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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 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 payments, “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 to instead 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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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.\textsuperscript{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 must reduce consumer welfare if the size of the reverse payment exceeds the patentee's litigation costs.\textsuperscript{9} These analyses have been used to support antitrust rules that would enjoin reverse payments that exceed the cost of litigation.\textsuperscript{10}

We demonstrate that the simple monopoly-to-duopoly models 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.

Our key institutional insight is the fact that entry by multiple firms follows the invalidation of a patent.\textsuperscript{11} We incorporate this institutional reality into our


\textsuperscript{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.)

analysis. Instead of obtaining duopoly profits for the duration of the 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 one-hundred and eighty 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 entrant’s litigation threat point. Litigating a patent under a rule of defensive non-party non-mutual collateral estoppel imposes greater losses upon the patentee than in the case where there is a single entrant. This, in turn, increases the litigation threat point facing the patentee. The result is a broader settlement range than under the monopoly-to-duopoly model that yields robust incentives for the brand and generic entrant to settle the case.

This broad settlement range makes attempts to regulate the size of patent settlements ineffective at achieving consumer welfare increasing settlements, or inducing the invalidation of “bad” patents through higher litigation rates. Incorporating multiple serial entrants also decouples the litigation-adjusted expected value of the patent and the consumer welfare standard and, most important, weakens the relationship between patent strength and the size of the settlement which has motivated numerous calls to deem presumptively unlawful all payments greater than anticipated litigation costs.

In addition to the positive analysis of litigation, the article examines the alternatives to the consumer-welfare only standard used in some analyses to evaluate reverse payment settlements. It seems clear that in this context one would want to consider a welfare standard that includes more than static consumer surplus. The design of the Hatch-Waxman Act, which includes provisions that encourage generic entry and patent term restoration, embodies the use/access-creation/incentives tradeoff that is a central focus of the economic analysis of intellectual property rights and contemplates consideration of incentives to innovate and dynamic efficiencies. A static consumer welfare-only antitrust

standard considers only access and ignores the incentive aspect underlying the Hatch-Waxman Act.

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

We begin by examining 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 in 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. In a Paragraph IV ANDA, the generic entrant certifies that the brand firm’s unexpired patent is invalid or not infringed. The filing of a Paragraph IV ANDA creates an act of infringement that allows the patentee to file an infringement suit.

The EHHS and other simple monopoly-to-duopoly models, are a special case of the more general model presented in the appendix. 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, where profits are denoted along the vertical axes and time, $t$, is denoted along the horizontal axes. The top and middle panels show the litigated profits for the Brand and the Generic if the Brand wins and if the Generic wins, respectively. The middle panel in particular shows the effect of the assumptions the simple monopoly-to-duopoly model makes. Instead of a short period of duopoly followed by free entry when the patent is invalidated, the simple monopoly-to-duopoly model assumes that the settlement yields duopoly profits from the time the patent is invalidated until the expiration of the patent.

Instead of litigating, the brand and the initial generic entrant can settle the litigation. The terms of the settlement contains a reverse payment $X$ and an agreed upon early entry date $E \leq T$, where $T$ is the patent expiration date. The bottom panel shows the profits for the Brand and the Generic if they settle: the Brand enjoys monopoly profits until the Generic enters at time $t=E$, and after the entry the Brand and the Generic both obtain duopoly profits until the patent expires.
b. Litigation and Settlement in the simple Monopoly-to-duopoly Model

In this section, we illustrate the litigation/settlement decision using the simple monopoly-to-duopoly model. The example assumes that the Brand (B) files and litigates a lawsuit within 45 days of the filing of the initial Paragraph IV certification, incurs litigation costs $C_B$, and estimates that the patent will be successfully defended with probability $p_B$ and invalidated with probability $1 - p_B$.

