

New Law on Reverse Payment Settlements— The Agenda for Courts and the Legislature After the Supreme Court’s *Actavis* Ruling

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I. INTRODUCTION

Antitrust interference with so-called “reverse payment settlements” (RPS) in intellectual property (IP) litigation is presently one of the most prominent issues at the overlap of IP and antitrust law. In spite of many scholarly contributions and a number of Federal Trade Commission (FTC) and court rulings, a clear consensus on the best reconciliatory approach has not yet formed. Circuit courts have split over the issue. Now, after a number of unsuccessful petitions, the United States Supreme Court has finally granted certiorari and recently handed down its eagerly awaited ruling in *Federal Trade Commission v. Actavis, Inc.* Legislature may soon act as well.¹ Two bills are currently in development, both aimed at restricting RPS. Furthermore, not only are RPS an issue in the United States, but the European Commission has also, in a recent pharmaceutical sector inquiry, identified RPS as a core

1. See generally Kendyl Hanks et al., “Pay-for Delay” Settlements: Antitrust Violation or Proper Exercise of Pharmaceutical Patent Rights?, *BUS. L. TODAY*, Jan. 2011, at 1, 4; Timothy A. Cook, Note, *Pharmaceutical Patent Litigation Settlements: Balancing Patent & Antitrust Policy Through Institutional Choice*, 17 *MICH. TELECOMM. & TECH. L. REV.* 417, 441-43 (2011).

concern of European antitrust enforcement.² As a result of this enforcement priority, the Commission recently sanctioned a number of pharmaceutical companies for delaying the market entry of generic drugs.

Against this background, the present Article gives an overview of the current situation and the likely developments in the law on RPS. It analyzes the *Actavis* ruling, explains why the presently proposed bills should not be pursued, and casts a short glance at how European Union law can react to RPS.

Part II describes a typical RPS scenario, the core anticompetitive concern regarding these settlements, and their specific legal environment as created by the Hatch-Waxman Act. Part III gives a very brief overview of the existing scholarly literature and the pre-*Actavis* case law. Parts IV and V present the *Actavis* decision and analyze which questions it answers and which remain. Part VI discusses whether legislative action is needed in reaction to the Supreme Court's ruling, and Part VII casts a comparative glance at the European Union.

II. BACKGROUND ON REVERSE PAYMENT SETTLEMENTS: TYPICAL STRUCTURE, LEGAL FRAMEWORK, AND ECONOMIC THEORY

A. *Typical RPS Structure and the Core Anticompetitive Concern*

So far, RPS have typically occurred in the pharmaceutical sector and in connection with the market entry of a generic drug. When this market entry takes place, the company selling the original drug—the “brand manufacturer” (BM)—sues the company manufacturing and selling the generic drug—the “generic manufacturer” (GM)—for patent infringement. The ensuing litigation is then terminated by a settlement, which obliges the GM to delay its market entry. The date for the GM's market entry is set closer to, but usually before, the expiry of the BM's patent on the drug at issue. In return for the delayed entry, the BM pays the GM a certain compensation. It is due to these characteristics that such settlements have also come to be called “pay for delay” settlements.

Terminating litigation by settlement has, at least intuitively, a positive connotation because it saves resources and achieves speedy

2. For a readable summary of the inquiry results, see *Communication from the Commission: Executive Summary of the Pharmaceutical Sector Inquiry Report*, at 2-24, COM (2009) 351 final (Aug. 7, 2009), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0351:FIN:EN:PDF>.

conflict resolution.³ At first sight, it is therefore surprising that RPS should be under close antitrust scrutiny at all. However, the core reason for this scrutiny is the concern that through the settlement, the BM buys off competitive pressure exercised by the GM.⁴ If the BM's patent is valid and infringed, the BM seems to have no reason to accept early market entry by the GM or to pay the GM in addition to providing the early-market-entry option. If, on the other hand, the BM's patent is invalid or not infringed, the rationale of IP protection cannot justify granting the BM a monopoly position. Instead, the market for the drug at issue should then be entirely open to competition. Hence, if the BM holds an invalid or noninfringed patent yet precludes competition by compensating the GM for temporary inactivity, it engages in conduct that seems to run contrary to the fundamental principles of both antitrust and intellectual property law.

B. Framing Provisions of the Hatch-Waxman Act

Part of the reason why RPS are most conspicuous in the pharmaceutical sector is the particular legal framework that the Hatch-Waxman Act established for that sector.⁵

The typical market process in the pharmaceutical sector has two stages. At first, the BM sells, based on its patent protection, a drug exclusively. After patent expiration, one or several GMs enter the market and sell products that are similar to the BM's drug at a lower price.⁶ One would expect that this price difference secures the GM a market share and profits attractive enough to incentivize vibrant GM activity in the pharmaceutical sector. Yet prior to the Hatch-Waxman Act, GMs were required, when they wanted to submit an application for their generic

3. See Ezra Friedman & Abraham L. Wickelgren, *No Free Lunch: How Settlement Can Reduce the Legal System's Ability To Induce Efficient Behavior*, 61 SMU L. REV. 1355, 1355 (2008).

4. See Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1721 (2003); Cook, *supra* note 1, at 419.

5. See Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1983) (codified in various sections of 15, 21, 28 & 35 U.S.C. (2006 & 2012)); Hovenkamp et al., *supra* note 4, at 1751; Hanks et al., *supra* note 1, at 2.

6. *Paying Off Generics To Prevent Competition with Brand Name Drugs: Should It Be Prohibited?: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. 7 (2007) (statement of Jon Leibowitz, Comm'r, Fed. Trade Comm'n), available at <http://www.gpo.gov/fdsys/pkg/CHRG-110shrg33401/pdf/CHRG-110shrg33401.pdf>. The first generic typically enters the market at 70-80% of the brand name drug's price. As further generic competition builds up, the price can drop to as low as 20%. *Id.* The sharp price difference between one-GM and multiple-GM competition demonstrates that market entry of the first GM, under an RPS with early-entry rights, for example, is not the per se desirable establishment of full competition, but often the establishment of a duopoly that still charges supracompetitive prices.

drug, to undertake and present the same full-blown efficacy and safety testing as the BM had previously presented. In addition, the procedure of proving efficacy and safety for the generic drug could only start after the BM's patent expired because otherwise it would have constituted a violation of the BM's patent.⁷ These conditions made market entry for a generic drug so cumbersome that GM activity was, in actuality, relatively low in the U.S. market.⁸ The Hatch-Waxman Act set out to invigorate GM competition by introducing three major changes to the legal framework.⁹

The first change was to allow GMs to start research and development for their drugs before expiry of the BM's patent without having to face patent infringement claims.¹⁰ Second, GMs can now refer to the BM's efficacy and safety data in their Food and Drug Administration (FDA) applications for a generic drug.¹¹ They still have to demonstrate bioequivalence, sound manufacturing procedures, and shelf stability,¹² but the huge burden of reproducing the BM's studies is gone.¹³ The third major improvement for a GM consists in the so-called

7. Erica N. Andersen, Schering *the Market: Analyzing the Debate over Reverse-Payment Settlements in the Wake of the Medicare Modernization Act of 2003* and In re Tamoxifen Citrate Litigation, 93 IOWA L. REV. 1015, 1019 (2008); 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, 379 (2007).

8. Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 607 (2003) (citing, inter alia, FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, at i (2002), available at http://www.ftc.gov/os/2002/07/generic_drugstudy.pdf). According to this study, the Hatch-Waxman Act has promoted growth of the generic drug market from 19% of the total pharmaceutical market in 1984 to more than 47% today. *Id.*

9. On further changes brought about by Hatch-Waxman, for example, the very important extension of the effective lifetime of pharmaceutical patents, see generally James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 CATH. U. L. REV. 433 (1986); Weiswasser & Danzis, *supra* note 8.

10. 35 U.S.C. § 271(e)(1) (2006). For more detail on this "safe harbor" provision, see Richard D. Chaves Mosier & Steven W. Ritcheson, In re Cardizem *and* Valley Drug: *A View from the Faultline Between Patent and Antitrust in Pharmaceutical Settlements*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 497, 500 (2004); Backus, *supra* note 7, at 381.

11. See 21 U.S.C. § 355 (2012). For more detail on this aspect, see Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 245, 262 (2012) (stating, on the basis of empirical studies, that "in stark contrast to the overall development cost of bringing an NDA on a new drug through FDA approval, the cost of preparing and filing an ANDA is only about \$1 million"); see also David Reiffen & Michael R. Ward, *"Branded Generics" as a Strategy To Limit Cannibalization of Pharmaceutical Markets*, 28 MANAGERIAL & DECISION ECON. 7, 251 (2007).

12. Reiffen & Ward, *supra* note 11, at 251.

13. Alan Devlin & Michael Jacobs, *Anticompetitive Innovation and the Quality of Invention*, 27 BERKELEY TECH. L.J. 1, 43-45 (2012) (discussing potentially anticompetitive "product hopping" strategies used by BMs to avoid reliance on their data).

Abbreviated New Drug Application (ANDA) IV procedure.¹⁴ Under ANDA-IV, a GM can certify that the BM's relevant patent is invalid or not infringed by the generic drug.¹⁵ The BM, to which the GM must give notice on the ANDA-IV certification,¹⁶ can then file a patent infringement suit. If it does so within a certain period of time, the FDA grants a thirty-month stay of the approval procedure for the generic drug.¹⁷ So far, ANDA-IV appears not to be very advantageous for the GM, but two elements of the procedure change this assessment. Firstly, the GM's claim of invalidity or noninfringement and the ensuing patent infringement litigation all take place before the generic drug is approved and marketed.¹⁸ The GM does, therefore, not run the risk of incurring the heavy costs of market entry first and then learning later that the drug infringes a valid patent.¹⁹ And secondly, the Hatch-Waxman Act provides a 180-day period of generic market exclusivity for the first generic manufacturer that certifies under ANDA-IV.²⁰ During these 180 days, the FDA will approve no other generic drug, and the first ANDA-IV user can establish a substantial market share.²¹

14. Backus, *supra* note 7, at 381-84.

15. Because BMs are obliged to list the patents related to their drugs in the so-called Orange Book, the GM can take easy notice of the relevant patent(s). See Mosier & Ritcheson, *supra* note 10, at 500; Natalie M. Derzko, *The Impact of Recent Reforms of the Hatch-Waxman Scheme on Orange Book Strategic Behavior and Pharmaceutical Innovation*, 45 IDEA 165 (2005); 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

16. See Andersen, *supra* note 7, at 1020.

17. To learn how the Hatch-Waxman Act barred the manipulative use of this instrument by BMs to create thirty-month stays until a modification, see Derzko, *supra* note 15, at 167-68, 235. See also Rudolf J. R. Peritz, "Reverse Payments" from Branded to Generic Drug Makers in the U.S.—Why They Are Legal, Why They Should Not Be, and What Is to Be Done, 40 INT'L REV. INTELL. PROP. & COMPETITION L. 499, 501 (2009) (favoring a complete elimination of the thirty-month stay).

