

A WELFARE ANALYSIS OF PROHIBITIONS ON REVERSE PAYMENTS IN PHARMACEUTICAL PATENT DISPUTES, WITH AND WITHOUT THE HATCH- WAXMAN ENTRY INJUNCTION

*Sencer Ecer and Richard S. Higgins**

INTRODUCTION

The Hatch-Waxman Act (“HWA”) is a 1984 law that governs the approval process for generic drugs and the potential competition between generic and branded drugs prior to the patent expiration date. One important aspect of the HWA is to provide the brand name drug patent holder an automatic thirty month stay of approval by the Food and Drug Administration (“FDA”) of the Abbreviated New Drug Application (“ANDA”) for the generic product. The HWA also provides a 180 day period of marketing exclusivity to the first generic drug manufacturer to file for an ANDA. These two aspects of the HWA aim to both expedite the approval and profitability of investing in generic drugs and provide a counterbalancing incentive for brand-name drug manufacturers to innovate.¹

Both the thirty month stay and 180 day exclusivity aspects of the law have led to some controversy in practice. In particular, the brand-name companies used repeated thirty month stays to keep a generic product off the shelves by listing additional patents to the FDA’s “Orange Book” after an applicant filed an ANDA. On the other hand, some generic firms, after obtaining FDA approval, agreed to license and market the brand-name product instead of their own ANDA products, thereby preventing later applicants from gaining FDA approval, since the first applicant would never trigger its exclusivity period. These controversial aspects of the HWA are widely referred to as “loopholes.”

On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act (“MMA”), which implemented significant changes to the Hatch-Waxman Act. Most relevant to the issues

* Corresponding author: Richard S. Higgins, Director, LECG, LLC, 1725 Eye Street, NW, Suite 800, Washington, DC 20006). Phone: (202) 973 6659, Fax: (202) 466-4487. Email address: rhiggins@lecg.com; Sencer Ecer is a Senior Economist at LECG, Washington, DC. We thank Yee Wah Chin, Amy Hebert, and Jack Staines for comments. All errors are solely ours. The views expressed here are ours and should not be construed as representing the positions of other experts at LECG.

¹ The ANDA procedure allows the generic manufacturer to bypass various safety and effectiveness requirements as long as it can demonstrate a bioequivalency between its drug and the pioneer’s approved drug.

discussed in this paper, the MMA currently allows only a single thirty month stay for a particular brand-name drug. In addition, the MMA requires that the 180 day exclusivity period will be forfeited for a first generic filer that has been sued by the brand name company for patent infringement if it does not launch within seventy-five days after receiving a favorable court decision, FDA approval, or settlement. These two amendments to the HWA closed the loopholes.²

Another controversial practice has been that of “reverse payments.” Reverse payments are cash payments made from the incumbent (brand-name) company to the potential entrant (generic) company in exchange for not entering the market, sometimes until the patent expires or until another generic entry occurs. Leffler and Leffler argue that reverse payments should be per se illegal.³ On the other hand, Chin and Krattenmaker argue that the dispute over the scope and validity of the patent is another aspect of cases involving reverse payments and a per se standard may not be appropriate for them.⁴ The Federal Trade Commission’s (“FTC”) recent *Schering-Plough* decision on December 18, 2003 states that while such payments are not per se illegal, they do “raise[] a red flag.”⁵ Specifically, future patent litigation settlements with generic manufacturers that include reverse payments and agreements not to research, develop, market or sell a generic product for any time period are prohibited.⁶

The controversies over the HWA have led several authors to take a closer look at the welfare effects of the HWA. Langenfeld and Li address the long-run effects on research and development (“R&D”) and innovation

² For more on the recent changes see: Richard J. Berman & Janine A. Carlan, *Changes to the Hatch-Waxman Act by the Recently Enacted Medicare Law*, ARENT FOX ALERTS, at <http://www.arentfox.com/publications/alerts/alerts2003/alert2003-12-23berman.html> (December 23, 2003); James O’Toole, *FTC rules that Patent Litigation Settlement Payments to Generic Competitors coupled with Agreements to Withhold Market Entry Violates the Federal Antitrust Laws*, STAYING AHEAD WITH SAUL EWING, LITIGATION: ANTITRUST UPDATE, at http://www.saul.com/articles/Litigation/LIT_2004_03a.pdf (March 2004); Michael Padden & Thomas Jenkins, *Food and Drug Law: Hatch-Waxman Changes*, NAT’L L. J., at <http://www.howrey.com/docs/00503040006Howrey.pdf> (February 23, 2004).

