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Bruce H. Kobayashi,
George Mason University School of Law

Joshua D. Wright,
Federal Trade Commission

Douglas H. Ginsburg,
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Joanna Tsai,
Federal Trade Commission

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Actavis and Multiple ANDA Entrants: Beyond the Temporary Duopoly

Bruce H. Kobayashi·
George Mason University School of Law

Joshua D. Wright
Federal Trade Commission

Douglas H. Ginsburg
George Mason University School of Law
Senior Circuit Judge, DC Circuit Court of Appeals

Joanna Tsai
Federal Trade Commission

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· Bruce H. Kobayashi is Professor of Law, George Mason University, and Director, Global Antitrust Institute. Joshua D. Wright is Commissioner, Federal Trade Commission, and Professor (on leave), George Mason University School of Law; the views expressed here are the author's and do not necessarily reflect those of the Commission or of any other Commissioner. Douglas H. Ginsburg is Senior Circuit Judge, United States Court of Appeals for the District of Columbia Circuit, and Professor of Law at George Mason University. Joanna Tsai is Economic Advisor to Commissioner Joshua D. Wright, Federal Trade Commission.

In *FTC v. Actavis*,[1] the Court, in a 5-3 decision, resolved a circuit split over the antitrust treatment of "reverse payments" included in agreements to settle the litigation generated by the Hatch-Waxman regulatory scheme.[2] The court held that reverse payments would be analyzed under the rule of reason, leaving "to the lower courts the structuring of the present rule-of-reason antitrust litigation."[3] In adopting the rule of reason approach, the Court rejected the use of more administrable per se rules used by the lower courts to evaluate reverse payments.

Specifically, the Court declined to adopt the "scope of the patent test" adopted by the Eleventh Circuit.[4] This test recognizes the brand firm's legal ability to use a valid and unexpired patent in order to prevent entry until the expiration of the patent. In contrast, the Court found there is "reason for concern that settlements taking this form tend to have significant adverse effects on competition."[5] In particular, the Court suggested that an otherwise unexplained large reverse payment "likely seeks to prevent the risk of competition. And … that consequence constitutes the relevant anticompetitive harm."[6] The Court also declined the FTC's invitation to apply to settlements involving such payments a rule of per se illegality or, alternatively, to subject them to a "quick look" analysis in which such settlements would be presumptively unlawful.[7]

This paper examines the economics of litigation and settlement of patent disputes arising from Paragraph IV ANDA filings under the Drug Price Competition

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[1] *FTC v. Actavis*, 133 S.Ct. 2223 (2013).

[2] For a history of antitrust enforcement activity and litigation over Hatch-Waxman settlements, see Henry N. Butler & Jeffrey P. Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 IA. L. REV. 57(2010); Sumanth Addanki & Henry N Butler, *Activating Actavis: Economics Issues in Applying the Rule of Reason to Reverse Payment Settlements*, 15 MINN. J. L. SCI. & TECH. 77 (2013). For earlier analyses of reverse payment settlements that focus on the merits of per se rules, see David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L. J. 321 (2000); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlements of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003); Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 ANTITRUST BULL. 491 (2002); Michael A Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive* Illegality, 108 MICH. L. REV. 37 (2009); Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 49 ANTITRUST BULL. 655 (2004).

[3] *Id.* at 2238.

[4] *FTC v. Watson Pharmaceuticals*, 677 F.3d 1298 (11th Cir. 2012). See also *Schering–Plough Corp. v. FTC,* 402 F.3d 1056 (11th Cir. 2005). This test was also applied by the Second and Federal Circuits. See *In re Tamoxifen Citrate Antitrust Litigation,* 466 F.3d 187 (2nd Cir., 2006); *In re Ciprofloxacin Hydrochloride Antitrust Litigation,* 544 F.3d (Fed. Cir. 2008).

[5] *Id*. at 2231.

[6] *Id.* at 2236.

[7] *Id*. at 2237 (citing *California Dental Assn. v. FTC*, 526 U.S. at 775).

and Patent Term Restoration Act ("Hatch-Waxman Act") within the framework set out in *Actavis*.[8] Recent economic analyses of reverse payment settlements are based upon a monopoly-to-duopoly model that assumes a single generic entrant. These models demonstrate how agreements to settle patent litigation that delay the date of generic entry beyond the litigation-adjusted expected life of the patent reduce consumer welfare. An important implication of these monopoly-to-duopoly models is that settlements are very likely to reduce consumer welfare if the size of the reverse payment exceeds the patentee's litigation costs.[9] These analyses have been used to support antitrust rules that would enjoin reverse payments that exceed the cost of litigation.[10]

We demonstrate that the simple monopoly-to-duopoly model providing the analytical basis for the litigation cost benchmark for analyzing reverse payment settlements is incomplete. Specifically, the model fails to take into account important institutional features of the Hatch-Waxman Act regulatory regime and of procedural law. We further show that departures from the simple monopoly-to-duopoly framework in favor of a more realistic setting alters significantly the economic analysis of reverse payment settlements and, in turn, has important implications for the consumer welfare-maximizing approach to their regulation under the antitrust laws.

The simple monopoly-to-duopoly models assume in effect that the marketing exclusivity period lasts precisely until the expiration of the patent. Under this assumption, there is a single ANDA generic entrant prior to the expiration of the patent and the first ANDA entrant that invalidates the brand patent obtains duopoly profits until the patent expires. Our key institutional insight is that in fact entry by multiple firms follows the invalidation of a patent.[11] We incorporate this

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[8] See *Drug Price Competition and Patent Term Restoration Act of 1984*, PUB. L. NO. 98-417, as modified by the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, PUB. L. NO. 108-173 §1102(b).