18. This is why infringement suits under ANDA-IV have, rightly, been called "artificial"; because the generic drug is not on the market yet, no infringement has actually happened. Morris, *supra* note 11, at 271.

19. Laura J. Robinson, *Analysis of Recent Proposals To Reconfigure Hatch-Waxman*, 11 J. INTELL. PROP. L. 47, 78 (2003).

20. Under the original version of ANDA-IV, the GM could obtain patent protection but remain passive for a long time, thereby extending the protection far beyond the intended 180 days; this option was removed by an amendment of the Hatch-Waxman Act, which established forfeiture rules for the 180-day protection period, including limitations on the time period for which a GM can remain passive without losing exclusivity. See Andersen, *supra* note 7, at 1021-25.

21. 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2012). This stay is "the big prize that generic manufacturers fight over." Colman B. Ragan, *Saving the Lives of Drugs: Why Procedural Amendments in Hatch-Waxman Litigation and Certification of Markman Hearings for Interlocutory Appeal Will Help Lower Drug Prices*, 13 FED. CIR. B.J. 411, 413 (2004).

Hatch-Waxman proved successful in fueling competition on the generics markets,²² but it also created an environment that can induce²³ anticompetitive RPS.²⁴

C. RPS Incentives Created by the Hatch-Waxman Act

Coherent with the empirical data on RPS activity in the pharmaceutical sector,²⁵ Hatch-Waxman conditions substantially increase the incentive and, accordingly, the likelihood of settlements that include a reverse payment. As total producer profit in a monopoly exceeds total producer profit in a duopoly, the BM has more to lose than the GM has to gain. The result is an incentive for both to create a win-win situation by splitting the difference.²⁶ This incentive is particularly strong under Hatch-Waxman because the infringement litigation takes place *before* the GM starts to enter the market. It is therefore of higher value to the BM to keep the GM entirely from making market-entry efforts. And, importantly, the GM has not yet incurred market-entry costs, which increases the net value of a payment made by the BM under the settlement.²⁷ Furthermore, the chance to receive the thirty-month stay almost necessitates that the BM sue for infringement, starting litigation that in turn creates settlement potential. In fact, the thirty-month stay is

22. See Weiswasser & Danzis, *supra* note 8, at 607; Morris, *supra* note 11, at 265-66 (pointing to other possible causes for stronger generics penetration of pharmaceutical markets, namely that the generic market increased from 19% to over 47% of the overall pharmaceutical market and that while in 1984 only 36% percent of the most frequently prescribed drugs with expired patents had a generic equivalent, now virtually all of these drugs have a generic competitor).

23. Not least the E.U. experience shows, however, that Hatch-Waxman conditions cannot be the exclusive reason for RPS. See *infra* Part VII.

24. Thomas F. Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship*, 71 ANTITRUST L.J. 1069, 1078 (2004). For an overview on the reforms, on the duty to notify the FTC when settlement occurs, and on attempts to push back RPS, see Derzko, *supra* note 15.

25. For empirical data on the settlements filed with and reported by the FTC, see BUREAU OF COMPETITION, FED. TRADE COMM'N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003 (2003), available at <http://www.ftc.gov/os/2011/10/1110mmaagree.pdf>. According to this report, the number of reported final settlements in the past years increased steadily from 14 (2004), 11 (2005), 28 (2006), 33 (2007), 66 (2008), 68 (2009), and 113 (2010) to 156 (2011). *Id.* at 2.

26. See Cotter, *supra* note 24, at 1075.

27. 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, 20 (2011); Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives*, ANTITRUST, Spring 2003, at 68, 69-70.

so attractive for a BM facing an ANDA-IV filing that the attempt to obtain the stay will trigger litigation even if the BM's patent is relatively weak.²⁸ A final important Hatch-Waxman factor is the 180-day exclusivity period. This period starts, absent forfeiture,²⁹ with market entry and not with the settlement. Therefore, the GM must *not* enter the market as early as possible, in order to acquire and maintain a first-mover advantage over other GMs. A delayed market entry under the settlement is, in consequence, more acceptable to the GM.

III. PREVIOUS TREATMENT OF RPS: FTC, COURTS, AND ACADEMIC DISCUSSION

RPS became a focus of antitrust enforcement and debate when the FTC started to investigate the subject in the late 1990s.³⁰ In the following years, a number of consent decrees were signed by parties to allegedly anticompetitive settlements.³¹ Overall, the FTC's position came at least close to holding RPS per se illegal.³² This led to a drop in the number of (known) settlements.³³ Soon, courts started to hand down their first rulings on RPS. Initially, the courts adopted the very critical view of the FTC and held that RPS were per se antitrust violations.³⁴ Subsequently, however, other courts moved toward a position that is more nuanced and, in general, RPS-friendlier.³⁵ The United States Court of Appeals for the Eleventh Circuit's *Schering-Plough Corp. v. Federal Trade Commission* ruling,³⁶ in particular, developed a three-factor test for RPS, which amounts not quite, but almost, to a per se legality approach. According to this test, antitrust analysis requires an examination of (1) the scope of the exclusionary potential of the patent, (2) the extent to which the

28. See Backus, *supra* note 7, at 387; see Cotter, *supra* note 24, at 1078-79.

29. See Andersen, *supra* note 7, at 1023-25 (discussing forfeiture of the 180-day period).

30. Cook, *supra* note 1, at 437.

31. See *id.* at 437.

32. Backus, *supra* note 7, at 387.

33. See BUREAU OF COMPETITION, *supra* note 25, at 4; Backus, *supra* note 7, at 393.

34. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 907-09 (6th Cir. 2003). On *In re Cardizem*, see Mosier & Ritcheson, *supra* note 10, at 501-06.

35. The "scope of the patent" approach was the position of the United States Courts of Appeals for the Second, Eleventh, and Federal Circuits and, with apparently only the United States Court of Appeals for the Sixth Circuit following a stricter approach, the majority view among the circuits. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 206; *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1341 (Fed. Cir. 2008); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1064 (11th Cir. 2005); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1309 (11th Cir. 2003); *Ark. Carpenters Health & Welfare Fund v. Bayer, AG*, 604 F.3d 98, 105-06 (2d Cir. 2010). For further information on *Valley Drug*, see Mosier & Ritcheson, *supra* note 10, at 506-10.

36. *Schering-Plough Corp.*, 402 F.3d at 1066.

agreements exceed that scope, and (3) the resulting anticompetitive effects. Because RPS usually remain within the scope of the BM's patent, mainly because they do not extend market exclusivity for the BM beyond the patent term, they are safe under the *Schering* test. Up until the Supreme Court granted certiorari in *Actavis*, RPS-critical and RPS-friendly circuit courts remained split.

Not only is the scholarly literature on RPS very voluminous, but it also reflects a wide array of approaches. At this point, it is sufficient to group the contributions roughly based on how lenient they are toward RPS. At the two extremes are those that tend toward per se legality³⁷ or per se illegality.³⁸ A very fact-sensitive approach proposes a full-blown rule of reason.³⁹ Arguably the majority of scholars follow a two-prong approach. On the one hand, they look at the relation between the reverse payment and the expected litigation costs.⁴⁰ If the payment does not exceed litigation costs, it usually constitutes no antitrust violation. If the payment is substantially above litigation costs, some scholars favor per se illegality of the payment,⁴¹ while others merely presume illegality⁴² or

37. Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 FED. CIR. B.J. 617, 632 (2005) (proposing to allow settlements “unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it”); Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 585 (2007); Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1055-57 (2004).

38. Cristofer Leffler & Keith Leffler, *Settling the Controversy over Patent Settlements: Payments by the Patent Holder Should Be Per Se Illegal*, 21 RES. L. & ECON. 475, 479-81 (2004); see also Sheila Kadura, *Is an Absolute Ban on Reverse Payments the Appropriate Way To Prevent Anticompetitive Agreements Between Branded—and Generic—Pharmaceutical Companies?*, 86 TEX. L. REV. 647 (2008).

39. See Yu & Chatterji, *supra* note 27; Linda Gratz, *Economic Analysis of Pay-for-Delay Settlements and Their Legal Ruling* 23 (2012) (unpublished manuscript) (on file with the Munich Graduate School of Economics), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1979699; see also Yuki Onoe, Comment, *“Pay-for-Delay” Settlements in Pharmaceutical Litigation: Drawing a Fine Line Between Patent Zone and Antitrust Zone*, 9 J. MARSHALL REV. INTEL. PROP. L. 528, 549-51 (2010).

40. For high relevance of that factor, see, e.g., Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 25 (2004); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1596; Hovenkamp et al., *supra* note 4, at 1759; Maureen A. O'Rourke & Joseph F. Brodley, Commentary, *An Incentives Approach to Patent Settlements: A Commentary on Hovenkamp, Janis & Lemley*, 87 MINN. L. REV. 1767, 1782 (2003); Carl Shapiro, *Antitrust Analysis of Patent Settlement Between Rivals*, ANTITRUST, Summer 2003, at 70, 76.