The bargaining range when $p = p_B = p_G = .9$ is depicted in Figure 2. The vertical axis measures the size of the reverse payment $X$, and the horizontal axis measures the date of early entry $E$. The set of feasible settlements lie in the shaded area to the right and below the Brand’s minimum acceptable entry date line $E_B(X)$ and to the left and above the Generic’s maximum acceptable entry date line $E_G(X)$. Examining Figure 2, if there are no constraints on settlement, the set of Pareto settlements are

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

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13 Figure 2 is based on a figure used by Harris, et al., *supra* note _. The example in Figure 2 assumes the demand for the drug is given by $P = A - BQ$, with $A = 100$ and $B = .1$, $C_B = C_G = 1000$, and $T = 10$ years. Monopoly profits for the drug are 20,250. If this is up scaled to be a 200 million dollar per year drug, then paragraph IV litigation costs in the example would equal just over 1 million dollars.
settlements that set $E = T$ and have reverse payments $X$ between 8 and 12 times the Brand’s litigation costs.\textsuperscript{14}

**Figure 2 – Feasible Settlements in the Simple Monopoly Duopoly Model**

c. Equilibrium Settlement, Welfare, with the Simple Monopoly-to-duopoly Model

In this section, we consider how litigation settlements affect static consumer welfare. It is easy to verify that the consumer welfare of a settlement is strictly decreasing in $E$. The consumer welfare of a settlement that specifies an early entry time $E$ equals:

\begin{equation}
CW_{\text{settlement}} = E \times CW^M + (T - E) \times CW^D
\end{equation}

The expected consumer welfare from a litigated patent that has a probability $p$ of being held valid equals:

\begin{equation}
CW_{\text{litigation}} = pT \times CW^M + (1 - p)T \times CW^D
\end{equation}

\textsuperscript{14}To see this, suppose that there is some settlement $(E^0, X^0)$ in the interior of the shaded feasible settlement set in Figure 3 where $E < T$. The Brand prefers higher $E$ and lower $X$ and the Generic prefers lower $E$ and higher $X$. In addition, the Brand’s indifference curves in $E,X$ space have a steeper slope (equal to $(\pi^M - \pi^D)$ per period, the slope of $E_B(X)$ in the figure) than the Generic’s indifference curves (equal to $\pi^G$ per period, the slope of $E_G(X)$ in the figure). The parties can always find an alternative settlement $(E^1, X^1)$, where $E^1 > E^0$ and $X^1 > X^0$, that is preferred by both parties. A similar point is also made by Edlin, et al., (2014), \textit{supra} note \_.
Comparing (8) and (9) when $E = pT$, it is easy to confirm that $CW_{\text{settlement}} = CW_{\text{litigation}}$. Thus, when $E <(>) pT$, the consumer welfare from a settlement is greater (less) than the expected consumer welfare from litigation. The dark shaded triangle in Figure 2 shows the set of feasible and consumer welfare increasing settlements where $E < pT$.

In order to limit settlements to those that increase consumer welfare relative to litigation, one could in theory impose a rule that limits the generic entry date $E < pT$.$^{15}$ As the Court discussed in Actavis, the problem with attempting to use such a rule in practice is that $p$ is not easily observable without a costly inquiry into the validity of the patent.$^{16}$

Rather than attempt to observe $p$ directly, one can instead use a more observable proxy for strength of the patent. As noted above, however, the Court and economic analysts have focused thus far upon the size of Brand’s avoided litigation costs.$^{17}$ Note that under the assumptions of the simple monopoly-to-duopoly model, the Brand’s minimum acceptable entry time equals the litigation adjusted life of the patent at $X = C_B$, i.e., $E_B(X=C_B) = pT$. Thus, a necessary (but not sufficient) condition for a settlement to increase consumer welfare is that $X < C_B$. That limitation will not result in a settlement that increases consumer welfare relative to forcing the parties to litigate. For the same reasons that unrestricted settlements where $E = T$ are Pareto preferred to unrestricted settlements where $E < T$, settlements where $X = C_B$ and $E \geq pT$ Pareto dominate feasible settlements that increase consumer welfare and comply with an antitrust rule that restricts reverse payments to $X \leq C_B$.

In addition, a limit on the size of reverse payments can prevent settlement.$^{18}$ Figure 3 illustrates the feasible settlement range under the same conditions as Figure 2 except for the fact that both parties are mutually optimistic, e.g., $p_B = .912 > p_C = .888$. Optimism causes the Brand’s minimum acceptable entry date $E_B(X)$ to shift to the right and causes the Generic’s maximum acceptable date $E_G(X)$ to shift to the left. As is illustrated in Figure 3, a rule that constrained reverse payments to $X < X^*$ would preclude settlement. In the example, this would include a rule that limited reverse payments to be less than the Brands’ litigation costs ($X < C_B$).

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$^{16}$ See Actavis, 133 S.Ct. at 2247.

$^{17}$ 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.")