[9] Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003); Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, & Carl Shapiro, *Activating Actavis*, 28 ANTITRUST 16 (2013), *Actavis and Error Costs*, _ ANTITRUST SOURCE _ (2014); Murat Mungan, *Reverse Payments, Perverse Incentives,* 27 HARV. J. L. & TECH. _ (2013); Einer Elhauge & Alex Krueger, Solving the Patent Settlement Puzzle, 91 TX. L. REV. 283 (2012). But *see* Barry C. Harris, Kevin M. Murphy, Janusz A. Ordover, Robert D. Willig, & Matthew B. Wright, *Activating Actavis: A More Complete Story,* 28 ANTITRUST 83 (2014) (using simple monopoly-duopoly model, but criticizing antitrust limits on reverse settlements); Mark R. Patterson, *Leveraging Information about Patents: Settlements, Portfolios and Holdups*, _ HOUS. L. REV. _ (2012) (analyzing the informational effect of patent challenges and estoppel rules).

[10] See *FTC v. Actavis*, 133 S.Ct. 2223, 2236 (2013) ("the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness" and that a large reverse payment creates an inference that the settlement is anticompetitive.")

[11] Joseph Farrell & Carl Shapiro, *How Strong Are Weak Patents?* 98 AM. ECON. REV. 1347 (2008) (examining the effect of multiple entrants on the incentive to litigate patents

institutional reality into our analysis. Instead of obtaining duopoly profits for the remaining life of the patent, as is assumed in the monopoly-to-duopoly model, the generic entrant that successfully challenges the validity of the patent obtains duopoly profits only for a period limited to a 180-day exclusivity period. After this period, both the brand firm with the invalidated patent and the generic entrant that invalidated the patent obtain only the lower profits associated with free entry. This limitation is jointly imposed by the Hatch-Waxman Act and by the doctrine of collateral estoppel under *Blonder-Tongue v. University of Illinois Foundation*,[12] which prevents the patentee with an invalidated patent from relitigating the validity of the patent.

Accounting for this critical institutional detail in a more generalized monopoly-to-duopoly model results in important and different implications for patent settlements, welfare, and application of the rule of reason pursuant to *Actavis*. The more realistic model implies the payoff for the generic entrant who files the first Paragraph IV ANDA and invalidates the patent is smaller than the litigation payoffs assumed in the monopoly-to-duopoly model. This reduced payoff decreases the incentive for the entrant to litigate and, likewise, the amount for which it will settle.. Litigating a patent under a rule of defensive non-party non-mutual collateral estoppel imposes greater losses upon the patentee than is the case when there is a single entrant. This, in turn, increases the the risk of litigation facing the patentee and, likewise, the amount it will pay to settle. Compared to the simple monopoly-to-duopoly model, the result is a signficantly broader range of settlements in which the brand and generic entrant have legitimate incentives to settle the case.

This broad settlement range renders ineffective attempts to regulate the size of patent settlements, or to infer a settlement is anticompetitive based upon its size. Incorporating multiple serial entrants also decouples the litigation-adjusted expected life of the patent from the consumer welfare standard and, most important, weakens the relationship between the strength of the patent and the size of the settlement, which has motivated numerous calls to deem presumptively unlawful all payments greater than anticipated litigation costs. Thus, using litigation cost as a benchmark would neither induce litigation that invalidate "bad" patents nor encourage settlements that would increase consumer welfare.

In addition to the positive analysis of litigation, the article examines the alternatives to the static consumer-welfare-only standard used in some analyses to evaluate reverse payment settlements. It seems clear that in this context one would

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generally), C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem,* 81 N. Y. U. L. Rev. 1553, 1588-94 (2006) (model with zero profit competition occurring 180 days after the invalidation of the patent or after entry resulting from settlement of the patent litigation).

[12] *Blonder-Tongue v. University of Illinois Foundation,* 402 U.S. 313 (1971).

want to consider a welfare standard that includes more than static consumer surplus. Settlement avoids the incremental private and social costs of litigation. In addition, the design of the Hatch-Waxman Act, which includes provisions that encourage generic entry and patent term restoration, embodies the tradeoff between producers' incentive to innovate and consumers' need for access that is a central focus of the economic analysis of intellectual property rights.

I. The Simple Monopoly-to-duopoly Model and the Litigation Cost Benchmark

We begin by reviewing the simple monopoly-to-duopoly models, such as those used by Edlin, Hemphill, Hovenkamp and Shapiro (EHHS), that provide analytical support for the Court's inference that reverse payments greater than anticipated litigation costs are likely to harm competition.

a. Market Structure and Profits under the Simple Monopoly-to-Duopoly Model

Litigation under the Drug Price Competition and Patent Term Restoration Act begins when a generic entrant files an Abbreviated New Drug Application (ANDA) with a Paragraph IV Certification that the brand firm's unexpired patent is either invalid or would not be infringed. The filing of a Paragraph IV ANDA creates an act of infringement that allows the patentee to file an infringement suit.

The EHHS model and other simple monopoly-to-duopoly models concern a special case of the more general model we discuss below. In particular, the monopoly-to-duopoly model makes the simplifying assumption that the first ANDA entrant that invalidates the brand patent obtains duopoly profits until the patent expires. The undiscounted profits in the EHHS model are illustrated in Figure 1. The vertical axis measures profits and the horizontal axis measures time, in years. The top panel shows the post-litigation profits for the Brand and the Generic if the Brand wins, which occurs with probability p. The middle panel shows the post-litigation profits if the Generic wins, which occurs with probability 1-p. The middle panel in particular shows the effect of the assumptions made in the simple monopoly-to-duopoly model. Instead of a short period of duopoly followed by free entry when the patent is invalidated, the simple monopoly-to-duopoly model generates duopoly profits from the time the patent is invalidated until the time at which the patent would have expired.