41. See Mosier & Ritcheson, *supra* note 10, at 511; O'Rourke & Brodley, *supra* note 40, at 1786; Derzko, *supra* note 15, at 243.

42. Hovenkamp et al., *supra* note 4, at 1759; Andersen, *supra* note 7, at 1028 (explaining that illegality is presumed if the reverse payment is greater than what the generic would have

even propose presumptive legality.⁴³ On the other hand, this last group of scholars requires—with variations as to the exact standard—a sufficient likelihood that the BM would prevail in the infringement litigation.⁴⁴

IV. THE *ACTAVIS* RULING

A. *Facts and Proceedings*

1. Facts

Between 1999 and 2003, Solvay Pharmaceuticals obtained FDA approval for and a patent on its drug AndroGel. First, Actavis, Inc., (then named Watson Pharmaceuticals) and later Paddock Laboratories filed ANDAs under chapter IV of the Hatch-Waxman Act. The ANDA applicants certified that Solvay's listed patent was invalid and their drugs did not infringe it. Solvay initiated patent litigation under Hatch-Waxman chapter IV against Actavis and Paddock. Thirty months later, the FDA approved Actavis's first-to-file generic product, but in 2006, the parties settled. Under the terms of the settlement, Actavis and Paddock/Par Pharmaceutical agreed that they would not bring their generics to market until August 31, 2015, sixty-five months before Solvay's patent expired. In return, Solvay agreed to pay large sums of money: \$12 million in total to Paddock, \$60 million in total to Par, and an estimated \$19–\$30 million annually, for nine years, to Actavis. The companies described these payments as compensation for other services the generics promised to perform.⁴⁵

2. Proceedings

In 2009, the FTC filed suit against the settling parties, alleging that they violated section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. In particular, the agency contended that the “other services” had little value and that the payments were really meant to compensate the

gained through entering the market, while presumptive legality usually applies when the payment is between market-entry gains and litigation cost); see Hemphill, *supra* note 40, at 1561.

43. Daniel A. Crane, *Ease over Accuracy in Assessing Patent Settlements: A Response to Herbert Hovenkamp, Mark Janis, and Mark A. Lemley*, 88 MINN. L. REV. 698, 709 (2004); see Schildkraut, *supra* note 37, at 1055-57 (arguing in favor of presumptive legality, but finally opting for *per se* legality because of the difficulties of carrying out in-depth analysis).

44. *E.g.*, Hovenkamp et al., *supra* note 4, at 1759; Crane, *supra* note 43, at 709 (calling, however, for a very reduced standard of review); 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, 1802-04 (2003).

45. *In re Androgel Antitrust Litig.* (No. II), 687 F. Supp. 2d 1371, 1373-76 (N.D. Ga. 2010).

generics for their agreement not to compete. The United States District Court for the Northern District of Georgia dismissed the FTC's complaint.⁴⁶ The Eleventh Circuit affirmed, "Absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent."⁴⁷ The Supreme Court reversed the Eleventh Circuit's holding and remanded for further proceedings consistent with its opinion. Chief Justice Roberts filed a dissenting opinion in which Justices Scalia and Thomas joined.⁴⁸

B. Holdings

Justice Breyer's opinion for the majority starts by rejecting the circuit court's position that the mere existence of a patent shields RPS from antitrust scrutiny as long as the settlement does not exceed the patent's scope:⁴⁹

For one thing, to refer, as the Circuit referred, simply to what the holder of a valid patent could do does not by itself answer the antitrust question. . . . But an *invalidated* patent carries with it no such right. And even a valid patent confers no right to exclude products or processes that do not actually infringe. . . . [T]here is reason for concern that settlements taking this form tend to have significant adverse effects on competition. . . . And indeed, contrary to the Circuit's view that the only pertinent question is whether "the settlement agreement . . . fall[s] within" the legitimate "scope" of the patent's "exclusionary potential," this Court has indicated that patent and antitrust policies are both relevant in determining the "scope of the patent monopoly"—and consequently antitrust law immunity—that is conferred by a patent. . . . In short, rather than measure the length or amount of a restriction solely against the length of the patent's term or its earning potential, as the Court of Appeals apparently did here, this Court answered the antitrust question by considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents.⁵⁰

In response to the dissenting opinion's contention that the majority's approach is novel, the majority cites cases to show that the Court had previously held patent-related settlements to violate antitrust laws, and it states that the "procompetitive thrust" of the Hatch-Waxman Act runs

46. *Id.* at 1379.

47. *FTC v. Watson Pharms., Inc.*, 677 F.3d, 1298, 1312 (11th Cir. 2012).

48. *FTC v. Actavis*, 133 S. Ct. 2223, 2238 (2013).

49. *Id.* at 2230-31.

50. *Id.* at 2231.

contrary to the Eleventh Circuit's view.⁵¹ In its core section, the holding then sets out the five considerations that justify antitrust intervention in spite of the general value of settlements:

The Eleventh Circuit's conclusion finds some degree of support in a general legal policy favoring the settlement of disputes We recognize the value of settlements and the patent litigation problem. But we nonetheless conclude that this patent-related factor should not determine the result here. Rather, five sets of considerations lead us to conclude that the FTC should have been given the opportunity to prove its antitrust claim.

First, the specific restraint at issue has the "potential for genuine adverse effects on competition." The payment in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product We concede that settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition, again to the consumer's benefit. But settlement on the terms said by the FTC to be at issue here—payment in return for staying out of the market—simply keeps prices at patentee-set levels, potentially producing the full patent-related \$500 million monopoly return while dividing that return between the challenged patentee and the patent challenger. The patentee and the challenger gain; the consumer loses.

[The Court then goes on to explain why the Hatch-Waxman framework may prevent other generic manufacturers from attacking the patent, although the reverse payment indicates its weakness.]

Second, these anticompetitive consequences will at least sometimes prove unjustified. As the FTC admits, offsetting or redeeming virtues are sometimes present. The reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement. That payment may reflect compensation for other services that the generic has promised to perform There may be other justifications An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby . . . showing the lawfulness of that term under the rule of reason.

Third, where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice. At least, the "size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power"—namely, the power to charge prices higher than the competitive level

Fourth, an antitrust action is likely to prove more feasible administratively than the Eleventh Circuit believed. The Circuit's holding

51. See *id.* at 2230-35.

does avoid the need to litigate the patent's validity (and also, any question of infringement). But . . . there is no need to take that drastic step. That is because it is normally not necessary to litigate patent validity [in order] to answer the antitrust question (unless, perhaps, to determine whether the patent litigation is a sham). An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm

Fifth, the fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit. They may . . . settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration

. . . In our view, these considerations, taken together, outweigh the single strong consideration—the desirability of settlements—that led the Eleventh Circuit to provide near-automatic antitrust immunity to reverse payment settlements.⁵²

In its final part, the holding turns to the appropriate standard of judicial review:

The FTC urges us to hold that reverse payment settlement agreements are presumptively unlawful and that courts reviewing such agreements should proceed via a “quick look” approach, rather than applying a “rule of reason.” . . . We decline to do so. In *California Dental*, we held (unanimously) that abandonment of the “rule of reason” in favor of presumptive rules (or a “quick-look” approach) is appropriate only where “an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets.”

That is because the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification. . . . These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases.

To say this is not to require the courts to insist, contrary to what we have said, that the Commission need litigate the patent's validity,

52. *Id.* at 2234-37 (citations omitted).

empirically demonstrate the virtues or vices of the patent system, present every possible supporting fact or refute every possible pro-defense theory “[T]here is always something of a sliding scale in appraising reasonableness,” and as such “the quality of proof required should vary with the circumstances.”

. . . [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.⁵³

C. *Dissenting Opinion*

In his dissenting opinion, Chief Justice Roberts (joined by Justices Scalia and Thomas) contends that the majority’s approach is novel and without support in statute or previous holdings of the Court.⁵⁴ This approach would subject even valid patents to antitrust scrutiny, despite it being the very essence of a patent to carve out an exception to the applicability of antitrust laws. It is, according to the dissenting opinion, flawed to consider a settlement a violation of antitrust laws merely because the parties were uncertain about patent validity or because the settlement took away some chance that the patent would be declared invalid.⁵⁵

Indeed, the majority’s rule discourages settlements and possibly even patent litigation by generics in the first place. The hope of being able to rule on a settlement without litigating patent validity is futile because the settlement parties will claim patent validity as a defense. The antitrust rule of reason is ill-suited to judge the proper tradeoff between competition and the incentive to innovate in the long run, i.e., the patent law issues at stake here. Settlements within the scope of the patent should therefore remain free from antitrust scrutiny.

V. ANSWERED AND OPEN QUESTIONS AFTER *ACTAVIS*

A. *End of the “Scope of the Patent” Approach*

The *Actavis* ruling defeated the “scope of the patent” approach hitherto applied by the majority of circuit courts. This is good news. “Scope of the patent” effectively amounts to no antitrust scrutiny of RPS

53. *Id.* at 2237-38 (citations omitted).

54. *Id.* at 2238 (Roberts, J., dissenting).

55. *Id.* at 2239.

at all. Because the courts do not, under this approach, investigate patent infringement at all, it is sufficient for the settlement parties to claim that the GM's drug infringes the BM's patent. The settlement lies then within the scope of the patent in this regard. And because the courts do not investigate patent validity, it is sufficient not to prohibit market entry by the GM for a period that is longer than the remaining patent term. If the settlement manages to meet these two very low thresholds, it is within the scope of the patent and hence immune from antitrust scrutiny.

This limited extent of antitrust restraint could only be justified if patent law made sure that granted patents are indeed valid and that infringement suits can be brought only in cases of real infringement. The latter is evidently not the case, however, and many granted patents fare poorly if their validity is contested. In fact, case-law-based estimates tell us that 40-50% of attacked patents are held invalid.⁵⁶ In consequence, because the existence of a patent and RPS do not reliably detect validity and infringement, antitrust scrutiny remains necessary even if the RPS remains within the scope of the patent.