$^{18}$ Harris, et al., supra note _ at _ contains an example of litigation generating optimism.
It is important to note that the absence of a settlement is not necessarily a “failure.” In patent litigation, a judgment can be valuable and produce benefits not produced when parties settle. In particular, a judgment produces such benefits when it correctly invalidates a patent, or when it correctly upholds a valid patent. Thus the welfare associated with a judgment can be greater than the welfare associated with a settlement.

![Diagram](image)

**Figure 3 – Litigation with Mutual Optimism in the Monopoly-to-duopoly Model**

Indeed, in the example presented in Figure 3, all feasible settlements will reduce consumer welfare as any feasible settlement would require that $X > X^C$ and $E > E^C$. Because $E^C > pT$, consumer welfare must fall relative to the litigation outcome for any feasible settlement. The standard benefit of a settlement, however, is that the parties and society save the costs of litigation. If one adopts a consumer welfare standard, but recognizes the social costs of litigation, a settlement will be socially beneficial only if the savings in litigation costs are greater than the reduction in consumer welfare. In the monopoly-to-duopoly model, this is true for feasible settlements where $E^C < E < E^*$ where $E^*$ is defined as:

\[
E^* = pT + \frac{C_B + C_G + C_S}{CW^D - CW^M} > pT
\]


\[20\] The examples assume that the attorney’s fees and parties’ costs are 1,000 each. In addition, the example in Figure 4 assumes that litigation produces an additional 1,000 in non-party costs $C_S$ (e.g., court costs, opportunity costs of witnesses, etc.).
The set of feasible settlements that increase consumer welfare relative to the expected consumer welfare that would be obtained through litigation net of litigation costs is depicted by the cross-hatched area in Figure 3.

The example suggests that proposals to limit the size of reverse settlements to the Brand’s litigation costs will preclude the parties from reaching settlements, some of which are not only mutually beneficial but also would result in litigation costs savings that outweigh the loss of consumer welfare. On the other hand, left unconstrained by antitrust limits on settlements, the monopoly-to-duopoly model would still predict the settlement of litigation under the conditions depicted in Figure 3. Moreover, for the reasons set out above, the model predicts that unconstrained settlement will include a reverse payment X between 9000 and 11000, and specify that $E = T$. This settlement will reduce consumer welfare compared to the expected consumer welfare generated by litigation net of litigation costs.

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 Blonder-Tongue that render the duopoly assumption unrealistic. Accounting for the effect of these institutional features significantly increases the size of the reverse payment from which a court should infer anticompetitive harm. We begin by setting out a general monopoly-to-duopoly model of litigation and settlement under the Hatch-Waxman Act.

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

Recall that litigation under the Drug Price Competition and Patent Term Restoration Act begins when a generic entrant files an ANDA with a Paragraph IV Certification. In a Paragraph IV ANDA, the generic entrant certifies that the Brand firm’s unexpired patent is invalid or not infringed. The filing of a Paragraph IV ANDA creates an act of infringement that allows the patentee to file an infringement suit.

Figure 4 shows the undiscounted profits for the Brand and first generic entrant that files a Paragraph IV certification, where profits are denoted along the vertical axes and time, $t$, is denoted along the horizontal axes. The top panel shows the litigation payoff of a successful brand plaintiff. Under the assumption that a successfully defended patent will not be challenged a second time, all generic

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21 This point is made by Harris, et al., supra note _.
22 The problem of measuring welfare appropriately is discussed in more detail in Section IV below.
entrants must wait until the patent expires at time \( t = T \) to enter. As a result, the Brand makes monopoly profits \( \pi^M \) during the remaining life of the patent (from time \( t = 0 \) to time \( t = T \)).

\[ \pi^M \]

\[ \pi^C \]

\[ \pi^D \]

\[ \pi^C \]

Figure 4 – Litigation and Settlement Profits for the Brand and Generic Firm

The middle panel in Figure 4 shows the payoffs when the first generic entrant wins the litigation and the Brand’s patents are invalidated. If the Brand firm that owns the patent 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 patentee

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\(^{23}\) 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).

\(^{24}\) 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 because the parties wanted to avoid the costs of continuing litigation.
will continue to make monopoly profits (from $t = 0$ to $t = S$). The first generic to file Paragraph IV certification is entitled to 180-day marketing exclusivity under some circumstances, including when the patent invalidated in litigation. 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 this first Paragraph IV ANDA and the Brand (i.e., both the Brand patentee and Generic entrant make duopoly profits $\pi^D$ during the period of marketing exclusivity from $t = S$ to $t = S + H$ in Figure 4).