³ Cristofer Leffler & Keith Leffler, *Settling the Controversy Over patent Settlements: Payments by the Patent Holder Should be per se Illegal*, in ANTITRUST LAW AND ECONOMICS 475-504 (John B. Kirkwood ed., 2004).

⁴ See Yee W. Chin & Thomas G. Krattenmaker, *Antitrust Update*, MERGERS AND ACQUISITIONS, THE MONTHLY TAX JOURNAL, 30 (Dec. 2001), available at <http://www.ftc.gov/opp/intellect/020522chindoc3.pdf>; see also Pet. for Writ of Cert., *Andrx Pharmaceuticals, Inc. v. The Kroger Co.*, 124 S. Ct. 1194 (2004) (No. 03-779), 2003 WL 22867750.

⁵ *Schering-Plough Corp.*, Docket No. 9297, at 29 (F.T.C. Dec. 18, 2003), <http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf>.

⁶ See *id.* at 15-29.

of the HWA.⁷ Higgins analyzes the short-run welfare effects of FTC antitrust oversight of settlements of patent litigation under the HWA.⁸ He focuses on the principal aspect of the HWA—the entry injunction imposed by the statute pending the outcome of litigation over the validity of the incumbent drug’s patent. Unfettered, a settlement between the entrant (the generic firm) and the incumbent (the brand name firm) could take the form of cash payments to delay entry, in many cases, until the patent expires.⁹ However, the FTC restricted these reverse payments through public case-by-case antitrust enforcement and finally by *Schering-Plough*. Prohibited in this way from making reverse payments, the firms are likely to agree to a second type of settlement, whereby they agree on delaying entry for a certain period. Higgins compares the total welfare under the HWA *with* and *without* these restrictions on reverse payments.¹⁰ Based on the expected benefits and costs of litigation for the incumbent and the potential entrant, he finds the equilibria of two multi-stage games involving decisions whether or not to enter, to file an infringement suit, to file an antitrust counterclaim and to agree on a settlement. He concludes that FTC restrictions on settlements may raise short-run welfare if the costs of FTC litigation and enforcement are ignored, but are unlikely to increase welfare otherwise.¹¹

Most recently, Shapiro proposes an antitrust rule for the antitrust oversight of settlement agreements, where a settlement must leave consumers at least as well off as they would have been with the patent litigation.¹² Then, without being specific about the type of settlement, he shows that under general conditions, profitable settlements that satisfy this constraint always exist. He also shows that such settlements can feasibly take the form of delayed entry, and he shows that reverse cash payments in this environment (on top of the delayed entry) signal an anticompetitive settlement.¹³ The current paper differs from those of Higgins and Shapiro principally because it seeks to evaluate the HWA itself relative to a legal framework without the HWA entry injunction.

In this paper, we consider the welfare effects of two types of settlement agreements—reverse payments without entry and no reverse payments with delayed entry—*with and without* the HWA entry injunction,

⁷ James Langenfeld & Wenqing Li, *Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers*, 70 ANTITRUST L. J., 777 (2003).

⁸ See Richard S. Higgins, *A Short-run Welfare Analysis of FTC Antitrust Oversight of Patent Litigation Settlements under the Hatch-Waxman Act*, 47 ANTITRUST BULL. 661 (2002).

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.* at 675-676. The analysis in Higgins and herein ignores the long-run incentives federal antitrust oversight may have on innovation as well as the long-run welfare effects of such oversight. See Langenfeld & Li, *supra* note 7.

¹² Carl Shapiro, *Antitrust Limits to Patent Settlements*, RAND J. OF ECON., 391 (2003).

¹³ *Id.*

yielding four cases in total. Normally, an entrant does not require prior approval to enter a market, but the HWA imposes such a duty. Under the HWA, the potential harm to an incumbent from patent infringement is insignificant relative to the potential antitrust harm to the prospective entrant foreclosed from the market, pending the outcome of litigation. A potential entrant can bring an antitrust countersuit alleging monopolization (which might result from enforcement of an invalid or fraudulently obtained patent, from sham litigation, etc.). This prospect changes the calculus from the way it has heretofore been analyzed. In contrast, absent an entry injunction, the incumbent is subject to injury from patent infringement, but there is no significant threat of antitrust damage to either party. Thus, there is a fundamental asymmetry in antitrust liability with and without the HWA. This asymmetry is magnified because treble damage awards are available. In this paper, we explore the nature of this asymmetry and its welfare consequences. In summary, using the same setup as Higgins, we compare the total welfare in the following four cases:

- Case 1: No Settlement Restrictions in the absence of the HWA.
- Case 2: Settlement Restrictions in the absence of the HWA.
- Case 3: No Settlement Restrictions under the HWA.
- Case 4: Settlement Restrictions under the HWA.

