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I. INTRODUCTION

Patent settlement agreements that involve payments from brand-name drug manufacturers to generic drug manufacturers (so called "reverse payments" or "pay for delay") have been hotly contested in the courts. Last year, two U.S. Courts of Appeals reached opposite verdicts regarding the legality of "reverse payment" agreements.

In April 2012, in *FTC v. Actavis, Inc.*, the Eleventh Circuit held that payments made by brand-name patent holders to potential generic entrants in exchange for the latters' delayed market entry in settlement of Paragraph IV litigations were virtually *per se* legal if such settlements fell within the bounds of the so-called "scope of the patent test."[2] In effect, the Eleventh Circuit assumed that the patent should be treated as valid until proven otherwise.

Three months later, the Third Circuit in *Louisiana Wholesale Drug Co., Inc. v. Merck & Co. et al.* ("the K-Dur case II"), in stark conflict with the Eleventh Circuit, held that such settlements are, in effect, presumptively illegal.[3] From an economics perspective, this decision assumed the likelihood of a patent being found valid in these circumstances is typically very low, and the harm to consumers is likely very high.

On June 17, 2013, the U.S. Supreme Court issued its ruling on the reverse payment agreements in *Federal Trade Commission v. Actavis, Inc. et al.*[4] The Supreme Court reversed the Eleventh Circuit's decision that reverse payments from patent holders to generics are legal if within the scope of the patent. At the same time, the Supreme Court also rejected the FTC's urging and the Third Circuit's findings that reverse payments were virtually *per se* illegal. Instead, the Supreme Court found that such payments should be evaluated under a rule of reason. In particular, the majority of the Court wrote:

> [T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent

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[2] FTC v. Watson Pharms., Inc., 677 F.3d 1298 (11th Cir. 2012).

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

[4] Supreme Court of the United States, Federal Trade Commission v. Actavis, Inc., et al., Decided June 17, 2013, 133 S. Ct. 2223 (2013).

> payment, and the lack of any other convincing justification. The existence and degree of any anticompetitive consequence may also vary as among industries. These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases.[5]

The Court's majority decision seems to find that the probability of a patent being valid in a reverse payment case should not be assumed to be 100 percent (as implied by the Eleventh Circuit) or necessarily near zero (as implied by the Third Circuit). However, determining whether a patent would have been found to be valid in the context of a settlement can be challenging. In part to address this issue, the Court majority placed great emphasis on the size of the reverse payments. For example, the Court stated:

> In sum, a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it; such a firm or individual may well possess market power derived from the patent; 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[.][6]

Although the Supreme Court acknowledges there may be other justifications for reverse payments, it appears that the Court believes that if the reverse payments are larger than litigation costs and do not reflect the value of other services rendered by the generics, a large payment may provide strong evidence that the agreement is anticompetitive.[7]

The rest of this article (1) provides some background on the economics of reverse payment settlements, (2) explains why the size of the reverse payment alone is not a sufficient indication that a reverse payment agreement is anticompetitive, (3) discusses some economic tests that can be implemented to assess the competitive effect of a reverse payment agreement under a rule of reason approach, and (4) shows the potential detrimental impact on innovation if reverse payments are condemned as illegal based on the size of payment alone.

II. ECONOMICS OF REVERSE PAYMENTS IN THE PHARMACEUTICAL INDUSTRY

It is not surprising that reverse payments have resulted in many lawsuits and much research in the pharmaceutical industry, given the unique regulatory requirements in the Hatch-Waxman Act[8] and the basic economics of the industry.[9] The dollar sales of brand name drugs can amount to a billion dollars annually, and a generic typically captures a large proportion of the

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

[6] *Id.*

[7] *Id.* at 2232-35.

[8] Pub. L. No. 98-417, 98 Stat. 1585 (1984). For a discussion of the relevant aspects of the Hatch-Waxman Acts, *see*, for example, 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. 778-80 (2003).