Under the Court’s holding in Blonder-Tongue v. University of Illinois Foundation, the brand firm whose patents were invalidated by the first Paragraph IV litigant is 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 to file a Paragraph IV certification, make free entry profits $\pi^C$ from the end of the marketing exclusivity period ($t = S + H$) to the expiration of the patent ($t = T$). 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.

Instead of litigating, the brand and the initial generic entrant can settle the litigation. The settlement calls for the Brand firm to pay $X$ to the Generic, which agrees not to enter until a date $E \leq T$. The bottom panel of Figure 4 depicts the undiscounted profits for the Brand and the Generic firm if they settle. Under the assumption that subsequent challenges to the patent will not occur after the settlement, the Brand firm will make monopoly profits until $t = E$, and duopoly profits between $t = E$ and the expiration of the patent at $t = T$. Under the same assumption, the Generic entrant will make duopoly profits from time $t = E$ until the expiration of the patent at time $t = T$.

Although the top and bottom panels in Figure 4 are the same as in Figure 1, the middle panel in Figure 4 shows the effect of the assumptions of the simple

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25 If no infringement suit is filed, the FDA can approve the ANDA. The branded firm, however, can sue the entrant for infringement and a successful plaintiff can collect damages based upon the generic’s infringing sales. After the Supreme Court’s holding in Medimmune, the generic entrant can file a declaratory judgment action challenging the validity of the patent if it does not want to enter without first having invalidated the patent. See Caraco Pharm. Labs. Ltd. v. Forest Labs, __ F.3d, _ (Fed. Cir. 2008).


27 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.
monopoly-to-duopoly model. If the first generic entrant wins and invalidates the Brand firm’s patent, a 180-day period of duopoly is followed by free entry when the patent is invalidated, instead of duopoly profits from the time the patent is invalidated until the expiration of the patent in the simple monopoly-to-duopoly model.

b. Litigation and Settlement Payoffs 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 \( r = 0 \) and \( S = 0 \). We also assume that entry through a Paragraph IV ANDA litigation challenge to the patent will not occur absent a period of exclusivity. However, the examples in this section explicitly take into account the potential for multiple serial entry when a patent is invalidated, and the effect of the limited 180-day marketing exclusivity period \( H \).

Figure 5 depicts the range of feasible settlements in the case where \( p = p_B = p_G = .9 \) and the parties both anticipate there will be three additional entrants.\(^{28}\) Taking into account free entry after the invalidation of a patent expands the set of feasible settlements. If the patent is invalidated through litigation with the first generic to file a Paragraph IV ANDA, the Brand is estopped from re-litigating the validity of the patent and faces free entry upon expiration of the Hatch-Waxman Act 180-day marketing exclusivity period. This imposes additional litigation losses on the patentee, and shifts the Brand’s minimum acceptable entry date to the earlier date \( E_B(X) \).\(^ {29}\) Similarly, the litigation payoff for the first generic entrant to file a Paragraph IV ANDA is lowered by the fact that it obtains only duopoly profits for the duration of the 180-day period of market exclusivity, and lower free entry profits afterwards. This shifts his maximum acceptable entry date \( E_G(X) \) to the right.\(^ {30}\)

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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, the first Paragraph IV generic entrant, and three subsequent ANDA entrants.

29 Note that the first two terms of equation (3”) are identical to the expression for \( E_B(X) \) from the monopoly-duopoly model given by equation (3’). The magnitude of the shift that results from the anticipation of multiple entrants is given by the third term in equation (3”), which is the time equivalent expected value of the difference between duopoly and free entry profits from \( t = H \) to \( t = T \).

30 Note that the first two terms of equation (6”) are identical to the expression for \( E_G(X) \) from the monopoly-duopoly model given by equation (6’). The magnitude of the shift that results from the anticipation of multiple entrants is given by the third term in equation (3”), which is the time equivalent expected value of the difference between duopoly and free entry profits from \( t = H \) to \( t = T \).
Figure 5 – Feasible Settlements in the Multiple-Entrant Model

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

If there are no constraints upon settlement, the multiple entry model predicts a set of Pareto settlements that set $E = T$ and have reverse payments $X$ that are 1.5 to more than 18 times the Brand’s litigation costs. The set of Pareto settlements is depicted in Figure 6.