In Part I, we specify our model. In Part II, we cover the case of no settlement restrictions with no HWA-imposed injunction period (Case 1). In Part III, we turn to the case of settlement restrictions (Case 2). Cases 3 and 4 are borrowed from Higgins. In Part IV, we provide welfare comparisons among the four cases.

I. MODEL

In this paper, the incumbent and the entrant play a two-stage game of complete information:

Stage 1: The entrant decides whether to enter. Without entry, the game ends and the incumbent prices as a monopolist.

Stage 2: Given entry, the incumbent takes one of the following three "actions":

- (1) Accommodate entry (the game ends)
- (2) File an infringement suit and promptly settle (the game ends)
- (3) File an infringement suit and litigate (the game ends with the disposition of litigation)

The incumbent chooses the action that brings the highest expected profits. For example, it chooses Action 2 when the expected value of settlement for the incumbent exceeds both its expected value of litigation and

the present value of profits from accommodation. If the incumbent chooses Action 1, then the game ends with duopoly pricing over the remaining time to patent expiration.¹⁴ Certain payoffs correspond to the different terminations of the game. We specify these payoffs below.

If the potential entrant chooses to enter, it incurs a sunk, fixed cost of F . Otherwise, the entrant receives zero profits and the incumbent receives the monopoly profit $\Pi^m > 0$ up to the time of patent expiration, $T > 0$, and zero profits afterwards (we assume perfect competition after time T). If the incumbent accommodates entry, the entrant and the incumbent compete as duopolists for the period T , each receiving $\Pi > 0$ over the period.¹⁵ When an infringement suit is filed and litigated, both the entrant and the incumbent receive *ex ante* their respective expected values of litigation, EVL_E and EVL_I , and entry occurs at time $0 < t' < T$, at the earliest, where $[0, t']$ is the litigation period.

Finally, we consider two types of settlement agreements. In the first type, the incumbent may compensate the entrant for not competing by making reverse payments. In this case, the entrant and the incumbent receive their respective present values of settlement $PVS_E = EVL_E + \varepsilon$, where $\varepsilon > 0$ is as small as desired, and $PVS_I = \Pi^m T - PVS_E$. Thus, almost all surplus goes to the incumbent.¹⁶ In the second type of settlement, there are no reverse payments but entry may be postponed for a period of $t^* > 0$, where t^* must be less than T in equilibrium for a feasible settlement.

In Parts II and III, we provide an equilibrium analysis of both types of settlement agreements. In the rest of the current Part, we explicitly describe the payoffs of both the incumbent and the entrant for alternative terminations of the game and discuss some of our assumptions in detail.

The expected value of litigation for the incumbent is

$$EVL_I \equiv p^w \Pi^m T + (1 - p^w) \Pi T - L_I,$$

where p^w is the probability that the incumbent prevails in litigation and L_I is the cost of litigation for the incumbent. Thus, if the incumbent prevails, the entrant compensates the incumbent so that it receives its monopoly entitlement throughout the whole period. Otherwise, the incumbent receives no compensation from the entrant, and the incumbent enjoys only duopoly profits for the whole period. We assume that $\Pi^m > 2\Pi$ and $\Pi T > L_I$, and

¹⁴ The incumbent decides whether litigation or settlement results because, by assumption, the entrant gets its expected value of litigation in either case.

¹⁵ If the entrant enters, then a fixed cost of F is sunk, and hence F does not affect the subsequent decisions. Therefore, initially, as a convention, we do not include F when specifying the payoffs of the entrant, however, we later analyze its crucial role in the entrant's entry decision. In addition, we assume no time discounting of income in the future. Thus, the present value of Π^m for period T is $\Pi^m T$.

¹⁶ The usage of an arbitrarily small $\varepsilon > 0$ is equivalent to assuming that the entrant always prefers settlement to litigation even if both settlement and litigation yield the same expected payoff.

hence, it follows that $EVL_I > 0$. Win or lose, the incumbent must pay litigation costs, L_I , and, note that the expression for EVL_I is the same, regardless of any restrictions on settlement.

