt about the validity, scope, and term of its patents."[227] 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."[228]

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.[229] 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.[230] The generic manufacturer also benefits because it receives an earlier entry date than if the patent is found valid, and avoids 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 the 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 notable pro-competitive benefits for consumers

[226] *See* Bieri, *supra* note 152, at 142.

[227] *Id*.

[228] *Id.* at 142–43 (citing a study that finds "across all patent cases, 95% are resolved by settlement").

[229] *See, 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).

[230] *See* Bieri, *supra* note 152, at 142.

and pharmaceutical companies,[231] thus improperly deterring potentially pro-competitive behavior.[232]

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."[233] While bad or invalid patents harm consumers, good or valid patents have notable benefits and thus their protection should be encouraged.[234] Allowing some justifiable payment for exclusivity provides an additional form of protection for good patents.[235] Prominent antitrust scholars have also suggested the viability of a pricing factor that allows for a range of pro-competitive values.[236]

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 described as the presence of a less anticompetitive alternative that achieves similar pro-competitive benefits.[237]

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

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[231] *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 223, at 416 (discussing prominent antitrust scholars who agree that "reverse payment settlement[s] could be beneficial to consumers.").

[232] *See infra* Part III.E for a discussion of the pro-competitive benefits of reverse payment settlements; *see supra* Part III.C.2 for a discussion of the benefits of avoiding prolonged litigation.

[233] Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 ANTITRUST BULL. 491, 525 (2002).

[234] *See Actavis*, 133 S.Ct. at 2232 ("'[T]he public interest in granting patent monopolies' exists only to the extent that 'the public is given a novel and useful invention'" (citing United States v. Singer Mfg. Co., 374 U.S. 174, 199 (1963))).

[235] *See supra* Part III.C.2 (discussing the benefits associated with allowing settlement to protect patents and innovation in more detail).

[236] *See* Butler & Jarosch, *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).

[237] *See supra* Part III.B.

appears as a consideration in numerous antitrust contexts.[238] "Evidence of intent can be highly probative . . . because knowledge of intent may help the court to interpret facts and to predict consequences."[239] 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.[240] Intent becomes most beneficial in close-call cases, where the activity under consideration could easily be either anticompetitive or pro-competitive.[241] Reverse payment settlements are an example of such close-call cases;[242] 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.[243] Intent has also been used to determine the legality of competitor agreements in other intellectual property antitrust contexts.[244]

Intent can be found in direct evidence or may be inferred from conduct.[245] 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.[246] 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

[238] *See supra* note 150 (citing an array of cases where intent was an important consideration).

[239] Graphic Prods. Distribs., 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)).

[240] *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.

[241] *See* Cal. Dental Ass'n v. F.T.C., 224 F.3d 942, 948 (9th Cir. 2000).

[242] *See supra* Part II.C.

[243] *See* Morse, *supra* note 4, at 368.

[244] 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 good-faith agreement to settle a legitimate dispute. *See* Blair, *supra* note 233, at 518–19 (discussing Clorox Co. v. Sterling Winthrop, Inc., 117 F.3d 50 (2d Cir. 1997) (requiring that the agreement be no more anticompetitive than a decision on the merits)).

[245] *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).

[246] *See* Steven R. Beck, *Intent as an Element of Predatory Pricing Under Section 2 of the Sherman Act*, 76 CORNELL L. REV. 1242, 1249 (1991).

issue, but rather only brought suit to attain an additional period of market exclusivity for a patent it knew would be deemed invalid.[247]

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.[248] An evaluation of a pharmaceutical firm's desire to protect its trade secrets may impact this consideration as well.[249] 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 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."[250]

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 serves 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 for a consideration of pro-competitive benefits,[251] which

[247] *See* Picht, *supra* note 139, at 111–12. In order to receive the 30 months of market exclusivity the brand-name manufacturer must initiate an infringement lawsuit against the generic manufacturer.

[248] *See* Picht, *supra* note 139, at 120.

[249] *See* Yu, *supra* note 156, at ¶ 35.