B. Relevant Factors Under the New Test

1. Relevant Factors

The exact shape of the Supreme Court's new approach is much less clear. The Court broadens the antitrust review, and additional elements besides the patent scope are taken into consideration. Calling the result a "rule of reason" approach, the Court hurries to emphasize that the review can be limited to the most relevant factors. Determining these factors is a core follow-up issue after *Actavis*.

a. Existence of an RPS and Atypical Forms of Compensation

The first factor to be considered is, of course, whether the parties have concluded an RPS at all. As said, this means that the parties have concluded a settlement under which the GM delays its market entry and receives some kind of value transfer that constitutes the "reverse payment." In practice, it can be difficult to determine the existence and size of a reverse payment. Two reasons stand out. Firstly, the parties may hide (parts of) the reverse payment, for example by splitting up the RPS into one part that terminates litigation and early market entry, and

56. Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 U. PA. L. REV. 761, 766-71 (2002).

another—potentially secret—part that establishes the payment.⁵⁷ These constellations show that antitrust interference with RPS should not be limited to settlements that stipulate the payment openly together with other parts of the settlement.⁵⁸

Secondly, value transfers in a noncash form can make it harder to determine the existence, extent, and anticompetitive nature of a reverse payment.⁵⁹ For instance, a partial waiver of damages for patent infringement by the patent holder constitutes a transfer of value. Yet such a waiver is not a “payment” that the BM makes to the GM because of the weakness of its patent claim. It is a reduction in the payment that the GM makes to the BM because of the *strength* of the BM’s patent. A damages reduction can therefore not serve as a good indicator of anticompetitive conduct.⁶⁰ Whether the grant of a license by the BM on the patent at stake—another potential form of noncash value transfer—constitutes a “payment” depends on the licensing conditions. The license can amount to a payment, particularly if the license fees are, considering the likely revenues from the license, anomalously low. The license is, in this case, nothing but a more limited early-entry right combined with a payment. Licensing schemes should therefore not be uncritically accepted as the “good,” procompetitive form of BM-GM settlement.⁶¹ The right of early market entry is also in itself an atypical value transfer. Market presence has a dollar value for the GM, and the earlier its market entry happens, the higher that value will be.⁶² Therefore, the time of

57. See Hovenkamp et al., *supra* note 4, at 1762-63.

58. It is therefore problematic when section 28(b)(3) of the Kohl-Leahy proposal refers to the “consideration received by the ANDA filer *in the agreement*” (emphasis added). Settlement parties may use this language to claim that termination of litigation and payment must be integrated into one single contract. *Id.*

59. For various forms of non-cash value transfers, see Cook, *supra* note 1, at 428-30; C. Scott Hemphill, Drug Patent Settlements Between Rivals: A Survey (Mar. 12, 2007) (unpublished paper), <http://ssrn.com/abstract=969492>.

60. See Schildkraut, *supra* note 37, at 1067.

61. Furthermore, a licensing scheme may help to create a stable duopoly by deterring other GMs. For an overly positive view on licensing, see Hovenkamp et al., *supra* note 4, at 1735, 1739-40 (“The granting of a non-exclusive license itself almost never harms competition, regardless of the presence or absence of any IP dispute [T]he non-exclusive license itself adds at least one new producer to the market.”). On licenses as a potentially anticompetitive value transfer, see also Cook, *supra* note 1, at 428-30.

62. It would not be correct to say that the time of market entry does not substantially alter the GM’s profits from its drug because, in the case of later entry, the same profits are reaped, just at a later period in time. Drugs have a certain life cycle before they are (partially) replaced by new products. Furthermore, the number of generic competitors tendentially increases over time as more GMs develop their own generic product. Because of these factors, it may well be that a delayed market entry results in a partial loss of profits. Therefore, early market entry often really is of dollar value to the GM.

market entry in relation to the remaining patent protection period does tell something about the extent of value that the GM receives under the settlement.

The reason why most of the scholarly literature treats early-entry rights more favorably than other value transfers lies in the procompetitive potential of these rights.⁶³ Market entry yields profits for the GM, but it also puts competitive pressure upon the BM and potentially lowers consumer prices. Nonetheless, early-entry rights do not guarantee an optimal level of competition.⁶⁴ A settlement that includes early entry brings about duopoly competition while terminating litigation that could have established invalidity or noninfringement of the BM's patent and induced market entry by multiple generic drugs.⁶⁵ In a way, a BM holding an invalid or noninfringed patent buys, by granting the early-entry right, softer instead of fiercer competitive pressure. This investment may generate lasting benefits to both the BM and the GM; the risk and cost of new infringement litigation, combined with the knowledge that the 180-day exclusivity period provides a substantial first-mover advantage to the settling GM,⁶⁶ may well deter other GMs from market entry altogether.⁶⁷

b. Size and Motivation of the Reverse Payment

Both a major factor and a major difficulty in the assessment of an RPS is the motivation for the payment. The BM and GM may transfer value for many reasons, sometimes even on an ongoing basis. Antitrust scrutiny, of course, only takes into account those transfers that are actually caused by the RPS.⁶⁸ It is necessary to differentiate even further

63. See Hovenkamp et al., *supra* note 4, at 1762; Timothy A. Weil, *Devising a Legislative Solution to the Reverse Payment Dilemma: How Congress Can Balance Competition, Innovation, and the Public Policy Favoring the Settlement of Disputes Without Litigation*, 55 ST. LOUIS U.L.J. 741, 762-65 (2011).

64. See Hovenkamp et al., *supra* note 4, at 1762-65; Weil, *supra* note 63, at 762-65.

65. See Morris, *supra* note 11, at 272; Hemphill, *supra* note 40, at 1579-83.

66. Even under the reformed Hatch-Waxman Act, the 180-day period does not necessarily start on the date of the settlement, and the GM may enjoy full 180-day exclusivity from its market entry onwards. Some authors argue that even forfeiture of the 180-day exclusivity can be a method of discouraging further GMs from entering the market because they themselves can no longer profit from the exclusivity period. See Andersen, *supra* note 7, at 1021-25 (explaining especially the FTC's view); Cook, *supra* note 1, at 428-30; Hemphill, *supra* note 40, at 1583-86.

67. See Hemphill, *supra* note 40, at 1586; Backus, *supra* note 7, at 406; FTC v. Actavis, Inc., 133 S. Ct. 2223, 2225 (2013).

68. On anticompetitive clauses that do not (directly) concern the patent at issue, such as price, output, or market division provisions outside the scope of the patent, see Hovenkamp et al.,

among the RPS-caused transfers: a very broad consensus has formed that reverse payments are acceptable as long as they only compensate for litigation costs. The Supreme Court has now adopted this position. Indeed, allowing this compensation can incentivize GMs to take the risk to attack BM patents. And this in turn can generate procompetitive effects by removing patent monopoly rights that are unjustified because the patent turns out to be invalid.

In addition to litigation cost compensation, the payment may be explained by other reasons that do not cause anticompetitive concern. The Supreme Court sounds this theme when referring to “other services” that may justify the payment. Other grounds for the payment may exist as well, such as an obligation of the BM to pay license fees for the GM’s patents. In any case, the burden to prove that a particular value transfer is *not* caused by an RPS must be on the parties.

2. Typically Unsuitable Factors

a. Cash Situation of the Parties

It has been argued that RPS may, in some cases, not reflect weakness of the BM’s patent, but instead the difficulties of a party in paying potential litigation costs,⁶⁹ doubts about the GM’s ability to pay eventual damages,⁷⁰ or simply the GM’s urgent need for cash.⁷¹ This may be true, and it may suggest taking the cash situation into consideration. However, lack of cash may push the GM towards a settlement although its chances of winning the infringement suit are good. The cash situation can therefore hardly be a reliable indicator of whether a particular RPS is anticompetitive.

b. Net Consumer Surplus

Some contend that RPS should, in principle, be lawful only when they leave consumers with as much surplus as they would have enjoyed

supra note 4, at 1726, 1763-65. Although these clauses are not directly relevant to the assessment of the RPS, they may shed doubt on the RPS’ general compliance with antitrust law.

69. *See* Cotter, *supra* note 24, at 1082.

70. *See id.*

71. John P. Bigelow & Robert D. Willig, “Reverse Payments” in *Settlements of Patent Litigation: Schering-Plough, K-Dur, and the FTC (2005)*, in *THE ANTITRUST REVOLUTION: ECONOMICS, COMPETITION, AND POLICY* 248, 257 (John E. Kwoka, Jr., & Lawrence J. White eds., 2009).

absent the settlement.⁷² In theory, under a consumer welfare antitrust standard, this approach does have its merits. However, net consumer surplus is difficult to measure. This is particularly true for pharmaceutical markets because they are typically “innovation markets” in which dynamic efficiency must be a major goal.⁷³ Long-run consumer benefits from strong patent-based innovation incentives may be at least as important as short-run benefits from lower prices. These long-run innovation benefits are so difficult to quantify that, in most cases, it will not be possible to calculate net consumer surplus and make it a relevant factor in the assessment of a particular RPS.

c. Settlement on Less Restrictive Terms

One may discuss the unlawfulness of an RPS if the parties could have reached a settlement that would have restricted competition less (e.g., earlier entry of the GM or immediate licensing). Importantly, though, the potential for a less restrictive settlement cannot be judged in hindsight, depending on the subjective view of a court or agency. If at all, it must be asked whether the parties knowingly abstained from a less restrictive settlement that they could have agreed upon. Because this is hard to determine, a less restrictive settlement criterion will be relevant only in exceptional cases.

d. Risk Aversion, Information Asymmetries, and Bargaining Strength

In the economic models on RPS, subjective characteristics of the settling parties play a prominent role. The risk aversion of a party, its bargaining strength, and the information it possesses shape the party’s reaction to a given situation. In particular, these factors may induce an RPS even when the BM’s position is objectively very strong. Subjective factors can therefore raise doubts about the indicative relation between reverse payment and antitrust violation.⁷⁴ Although theoretically very

72. Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 396, 410 (2003). In favor of a consumer welfare criterion, see also Yu & Chatterji, *supra* note 27, at 20.