The expected value of litigation for the entrant is

$$\begin{aligned} EVL_E &\equiv p^w \Pi t' + (1 - p^w) \Pi T - p^w (\Pi^m - \Pi) t' - L_E \\ &= -p^w (\Pi^m - 2\Pi) t' + (1 - p^w) \Pi T - L_E, \end{aligned}$$

where L_E is the litigation cost for the entrant. If the entrant loses, it both earns duopoly profits during the litigation period and compensates the incumbent in the amount of $(\Pi^m - \Pi)t'$, the lost profits during the litigation period. Otherwise, the entrant is entitled to duopoly profits during the entire period. Depending on p^w and t' , EVL_E may be positive or negative. We assume that $\Pi T > L_E$, and hence when $p^w = 0$, $EVL_E > 0$. Note also that $EVL_E < \Pi T$. What is especially noteworthy here is that when the incumbent loses, it is not required to pay anything to the entrant because antitrust injury born by the entrant is insignificant. In contrast, under HWA, which enjoins entry for a specified litigation period, if the incumbent loses it pays treble damages to the entrant. Here, only if the incumbent wins is there a damage award ordered by the court, that is, a payment of $(\Pi^m - \Pi)t'$ from the entrant to the incumbent. For this reason, as Π^m increases (*ceteris paribus*), EVL_E decreases. The last item in the list of payoffs is the present value of accommodation ("PVA"). This value equals ΠT for both firms, ignoring the entrant's fixed entry cost.

Before proceeding to the solutions of these games, we highlight and discuss our critical assumptions:

- (1) The incumbent and the entrant are risk neutral;
- (2) The incumbent and the entrant have symmetric and common beliefs about the probability of prevailing in litigation;
- (3) The duration of litigation is t' and settlement is instantaneous; the cost of litigation is fixed; in particular, this cost is independent of effort for both parties;
- (4) As a result of the settlement, the entrant receives (slightly more than) its expected value of litigation, represented by $EVL_E + \varepsilon$, where $\varepsilon > 0$;
- (5) The entrant's cost of entry and costs of litigation are sunk fixed costs;
- (6) Litigation costs including the attorneys fees are born by the litigant who incurs them, win or lose;
- (7) The incumbent and the entrant have zero time preference; and
- (8) Follow-on entry is barred during the period, T .

The risk neutrality assumption is not material to the model, unless one assumes asymmetry in this regard, for which there is likely to be no justification. The symmetric information assumption may be unrealistic, espe-

cially if the validity of the incumbent's patent is at issue. If the incumbent has private information about the probability that its patent would be found invalid, the entrant may have biased or unbiased information about this parameter. Under these circumstances, only biased information would make a material difference in the analysis, and there is not likely to be any justification for assigning the degree or direction of the bias. As a result, symmetric information is as good as any assumption. Assumption 3 is unlikely to be material unless it is assumed that defendants have advantages over plaintiffs, or vice versa. Assumption 4 guarantees that the entrant prefers settlement to litigation. In effect, this assumption also serves to rule out multiple equilibria in this game, which simplifies the analysis. Assumptions 5, 6 and 7 simplify the analysis. According assumption 7, profit at a rate of 100 dollars has present value, $\$100 \cdot T$, over the entire period. The last assumption comports with the Hatch-Waxman regulations for Paragraph IV filings.

II. NO SETTLEMENT RESTRICTIONS AND NO STATUTORY INJUNCTION PERIOD

As indicated above, no settlement restrictions mean something quite specific in this paper: for patented drugs, settlement payments from brand-name companies to generics to compensate the generic for postponing its entry would be permitted. We now proceed to the solution via backward induction.

A. *Stage 2*

As indicated, the entrant always prefers settlement to litigation. The incumbent settles whenever $PVS_I = \Pi^m T - EVL_E - \varepsilon > EVL_I$ and $PVS_I > PVA$. Here, it can be shown that for all p^w , $PVS_I > EVL_I$. Also, $PVS_I > PVA$ is easy to show and hence the settlement solution applies for all values of p^w when there is entry.

B. *Stage 1*

Finally, the entrant enters whenever $EVL_E > F$. Rearranging terms, entry takes place if and only if the probability that the incumbent prevails is not too high, i.e., provided that

$$p^w < [\Pi T - L_e - F] / [\Pi(T-t') + (\Pi^m - \Pi)t'] = p^{w0} < 1.$$

As the monopoly profits increase relative to the duopoly profits or as t' increases, EVL_E and p^{w0} decrease, making entry more difficult. Similarly, as L_E or F increase relative to ΠT , p^{w0} decreases.