Instead of litigating to judgment, the Brand and the initial generic entrant can settle the case. The terms of the settlement contains a reverse payment X and an agreed upon early entry date E that is on or before the patent expiration date T,

which is precisely when, in this model, the marketing exclusivity period, *H*, ends.[13] The bottom panel shows the profits from settlement: the Brand enjoys monopoly profits until the Generic enters at time *E*. The Brand and the Generic obtain duopoly profits from *E* until the patent expires, after which they obtain only free entry profits.

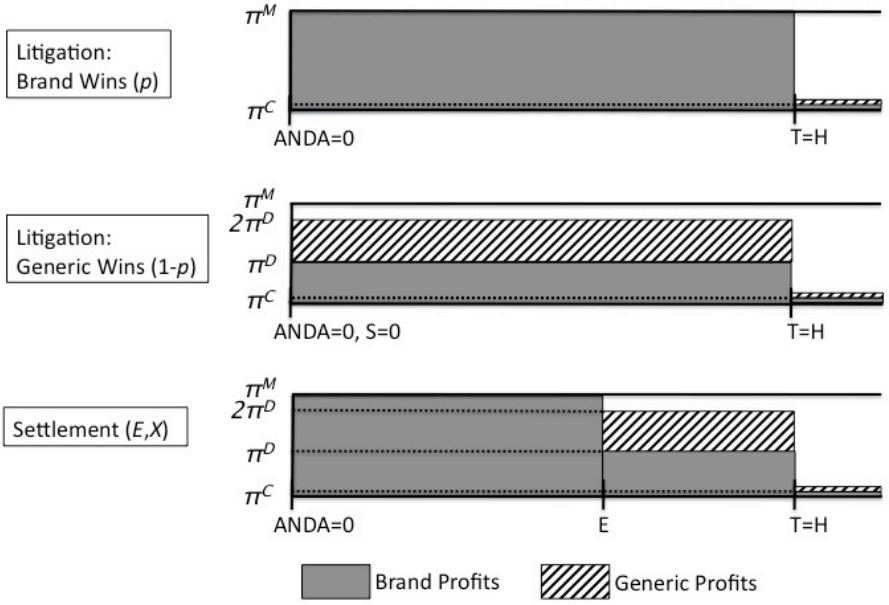

Figure 1 – Litigation and Settlement Profits for the Brand and Generic Firm (Simple Monopoly-to-Duopoly Model)

b. Feasible Settlements in the Simple Monopoly-to-Duopoly Model

This section illustrates the set of feasible settlements using the simple monopoly-to-duopoly model. Figure 2 depicts the set of feasible settlements when both the Brand and the generic entrant estimate the probability the patent will be upheld (*p*) is relatively high and equals 0.9.[14] The vertical axis measures the size of the reverse payment *X*, and the horizontal axis measures the date of early entry *E* in

[13] Under this assumption, there is a single ANDA generic entrant prior to the expiration of the patent. If the marketing exclusivity period ends before the expiration of the patent, then there would be multiple entrants.

[14] Figure 2 is based on a figure used by Harris, et al., *supra* note _. The limits of the bargaining range illustrated in the Figure are explicitly derived in Bruce H. Kobayashi, Joshua D. Wright, Douglas H. Ginsburg & Joanna Tsai, Actavis and Multiple ANDA Entrants: Beyond the Temporary Duopoly, GMU Law and Economics Research Paper Series 14-62 (2014), available at http://www.law.gmu.edu/assets/files/publications/working_papers/1462.pdf.

years. The set of feasible settlements lie in the shaded area to the right and below the Brand's minimum acceptable entry date line ($E_B(X)$ in the Figure) and to the left and above the Generic's maximum acceptable entry date line ($E_G(X)$ in the Figure). With no constraints on settlement, the set of equilibrium settlements, which maximize the joint benefit to the parties, would not allow early entry and would have reverse payments that are between 8 and 12 times the Brand's litigation costs.[15]

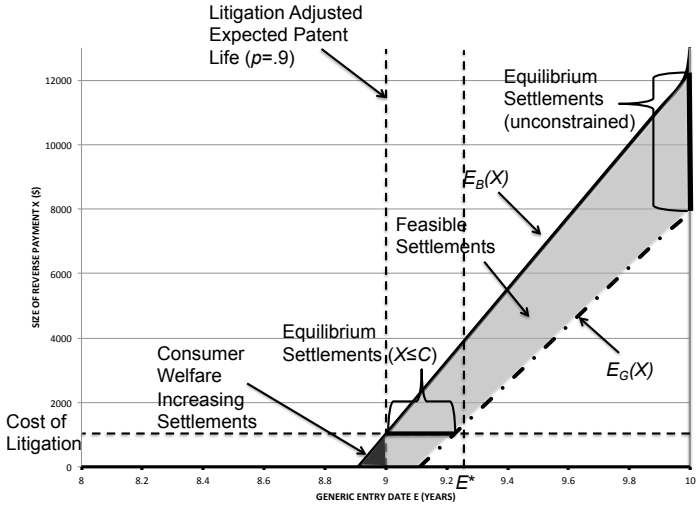

Figure 2 – Feasible Settlements in the Simple Monopoly-to-Duopoly Model

c. Equilibrium Settlement and Welfare in the Simple Monopoly-to-Duopoly Model

This section considers how settlements affect static consumer welfare. Settlements that set the early entry date E equal to the litigation adjusted patent life pT (equal to 9 years in the example in Figure 2) generate consumer welfare equal to the expected consumer welfare generated by litigation. Settlements with entry dates that are sooner (or later) than the ligitation adjusted patent life generate consumer welfare that is larger (or smaller) than is expected under litigation.