[9] For an interesting articles discussing the implications of the Court's Actavis decision, *see* Sumanth Addaki & Henry Butler, *Activating* Actavis*: Economic Issues in Applying the Rule of Reason to Reverse Payment Settlements*, 15 Minn. J. L. SCI. & TECH. (Forthcoming 2013), and Stuart N. Senator & Rohit Singla, *FTC v. Actavis: Antitrust Litigation Over "Reverse Payments" Pharmaceutical Patent Settlements,* 22 COMPETITION. 2. 153 (Fall 2013).

quantity sales of the drug after entry.[10] As a result, a brand name can suffer significant sales loss and the associated profit loss if a generic enters while the patent litigation is ongoing.[11]

A generic is usually sold at a significantly discounted price relative to the price of the brand name and takes sales away from the branded drug, but may have little overall effect on the total quantity sales of a drug.[12] Consequently, the expected profits gained by the generic are usually much lower than the profits lost by the brand name,[13] and the sum of the branded and generic drugs' expected profits in competition can be much lower than the expected profits of the branded drug sold without generic entry.

The economics of reverse payment agreements can be complex, and vary by the specific type of agreement and the facts of each case. There is general agreement that analyzing the impact of any particular settlement should take as a starting point the trade-off between short-run price and long-run innovation competition as determined by the existing patent and competition laws and the statutes of the Hatch-Waxman Act. However, even starting from the same point, there is disagreement over exactly how to model these settlements and whether they are, on balance, anticompetitive or improve overall consumer welfare.

Most economists use probabilistic game theory models to analyze these settlements,[14] but some commentators believe such an approach is not appropriate because of its complexity and the potential problems with developing clear and reliable tests.[15] To see why the analysis is complex, consider agreements that completely settle patent disputes. These agreements, in general, fix a date for generic entry that is before the expiration of the patent. However, since the

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[10] *See* Langenfeld & Li, *supra* note 8, App. 3. That article focuses on the "partial" or "interim" settlement agreements, where there are payments from patent holders to would-be generic manufacturers in exchange for the generics not entering the market before a final resolution of patent litigation. The results in that article can be generalized to agreements where there is the possibility of "at risk" entry by the generic. In contrast, "complete" settlement agreements "reverse payments" from the brand-name to the generic with no threat of at risk generic entry and a settlement of the patent litigation with specific agreed-upon entry dates for the generic.

[11] For example Hoechst Roussel, Inc. could lose $280 million in sales in the first year after generic entry. According to FTC, "Hoechst forecasted internally that a generic version of Cardizem CD, sold at 70% of the brand price, would capture approximately 40% of the Cardizem CD sales within the first year." *See* "Prepared Statement of the Federal Trade Commission on Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlement before the Committee on the Judiciary United States Senate," (May 24, 2001), *available at* http://www.ftc.gov/os/2001/05/pharmtstmy.htm. The annual sales of the brand name Cardizem CD amount to $700 million. *See* Hoechst Roussel, Inc., FTC Docket No, 9293 (Mar. 16, 2000) (complaint), *available at* http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm. Assuming the price of the brand name Cardizem CD and the total quantity sales of Cardizem CD stay constant after generic entry, the loss of sales of the brand name Cardizem CD is equal to $700 million times 0.4, or $280 million, in the first year after generic entry.

[12] *See* Langenfeld & Li, *supra* note 8, App. 3.

[13] For numeric illustration of this point, *see* Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 ANTITRUST BULL. 491 (2002).

[14] *See, e.g.*, Carl Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, 17 ANTITRUST 70–76 (2003); Robert D. Willig & John P. Bigelow, *Antitrust Policy toward Agreements that Settle Patent Litigation*, 49 ANTITRUST BULL. 655-98 (2004).