Figure 1

No Entry Injunction – No Restrictions on Settlement Agreements (Case1)

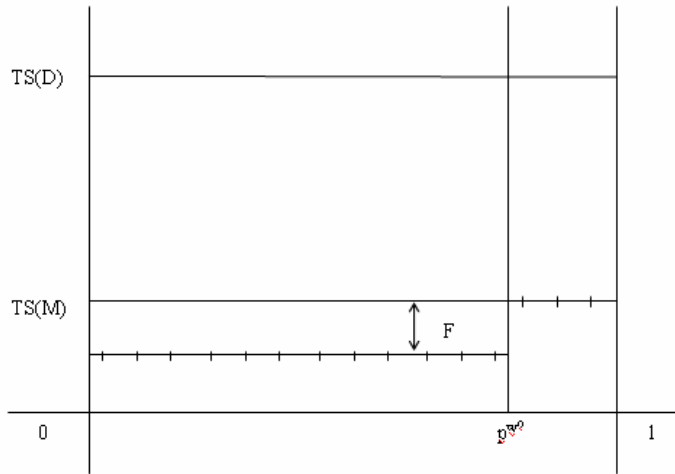


Figure 1 displays these results. The graph there presents total welfare (i.e., total surplus) as a function of p^w . The total surplus levels for monopoly and duopoly throughout the whole period are shown as horizontal lines. In the unique subgame perfect Nash equilibrium of this game (where there is no injunction period for the entrant and no settlement restrictions), if $p^w > p^{w0}$, there is no entry, and hence monopoly is the outcome. Otherwise, there is entry followed by instantaneous settlement that entails a cash payment to the entrant. This again leads to the monopoly outcome, but with fixed cost F incurred by the entrant, and hence the total surplus decreases by F .

III. SETTLEMENT RESTRICTIONS AND NO STATUTORY INJUNCTION PERIOD

In this Part, we assume that there is a proscription on cash payments from the incumbent to the entrant, as established through FTC enforcement. The only way for the entrant to be compensated is through actual production. Thus, settlement involves a mutual agreement on an entry date. We assume that a prohibition on reverse payments entails competition from the entrant at some future date, t^* , where $t^* > 0$. The value of t^* must satisfy

$PVS_E = \Pi(T - t^*) \geq EVL_E$. That is, the entrant must be able to earn through competition a present value equal to what it foregoes by not litigating to the finish. The game here is the same as the one in Part II, except that the entrant cannot receive cash in case of settlement, but instead receives the right to enter after an initial period of length t^* , which provides the entrant with duopoly profits for the rest of the period, i.e., $\Pi(T - t^*)$.

A. Stage 2

In Stage 2, the incumbent has the three options described above: (1) it may accommodate entry; (2) it may file an infringement suit and settle; or (3) it may file an infringement suit and refuse to settle. We show below that settlement dominates both litigation and accommodation for all p^w .

First, we show that settlement dominates litigation for the incumbent. Assuming entry and a suit filed by the incumbent, the suit settles only if:

- (1) $PVS_I = \Pi^m T - EVL_E > EVL_I$ and
- (2) t^* exists such that $(T - t^*) \Pi \geq EVL_E$.

Now we prove that (1) holds. Due to the litigation cost L_I , EVL_I is less than ΠT at $p^w = 0$ and less than $\Pi^m T$ at $p^w = 1$. Inspection of EVL_E shows that at $p^w = 0$ we have $EVL_E < \Pi T$ and, at $p^w = 1$, $EVL_E < 0$. At $p^w = 0$, $\Pi^m T - EVL_E = \Pi^m T + L_E - \Pi T > \Pi T > EVL_I$ since $\Pi^m > 2\Pi$, and at $p^w = 1$, $\Pi^m T - EVL_E > \Pi^m T > EVL_I$. Finally, (2) holds because there is a $t^* > 0$ satisfying $t^* = T - (EVL_E/\Pi)$, since with entry $EVL_E > F > 0$ and $EVL_E < \Pi T$. If the incumbent files a suit it settles because the value of settlement exceeds ΠT for all p^w .

Now we show that settlement dominates accommodation. Recall that $\Pi^m > 2\Pi$ and $EVL_E < \Pi T$. Then, it follows that $PVS_I = \Pi^m T - EVL_E > \Pi T = PVA$.