$E^* = 8.16$

Figure 6 – Pareto Settlements and Welfare in the Multiple-Entrant Model

A settlement increases Welfare net of litigation costs if $E < E^*$, where

$$E^* = \frac{(p_B T) W^M - (T - H) p_B H W^D + (1-p_B) (T - H) W^G C_B - C_G - C_S}{W^M - W^D}$$
Under the conditions depicted in Figure 6, $E^* = 8.16$. The entry date at which the measure of welfare under settlement equals the welfare under litigation is earlier than the breakeven entry date under the monopoly-to-duopoly model, and less than the litigation adjusted life of the patent $pT$. Intuitively, the breakeven date for early entry ($E^*$) is earlier because litigation now produces greater static expected welfare. Instead of producing duopoly for the remainder of the patent life, when the patent is invalidated the model with multiple entry 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 generated by litigation.

As illustrated in Figure 6, the breakeven early settlement date is less than the minimum acceptable entry date $E_B(X=0)$, 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 litigation is unlikely. Figure 7 shows the effect of optimism on the settlement range. In the monopoly-to-duopoly model, the level of mutual optimism generated litigation. When multiple entry is considered, however, optimism still generates a robust settlement range.

![Figure 7 - The Effect of Optimism in the Multiple-Entrant Model](image)

Figure 7 shows this effect more generally.\(^{31}\) The axes in Figure 8 show the parties’ estimates of the probability the patent will be upheld, with the Generic’s estimate on the horizontal axis and the Brand’s estimate on the vertical axis. The

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\(^{31}\) See Jonah B. Gelbach, *Is Everything You Know About Litigation Selection and the Plaintiff’s Win Rate Wrong?*, working paper, University of Pennsylvania Law School (January 2014) (on file with author).
dark shaded area to the right of $p_G^*$ shows the set of cases where the Generic’s paragraph IV challenge has negative expected value. The dark shaded area below $p_B^*$ shows the set of cases where Brand’s infringement lawsuit has negative expected value. The 45-degree line shows the points where there is agreement between the parties over the probability the patent will be upheld. When the parties are mutually optimistic, the probability pair $(p_G, p_B)$ will lie above the 45 degree line (i.e., $p_B > p_G$).

![Figure 8 - Litigation/Settlement](image)

**Figure 8– Litigation/Settlement**

The lighter shaded area in left panel shows when the level of mutual optimism is sufficient to generate litigation (when $(p_G, p_B)$ lies above litigation settlement line). The circles can represent a confidence interval that would contain a certain percentage $\alpha$ of the estimates of $(p_G, p_B)$. The smaller circle depicts estimates based on a patent that would be upheld with probability $p = .9$. The larger circle shows a confidence interval for a patent that would be upheld with probability $p = .5$.

The left panel in Figure 8 shows the litigation-settlement line generated by the monopoly-to-duopoly model. Note that both the depicted confidence intervals would include cases that would generate litigation. In contrast, the right panel depicts the litigation settlement line for the multiple entrant model when free entry results in three additional generic entrants in addition to the Brand and first generic ($N = 5$). Note that the litigation settlement line is much further away from the 45-degree line, with the distance growing larger as patents get weaker. Neither of the

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confidence intervals depicted in the Figure would include cases that would generate litigation.

Finally, Figure 9 depicts the case where the probability of the patent being upheld \( p = .5 \). The lighter lines represent the plaintiff’s minimum acceptable and the Generic’s maximum acceptable entry date \( E(X) \) under the conditions of the monopoly-to-duopoly model. The dark lines in the figure incorporate multiple entrants as well as a positive discount rate of 5\%, and a stay/litigation period of 2 years. The Figure shows the substantial range in the potential unrestricted entry dates (from approximately 3 \text{ years} and one half years to just under 9 \text{ years}), as well as a substantial range in the size of feasible reverse payments. The Figure also shows little overlap between welfare increasing settlements \( (E < E^*) \) and feasible settlements.