73. Josef Drexl, “Pay-for-Delay” and Blocking Patents—Targeting Pharmaceutical Companies Under European Competition Law, 40 IIC: INT’L REV. INTEL. PROP. L. 751, 753 (2009); PETER PICHT, STRATEGISCHES VERHALTEN BEI DER NUTZUNG VON PATENTEN IN STANDARDISIERUNGSVERFAHREN AUS DER SICHT DES EUROPÄISCHEN KARTELLRECHTS [STRATEGIC BEHAVIOR IN THE USE OF PATENTS IN THE STANDARDIZATION PROCESS FROM THE PROSPECTIVE OF EUROPEAN ANTITRUST LAW] 247 (2013).

74. See, e.g., Yu & Chatterji, *supra* note 27, at 25; Backus, *supra* note 7; Cotter, *supra* note 24, at 1073; Bigelow & Willig, *supra* note 71, at 257-60.

relevant for RPS scrutiny, these factors are difficult to prove and measure in practice, while they are easy to abuse as a defense.⁷⁵ They should therefore count only if proven very clearly.

C. Patent Validity/Infringement and Antitrust Enforcement Under Uncertainty

1. The Patent Validity/Infringement Axiom and Its Repercussions

Hitherto, it has been widely accepted that validity and infringement of the BM's patent, together, are the ultimate touchstone for an RPS. If the patent is valid and infringed, the BM does not have to accept any competition from the GM drug during the term of the patent. Consequently, settlements under which the BM pays the GM money or grants the right of early entry before patent term expiration are not antitrust violations. In fact, granting early entry can even be procompetitive. If, on the contrary, the BM's patent is invalid or not infringed, any settlement that prevents immediate market entry of the GM's drug does, in principle, buy off competition and therefore constitute an antitrust violation. This axiom renders patent validity/infringement the single most important factor in the assessment of an RPS.

Alas, this factor can be very hard to assess in practice. If no detailed assessment of patent validity and infringement has yet been undertaken at the time of the settlement, scrutiny of the RPS under this criterion may be very costly and time-consuming.⁷⁶ In fact, it may amount to running the very infringement lawsuit the settlement tries to end.⁷⁷ Furthermore, the exercise of patent review as part of antitrust enforcement creates competence problems. Antitrust agencies and courts are not necessarily experts in patent matters. Furthermore—an aspect that loomed large in the circuit court decisions prior to *Actavis*—the grant of a patent by the United States Patent and Trademark Office (USPTO) under the Patent Act creates a certain presumption of patent validity.⁷⁸ Antitrust enforcers disregard this presumption and invade the realm of patent law if they carry out a full review of the BM's patent. The academic discussion on infringement claim review reflects these difficulties. Some scholars favor patent validity and infringement

75. *But cf.* Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, 4 INNOVATION POL'Y & ECON. 145, 145-48 (2004) (addressing whether asymmetric information, risk adversity, and other factors can be detected in reality).

76. *See* Hovenkamp et al., *supra* note 4, at 1732.

77. *See* Mosier & Ritcheson, *supra* note 10, at 511.

78. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066-68 (11th Cir. 2005).

examination.⁷⁹ Their positions vary somewhat on the extent and procedural structure of the scrutiny.⁸⁰ Others are skeptical, pointing especially to the primacy of patent law's presumption of patent validity⁸¹ and the potentially heavy costs of in-depth antitrust review.⁸²

The majority's ruling in *Actavis* tries, at first sight, to avoid these difficulties with a shortcut: a reverse payment not explainable as litigation cost compensation or the like strongly indicates patent invalidity/noninfringement and therefore warrants antitrust intervention, even without a determination of validity/infringement in the first place. At least two aspects do, however, cast heavy doubts on this approach. Firstly, economic modeling of RPS situations shows that substantial reverse payment may be a sensible strategy for the BM, even where the probability of the BM's patent being found invalid/noninfringed is small (i.e., the patent is very strong).⁸³ Secondly, under the aforesaid axiom, it is hard to deny the patent holder a defense based on patent validity/infringement. If, however, the patent holder is allowed to claim and prove patent validity/infringement as a defense, the result is likely to be the unwanted infringement litigation within the antitrust litigation. To have pointed out this seeming weakness of the majority ruling is maybe the greatest merit of the dissenting opinion.

2. Conceiving Rules for Antitrust Enforcement Under Uncertainty

Maybe the best way out of the dilemma is to work candidly on antitrust rules that cope with validity/infringement uncertainty without

79. See Bernard & Tom, *supra* note 37, at 632; Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 797 (2002); Yee Wah Chin & Thomas G. Krattenmaker, *Antitrust Update*, 2 MERGERS & ACQUISITIONS TAX J. 30, 37-38 (2001); Cotter, *supra* note 24, at 1082; Mosier & Ritcheson, *supra* note 10, at 511; Hovenkamp et al., *supra* note 4, at 1760; Yu & Chatterji, *supra* note 27, at 20; Backus, *supra* note 7, at 417.

80. See Hovenkamp et al., *supra* note 4, at 1760 (arguing for a "limited inquiry"); Mosier & Ritcheson, *supra* note 10, at 511 (discussing "whether the exclusion agreement—the promise given as consideration for the exclusion payment—facially exceeds the patent grant, i.e., exceeds the relief that the patent owner could have obtained from a reviewing court"); Cotter, *supra* note 44, at 1811-15 (2003) (discussing the possibility of truncated review).

81. *But cf.* Schildkraut, *supra* note 37, at 1067. See Bernard & Tom, *supra* note 37; Crane, *supra* note 43, at 709.

82. On the general relevance of that factor, see Cotter, *supra* note 24, at 1093; see also Crane, *supra* note 79, at 785-97; Kristopher L. Reed, *A Return to Reason: Antitrust Treatment of Pharmaceutical Settlements Under the Hatch-Waxman Act*, 40 GONZ. L. REV. 457, 478 (2005).

83. See, e.g., Cotter, *supra* note 44, at 1802-04; Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 ANTITRUST BULL. 491, 517-20 (2002). For an additional element, including time and consumer benefit aspects, see Cotter, *supra* note 24, at 1085-90. Compare, in the same vein, the dissenting opinion in *Actavis*. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2238-47 (2013) (Roberts, J., dissenting).

fully resolving it. One may, for example, bar the validity/infringement defense and require the BM to either fight the infringement litigation to its end or settle on terms that are less likely to harm competition than typical RPS terms would be. A settlement package that terminates litigation, compensates the GM for litigation costs, and grants it early market entry would, for example, usually be acceptable.⁸⁴ An exception may apply if strong indicators on patent validity/infringement, such as lower courts' rulings, exist. If lower courts held the patent to be valid and infringed, even a cash payment beyond litigation-cost compensation may be acceptable. If, on the contrary, the patent was considered invalid or noninfringed, even an RPS limited to litigation-cost compensation and/or an early-entry right may be anticompetitive.

Maybe this type of solution is what the majority had in mind when they stated that a payment seeking to prevent the risk of competition constitutes an anticompetitive harm. If so, however, the Court should have made this point much clearer because it is no minor change to the conventional wisdom on RPS. Under the new approach, uncertainty about patent validity/infringement at the time of the settlement would weigh against the parties by limiting their settlement options. This evokes two major concerns, namely the risk of preventing beneficial settlements and uneasiness about excessive antitrust intrusion into the realm of patent law and the monopoly granted by it.

3. Preventing Beneficial Settlements?

To begin with, there is no doubt that the aforescribed approach makes RPS less attractive. The argument that a restrictive antitrust approach will cripple beneficial patent settlements and even BM-GM litigation from the start has been made many times before. It has never been proven. In fact, the dissenting opinion itself cites data showing that BM patents often turn out *not* to be valid/infringed.⁸⁵ Other sources are in accord.⁸⁶ Very recent antitrust enforcement in the European Union⁸⁷

84. *Actavis*, 133 S. Ct. at 2227-38. The safe harbor provision in the Kohl-Leahy bill follows a similar concept. See *infra* Part VI.B.

85. *Actavis*, 133 S. Ct. at 2240-41 (Roberts, J., dissenting).

86. See, e.g., John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205-21 (1998) (contending that 46% of patents litigated to judgment are held invalid).

87. On June 19, 2013, the European Commission published its decision to fine a number of pharmaceutical companies (including a subsidiary of *Actavis*) a total of more than 145 million euros for agreeing to delay the market entry of generics. Press Release, European Commission, Antitrust: Commission Fines Lundbeck and Other Pharma Companies for Delaying Market Entry of Generic Medicines (June 19, 2013), available at http://europa.eu/rapid/press-release_IP-13-563_en.htm.

and the results of the European Commission's inquiry into the pharmaceutical sector⁸⁸ support the impression that BMs engage, on a large scale, in stratagems to buy off GM competition.⁸⁹ It is certainly important to monitor closely the effect of antitrust enforcement regarding RPS on general patent litigation and settlement activity. If unwanted effects are empirically demonstrated, the antitrust approach must be adjusted. But it is no less certain that RPS are not across-the-board harmless attempts to terminate debilitating litigation over patents that both parties consider valid and infringed. Many pieces of evidence indicate that a considerable number of RPS do, in fact, buy off competition and harm consumers. These are solid grounds for not giving RPS the benefit of the doubt.

4. Antitrust Purpose of and Limits to Patent Protection

Some would say that to regulate this intersection appropriately, the conflict between antitrust and patent laws is a fundamental challenge that rules on RPS must meet. Should the scope of the patent be the demarcation line beyond which antitrust law shall not venture? It is important to keep in mind that IP rights are regarded as a necessary tool for incentivizing innovation and thereby furthering, in the long run, innovation-based competition. They are also a strong interference with the market, blocking free competition by granting monopoly rights.⁹⁰ In this regard, patents are a costly investment made by society to achieve welfare through dynamic, innovation-driven competition. In the antitrust assessment of RPS, this goal of patent protection must loom large. The fencing off of competition by an RPS is very likely to reduce pressure on the BM to replace its drug with a new and better one. As this effect results while patent validity/infringement is uncertain, the boundaries of patent scope should not immunize RPS, especially in the presence of factors indicating anticompetitive harm.