[250] *See* Crane, *supra* note 118, at 757.

[251] Recall that these justifications are distinct from the services rendered, discussed in *supra* Part III.D.2. While pro-competitive justifications are associated

continued . . .

increases consumer welfare.[252] There are numerous benefits that can accrue from reverse payments that could justify their use;[253] however, any claimed pro-competitive justification must be proven by the defendants to be actual and cognizable.[254] 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.[255] Valuable services associated with the existence of guaranteed profits include efficient quality control[256] and higher marketing expenditures, which increase overall consumption.[257] Decreases in brand marketing lead to a loss of "non-price competition benefits," including "continuing professional education and patient awareness for under-diagnosed diseases as well as preventative care."[258] Further, payment in exchange for a generic manufacturer's assistance with continued clinical testing and analysis could be deemed a cognizable justification.[259]

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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.

[252] *See* Jordan A. Dresnick & Thomas A. Tucker Ronzetti, *Vertical Price Agreements in the Wake of* Leegin v. PSKS*: Where Do We Stand Now?*, 64 U. MIAMI L. REV. 229, 246 (2009) (citing Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 551 U.S. 877, 895 (2007) (finding that per se rules diminish pro-competitive conduct)).

[253] *See e.g.*, F.T.C. v. Actavis, Inc., 133 S.Ct. 2223, 2234-37 (2013).

[254] *See supra* note 208 (discussing how courts require pro-competitive justifications be proven cognizable).

[255] *See* Ashley Doty, Leegin v. PSKS: *New Standard, New Challenges*, 23 BERKELEY TECH. L.J. 655, 657–58 (2008) (discussing how guaranteed profits induce retailers to provide customer services).

[256] *See* Dresnick & Ronzetti, *supra* note 252, at 251.

[257] *See* Butler & Jarosch, *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.").

[258] Yu, *supra* note 156, at 32.

[259] *See* Andrew D. Regan & Charles E. Miller, *Hatch-Waxman Litigation Post-*Actavis*: Crafting a Pro-Competitive Settlement Agreement*, LANDSLIDE, Sept.-Oct. 2013, at 52, 53 ("By having the brand name exchange payment for services such as

continued . . .

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.[260] "[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.[261] Guaranteed profit can also help facilitate and incentivize new market entry.[262]

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.[263] 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.[264]

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."[265] Courts should be open to the possibility of other justifications, and evaluate them with attention towards increased 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

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.").

[260] *See* Butler & Jarosch, *supra* note 13, at 90; *see also* Christine A. Varney, *A Post*-Leegin *Approach to Resale Price Maintenance Using a Structured Rule of Reason*, ANTITRUST, Fall 2009, at 22, 23.

[261] Hogges-Thomas, *supra* note 25, at 1442 (internal quotation marks omitted).

[262] *See* Dresnick & Ronzetti, *supra* note 252, at 245.

[263] Butler & Jarosch, *supra* note 13, at 90.

[264] Carrier, *supra* note 12, at 62 (citing Schering-Plough Corp. v. F.T.C., 402 F.3d 1056, 1075 (11th Cir. 2005)).

[265] Edlin, *supra* note 211, at 20.

subject to antitrust scrutiny under a rule of reason analysis.[266] 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?[267] 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.[268]

This Article has laid out a list of key factors for courts to analyze—based on the *Actavis* decision and traditional antitrust theories—and upon which they 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 determination of the competitive effects of any particular reverse payment will ultimately depend on the precise facts of the case.

[266] *See* F.T.C. v. Actavis, Inc., 133 S.Ct. 2223, 2238 (2013).

[267] *See id.*

[268] Robert F. Leibenluft & Lauren Battaglia, *Federal Judge Limits Antitrust Scrutiny of Pharmaceutical Reverse Payments to Settlements Involving Monetary Transfers*, FOCUS ON REGULATION (Feb. 7, 2014), http://ehoganlovells.com/rv/ff0015450afb3b8d830b24c62a4e92e63985aa39 (noting the disparate outcomes in district courts as to what constitutes a "payment" for reverse payment purposes).