B. Stage 1

Finally, at Stage 1, the entrant commits to enter whenever $EVL_E - F > 0$. Again the same cutoff value as in Part II defined by $EVL_E(p^{w0}) = F$ constitutes the threshold probability, and for all $p^w < p^{w0}$, the entrant commits to its entry fee and for greater p^w , the entrant stays out.

Figure 2

No Entry Injunction – Restrictions on Settlement Agreements (Case 2)

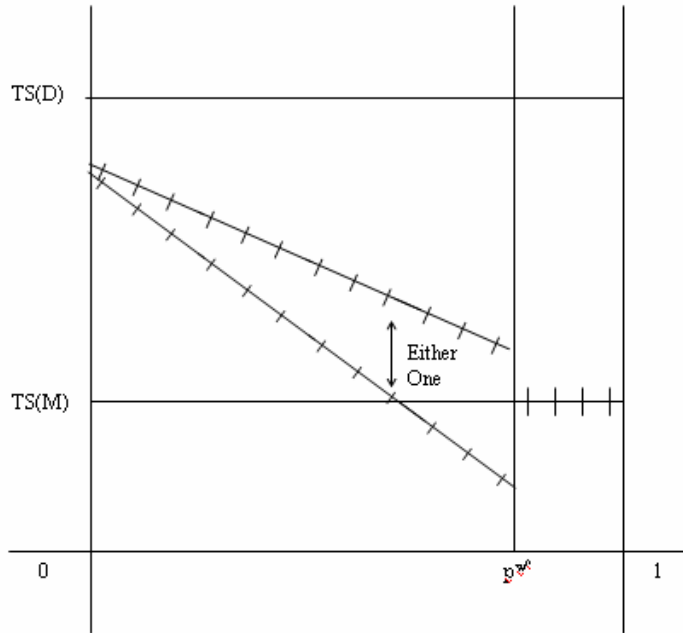
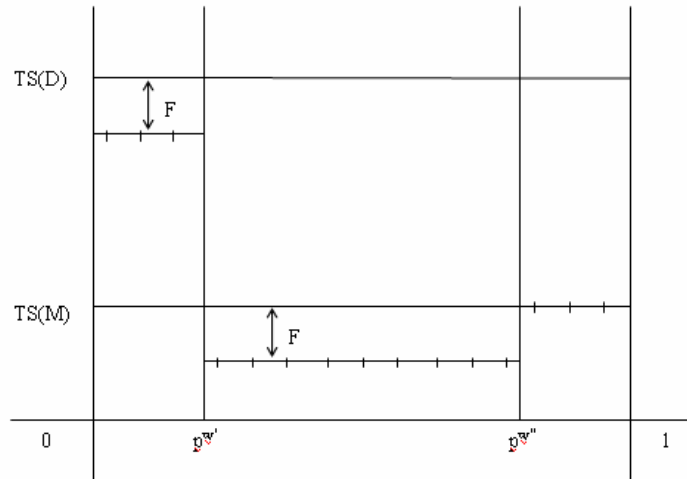


Figure 2 displays the results related to Case 2. The monopoly outcome only obtains for $p^w > p^{w0}$. Otherwise, there is entry, but again there is an immediate settlement that postpones entry until t^* , where $0 < t^* < T$, and $t^* = T - (EVL_E/\Pi) = T - (1/\Pi)(p^w \Pi^m T + (1 - p^w)\Pi T - L_E)$. Hence, total welfare for $p^w < p^{w0}$ is given by the weighted average $(t^*/T) TS^M + ((T-t^*)/T) TS^D - F$, where TS^M and TS^D respectively denote the total welfare in the cases of monopoly and duopoly for the whole period T . When $p^w = 0$, $t^* = L_E/\Pi$ and when $p^w = p^{w0}$, $t^* = T - (F/\Pi)$. The corresponding welfare values are respectively close to $TS^D - F$ and $TS^M - F$ when, respectively, L_E and F are relatively small compared to ΠT .