D. The Appropriate Standard of Review

Defining a set of criteria relevant to the assessment of RPS does not yet answer the question of how to structure the examination of these criteria and how to assign the burden of proof. An appropriate standard

88. For a readable summary of the inquiry results, see *Communication from the Commission: Executive Summary of the Pharmaceutical Sector Inquiry Report*, *supra* note 2.

89. In addition, these E.U. data prove that RPS are—contrary to what is often stated in the United States—not limited to a Hatch-Waxman framework. *Id.*

90. See Carrier, *supra* note 56, at 766-71.

of review has yet to be found. The Supreme Court purports to favor some sort of truncated rule of reason, placing on the trial courts the heavy burden of working out a detailed standard of review. Some indications in the ruling do, however, provide additional guidance. They seem to sketch out a test that is, in fact, not that far from presumptive illegality. The Court appears to require the FTC to show that there is a settlement including a reverse payment. In case of hidden or atypical value transfers to the GM, a prima facie showing by the FTC may be sufficient, shifting the burden of rebuttal to the settlement parties. If no value transfer other than an early-entry right can be demonstrated, the settlement is usually safe from antitrust interference. After the showing of a relevant value transfer, the antitrust defendants may justify the transfer, e.g., as compensation for litigation expenses or other services. As noted, the validity/infringement defense would usually be barred. An exception may apply in case of strong indicators on validity and infringement. From the statement that “the FTC must prove its case,” one might infer that the agency has to show not only the mere existence of an RPS, but also anticompetitive effect and the lack of circumstances justifying the payment.⁹¹ But this burden cannot go very far. Because the FTC will usually not possess detailed information on the parties’ litigation expenses or potential services rendered by the GM, it can only be required to show the absence of circumstances that evidently justify the payment. Furthermore, the showing of a reverse payment without apparent justification will usually be sufficient to establish the anticompetitive potential of the settlement. The factors qualified as unsuitable here⁹² are not categorically excluded, but they should matter only in very exceptional situations.

VI. NEED FOR LEGISLATIVE ACTION?

Actavis is an important, but most likely not the final, step in defining the U.S. antitrust course regarding RPS. This raises the questions of whether legislative action is still necessary after the ruling and how to proceed with the two bills currently under construction.

91. *Id.*

92. *Cf. supra* Part IV.B.2.

A. *The Rush-Waxman Proposal*

1. Chief Contents

The proposal initiated by Congressmen Rush and Waxman (Rush-Waxman proposal) is tough at the statutory level but allows for flexibility at the administrative level.⁹³ Its section 2 prohibits any settlement under which a GM receives “anything of value” in return for (temporary) inactivity (section 2(a)).⁹⁴ The only “values” a GM may lawfully accept under a settlement are the right to market its drug before expiry of the BM’s IP protection and a waiver of patent infringement claims for prior damages (section 2 (b)).⁹⁵ However, according to section 3, the FTC may by rule

exempt certain agreements described in section 2 if the Commission finds such agreements to be in furtherance of market competition and for the benefit of consumers. Consistent with the authority of the Commission, such rules may include interpretive rules and general statements of policy with respect to the practices prohibited under section 2.⁹⁶

2. Concerns

a. Overly Rigid

Declaring RPS almost per se illegal, the Rush-Waxman proposal contradicts the largest part of the academic literature and the Supreme Court’s position in *Actavis*, which advocate a somewhat more flexible approach. This is, of course, not an argument in itself as numbers do not equal truth and even the Supreme Court may err. At least two aspects show, however, that Rush-Waxman’s rigidity goes too far.

Firstly, Rush-Waxman does not even allow for reverse payments that merely compensate litigation costs. As said, though, a broad consensus has formed, now including the Supreme Court, that these payments are not anticompetitive. This view is convincing in general, as litigation costs are different in nature from profits that are lost because the GM refrains from competitive market activity. Compensating them does not buy off competition and it does not reduce the GM’s incentive to compete. If at all, settlements under which the BM compensates the GM for litigation costs may even have the opposite effect, encouraging future

93. See Protecting Consumer Access to Generic Drugs Act of 2012, H.R. 3995, 112th Cong. (2d Sess. 2012).

94. See *id.* § 2(a).

95. See *id.* § 2(b).

96. *Id.* § 3.

GMs to attack BM patents under ANDA-IV because they can at least hope to recover the cost of a failed attempt.

Secondly, and more generally, it is a longstanding principle of U.S. antitrust law that per se rules should be established only if sufficient experience has proven that a particular type of conduct is almost always and to an overwhelming extent anticompetitive.⁹⁷ Looking at the variations in their present treatment, this is quite clearly not the case yet with regard to RPS. Not without reason, the Supreme Court has mandated that the lower courts work out factors relevant to the assessment of RPS. This is not the environment for establishing a per se rule.

b. Overempowering the FTC

The broad exemption-making power granted to the FTC by section 3 of the Rush-Waxman proposal seems in a way to allay the previously stated concerns. If there are settlements that are not anticompetitive and should therefore escape per se treatment, let the FTC make a rule that exempts them! It is, in fact, of considerable appeal that the decision on specific types of settlements be assigned to an agency that arguably has the deepest empirical knowledge of the subject and can react more flexibly than a legislator to changing circumstances or new insight.⁹⁸ Nonetheless, the solution evokes severe doubts regarding both its fundamental concept and its effectiveness.

A fundamental doubt relates to the division of powers and functions between the legislature's statutes and an agency's rules.⁹⁹ It is the legislator's role to lay down the principle and the agency's role to concretize this principle by determining details and also by granting exemptions in exceptional cases.¹⁰⁰ Regarding RPS, however, the previous analysis has shown a per se rule to be unconvincing not only for a limited number of exceptional cases, but also for entire categories of settlements (for example settlements that limit reverse payments to litigation costs). Agency rulemaking exempting these entire categories

97. *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997); see Andersen, *supra* note 7, at 1025-27; Backus, *supra* note 7, at 412-18. *But cf.* *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013) (addressing the appropriateness of quick look standards of review).

98. Cook, *supra* note 1, at 449-51. In general, on this aspect in favor of administrative rulemaking, see Jeffrey E. Shuren, *The Modern Regulatory Administrative State: A Response to Changing Circumstances*, 38 HARV. J. ON LEGIS. 291 (2001).

99. See Cook, *supra* note 1, at 451 (criticizing agency RPS policy without referring to the Rush-Waxman Act).

100. *But cf.* Cook, *supra* note 1, at 451-52; Cassandra Burke Robertson, *Transnational Litigation and Institutional Choice*, 51 B.C. L. REV. 1081, 1089 (2010).

would therefore have to be so broad that it would amount to a partial reversion of the statutory principle. Legislation that necessitates its own partial annulment by administrative bodies is not only questionable craftsmanship, but also in a certain sense a contradiction of the notion of separation of powers.¹⁰¹

A broad and substantial contradiction between agency rules and the statute that granted the rulemaking power in the first place may also endanger effective enforcement of the agency rules. Judicial review of administrative rulemaking under 25 U.S.C. § 553 is limited, but it does exist.¹⁰² One element of the standard of review is compliance of the rulemaking with its statutory basis.¹⁰³ Even though the power granted by section 3 of the Rush-Waxman proposal is fairly broad, courts may critically scrutinize and potentially overturn a set of FTC rules that effectively turn the legislators' per se prohibition into a presumptive illegality or rule of reason standard for at least a substantial part of RPS.

A different concern could arise if the FTC's rulemaking activity is not far-reaching but, on the contrary, too restrained. The FTC itself is more skeptical about RPS than are many commentators and, for that matter, the Supreme Court. Furthermore, FTC rulemaking may take time in this intricate area. For these and other reasons, it could happen that the FTC does (temporarily) not provide exempting rules for cases that should be exempt.¹⁰⁴ Courts would then have to apply Rush-Waxman's rigid per se prohibition to cases that do not deserve this treatment.

In sum, the exception-making power of the FTC under section 3 of the Rush-Waxman proposal does not seem fit to cure the shortcomings of the per se prohibition in the proposal's section 2.

c. Conclusion

The Rush-Waxman proposal stands in stark contrast to the approach proposed by the Supreme Court. The aforemade remarks are sufficient

101. On the further danger that the FTC rulemaking may be influenced by lobbying, see Cook, *supra* note 1, at 450. This danger seems, however, to apply to the legislator.

102. 4 CHARLES H. KOCH, JR., ADMINISTRATIVE LAW AND PRACTICE § 11:31 (3d ed. 2010).

103. FCC v. Fox Television Stations, Inc., 556 U.S. 502, 515 (2009).

104. On the danger of overly restrictive rules resulting from "overspecialization," see Cook, *supra* note 1, at 451 ("These agencies [FTC and DOJ] while very capable of providing information about market structure and business motives in particular situations, are far less capable of striking a desirable balance between antitrust law and patent law because of their place within the antitrust—and not patent—regulatory system.").

to show that the bill's solution is not convincing enough to be adopted, thereby overturning the *Actavis* ruling.¹⁰⁵

B. The Kohl-Leahy Proposal

1. Chief Contents

For this Article's scope of analysis, five elements of the proposal made by Senators Kohl and Leahy (Kohl-Leahy proposal) are important.¹⁰⁶ These elements establish the presumption that RPS are illegal, and they declare this presumption rebuttable if the parties can show, under a clear-and-convincing-evidence standard, that "the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement."¹⁰⁷

Section 28(b) contains a list of factors that shall be considered in determining whether the presumption of illegality has been rebutted. These factors are:

- (1) [T]he length of time remaining until the end of the life of the relevant patent, compared with the agreed upon entry date for the ANDA product;¹⁰⁸
- (2) the value to consumers of the competition from the ANDA product allowed under the agreement;¹⁰⁹
- (3) the form and amount of consideration received by the ANDA filer in the agreement resolving or settling the patent infringement claim;¹¹⁰
- (4) the revenue the ANDA filer would have received by winning the patent litigation;¹¹¹
- (5) the reduction in the NDA holder's revenues if it had lost the patent litigation;¹¹²
- (6) [and] the time period between the date of the agreement conveying value to the ANDA filer and the date of the settlement of the patent infringement claim.¹¹³

105. See Cook, *supra* note 1, at 442-43; Backus, *supra* note 7, at 407-10 (providing further reasons and references to support rejection of the proposal).