[15] *See, e.g.*, Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives,* 17 ANTITRUST 68 (2003), and Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 *ANTITRUST L.J. 1033, 1048 (2004).*

outcome of patent litigation is uncertain and a generic may be bluffing about entering the market, one cannot pinpoint a date when entry would have taken place absent the agreement.

Accordingly, most economists look at entry "but for" the settlement by assigning a probability to the date when entry would have occurred absent the agreement and use the "expected value" of that date as an estimate of the specific date of entry. They then compare that expected entry date to the date in the settlement to determine the impact of the agreement on short run price competition.

Often they argue there must have been an offsetting consideration for the payment from the patent holder to the generic challenger, and that consideration would likely have been the generic deferring its entry beyond the date that would have resulted from a reasonable litigation compromise. Such a delay by definition would result in lower consumer surplus in the short run. Some, including the Court majority in *Actavis*, look to the strength of the patent and proxies for that strength, such as the size of the reverse payment, to infer the impact on the consumer welfare.[16]

Other authors have disputed this logic,[17] including the Court minority in *Actavis*. These authors argue that agreements with cash payments from a patent holder to a generic can save litigation (which the *Actavis* majority also recognizes) and other costs, reduce uncertainty for risk adverse firms, and eliminate asymmetric information about the value of the patent.[18] These authors show complete settlements with payments from a patent holder to a generic could actually lead to earlier entry by the generic. For example, these authors argue that settlement negotiations can be expected to break down frequently under the conditions the authors outline, and these breakdowns can result in a later expected generic entry date than would result from a complete settlement with payments from the patent holder to the generic.[19]

Consider this example to illustrate some of the economic issues involved in these cases.[20] Assume there are 10 years left on the life of a patent that has been challenged by a generic after a court decision on validity. Further assume the objective probability that the patent holder and generic will win the suit is the same (0.5 probability for each), but each party is more optimistic about prevailing in litigation. Assume the patent holder believes that it has a 60 percent chance (0.6 probability) of winning. In contrast, assume the potential generic entrant believes the patent holder has only a 40 percent chance of winning (0.4 probability).

Based on the different expected outcome of the litigation, the patent holder would not agree to allow generic entry in less than six years, and the generic would not agree to wait more

[16] *See, e.g.,* Shapiro, *supra* note 14, at 71–72.

[17] *See* Willig & Bigelow, *supra* note 14; Schildkraut, *supra* note 15, at 1033–68.

[18] *See* Schildkraut, *supra* note 15, and Addaki & Butler, *supra* note 9.

[19] A patent holder will be willing to accept entry date earlier than the expected entry date under litigation if the patent holder is risk averse. However, a negotiation without "reverse payment" may still breakdown if, for example, the generic is cash strapped or is too optimistic about its chance of winning the patent litigation. As a result, the generic wants to enter earlier than the entry dates that are acceptable for the patent holder. A payment from the patent holder to the generic can help bridge the gap between the acceptable entry dates for the generic and the acceptable entry dates for the patent holder and lead to generic entry earlier than that expected under litigation. *See id.*

[20] This example is based on Addaki and Butler *supra* note 9.

than four years before entering. There would be no settlement based purely on a negotiated date of entry absent other considerations, such as reverse payments. However, it is not clear that such asymmetric expectations by themselves indicate reverse payments can be justified in terms of the expected value of consumer welfare based on a short-run reduction in price. Assuming the generic has sufficient resources to continue the litigation to conclusion, entry would be delayed until either the outcome of the trial (if the generic is successful in its challenge of the patent) or the end of the patent term (if the patent holder prevails). With reverse payments, entry would presumably occur in the sixth year of the 10 remaining on the patent.

If we look at 10 such situations, there would be 100 years of potential patent protection involved for the 10 drugs, and consumers would benefit from lower prices due to generic entry for 40 of those 100 years due to the reverse payments settlement. However, if the alternative is no settlement and trial, then the generic should win half the time and the patent holder half, based on 50 percent objective probability of each side winning each case.