The dark shaded triangle in Figure 2 shows the set of feasible settlements that increase consumer welfare. In theory, a rule that required the generic entry date E to be on or before the litigation adjusted patent life pT could be used to promote consumer welfare increasing settlements.[16] As the Court discussed in *Actavis*, the problem with attempting to use such a rule in practice is that measures of patent

[15] See Kobayashi, et al., (2014), *supra* note _, Edlin, et al., (2014), *supra* note _.
[16] See Carl Shapiro, *Antitrust Limits Patent Settlements,* 34 RAND J. ECON. 391 (2003); Mark A. Lemley & Carl Shapiro**.** *Probabilistic Patents*, 19 J. ECON. PERSP. 75 (2005).

strength, including *p*, are not easily observable without a costly inquiry into the validity of the patent.[17]

Rather than attempt to observe *p* directly, a more observable proxy for strength of the patent could be used. As noted above, the Court and economic analysts have focused upon the size of Brand's avoided litigation costs.[18] Under the assumptions of the monopoly-to-duopoly model, the Brand's minimum acceptable entry time equal to the litigation adjusted life of the patent when the size of the reverse payment equals the Brand's litigation costs. Moreover, any feasible settlement in which the reverse payment exceeds the Brand's litigation costs must reduce consumer welfare. Thus, a necessary but not sufficient condition for a feasible settlement to increase consumer welfare is that the size of the reverse payment be less than the Brand's litigation costs.

A rule that limits the size of reverse payments to no more than a party's litigation costs will result in equilibrium settlements that decrease consumer welfare relative to expected welfare generated through litigation. As shown in Figure 2, equilibrium settlements under such a rule result in entry dates that are later than the litigation adjusted life of the patent.

In addition, a limit on the size of reverse payments to the Brand's litigation costs can prevent a settlement that would result in litigation costs savings that would outweigh any loss in consumer welfare.[19] If such costs are taken into account, then E^*, the breakeven line for settlements that increase consumer welfare compared to the litigation-generated expected consumer welfare net of litigation costs, will be later than the litigation adjusted patent life.[20] In the example illustrated in Figure 2, $E^* = 9.254$.

Although litigation will force the parties to incur higher costs and can lower consumer welfare net of litigation costs, it is important to note that the absence of a settlement is not necessarily a "failure."[21] In patent litigation, whenever a judgment correctly invalidates or correctly upholds a patent, it produces benefits that

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

[18] See *Actavis*, 133 S.Ct. at 2236 ("Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.")

[19] This point is made by Harris, et al., *supra* note _. See also Kobayashi, et al., *supra* note _ (showing how feasible settlements in the presense of mutual optimism by the parties require reverse payments in excess of litigation costs).

[20] The problem of measuring welfare appropriately is discussed in more detail in Section IV below.

[21] *See generally,* Ezra Friedman and Abraham L. Wickelgen, *Chilling, Settlement, and the Accuracy of the Legal Process,* 26 J. L. Econ. & Org. 144 (2010); Owen M. Fiss, *Against Settlement*, 93 Yale L. J. 1073 (1984).

generally inure to non-parties, including other generic entrants and consumers. It follows that the welfare associated with a judgment can be greater than the welfare associated with a settlement. The benefits to non-parties, however, are not taken into account in the simple monopoly-to-duopoly model, which is another reason to move the analysis beyond the temporary duopoly.

II. A Model of Litigation and Settlement under Hatch Waxman and *Blonder-Tongue*: Accounting for Serial Entry

The simple monopoly-to-duopoly models do not account for key institutional features of the Hatch-Waxman Act and of *Blonder-Tongue* that render the duopoly assumption unrealistic. This section sets out a more general model of litigation and settlement under the Hatch-Waxman Act that explicitly accounts for the effect of these institutional features.

a. Market Structure and Profits under Hatch-Waxman andBlonder-Tongue

Figure 3 modifies Figure 1 to show the effects of serial entrants. The monopoly-to-duopoly model implicitly assumes that after settlement there will be no further challenge to the patent and hence no entry before the date (time T) provided in the settlement;[22] therefore, the profits of the Brand and of the Generic, depicted in the bottom panel of Figure 3, are identical to those depicted in Figure 1. The profits depicted in the top panel of Figure 2, which show the profits when the Brand plaintiff successfully defends the patent, are also identical to those depicted in Figure 1. g As a result, the Brand makes monopoly profits π^M during the remaining life of the patent (from time 0 to time T).

[22] Under the rules of non-mutual collateral estoppel, a second generic entrant that files a Paragraph IV ANDA could relitigate the validity of the patent. We assume that subsequent ANDA filers will be deterred from filing Paragraph IV ANDAs and entering if the first generic fails to invalidate the patent. The expected benefits of such a filing are reduced for two reasons. The first is the persuasive effect of the first case, which will increase the probability the patent will be upheld in any subsequent case. The second is lack of market exclusivity for subsequent Paragraph IV ANDA filers. For a more complete analysis of these issues, see Bruce H. Kobayashi, *An Economic Analysis of Relitigation Rules in Intellectual Property Litigation*, working paper, George Mason Law School (May 2014) (on file with author).