106. See Preserve Access to Affordable Generics Act, S. 27, 112th Cong. § 28 (1st Sess. 2011).

107. *Id.*

108. *Id.* § 28(b)(1).

109. *Id.* § 28(b)(2).

110. *Id.* § 28(b)(3).

111. *Id.* § 28(b)(4).

112. *Id.* § 28(b)(5).

113. *Id.* § 28(b)(6).

Section 28(c) addresses two presumptions that the fact finder shall *not* make.¹¹⁴ Section 28(c)(1) excludes the presumption “that entry would not have occurred until the expiration of the relevant patent or statutory exclusivity;”¹¹⁵ and section 28(c)(2) excludes the presumption “that the agreement’s provision for [early] entry . . . means that the agreement is pro-competitive.”¹¹⁶

Section 28(d) of the Kohl-Leahy proposal, a safe harbor provision, exempts a specific type of settlement from the presumption of illegality. Under these settlements, the only consideration received by the GM is the right to enter the market before patent expiry and/or “[a] payment for reasonable litigation expenses not to exceed \$7,500,000,”¹¹⁷ and/or a covenant not to sue for patent infringement by the generic drug.¹¹⁸

Finally, section 28(e)(1) grants the FTC rulemaking power for “implementing and interpreting” purposes, and section 28(f) addresses the relation between the proposed bill and the general antitrust laws.¹¹⁹

2. Concerns

Overall, the Kohl-Leahy proposal is much more flexible than Rush-Waxman. In fact, its combination of presumptive illegality, a safe harbor for RPS granting only early entry, and a rule-of-reason-like consideration of multiple relevant factors appear to be quite close to the Supreme Court’s approach. For these reasons, Kohl-Leahy is clearly the preferable of the two proposed bills. Nonetheless, as the balance of this Part will show, it is not evident why U.S. antitrust law would need this piece of legislation.

a. Unclear Set of Criteria

To begin with, the guidance provided by the Kohl-Leahy list of criteria is not always clear and convincing. For example, section 28(b)(2) of the bill refers to “the value to consumers of the competition from the ANDA product allowed under the agreement.”¹²⁰ Evidently, this raises

114. *See id.*

115. *Id.* § 28(c)(1).

116. *Id.* § 28(c)(2).

117. *Id.* § 28(d)(2).

118. The Kohl-Leahy bill seems to be criticized for not permitting settlements that exclusively split the remaining patent protection period. Backus, *supra* note 7, at 407. In view of section 28(d)(1), this criticism is not justified.

119. Under Kohl-Leahy, this power is significantly less problematic than under Rush-Waxman because the proposed bill is, in itself, more balanced and makes it more likely that future FTC rulemaking will be limited to an—appropriate—implementing function.

120. S. 27 § 28(b)(2).

the question of how the “value” of the “ANDA product” (the generic drug) will be measured. A *qualitative* standard, which looks at the medical importance of the drug, appears to be highly subjective and difficult to apply. Agencies and courts should not have to take a stance on whether a drug against cancer is more important than a drug against Alzheimer’s Disease. A *quantitative* standard could, in particular, look at the price drop due to the generic’s market entry, at the overall consumer savings it causes, or at a combination of both figures. Alternatively, value could be determined with regard to market structure if, for example, there are no other equally effective drugs against a particular disease on the market, and the market entry of a second product may have a particularly strong influence.¹²¹ The bill provides no indication of how the consumer value criterion is to be interpreted. At least without such guidance, the consumer value criterion remains a doubtful one. Provided the BM does not hold a valid and infringed patent, there should be no settlement that buys off competition, regardless of consumer value. If, for example, upon market entry of the generic, the RPS causes a sharp price drop in a sizeable market and consequently seems of high value to consumers, the settling parties’ conduct is still anticompetitive—and even heavily so—when they prolong the BM’s unjustified monopoly in that market.

To give another example, section 28(b)(1) of the Kohl-Leahy proposal declares relevant “the length of time remaining until the end of the life of the relevant patent, compared with the agreed upon entry date for the ANDA product.”¹²² This factor seems to be aimed at identifying settlements whose anticompetitive impact is particularly great, but which settlements are those? On the one hand, the longer the BM conserves its monopoly under the settlement, the more competition is bought off and the higher the total amount that consumers have to pay for the monopoly component in the drug price. Early entry may therefore indicate that the RPS is not anticompetitive. On the other hand, buying off competition is still anticompetitive, even if the period for which that happens is short. Furthermore, market presence has a dollar value for the GM, and the earlier market entry happens, the higher that value.¹²³ Early market entry may therefore (less convincingly) also be taken to indicate a reverse

121. It is important not to confuse patent-scope monopoly with entire-market monopoly. A BM has exclusive rights to its drug, i.e., to the subject matter of its patent. On the market for the treatment of a particular disease, however, several drugs may exist. Each of these drugs may be protected by a patent, and with regard to each drug, a BM-GM scenario (and, for that matter, an RPS) can unfold.

122. S. 27 § 28.

123. See discussion *supra* note 61.

value transfer that exceeds litigation cost compensation and is anticompetitive. Section 28(b)(1), however, does not explain which conclusions an agency or court should draw from a particular relation between the protection period and envisaged market entry.

Just like some of the listed criteria, the litigation cost threshold in Kohl-Leahy's safe harbor provision (section 28(d)(2)) is doubtful as well. Certainly, establishing a \$7.5 million threshold for compensable litigation costs has the advantage of being clear and easy to apply. On the other hand, every inflexible number bears the risk of being too high for some cases and too low for others.¹²⁴ Furthermore, average litigation costs vary over time due to inflation and changing market conditions. The bill provides no built-in mechanism to adapt the threshold to the particularities of a case or to the effects of the passage of time. To have Congress relegislate whenever there is a fluctuation in patent litigation costs is hardly a workable solution. The inappropriate results that the threshold would cause over time are therefore very likely to outweigh its advantages.

b. Expendability

The described shortcomings of Kohl-Leahy, and others not specified here, may be cured. More fundamental is the doubt that the bill would contribute much additional value after the *Actavis* ruling. Kohl-Leahy provides a presumptive illegality framework, proposes a nonexclusive set of assessment parameters, and leaves the fine-tuning to the courts. This is very much what the Supreme Court has already done. Under Kohl-Leahy, as well as under *Actavis*, a phase of renewed academic discussion and a set of interpretative court rulings would be necessary to work out details within the given framework. Not least to save the resources of the legislature, it seems wiser to await the results of the fine-tuning process. If things do not settle down in a satisfactory manner, Congress may still step in.

124. Weil, *supra* note 63, at 762-65 (arguing that indirect litigation costs, like having to grant access to vital business information, should be priced in, too, although these indirect costs often will be too difficult to measure).

VII. COMPARATIVE GLANCE: THE POSSIBILITY OF A COHERENT U.S.-
E.U. APPROACH

A. *Relevance of the U.S. Discussion to the E.U. Legal Framework?*

The conditions for RPS are different in Europe than they are in the United States, especially because the E.U. has no Hatch-Waxman Act. Instead, generic drugs can be approved in a centralized and a national approval procedure.¹²⁵ The centralized marketing authorization is handled by a committee within the European Medicines Agency (EMA). Like the FDA, the EMA requires drug makers to provide it with the results of extensive testing and clinical trials. Once the EMA approves a drug for marketing, this authorization is effective throughout the European Union. The decentralized procedure requires similar testing, which is evaluated by the Reference Member State (RMS) of the applicant's choice. After the drug is approved, the RMS can prepare an assessment report for the applicant to send to other Member States for recognition. GMs are permitted to submit abridged applications, which, like ANDAs, rely on the testing performed for the BM's product. However, the BM's product is protected by data exclusivity for up to eleven years under the so-called "8+2(+1) formula." The GM may not submit an application for the first eight years of the BM's marketing authorization and may not enter the market for another two years after that. A final, eleventh year of exclusivity for the BM is possible under certain circumstances. Patent protection in the European Union is considered separately from marketing authorization. Unlike the ANDA-IV, applications for generic drug authorization in the European Union do not require an affirmation of patent status. In fact, patent linkage is prohibited, and marketing authorization for a generic does not take relevant patents into account. Once a generic is approved, the GM may enter the market, though it does so at the risk of infringement action by the BM if the BM's patent has not yet expired.

In spite of these differences, RPS frequently happen in Europe, as well. A recent pharmaceutical sector inquiry by the European Commission reported various RPS and even declared them a major

125. See *Authorisation Procedures in the European Union*, EUR. MEDS. AGENCY, http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/landing/human_medicines_regulatory.jsp&mid=WC0b01ac058001ff89 (last visited Oct. 11, 2013); CHRISTIAN R. FACKELMANN, PATENTSCHUTZ UND ERGÄNZENDE SCHUTZINSTRUMENTE FÜR ARZNEIMITTEL IM SPANNUNGSFELD VON WETTBEWERB UND INNOVATION [PATENTS AND SUPPLEMENTARY PROTECTION INSTRUMENTS FOR PHARMACEUTICALS IN THE CONTEXT OF COMPETITION AND INNOVATIONS] 21 (2009).

concern of E.U. antitrust law,¹²⁶ although the Commission's legal assessment seems not to be firmly established yet.¹²⁷ Accordingly, the European Commission has launched investigations and very recently sanctioned several companies for delaying GM market entry.¹²⁸ In the still sparse academic discussion, some scholars seem to advocate per se illegality.¹²⁹ Others favor a case-by-case approach and interpret a substantial reverse payment as an indicator of the anticompetitive character of the settlement.¹³⁰

Overall, these facts clearly contradict the assumption that RPS are uniquely a U.S. phenomenon and that they are very unlikely absent Hatch-Waxman conditions. Rather, it seems that the United States would need RPS policing even absent Hatch-Waxman, and that it may be helpful to look into the E.U. data to understand more completely the factors that induce RPS. At the same time, the commencing E.U. discussion and practice on RPS may benefit very much from the U.S. experience.¹³¹ The fundamental IP and antitrust issues that RPS raise are the same in both jurisdictions. This transatlantic dialogue is important to the development of a coherent practice toward RPS, an outcome that is crucial not least to the many companies operating in both jurisdictions.