In this example, denying reverse payment settlements and forcing trials would benefit consumers from short-term lower prices in 50 of the 100 years of patent validity at issue over the 10 different patent cases. If one abstracts from litigation costs, risk aversion, long-run consumer welfare from innovations, and other real world considerations, then the probabilistic approach to evaluating consumer welfare would indicate that forcing trial benefits consumers over reverse payments by 50 to 40 years of lower prices.

Asymmetric expectations of winning can be an important factor in evaluating the implications of reverse payments, but by themselves do not determine the net impact of these payments on consumers. Similarly, the size of a reverse payment does not by itself determine the likely competitive impact of the payment.

It is true that the size of the reverse payment is one factor to take into consideration as the majority in *Actavis* suggests, but the size needs to be put into the context of products that often sell hundreds of millions of dollars per year. The specific terms of a settlement and specific facts about the market will greatly affect an agreement's impact on the firms involved and on consumers in the long run.

As discussed in more detail below, research has shown that if banning patent settlement agreements such as ones that involve reverse payments deters the probability of a new product coming out by as little as thirty percent, then net consumer welfare will likely be reduced.[21] Moreover, there are other measurable tests for certain case and fact patterns that can be more important than the size of a reverse payment. Additional tests that address the specific settlements and market facts should be developed to evaluate accurately the implications of each type of patent settlement with reverse payments.

III. THE SIZE OF THE REVERSE PAYMENT AND OTHER CONSIDERATIONS

As quoted above, the majority of the Court found "the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might

[21] Langenfeld & Li, *supr*a note 8 at 803–04.

represent payment, and the lack of any other convincing justification." Clearly the size of a reverse payment is correctly a consideration in a rule of reason analysis as set out by the Court. However, the size of the payment should not be relied upon to show all the necessary aspects of finding an anticompetitive agreement. The size of a reverse payment needs to be measured not only against litigation costs, but also against other aspects of the market, such as the market's size.

First, the Court majority argues "the 'size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power'—namely, the power to charge prices higher than the competitive level."[22] However, as the Court recognizes, most alleged reverse payments reflect savings from litigation costs and the provision of other services by the generic to the patent holder. Netting out these portions of the amount of payment from a generic to a patent holder can require detailed analyses, which are often subject to dispute. Absent a very clear showing of a substantial payment that has no other explanation, inferring market power from the size of a reverse payment is inappropriately asking a single number, typically in dispute, to substitute for the normal analyses of market power.

Second, the *Actavis* majority appropriately highlighted concerns that payments to generic challengers to stay out may lead to generic profits that are even higher than they would make if they had litigated to a favorable result and started selling the drug at issue.[23] It appears clear that payments to the generic must benefit the generic more than entry, or the generic would not agree to a reverse payment settlement. However, payments at or below the expected profits from entry do not necessarily suggest a substantial delay for a generic entrant.

The value of entry to the generic can be estimated from market facts, as well as considering company projections. This estimate would need to be added to litigation costs after removing the value of other services provided by the generic to provide a benchmark against which to see if the size of the reverse payment suggests anticompetitive effects. Under reasonable assumptions, this type of calculation can justify reverse payments much larger than just considering settlement costs and, for very successful drugs, can be tens of millions of dollars or more.

Third, although the large potential disparity between profit gains for the generic and profit losses for the brand name can give the brand name incentives to make reverse payments to the generic in exchange for the generic agreeing to delay its entry, this large potential disparity can also provide justifications for the brand name to make reverse payments to the generic to protect itself from possible under-compensation for the generic infringing a patent that would later be found to be valid. In particular, a generic found liable for patent infringement may not be able to fully compensate a brand name manufacturer for the losses it suffered because the profit made by the generic is much smaller than the profit lost by the brand name due to generic entry. Such expected under-compensation due to a generic's potential inability to pay damages if found infringing would presumably deter investment in innovations that benefit consumers in the long run.