![Figure 9 – 50/50 Case with Discounting and Litigation Stay](image)

**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 the standard error cost approach, the optimal rule minimizes the sum of error costs and direct costs.\(^{33}\) Use of a bright line rule can be

optimal if the bright line rule results in cost savings and benefits from increased certainty that outweigh the associated increase in error costs.\textsuperscript{34}

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

<table>
<thead>
<tr>
<th>Patent Valid</th>
<th>No Antitrust Violation (Scope of the patent test)</th>
<th>Antitrust Violation (Per se illegal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specificity</td>
<td>Type I error (condemning lawful exercise of market power generated by valid patent)</td>
<td></td>
</tr>
<tr>
<td>Patent Invalid</td>
<td>Type II error (allow the use of an invalid patent to prevent the risk of competition)</td>
<td>Sensitivity (condemning use of an invalid patent to prevent the risk of competition)</td>
</tr>
</tbody>
</table>

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 erroneously invalidating 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.’”\textsuperscript{35}

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


\textsuperscript{34} See, e.g., \textit{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 and qualification may well, through the vagaries of administration, prove counterproductive, undercutting the very economic ends they seek to serve.”).

\textsuperscript{35} \textit{Actavis}, 133 S.Ct at 2233.
the bright line rule of per se illegality and the somewhat less error-prone quick-look rule with a presumption of illegality.\textsuperscript{36}

The antitrust policy question for the lower courts going forward 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.\textsuperscript{37} One possible alternative would be to have a detailed inquiry into the validity of the patent as part of the antitrust case.\textsuperscript{38} In theory, if this inquiry led to the accurate determination of the validity of the patent in question 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 11\textsuperscript{th} Circuit to adopt the bright line scope of the patent test.\textsuperscript{39} 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.”\textsuperscript{40}

Rather than a full blown inquiry into the merits of the patent, the Court suggested portion of the reverse payment that is not explained by traditional settlement considerations or other precompetitive 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.”\textsuperscript{41} Focusing upon this

\textsuperscript{36} Id. at 2237.
\textsuperscript{38} See Crane, supra note \_.
\textsuperscript{39} \textit{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, \textit{Muddying the Settlement Waters: Open Questions and Unintended Consequences Following FTC v. Actavis}, 28 ANTITRUST 9, 15 (2013).
\textsuperscript{40} \textit{Actavis}, 133 S.Ct. at 2234.
\textsuperscript{41} Id. at 2236-37. The Court notes that the FTC admits that reverse payments can have offsetting or 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
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.”

As we demonstrated above, however, even with the simple monopoly-to-duopoly model, Pareto settlements can involve very large payments. Although both parties in the example estimate that the patent will be upheld 90% of the time, the range of reverse settlements is eight to twelve times each party’s litigation costs. In the example illustrated in Figure 9, where both parties estimate the probability of the patent being upheld at only 50%, the range of reverse settlements is from seven to fifty-three times each party’s litigation costs. If the patent is valid, the reverse payment is the cost to the Brand of Type I error. Unconstrained Pareto settlements allow the Brand to minimize the costs of Type I error. That is, there is always some settlement $E = T$ that allows the Brand to reduce somewhat the full cost of litigation relative to litigation or an alternative settlement with an earlier entry date $E < T$.

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 with $E = T$ imposes the deadweight loss from monopoly for the maximum amount of time (the life of the patent) and reduces consumer welfare relative to settlements where $X > 0$ and $E < T$.

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 public good outcome of invalidating bad patents.

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. Indeed, the multiple entrant model shows the static welfare gains from invalidating a patent are much greater than those generated in the monopoly duopoly model. This has led many to

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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.

42 Id. at 2237.

43 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 that would have been produced.
advocate a policy that would not only ban reverse payments, but also have courts scrutinize closely all settlements of Hatch-Waxman patent litigation.44

Those more strict limitations upon settlements of Hatch-Waxman patent litigation do not reflect a full error cost analysis. The antitrust rule that maximizes consumer welfare is the rule that minimizes the sum of error costs and direct costs. The static consumer welfare standard considers only the direct costs of litigation and, moreover, is incomplete. This standard, at best, provides a proxy for the consumer welfare costs associated with Type II error.

Figure 10 – Total Welfare Net Litigation Costs Standard

Setting aside for the moment differences of opinion about the purpose of antitrust law45 and applying standard price theory, a more direct measure of the

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The standard in Figure 10, which only re-weights the relative importance of litigation costs and the Type II errors of reduced static welfare,\textsuperscript{47} 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 \textit{in terrorem} settlements paid to avoid this outcome.\textsuperscript{48} 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 10. 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 settlement agreements where $E = T$ 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.