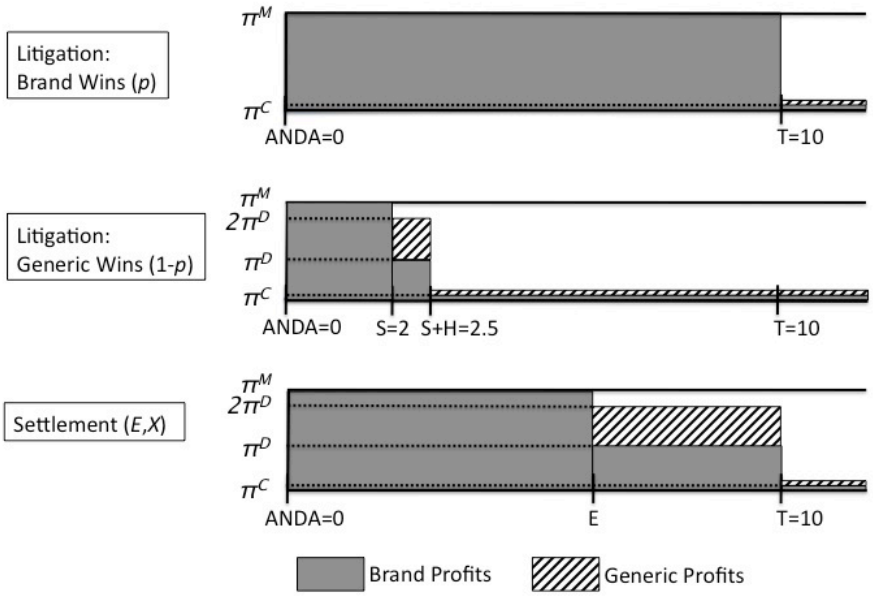

Figure 3 – Litigation and Settlement Profits for the Brand and Generic Firm

Relaxing the assumption of the monopoly-to-duopoly model changes the middle panel in Figure 3, which shows the payoffs when the first generic entrant invalidates the Brand's patents.[23] Our model accounts for two additional features of the process: the litigation stay and the limited period of exclusivity. If the Brand files an infringement suit within 45 days of the ANDA filing, then FDA action on the ANDA is stayed for 30 months, during which the Brand will continue to make monopoly profits (from time 0 to time *S*).[24] The first generic to file a Paragraph IV certification is entitled to 180-day marketing exclusivity under some circumstances, including when the patent is invalidated in litigation.[25] Thus, when the first generic entrant to file a paragraph IV ANDA invalidates the Brand's patent through litigation, the Hatch-Waxman regulatory regime produces a six-month period of duopoly competition between them; thus both the Brand and the Generic make

[23] The example assumes that $S = 2$, not 2.5 years (30 months). This assumes that the parties execute the settlement agreement prior to the expiration of the stay. This might occur, for example, if the parties wanted to avoid the costs of continuing litigation.

[24] If no infringement suit is filed, the FDA can approve the ANDA. The branded firm, however, can sue the entrant for infringement and, if successful, can collect damages based upon the generic entrant's infringing sales. If the would-be generic entrant does not want to enter without first having invalidated the patent then, following *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007)., the generic entrant can file a declaratory judgment action challenging the validity of the patent. See *Caraco Pharm. Labs. Ltd. v. Forest Labs*, _ F.3d. _ (Fed. Cir. 2008).

[25] 21 U.S.C. § 355 (j)(5)(B)(iv).

duopoly profits π^D during the period of marketing exclusivity from time *S* to time *S* + *H* in Figure 3.

With serial generic entrants, this short period of duopoly is followed by free-entry competition. Under the Court's holding in *Blonder-Tongue v. University of Illinois Foundation*, the Brand whose patents were invalidated by the first Paragraph IV litigant is collaterally estopped from relitigating the validity of the patent. Thus, at the end of the six-month exclusivity period, other firms that file Paragraph IV certifications can enter the market, and firms in the market, including the Brand and the first generic entrant, make free-entry profits π^C from the end of the marketing exclusivity period (at time *S+H*) to the expiration of the patent at time *T* (and, of course, beyond).[26] By invalidating a "bad" patent, the first Paragraph IV generic entrant provides a public benefit to others, including both other generic entrants, which can enter after the expiration of the 180-day period of marketing exclusivity, and consumers, who benefit from the lower prices brought on by the increase in competition.

b. Feasible Settlements under Hatch-Waxman and *Blonder-Tongue*

For simplicity and for a more direct comparison to the simple monopoly-to-duopoly model, we assume as that model does that the discount rate is zero, and we abstract away from the litigation stay.[27] We also assume that entry through a Paragraph IV ANDA litigation challenge to a patent that has not been invalidated will always include a period of exclusivity. The examples in this section, however, explicitly take into account the potential for serial entries once a patent has been invalidated and the effect of the limited 180-day marketing exclusivity period *H.*

[26] The free-entry profits are not zero. The extent of entry will be limited by the costs of entry, which are assumed to be positive. Thus, the model assumes that all firms, including the Brand, make the symmetric Cournot profits given N firms, with N being determined by the free entry condition.

[27] For an explicit analysis of these factors, see Kobayashi, *et al.*, *supra* note _.