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[22] *Actavis*, 133 S. Ct. at 2236.

[23] *Actavis*, 133 S. Ct. at 2235 (citing C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1581 (2006)).

As shown in Langenfeld & Li,[24] a "partial" or "interim" settlement payment that is equal to or less than expected under-compensation for the brand name can be an equilibrium cooperative solution, since it can make both the generic and the brand name better off. This expected under-compensation is equal to the amount of under-compensation multiplied by the probability that the brand-name manufacturer will prevail in the patent infringement litigation.

Because both the expected under-compensation for the brand name and the foregone profits for the generic resulting from delaying its entry may be significant, the equilibrium payments by the brand name manufacturer to get an agreement with the generic could be substantial. These findings are equally true for all situations where there is real possibility of "at risk" generic entry prior to a decision on the validity of the patent.

In these situations, if the payments from the brand-name manufacturer to the generic are lower than the expected under-compensation, then those payments would presumably cure a defect in compensating patent holders for their potential loss from infringement and should not be viewed as anticompetitive. Therefore, it is economically incorrect to presume the anticompetitive effects of a reverse payment just based on the size of the payment in these situations.

The economic test for potential under-compensation in these cases can be written more formally by assuming p is the probability that the patent holder will prevail in the patent infringement litigation, D is the amount of under-compensation, and S is the payment from the patent holder to the generic:

(1) If $p^*D \geq S$, then the payment is consistent with a settlement that addresses under-compensation and so is competitively neutral or pro-competitive.

(2) If $p^*D < S$, then payments could be anticompetitive.

One way this test can be implemented is by using public data available at the time of the agreement, plus data on the drugs included in the agreement and normal course of business documents. For example, assume we have information on the payments specified in a settlement agreement and an estimation of the under-compensation for the patent holder if the generic had entered the market during patent litigation. One can infer the threshold probability of a patent being upheld so that the patent holder's expected under-compensation is equal to or greater than the patent holder's expected payments. That is, we solve equation (1) for the threshold where an agreement is competitively neutral (p^t), based on information about the payments and the amount of under-compensation:[25]

(3) $p^t = S/D$

After obtaining this threshold probability, it can be compared to relevant statistics that provide an objective or other indication of how likely it is that the patent holder's patent would be upheld. If the threshold probability for under-compensation is smaller than the likelihood that the patent holder's patent would be upheld according to the relevant statistics, then the expected

[24] Langenfeld & Li, *supra* note 8.

[25] For a particular case, the potential value of the under-compensation may be approximated from case specific data.

under-compensation is likely to be greater than the expected payments. Hence, the settlement is likely to be pro-competitive. On the other hand, if the threshold probability for under-compensation is greater than the likelihood that the patent holder's patent would be upheld, then the expected under-compensation is likely to be smaller than the expected payments, and the settlement could be anticompetitive.[26]

Fourth, in addition to these examples, other economic conditions can give rise to reverse payments, such as asymmetric information, risk aversion, different expectations about the outcome of the litigation, and different evaluations about the value of the patent. Depending on the circumstances, a reverse payment can also be pro-competitive even though its size may be large.[27]

Finally, focusing on the size of a reverse payment does not take into account any dynamic efficiencies from the agreement that could stimulate further research by the patent holder or an increase in the ability of generics to challenge more patents. The models discussed above usually just focus on the impact of a reverse payment on short-run competition for the drug at issue, attempting to show through the size of the payment that generic entry would have occurred sooner absent the payment. This approach implicitly assumes that preventing a reverse payment based on the size of the payment will have no impact on innovation, and ignores any potential long-run consumer loss from fewer innovative products. As discussed in the next section, this assumption is unwarranted. Putting too much weight on the size of an apparent reverse payment can result in overall damage to consumers.