\textsuperscript{47} The consumer welfare minus litigation costs standard places greater weight on the reduction of surplus (a cardinal measure) relative to litigation costs than the total welfare (also a cardinal measure) net of litigation costs standard (which is equivalent to minimizing deadweight loss plus litigation costs).

\textsuperscript{48} Indeed, it is interesting that the Court’s opinion in \textit{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 \textit{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 \textit{in terrorem} increment to settlement value.” \textit{Bell Atl. Corp. v. Twombly}, 550 U.S. 544, 555 (2007) (citing \textit{Dura Pharmaceuticals v. Broudo}, 544 U.S. 336 (2005), quoting \textit{Blue Chip Stamps v. Manor Drug Stores}, 422 U.S. 723, 741 (1975)). See also Bruce H. Kobayashi, Law’s Information Revolution as Procedural Reform: Predictive Search as a Solution to the \textit{In Terrorem} Effect of Externalized Discovery Costs, 2014 U. ILL. L. REV. \_ (2014); David Rosenberg & Steven Shavell, \textit{A Model in Which Suits Are Brought for their Nuisance Value}, 5 INT. REV. L & ECON. 3 (1985).
IV. Conclusion

In Actavis v. FTC, 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.
MODEL APPENDIX

In this appendix, we derive the payoffs from patent litigation and settlement. The examples assume a initial Paragraph IV ANDA is filed at time $t = 0$ challenging a patent that expires at time $t = T$. The Brand patentee (B) that files a lawsuit for patent infringement within 45 days of the filing of the initial Paragraph IV certification incurs litigation costs $C_B$ and estimates that the patent will be successfully defended with probability $p_B$ and invalidated with probability $1 - p_B$. Let $r$ denote the discount rate. Based upon the sketch of the regulatory structure of the Hatch-Waxman Act set forth in the text, the expected litigation payoff for the Brand (B) plaintiff is:

$$\begin{align*}
V_B^L &= \int_0^S \pi^M e^{-rt} dt + p_B \int_S^T \pi^M e^{-rt} dt \\
&\quad + (1 - p_B) \left( \int_S^{S+H} \pi^D e^{-rt} dt + \int_T^T \pi^C e^{-rt} dt \right) - C_B \\
&= \frac{\pi^M}{r} \left[ 1 - (1 - p_B)e^{-rS} - p_B e^{-rT} \right] \quad + (1 - p_B)\left( \frac{\pi^D}{r} \left[ e^{-rS} - e^{-r(S+H)} \right] \right) \\
&\quad \quad + \left[ e^{-r(S+H)} - e^{-rT} \right] - C_B
\end{align*}$$

The settlement payoff for the Brand plaintiff with entry time $E$ and reverse payment $X$ is:

$$\begin{align*}
V_B^S &= \int_0^E \pi^M e^{-rt} dt + \int_E^T \pi^D e^{-rt} dt - X \\
&= \frac{\pi^M}{r} \left[ 1 - e^{-rE} \right] + \frac{\pi^D}{r} \left[ e^{-rE} - e^{-rT} \right] - X
\end{align*}$$

For any settlement acceptable to B, $V_B^S > V_B^L$. Solving for $E$ yields:

$$E > E_B(X) = \frac{1}{r} \ln \left[ \frac{\pi^M(1-p_B)e^{-rS}+p_B e^{-rT}}{\pi^D} - \frac{\pi^D (1-p_B)\left[ e^{-rS} - e^{-r(S+H)} \right] + e^{-rT}}{\pi^M} - \frac{\pi^C \left[ e^{-r(S+H)} - e^{-rT} \right]}{r(X-C_B)} \right]$$

The Generic entrant that litigates incurs costs $C_G$. It estimates the probability the patent will be invalidated equals $1 - p_G$. The expected litigation payoff for the Generic entrant that files first Paragraph IV ANDA equals:

$$\begin{align*}
V_G^L &= (1 - p_G) \left( \int_S^{S+H} \pi^D e^{-rt} dt + \int_T^{T+H} \pi^C e^{-rt} dt \right) - C_G \\
&= (1 - p_G)\left( \frac{\pi^D}{r} \left[ e^{-rS} - e^{-r(S+H)} \right] \right) + \frac{\pi^C}{r} \left[ e^{-r(S+H)} - e^{-rT} \right] - C_G
\end{align*}$$
The settlement Payoff for the Generic entrant equals:

\[
V^S_G = \int_E^T \pi^D e^{-rt} dt + X \\
= \pi^D \left[ e^{-rE} - e^{-rT} \right] - X
\]