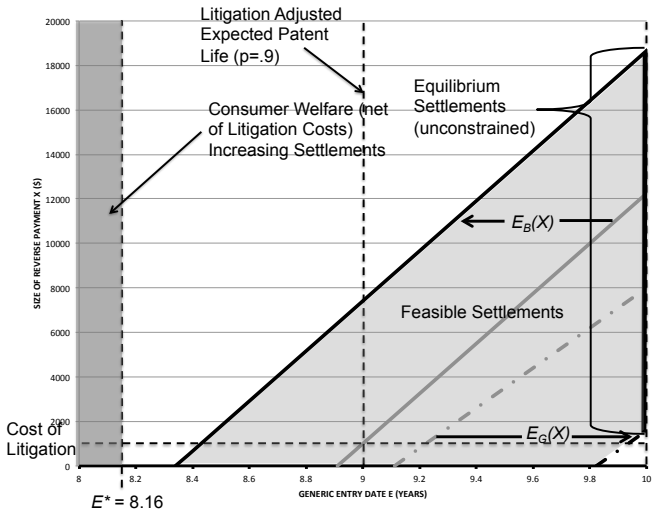

Figure 4 – Feasible Settlements and Welfare in the Multiple-Entrant Model

Figure 4 depicts the range of feasible settlements in the case where both parties estimate that p = .9 and where three additional entrants will enter if the patent is invalidated or expires.[28] Taking into account the effect of collateral estoppel and free entry after the invalidation of a patent expands the set of feasible settlements. Collateral estoppel imposes additional litigation losses on the Brand and shifts its earliest acceptable entry date $E_B(X)$ to the left. The litigation payoff for the first generic entrant to file a Paragraph IV ANDA is lowered because it obtains duopoly profits only for the duration of the 180-day period of market exclusivity and lower free entry profits afterwards. This shifts its latest acceptable entry date $E_G(X)$ to the right.

c. Equilibrium Settlement and Welfare with the Multiple-Entrant Model

If there are no legal constraints upon settlement, then the multiple entry model predicts a set of equilibrium settlements that do not allow early entry and in which reverse payments X are 1.5 to more than 18 times the Brand's litigation costs. The set of equilibrium settlements is depicted in Figure 4.

Figure 4 also shows the conditions under which a settlement raises consumer welfare compared to the expected consumer welfare net of litigation costs that would be generated through litigation, viz., when E is earlier than (less than) E^*. The breakeven entry date E^* with multiple entrants is earlier than the breakeven entry date under the monopoly-to-duopoly model, and earlier than the litigation adjusted life of the patent (pT). Under the conditions depicted in Figure 4, E^* =

[28] That is, if the patent is invalidated, market competition after the expiration of the Hatch-Waxman 180-day marketing exclusivity period will include 5 firms, viz., the Brand firm (perhaps competing through an authorized generic), the first Paragraph IV generic entrant, and three subsequent ANDA generic entrants.

8.16.[29] Intuitively, the breakeven date for early entry (E^*) is earlier because litigation will produce a greater static expected welfare gain with multiple entrants; instead of producing duopoly for the remainder of the patent life, invalidation of the patent produces six months of duopoly followed by the higher static welfare produced under free-entry competition. Therefore, welfare increasing settlements must allow entry and duopoly competition earlier than the litigation adjusted life of the patent in order to offset, to the extent feasible, the long period of free entry welfare gains generated by litigation.

As illustrated in Figure 4, the breakeven early settlement date is less than the Brand's minimum acceptable entry date (where X=0 and E_B intersects with the horizontal axis). Therefore, all feasible settlements, including those in which there is no reverse payment, reduce consumer welfare net of litigation costs. Moreover, the model predicts that absent bargaining failure or antitrust restrictions on settlement, litigation is unlikely. For example, litigant optimism that would generate litigation in the monopoly-to-duopoly model generates a robust settlement range when the effect of anticipated multiple entry after patent invalidation is taken into account.[30]

III. Patent Settlements, Antitrust Rules, and Welfare Standards

We turn now to the normative question of antitrust policy and welfare. Table 1 depicts the standard error cost matrix applicable to the antitrust evaluation of reverse payments. Under that approach, the optimal rule minimizes the sum of error costs and direct costs.[31] A bright line rule can be optimal if it results in cost savings and benefits from increased certainty that outweigh the associated increase in error costs.[32]

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[29] For a derivation of this threshold and the basis for the numerical example, see Kobayashi, et al., *supra* note _.

[30] *Id.* (providing example showing the effects of litigant optimism in the multiple entrant setting).

[31] *See* Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747 (2002); Bulter & Jarosh, *supra* note _. *See generally,* Isaac Erlich & Richard A. Posner, *An Economic Analysis of Legal Rulemaking*, 3 J. LEGAL STUD. 257 (1974) (setting out the general approach); Richard A. Posner, *An Economic Approach to Legal Procedure and Judicial Administration,* 2 J. LEGAL STUD. 399 (1973) (same); Frank H. Easterbrook, *The Limits of Antitrust*, 63 TEX. L. REV. 1, 9–16 (1984) (applying the error cost framework to antitrust law); Geoffrey A. Manne & Joshua D. Wright, *Innovation and the Limits of Antitrust*, 6 J. COMP L. & ECON. 153 (2010) (applying error cost analysis of antitrust law to innovation).

[32] *See, e.g.*, *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d. 227, 234 (1st Cir. 1983) ("[U]nlike economics, law is an administrative system the effects of which depend upon the content of rules and precedents only as they are applied by judges and juries in courts and by lawyers advising their clients. Rules that seek to embody every economic complexity

Table 1 – Error Cost Matrix for Settlements that Include Reverse Settlement Payments

	No Antitrust Violation (Scope of the patent test)	**Antitrust Violation (Per se illegal)**
Patent Valid	Specificity (Settlement within the scope of a valid patent)	Type I error (condemning lawful exercise of market power generated by valid patent)
Patent Invalid	Type II error (allow the use of an invalid patent to prevent the risk of competition)	Sensitivity (condemning use of an invalid patent to prevent the risk of competition)

The scope of the patent test would result in the application of a bright line rule that selects the left hand column in Table 1. Although the scope of the patent test would yield a correct outcome for valid patents and protect against the costs associated with the erroneous invalidation of valid patents (Type I error costs), the test produces the error costs associated with erroneously allowing invalid patents to remain in force (Type II error costs). The *Actavis* Court rejected this approach, expressing concern over the possibility of Type II errors. In particular, the Court noted that "[a]n important 'patent-related policy'" is to "eliminat[e] unwarranted patent grants so the public will not 'continually be required to pay tribute to would-be monopolists without need or justification.'"[33]

The bright line rule advocated by the FTC would select the rule in the right hand column of Table 1, which would protect against Type II errors, but would increase the costs of Type I error when valid patents were challenged. The Court, recognizing the legitimate value of settling litigation, as well as the complexities involved in the antitrust evaluation of reverse payment settlements, also rejected the bright line rule of per se illegality and the somewhat less error-prone quick-look rule with a presumption of illegality.[34]

The antitrust policy question for the lower courts now is how to fashion a relatively accurate and administrable procedure under the rule of reason that minimizes the sum of error costs and direct costs.[35] One possibility would be to

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and qualification may well, through the vagaries of administration, prove counterproductive, undercutting the very economic ends they seek to serve.").