IV. POTENTIAL IMPACT OF PROHIBITING REVERSE PAYMENTS ON LONG-RUN CONSUMER SURPLUS

Patent and antitrust laws are both presumably designed to strike a balance between ensuring long-run competition (i.e., providing incentives for firms to engage in R&D and bring new products to the market) and short-run competition (i.e., static price competition among existing products). As illustrated by Landes & Posner,[28] much of the literature on intellectual property protection has focused on viewing intellectual property protection as maximizing total welfare, which would include both the profits of the firms and consumer surplus. Antitrust enforcers have typically focused only on maximizing consumer welfare, not total welfare,[29] and both the majority and minority opinions in *Actavis* seem to adopt a consumer welfare

[26] The potential patent holder's option of seeking a preliminary injunction against generic entry would not substantially change this analysis. *See* Langenfeld & Li, *supra* note 8 at 796. In fact, an interim settlement agreement can be more cost efficient than formal legal proceedings for a patent holder to protect itself from the risk of under-compensation. *See* James Langenfeld & Wenqing Li, *Economic Analyses of Patent Settlement Agreements: The Implementation of Specific Economic Tests, the Evaluation of Dynamic Efficiency, and the Scope of Patent Rights*, 39 U. SAN FRANCISCO L. REV. 57-79 at 74-77 (2004).

[27] *See, e.g.,* Willig & Bigelow, *supra* note 14.

[28] William Landes & Richard Posner, *An Economic Analysis of Copyright Law*, 18 J. LEGAL STUD. 325, 326 (1989).

[29] *See, e.g.,* Timothy J. Muris, *Robert Pitofsky Public Servant and Scholar*, 52 CASE W. RES. L. REV. 25, 37 (2001). "[T]here is wide-spread agreement that the purpose of antitrust is to protect consumers." For a detailed discussion of the general trade-off between intellectual property protection and antitrust, see James Langenfeld, *Intellectual Property and Antitrust: Steps Toward Striking a Balance*, 52 CASE W. RES. L. REV. 91, 97-98 (2001).

approach.[30] It is possible that the implementation of antitrust policy that inappropriately over-weights certain evidence, such as the apparent size of a reverse payment, could undermine the goals of patent and antitrust law by reducing net consumer welfare, particularly when it weakens patent protection and thus discourages innovation.

One could argue that prohibiting reverse payment settlements and forcing the patent holder and generic to litigate will result in optimal innovation, since courts decisions would, on average, reflect the appropriate level of patent protection. However, pioneer drug makers already accept great risks since most drugs are not successes. The development of new drugs is not only a costly enterprise that involves substantial R&D expenditures, it is also subject to substantial *ex ante* risk. Pharmaceutical firms synthesize thousands of chemical compounds for each one that reaches the market,[31] but only one of four drugs that enter clinical trials ultimately is approved by the FDA.[32] The average time between the synthesis of a new drug compound and FDA approval is an estimated 14.2 years[33] and, according to a study published in the *Journal Of Health Economics,* only about 30 percent of drugs that reach the market produce revenues in excess of average development costs.[34]

A win-lose environment without the assurance coming from being able to flexibly negotiate settlements adds another layer of uncertainty that will, in all likelihood, reduce investments in potentially innovative products—especially in the light of any substantial risk aversion on the part of the pioneer drug firms.

Accordingly, prohibiting reverse payments based on their size may lead to more price competition for existing products in the short run, but such a prohibition could reduce the profits from selling patented products, and thereby tend to reduce the number of new products and the consumer surplus generated by these products in the long run. Empirical studies by economists indicate that patent protection plays a very important role in the development and commercialization of new products in the pharmaceutical industry,[35] so this reduction in long-run consumer surplus is particularly likely in the pharmaceutical industry governed by the Hatch-Waxman Act.

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

[31] Joseph DiMasi, *Trends in Drug Development Costs, Times, and Risks*, 29 DRUG INFO. 381 (1995) (and the references cited therein).