For any settlement acceptable to G, \(V^S_G > V^L_G\). Solving for \(E\) yields:

\[
E < E_G(X) = \frac{1}{r} \ln \left[ (1 - p_G)(e^{-rS} - e^{-r(S+H)}) + e^{-rT} + \frac{\pi^C}{\pi^D} (e^{-r(S+H)} - e^{-rT}) - \frac{rX}{\pi^D} \right]
\]

For a given reverse payment \(X\), any mutually acceptable settlement of the patent litigation must take the form of an early entry date \(E < T\), where:

\[
E_B(X) < E < E_G(X)
\]

In the primary examples presented in the text, we abstract away from the stay and discounting for expository simplicity. That is, we assume that \(S = 0\) and \(r = 0\), but take into account the effect of serial competition and the limited marketing exclusivity period \(H\). Under these assumptions, the litigation and settlement payoffs of the Brand are given by:

\[
(1') \quad V^L_B = p_B T \pi^M + (1 - p_B)(H \pi^D + (T - H) \pi^C) - C_B
\]

\[
(2') \quad V^S_B = E \pi^M + (T - E) \pi^D - X
\]

For any settlement acceptable to B, \(V^S_B > V^L_B\), or:

\[
(3') \quad E \geq E_B = p_B T + \frac{X - C_B}{\pi^M - \pi^D} + \frac{(1 - p_B)(T - H)(\pi^D - \pi^C)}{\pi^M - \pi^D}
\]

The litigation and settlement payoffs for the first Generic entrant are given by:

\[
(4') \quad V^L_G = (1 - p_G)(H \pi^D + (T - H) \pi^C) - C_G
\]

\[
(5') \quad V^S_G = (T - E) \pi^D + X
\]

For any settlement acceptable to G, \(V^S_G > V^L_G\), or:

\[
(6') \quad E \leq E_G = p_G T + \frac{X + C_G}{\pi^D} + \frac{(1 - p_G)(T - H)(\pi^D - (T - H) \pi^C)}{\pi^D}
\]

The simple monopoly-duopoly model used by EHHS and others is also a special case of the model set out above. In particular, the monopoly-duopoly model makes the simplifying assumption that \(H = T\), where \(H\) is the marketing exclusivity period
(180 days under the Hatch-Waxman Act) in the more general model set out above, and \( T \) is the patent expiration date. Under this assumption there is a single ANDA entrant prior to the expiration of the patent. In addition, the EHHS model also assumes that \( S = 0, \) and \( r = 0, \) where \( S \) is the regulatory stay when the brand firm files an infringement suit within 45 days after the generic entrant files the ANDA (up to 30 months under Hatch-Waxman), and \( r \) is the discount rate. The former assumption suppresses the time it takes to obtain a judgment and the latter ignores discounting.

Thus, under the assumptions of the simple monopoly-duopoly model, the Brand’s litigation and settlement payoffs equal:

\[
(1') \quad V_B^L = p_B T \pi^M + (1 - p_B) T \pi^D - C_B
\]

\[
(2') \quad V_B^S = E \pi^M + (T - E) \pi^D - X
\]

For any settlement acceptable to \( B, V_B^S > V_B^L. \) Solving for \( E \) yields:

\[
(3') \quad E > E_B(X) = p_B T + \frac{X - C_B}{\pi^M - \pi^D}
\]

The first Generic entrant (\( G \)) which files the initial Paragraph IV certification incurs litigation costs \( C_G \) and estimates that the patent will be successfully invalidated with probability \( 1 - p_G \) and unsuccessfully challenged with probability \( p_G. \) The Generic entrant’s litigation and settlement payoffs equal:

\[
(4') \quad V_G^L = (1 - p_G) T \pi^D - C_G
\]

\[
(5') \quad V_G^S = (T - E) \pi^D + X
\]

For any settlement acceptable to \( G, V_G^S > V_G^L. \) Solving for \( E \) yields:

\[
(6') \quad E < E_G(X) = p_G T + \frac{X + C_G}{\pi^D}
\]