[33] *Actavis*, 133 S.Ct at 2233.

[34] *Id*. at 2237.

[35] *See* Joshua D. Wright, *FTC v. Actavis and the Future of Reverse Payment Cases,* (September 26, 2013), available at:

make a detailed inquiry into the validity of the patent as part of the antitrust case.[36] In theory, if this inquiry enabled courts accurately to determine the validity of the patent at a low cost, the scope of the patent test could be applied to cases where the inquiry concludes that the patent is valid, while allowing antitrust claims to proceed in cases where the inquiry concludes the patent is not valid.

The uncertainty and cost of "deciding a patent case within an antitrust case, a turducken task," led the 11th Circuit to adopt the bright line scope of the patent test.[37] Likewise, under the Court's decision in Actavis, the rule of reason approach need not involve an inquiry into the validity of the patent. Indeed, the Court said it is "normally not necessary to litigate patent validity to answer the antitrust question" as such litigation would "prove time consuming, complex, and expensive," and likely "not be worth that litigation candle."[38]

Rather than a full blown inquiry into the merits of the patent, the Court suggested that the portion of the reverse payment that is not explained by traditional settlement considerations or other procompetitive justifications "can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself."[39] Focusing upon this surrogate, "a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments."[40]

As we demonstrated above, however, even with the simple monopoly-to-duopoly model, equilibrium settlements can involve very large payments. Even when both parties in the example estimate that the patent will be upheld 90% of the

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http://www.ftc.gov/sites/default/files/documents/public_statements/ftc-v.actavis-future-reverse-payment-cases/130926actavis.pdf.

[36] See Crane, *supra* note .

[37] *F.T.C. v. Watson*, 677 F.3d at 1315. Turducken refers to a complex culinary dish consisting of a chicken stuffed inside a duck that is stuffed inside a turkey. See Amanda P Reeves, *Muddying the Settlement Waters: Open Questions and Unintended Consequences Following FTC v. Actavis*, 28 ANTITRUST 9, 15 (2013).

[38] *Actavis*, 133 S.Ct. at 2234.

[39] Id. at 2236-37. The Court noted that the FTC admits reverse payments can have redeeming virtues: "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—such as distributing the patented item or helping to develop a market for that item. There may be other justifications. Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." *Id*.

[40] *Id.* at 2237.

time, the range of equilibrium reverse settlements is eight to twelve times each party's litigation costs. If, for example, both parties estimate the probability of the patent being upheld at only 50%, the range of equilibrium reverse settlements is from seven to fifty-three times each party's litigation costs.[41] If the patent is valid, the reverse payment is the cost to the Brand of Type I error.[42] Unconstrained equilibrium settlements allow the Brand to minimize the costs of Type I error. That is, there is always some settlement without early entry that allows the Brand to reduce its costs relative to litigating and an alternative settlement that allows generic entry prior to the expiration of the patent.

If the patent is not valid, then reverse payment settlements impose the highest Type II error costs. Under the assumption that invalid patents do not promote innovation, a settlement that does not allow early entry imposes the deadweight loss from monopoly for the maximum amount of time -- the life of the patent -- and reduces consumer welfare relative to settlements that allow generic entry before the expiration of the patent.

With the multiple entrant model in Section II, the positive analysis shows that the competitive setting generated by the Hatch-Waxman regulatory regime and the Court's collateral estoppel rules work to generate strong incentives for settlement. These incentives are much stronger than those generated by the simple monopoly-to-duopoly models. Indeed, the multiple entrant model predicts that litigation is unlikely, and so too, therefore, is the the invalidation of bad patents, a "public good" foregone.

Moving to the normative implications of the positive analysis, the multiple entrant scenario implies that an antitrust rule based upon the size of reverse payments will not produce settlements that increase consumer welfare net of litigation costs. As shown in the example, all feasible settlements, including those with no reverse payments, reduce static consumer welfare as compared to litigation. Indeed, the multiple entrant model shows the static welfare gains from invalidating a patent are much greater than those generated in the monopoly-to-duopoly model. This has led many to advocate a policy that would not only ban reverse payments, but also have courts scrutinize closely all settlements of Hatch-Waxman patent litigation.[43]

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[41] *See* Kobayashi, *et al*., *supra* note _ (Setting out alternative example where $p = .5$)

[42] In addition, as discussed below, the social costs of type I error can be larger, and include the foregone benefits of research deterred and of the drugs it would have been produced.

[43] See Joshua D. Wright, *Antitrust Analysis of Reverse Payment Settlements After Actavis: Three Questions and Proposed Answers - Remarks of Commissioner Joshua D. Wright at the Antitrust Masters Course VII,* available at http://www.ftc.gov/public-statements/2014/10/antitrust-analysis-reverse-payment-settlements-after-actavis-three

Those more strict limitations upon settlements of Hatch-Waxman patent litigation do not reflect a full error cost analysis. The optimal antitrust rule under such an analysis is the rule that minimizes the sum of error costs and direct costs. The static consumer welfare standard used by EHHS and others is incomplete as it ignores direct costs and considers only some of the error costs. In particular, this standard, at best, provides a proxy for the consumer welfare costs associated with Type II error.