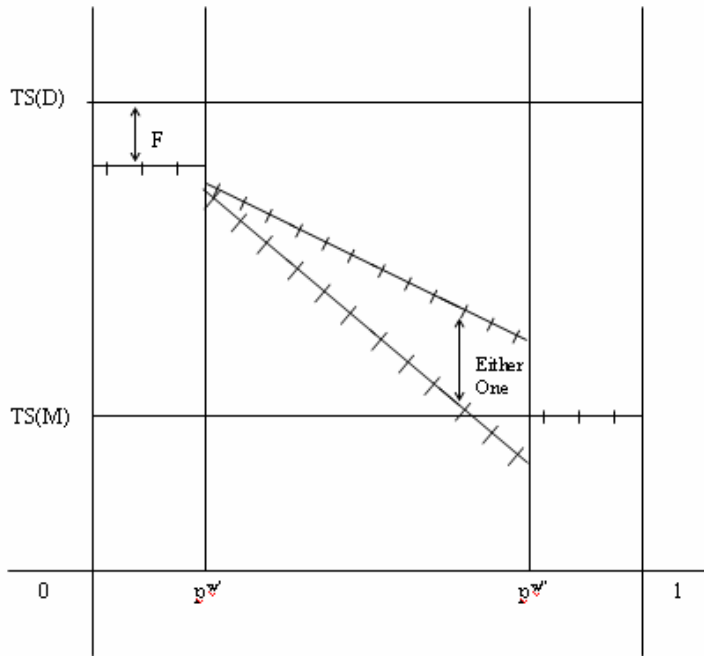
Figure 3**Entry Injunction – No Restrictions on Settlement Agreements (Case 3)**

We display the results of Case 3 in Figure 3. There are three intervals of p^w that result in different outcomes in Figure 3. If p^w is between 0 and $p^{w'}$, where $p^{w'} = ((4\Pi - \Pi^m)t' + L_I) / ((\Pi^m - \Pi)T + (4\Pi - \Pi^m)t')$, entry is accommodated so the total surplus is the duopoly surplus minus F . If p^w is between $p^{w'}$ and $p^{w''}$, $p^{w'} < p^{w''}$, where $p^{w''} = 1 - [(L_E + F) / (\Pi(2t' + T))]$ entry occurs and is followed by immediate settlement.¹⁷ In this intermediate interval, there are reverse payments, and the monopoly surplus minus the fixed cost F is obtained as the total surplus. Finally, if $p^w > p^{w''}$, entry does not take place, and the monopoly outcome obtains. We note that although the cutoff $p^{w''}$ from Higgins and p^{w0} in the current paper are both close to one, we cannot tell in general which is larger.

¹⁷ We deviate from Higgins' notation here. In particular, in Higgins' notation $p^{w'} = p^{w0}$ and $p^{w''} = p^{w*}$. See Higgins, *supra* note 8, at 670-672.

Figure 4

Entry Injunction – Restrictions on Settlement Agreements (Case 4)



In Case 4, there are restrictions on reverse payments under the HWA. We display the results of Case 4 in Figure 4. In Case 4 we have the same cutoff probabilities $p^{w'}$ and $p^{w''}$ as in Case 3, and the outcomes of Case 4 in the intervals $[0, p^{w'}]$ and $[p^{w''}, 1]$ coincide with those of Case 3. However, in the intermediate interval $[p^{w'}, p^{w''}]$ there is litigation in equilibrium, so total welfare decreases linearly with p^w . Welfare in this interval is given by $p^w TS^M + (1 - p^w) TS^D - L_I - L_E - F$. In this case, when $p^w = p^{w'}$, welfare is lower than $TS^D - F - L_I - L_E$ and when $p^w = p^{w''}$, welfare is higher than $TS^M - L_I - L_E - F$, but may or may not be lower than TS^M . Thus, in Figure 4, the graph in the mid region may fall below TS^M at $p^{w''}$ or lie above TS^M ; two such alternatives are depicted.

IV. WELFARE COMPARISONS

In this Part, the present analysis is combined with the previous analysis in Higgins to compare the various scenarios in terms of short-run welfare.¹⁸ Close inspection of the four tables makes clear that without an entry injunction, restrictions on reverse payments dominates no restrictions (Figures 1 and 2). Figures 3 and 4 show that with an entry injunction (i.e., under the HWA), prohibition of reverse payments also dominates no prohibition of reverse payments. A comparison of Figures 1 and 3 reveals that the least efficient outcomes result when there is no entry injunction and there are no settlement restrictions. Next in line is the case of the HWA entry injunction without restrictions on reverse payments. More beneficent than any of these regimes are the two cases involving settlement restrictions. Unfortunately, there is apparently no general means of ranking the latter two. The present HWA regulations together with FTC enforcement of prohibitions on reverse payments may be as good as it gets. We do not analyze one clear difference between these two best regimes, however. That is, in the absence of the HWA entry injunction, there is less demand for antitrust intervention. Only patent infringement would be at issue. Thus, abandoning the HWA would reduce the need for public antitrust enforcement. However, without public antitrust oversight or statutory settlement restrictions, anticompetitive settlement agreements would remain likely. Ultimately, the choice should be between the HWA entry injunction with statutory or regulatory prohibitions on reverse payments and repeal of the HWA with new legislation to prohibit reverse payments in drug patent settlements. As a matter of economic theory alone, one option is as good as another.