B. Potential Treatment of RPS Under E.U. Antitrust Law

1. Applicability and Structure of Article 101 TFEU

In European antitrust law, article 101 of the Treaty on the Functioning European Union (TFEU), the parallel provision to section 1 of the Sherman Act, prohibits anticompetitive agreements.¹³² The European Court of Justice (ECJ) has already clarified that IP litigation

126. *Pharmaceutical Sector Inquiry Final Report*, at 523-24, COM (2009) 351 final (July 8, 2009).

127. *Id.* at 524 (“Agreements that are designed to keep competitors out of the market may also run afoul of EC competition law. Settlement agreements that limit generic entry and include a value transfer from an originator company to one or more generic companies are an example of such potentially anticompetitive agreements, in particular where the motive of the agreement is the sharing of profits via payments from originator to generic companies to the detriment of patients and public health budgets.”).

128. See Press Release, European Commission, *supra* note 87.

129. See Drexler, *supra* note 73, at 753.

130. See ULRICH IMMENGA ET AL., *EU-WETTBEWERBSRECHT [EU COMPETITION LAW]* (5th ed. 2012).

131. See generally Melanie J. Brown, *Reverse Payment Settlements in the European Commission's Pharmaceutical Sector Inquiry Report: A Missed Opportunity To Benefit from U.S. Experience*, 33 COLUM. J.L. & ARTS 377 (2010) (criticizing the European Commission for not taking U.S. insight into account).

132. Consolidated Version of the Treaty on the Functioning of the European Union art. 101, May 9, 2008, 2008 O.J. (C 115) 47 [hereinafter TFEU].

settlements are “agreements” in the sense of article 101 and, in principle, subject to antitrust scrutiny under this provision.¹³³ Article 101 follows a two-prong structure. 101(1) codifies the requirements for an agreement to be, in principle, an antitrust violation. 101(1)(a)-(e) lists specific types of conduct that are considered anticompetitive.¹³⁴ The burden of proof pursuant to article 101(1) is on the antitrust enforcer (the European Commission, in particular).¹³⁵ Importantly, article 101(1) only requires, and the antitrust enforcer must only prove, that it is sufficiently *probable*, on the basis of objective criteria, that the agreement violates competition.¹³⁶ Article 101(3) exempts agreements that violate article 101(1) if they yield sufficient procompetitive benefits.¹³⁷ The burden of proof for the requirements of article 101(3) is on the antitrust defendant.¹³⁸ As for the factors relevant to the assessment of RPS, much depends on the placement of a particular factor under article 101(1) or 101(3) because this operation assigns the burden of proof.

C. Integrating Relevant Factors into the Statutory Structure

Looking at the list of specific types of conduct in article 101(1), anticompetitive RPS can be grouped under article 101(1)(b), which prohibits agreements that “limit or control production, markets, technical development, or investment.” If the RPS grants an early-entry right and thereby creates a duopoly, it may also constitute market-sharing conduct under article 101(1)(c).¹³⁹ After all, the types of conduct listed in article 101(1)(a)-(e) are also covered by article 101(1)’s general prohibition, so the identification of an applicable specific conduct provision is not of utmost importance.

In contrast, the essential question is what the European Commission will have to prove in order to establish a violation of article 101(1).

133. Case 65/86, Bayer AG v. Süllhöfer, 1988 E.C.R. 5249, 5286 (1988). For an application of article 101 to RPS, see also IMMENGA ET AL., *supra* note 130; Drexl, *supra* note 73, at 753; JOSEF DREXL, INTELLECTUAL PROPERTY IN COMPETITION: HOW TO PROMOTE DYNAMIC COMPETITION AS A GOAL IN ASCOLA COMP. LAW, MORE COMMON GROUND FOR INTERNATIONAL COMPETITION LAW? 226, 246 (2011); Pat Treacy, *Settlement Agreements: The European Perspective*, 1 J. INTELL. PROP. L. & PRAC. 223, 224 (2006).

134. TFEU art. 101(1)(a)-(e).

135. Council Regulation 1/2003, 2002 O.J. (L 1) 1 (EC).

136. *Cf., e.g.*, Case 19/77, Miller Int’l Schallplatten GmbH v. Comm’n, 1978 E.C.R. 131; Case T-13/89, Imperial Chem. Indus. v. Comm’n, 1992 E.C.R. II-1021.

137. Council Regulation 1/2003, art. 2, 2002 O.J. (L 1) 8 (EC). Obviously, this structure resembles the Kohl-Leahy proposal.

138. *Id.*

139. For a discussion on the market-sharing dimension of RPS, see also Hovenkamp et al., *supra* note 4, at 1727.

Under the lowered probability standard of the provision, it is arguably sufficient that it show (1) a settlement and (2) a reverse value transfer other than an early-entry right.¹⁴⁰ Alternatively, the European Commission may also show that an RPS granting only an early-entry right is, for exceptional reasons, nonetheless anticompetitive. The RPS parties can then try to show, under article 101(3), that their settlement creates sufficient procompetitive benefits. In doing so, they can, in principle, have recourse to largely the same factors that are, according to the previous analysis, relevant to the rebuttal of a presumption of illegality under *Actavis*. Patent validity and infringement should, again, not constitute a defense unless they are already apparent. Given the ECJ's holding that a competition-limiting use of an IP right is only justified by IP protection if the use is limited to the specific subject matter of that (valid) IP right,¹⁴¹ RPS are clearly anticompetitive if they extend the scope of the patent holder's monopoly beyond the scope of the granted patent.

In sum, article 101 seems fit to check anticompetitive RPS with an approach similar to the *Actavis* approach. This makes possible, at the same time, a coherent U.S. and E.U. policy.

VIII. CONCLUSION

The Article has discussed three main issues: the Supreme Court's *Actavis* ruling, the two bills on RPS that have been proposed, and the treatment of RPS under European antitrust law.

The *Actavis* ruling has ended the hitherto prevailing scope-of-the-patent approach. This is convincing because "scope of the patent" risked shielding anticompetitive settlements from antitrust scrutiny. Although the lower courts must still work out the details, the new test will most likely be a truncated rule of reason that comes quite close to establishing presumptive yet rebuttable illegality of RPS. The FTC will have to show that there is a settlement including a reverse payment. In case of hidden

140. For an apparently similar proposal—but without the litigation-cost element—see Drexl, *supra* note 73, at 753. For an indicative relation between a reverse payment and an antitrust violation, see also IMMENGA ET AL., *supra* note 130. On an assessment under German antitrust law, see Mortiz Lorenz, *Die kartellrechtliche Beurteilung der vergleichswisen Beilegung von Patentstreitigkeiten* [*Antitrust Assessment of Comparative Patent Litigation*], 29 PHARMA RECHT 221, 221 (2007).

141. Case C-10/89, SA CNL-SUCAL NV v. HAG GF AG, 1990 E.C.R. I-3711. Although the Community courts have not ruled on RPS yet, there are some IP-related holdings that support this view. For example, it was held that a license agreement cannot lawfully limit the licensee's right to production or sale after the patent expires. Case 320/87, Kai Ottung v. Klee & Weilbach A/S, 1989 E.C.R. 1177. Furthermore, a covenant made by the licensee not to attack the licensed patent was held invalid. Case 193/83, Windsurfing Int'l Inc. v. Comm'n, 1986 E.C.R. 611.

or atypical value transfers to the GM, a prima facie showing by the FTC may be sufficient, shifting the burden of rebuttal to the settlement parties. If no value transfer other than an early-entry right can be demonstrated, the settlement is usually safe from antitrust interference. After the showing of a relevant value transfer, the antitrust defendants may justify the transfer, e.g., as compensation for litigation expenses or other services. The validity/infringement defense will probably be barred in most cases; an exception may apply in case of strong indicators on validity and infringement. The cash situation of the parties, net consumer surplus, and possibility of settling on less restrictive terms, as well as the parties' risk aversion, information asymmetries, and respective bargaining strengths, will usually not constitute helpful parameters.

Because *Actavis* is a promising starting point for working out detailed antitrust rules on RPS, the two bills proposed at present should not be pursued, particularly in view of their shortcomings. The Rush-Waxman proposal is overly rigid, banning also RPS that are probably not anticompetitive. Furthermore, its overempowerment of the FTC is problematic both from a practical and a fundamental separation-of-powers perspective. The Kohl-Leahy proposal comes close to the Supreme Court approach. For this very reason, however, it does not sufficiently add to the *Actavis* framework to justify legislative action. This is even more so because the bill's catalogue of relevant criteria is partly vague and its litigation cost threshold lacks flexibility. Instead of acting now, the legislature should monitor the fine-tuning of the Supreme Court's approach. If the results are unsatisfactory, Congress may still step in.

A quick look at the European situation showed that RPS are far from occurring only under Hatch-Waxman conditions and that European antitrust enforcement increasingly focuses on them. Case law and scholarship are, however, still very limited and fail to take the U.S. experience sufficiently into account. Article 101 of TFEU, the core provision for checking anticompetitive RPS under E.U. law, can be used to shape an approach similar to that in *Actavis*. Both the United States and the European Union should aim at developing a coherent transatlantic approach. In this way, it should be possible to establish a legal framework that effectively fights anticompetitive RPS, leaves room for beneficial settlements, and provides a reliable guide of conduct for national and transnational competitors in the pharmaceutical sector.