[32] W. Kip Viscusi, John M. Vernon, & Joseph E. Harrington, Jr., ECONOMICS OF REGULATION AND ANTITRUST, *Third Edition,* (Cambridge, MA: The MIT Press, 2000), at 823.

[33] Pharmaceutical Research and Manufacturers of America, PHARMACEUTICAL INDUSTRY PROFILE 2001: A CENTURY OF PROGRESS, PhRMA, Washington D.C., (2001), at 17.

[34] Henry G. Grabowski & John M. Vernon, *Returns to R&D on New Drug Introductions in the 1980s*, 13 JOURNAL OF HEALTH ECONOMICS 399, (1994), Fig. 5. The authors compared, on an after-tax basis, the average net present value of net revenues to the average capitalized value of R&D cost.

[35] *See* Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MANAGEMENT SCIENCE 173 (1986); Bohumir Pazderka, *Patent Protection and Pharmaceutical R&D Spending in Canada*, 25 CAN. PUB. POL'Y 29(1999); Wesley M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)*, NBER Working Paper Series, Working Paper 7552 (Feb. 2000), *available at* http://www.nber.org/papers/w7552. Some of these studies suggest that the effect of patent protection on new product introduction may be small in other industries.

Making a reverse payment agreement illegal based on too much weight being given to the size of the payments could weaken patent protection below the optimal level, especially if the patent holder is a research-based firm that relies on patent protection. Consequently, the potential loss of dynamic efficiency could outweigh the gain from static efficiency, and total consumer welfare would decrease. On the other hand, if the patent holder is not a research-based firm, "it would be less likely that the patent holder has engaged in agreements to protect its intellectual property to enable it to bring out innovative products that will benefit consumers."[36]

To help determine which outcome is more likely, one could examine whether the patent holder is a research-based firm by analyzing its overall R&D investment in evaluating an agreement's likely impact on consumer welfare, since reverse payment settlements can protect the value of a patent holder's patent and encourage R&D investment and other innovative activities.[37]If the increase in long-run consumer surplus due to increased innovation from a higher level of patent protection that reverse payments afford is large enough, then the long-run gain in consumer surplus can be greater than the short-run loss, and these settlement payments can increase total consumer surplus. If a reverse payment is deemed illegal based on the size of payment alone, this can reduce the level of patent protection intended by the existing patent law. As result, it will reduce brand name drug companies' incentive to invest in R&D and introduce new drugs.

Langenfeld & Li have shown that the dynamic efficiency from introduction of new drugs can be very significant.[38] Specifically, that analysis shows if there is only a thirty percent probability that one additional new drug will be deterred for each reverse payment agreement blocked, then the weakening of patent protection will reduce total consumer welfare even though earlier generic entry can generate cost savings in the short run.

V. CONCLUSION

The Court majority in *Actavis* found that reverse payments should be evaluated under a rule of reason, but it gives relatively little guidance to lower courts on how to carry out this analysis. It is economically troubling, then, when one of the relatively few guideposts the majority decision discusses is the size of the reverse payment. Although the size of such payments is relevant to an economic analysis of their impact on consumers, a rule of reason analysis should not put too much weight on size, particularly considering the other short- and long-run consumer welfare issues that need to be addressed.

[36] Langenfeld & Li, *supra* note 8 at 808-09. However, it would be economically inappropriate to compare profits from the sales of a particular drug covered by the patent in dispute to the specific R&D costs incurred for the drug. Research in the pharmaceutical industry is similar to drilling for oil. There are many dry holes, and the small percentage of cases where oil is found must to pay for the dry holes if search is to continue. Because of the substantial risks associated with new drug development, a research-based firm's R&D investment must be viewed as a portfolio. *See* Langenfeld and Li *supra* note 26 at 69-73.

[37] Langenfeld & Li, *supra* note 8 at 808.

[38] *See* Langenfeld & Li, *supra* note 26 at 803-04.