CONCLUSION

The Hatch-Waxman Act was expressly designed to expedite entry of generic prescription drugs. To pass such legislation that is in principle inimical to the pioneer drug industry, the latter was granted the right to enjoin entry as a matter of course by simply notifying the FDA of its concern that its intellectual property would otherwise be expropriated. Initially, it appeared that incumbent drug manufacturers were going to be able to take advantage of the injunction provision and forestall entry for at least the thirty months provided for in the HWA and often for a multiple of this period based on subsequent patent listings. The HWA's entry injunction created, perhaps inadvertently, a demand for antitrust counterclaims by poten-

¹⁸ It is appropriate to remind the reader that the analyses are incomplete since only welfare in the short-run is considered. As observed by Langenfeld and Li, a less restrictive antitrust enforcement policy raises the value of intellectual property in pioneer drugs, which may or may not be desirable from a long-run perspective. See Langenfeld & Li, *supra* note 7.

tial entrants forced to await the outcome of patent litigation. In effect, the injunction creates the potential for antitrust damages since an incumbent with market power in the absence of entry will seek to maintain its monopoly rents perhaps even by defending an invalid patent. As a result, the would-be entrant is barred from realizing income through the production and sale of its product for the period of the injunction, of which, in addition to the 180 day exclusivity reward, injury can only be redressed at the antitrust bar. Moreover, since in antitrust law, damages are trebled, the demand for counterclaims is even greater. Thus, it would appear that the incentives for incumbent drug manufacturers to abuse the Hatch-Waxman process would be held in check by the threat of having to pay the plaintiff/entrant three times the profit the entrant would have made over the thirty month period pending the outcome of litigation.

The prospect of such an award undoubtedly inhibits the filing of lawsuits with virtually no merit. However, there is no denying the power of the purse: based on the law of demand, monopoly rent is greater than the sum of duopoly rents, sometimes by a lot. As a result, the litigants quickly realized the mutual benefit of settling. The settlements typically entailed the payment of cash by the incumbent to the potential entrant who in turn agreed not to enter, sometimes for a period beyond thirty months. The firm that most quickly established a colorable claim of bio-equivalence was paid an amount equal to the value of the potential entrant's counterclaim not to compete, in effect, sharing in the monopoly rent. This in turn led the FTC to challenge many of these settlement agreements on the grounds that they were anticompetitive; in particular, the FTC properly focused on the reverse payments from incumbent to entrant as evidence of harm to competition. In *Schering-Plough*, the FTC affirmed its position against patent litigation settlements with generic manufacturers that include reverse payments and agreements not to research, develop, market or sell a generic product for any time period.

In the present paper we provided a simple economic framework for evaluating the benefits and costs of the Hatch-Waxman Act itself. In the absence of the HWA's principal feature, the statutory entry injunction, entry would proceed as quickly as the FDA deemed consistent with efficacy and health and safety. There may still be patent infringement suits filed by incumbent drug manufacturers, but the accompanying demand for antitrust litigation would dry up. An incumbent is much more likely to be able to enjoin entry with the Hatch-Waxman Act in place than if it were not. The threat of anticompetitive settlements would remain, however. We found that with or without an entry injunction (alternatively, with or without the Hatch-Waxman Act) consumers are better off with prohibitions on reverse payments, but we are unable to rank these prohibitions with injunction and no-injunction in terms of total welfare. However, to the extent that the prohibition on reverse payments can be legislated more effectively than it can be enforced through public antitrust actions, repeal of the Act is probably

2004] REVERSE PAYMENTS IN PHARMACEUTICAL PATENT DISPUTES 937

an inferior public-policy solution, because the legislative and regulatory apparatus is already present in the HWA. That is, in addition to repealing the HWA, new legislation would be required to prohibit reverse payments in drug patent infringement suits, and there appears to be no obvious principled basis for stopping just with drug patents, or with patents in general. While conflicts in other areas of intellectual property law may also be settled in ways that are anticompetitive, there has been little commentary in this regard.