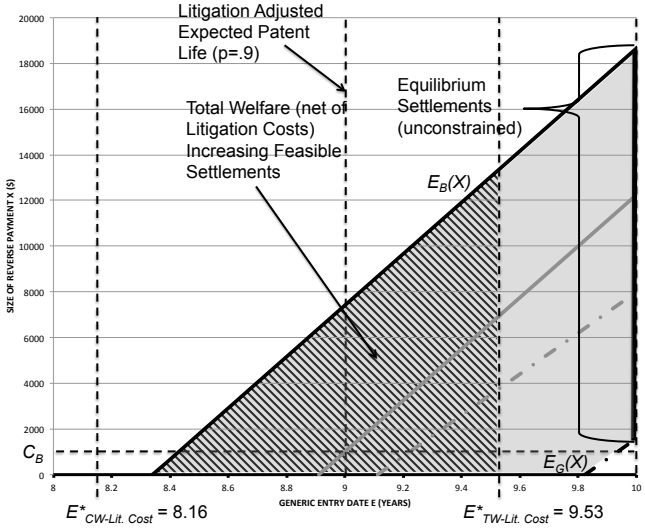

Figure 5 – Total Welfare Net Litigation Costs Standard

Setting aside for the moment differences of opinion about the purpose of antitrust law[44] and applying standard price theory, a more direct measure of the welfare costs of Type II error would be the deadweight loss rather than loss of consumer surplus. In determining the breakeven entry date for a settlement E^*, a welfare standard that attempted to minimize the sum of the deadweight losses plus litigation costs is equivalent to using a total welfare standard net of litigation costs. Figure 5 modifies Figure 4 to include that standard. Under a total welfare net litigation costs standard, $E_{TW\text{-}Lit.\ Cost}^* = 9.53$ in the multiple-entrant model. Using this standard, a large range of the feasible settlements would raise total welfare net of litigation costs.[45]

The total welfare net of litigation costs standard in Figure 5, which only re-weights the relative importance of litigation costs and the Type II errors of reduced

[44] See, e.g., Ken Heyer, *Welfare Standards and Merger Analysis: Why Not the Best?*,"2 CPI J. n.2 (Autumn 2006); Steven C. Salop, *Question: What is the Real and Proper Antitrust Welfare Standard? Answer: The True Consumer Welfare Standard*," 22 LOY. CONSUMER L. REV. 336 (2010).

[45] See Richard S. Higgins & Donald L. Martin, *The Economics of "Pay-For-Delay" Under Rule of Reason Generic Competition and Hybrid Settlements*, working paper (2014) (using total welfare standard).

static welfare,[46] still fails to address the costs of Type I error, i.e. the costs of forgone innovation due to the reduced incentives that result from the erroneous invalidation of patents and the *in terrorem* settlements paid to avoid this outcome.[47] Considering the full error cost analysis, including the costs of Type I error, the breakeven early entry date E^* may be even further to the right of the breakeven point shown in Figure 5. Indeed, because patent terms are not set optimally, but are based on the arbitrary statutory rule of 20 years from filing, it is possible that a full error cost analysis, taking Type I errors into account, would find that settlement agreements where generic entry is not allowed before the expiration of the patent in fact increase dynamic welfare, which would support the scope of the patent test. Inasmuch as the regulatory structure of the Hatch-Waxman Act includes patent term restoration, it is odd not to consider the costs of Type I error in any analysis of the patent/antitrust interface under the statute.

[46] The consumer welfare minus litigation costs standard places greater weight on the reduction of surplus (a cardinal measure) relative to litigation costs than does the total welfare (also a cardinal measure) minus litigation costs standard, which is equivalent to minimizing deadweight loss plus litigation costs.

[47] Indeed, it is interesting that the Court's opinion in *Actavis* suggests payment of the Brand's avoided litigation costs is a legitimate aim of settlement. In other contexts, the extraction of the other parties' litigation costs has been one of the primary reasons for adopting rules that truncate litigation at an early stage. For example, in moving to a plausibility standard at the pleading stage in *Twombly,* the Court expressed concern over a plaintiff with "a largely groundless claim" being allowed to "take up the time of a number of other people, with the right to do so representing an *in terrorem* increment to settlement value." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citing *Dura Pharmaceuticals v. Broudo*, 544 U.S. 336 (2005), quoting *Blue Chip Stamps v. Manor Drug Stores*, 4221 U.S. 723, 741 (1975)). See also Bruce H. Kobayashi, *Law's Information Revolution as Procedural Reform: Predictive Search as a Solution to the In Terrorem Effect of Externalized Discovery Costs*, 2014 U. ILL. L. REV. _ (2014); David Rosenberg & Steven Shavell, *A Model in Which Suits Are Brought for their Nuisance Value,* 5 INT. REV. L. & ECON. 3 (1985).

IV. Conclusion

In *FTC v. Actavis*, the Court rejected bright line rules of legality and illegality in favor of a standard to be fleshed out by the lower courts applying the rule of reason. At the same time, the Court recognized the costs of an unconstrained rule of reason analysis, and suggested a simpler rule, one based upon the size of the brand/patentee's litigation costs to establish an antitrust limit on the size of reverse payments. The analysis in this paper, which incorporates a more realistic model of regulation and competition under Hatch-Waxman, shows such a rule will not allow all welfare increasing settlements, will encourage litigants to use other, potentially more inefficient means to settle, and will increase the costs of Type I errors, all costs that are ignored in the prior economic analyses of reverse settlement.