

The Benefits of Patent Settlements: New Survey Evidence on Factors Affecting Generic Drug Investment

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Executive Summary

- Settlements of patent litigation in which a brand manufacturer (*i.e.*, the patent holder) provides compensation to a generic manufacturer (*i.e.*, the alleged patent infringer) continue to be one of the most hotly debated antitrust topics in the pharmaceutical industry, and even more broadly.
- As we and others have shown previously, the use of highly simplified economic models can lead to the inappropriate conclusion that settlements with consideration will always reduce competition by delaying generic entry beyond the date of expected entry from litigation. But such economic models ignore important economic realities that are inherent in the litigation process and which often make settlements with consideration procompetitive. In fact, under certain real-world conditions, without the ability for the branded company to pay the generic company, the parties will be unable to reach a settlement - even if that settlement would benefit consumers.
- These economic models focus on “short-term” or “static” effects. But “long term” or “dynamic” effects are often ignored in the policy debate and make be even more significant than the short term, static effects. The dynamic implications of settlements with consideration involve the extent to which the ability to enter into such settlements affect the incentives of branded and generic manufacturers and therefore the availability of future branded and generic drugs.
- As a first step in filling the lack of empirical evidence about the dynamic effects of patent settlements, we conducted a survey of all 27 manufacturer members of the Generic Pharmaceutical Association (GPhA) on their generic investment decisions and patent litigation experience. The results of our survey show:
 - Consistent with previous evidence, bringing a generic drug to market can be an expensive process.
 - Settlement is an important option for resolving patent litigation. On average, respondents reported resolving 64 percent (165 of 256 resolved patent suits) by settlement.
 - When patent litigation went to judgment, the generic respondent lost two out of every three times. Such evidence may suggest that branded patents were relatively strong, and where patents are strong, settlements with consideration are more likely to benefit consumers.
 - The ability to settle patent litigation was also recognized as an important factor in determining in which generic drugs to invest.

Introduction

Settlements of patent litigation in which a brand manufacturer (*i.e.*, the patent holder) provides compensation⁴ to a generic manufacturer (*i.e.*, the alleged patent infringer) continue to be one of the most hotly debated antitrust topics in the pharmaceutical industry, and even more broadly. The Federal Trade Commission (FTC) has argued that such settlements harm consumers by delaying the entry of lower-priced generic drugs and has aggressively investigated such settlements over the past decade. Numerous courts have evaluated the competitive effects of such settlements and have utilized different standards for evaluating whether settlements with consideration benefit or harm consumers. While much has been written on the appropriate policy towards settlements with consideration, little has been said on the importance of such settlements to generic drug investment. In this short paper, we first provide a brief overview of the economics of these settlements, and then present the results of a new survey of generic pharmaceutical manufacturers. While this paper focuses primarily on generic competition from products entering the market as a result of patent settlements, it is important to note that generic entry from patent expiry also increases competition in the pharmaceutical marketplace, resulting in savings.

The goal of this paper is modest: to provide empirical evidence to better inform the policy debate about the standard that should be applied in evaluating whether settlements with consideration benefit or harm consumers. While this survey evidence has limitations, we believe that the results provide additional information for the policy debate on certain key topics, such as the frequency of generic manufacturers prevailing in the underlying patent litigation and on the ability of being able to settle patent litigation on the incentives of generic manufacturers to invest in drug research and development.

The Economics of Patent Settlements

⁴ The FTC has defined compensation broadly to include cash payments, “excessive” payments associated with ancillary business transactions, and even agreements by the branded manufacturer not to launch an authorized generic.

As an initial matter, it is worth noting that the “reverse payment” moniker itself is based upon flawed logic.⁵ In a “typical” settlement of a patent lawsuit, the alleged infringer logically pays the patent holder, while in a reverse payment settlement the patent holder (branded manufacturer) pays the alleged infringer (generic manufacturer). The Hatch-Waxman Act creates an unusual circumstance in the pharmaceutical industry where the patent holder (branded manufacturer) can sue the alleged infringer (generic manufacturer) before the alleged infringer markets a product.⁶

In any patent case, the alleged infringer is going to require some compensation for abandoning the litigation. In a typical case where the patent infringer has been on the market for a significant period of time and would owe significant damages if found liable, the parties may agree to a settlement where the infringer pays damages to the patent holder, but those damages are far less than the damages the patent holder is seeking. In this case, the patent holder “pays” the infringer to settle the suit by accepting lower damages – this payment is just obscured by the fact that on net some compensation flows from the infringer to the patent holder. Settlements with consideration can be thought of in the same way, but the Hatch-Waxman framework means the patent holder typically does not incur any damages from sales of the infringing products, and so the net payment flows from the branded manufacturer to the generic manufacturer. Since nothing nefarious can be gleaned from the simple fact that the payment flows in a particular direction, one must examine the underlying economics of these settlement agreements.

As a general matter, the short-term (*i.e.*, considering only the drug at issue in the litigation) effect of a patent settlement is procompetitive if the generic entry date allowed for under the settlement is no later than the expected generic entry date that would result from continuing the litigation to judgment. The use of highly simplified economic models can inappropriately lead to the conclusion that settlements with consideration will always reduce competition by delaying generic entry beyond the date of expected entry from

⁵ Similarly, the term “exclusion payments” does not accurately reflect the nature of many of these settlements. Where the branded manufacturer’s patent is valid and infringed at the time of settlement, it is the patent itself that provides the ability to exclude, not the payment.

⁶ Generic manufacturers can enter “at risk” – that is enter before final judgment in the patent litigation.

litigation. But overly simple economic models ignore important economic realities that are inherent in the litigation process and which can make settlements with consideration procompetitive. In general, economists tend to agree that some settlements with consideration can be procompetitive and bring generic drugs to market sooner than litigation.⁷ The debate among economists, therefore, is over where and how to “draw the line” between procompetitive and anticompetitive settlements.

Most fundamentally, settlements of litigation, including patent litigation, reduce litigation costs. Other important realities that need to be accounted for to reach the appropriate economic conclusion include, but are not limited to (a) risk aversion, (b) information asymmetries, (c) differences in expectations, and (d) differences in discount rates. In fact, under certain (often real-world) conditions, without compensation flowing from the branded manufacturer to the generic manufacturer, the parties will be unable to reach a settlement agreement - even if that settlement would benefit consumers.

For example, suppose that both the branded and generic manufacturers are overly optimistic about their chances of success in the patent litigation - say the branded manufacturer believes that there is a 75% chance that it will win the litigation and the generic manufacturer believes that there is a 75% chance that it will win. In this case, the parties will be unable to reach a settlement based upon entry date alone. A settlement with consideration, however, can facilitate a settlement that is agreeable to both parties and, given the actual chance of success in the patent litigation, provide benefits to consumers relative to continued litigation. Dickey, Orszag, & Tyson (2010) offers a more complete development of the underlying economic model and additional examples of settlements with consideration which can be procompetitive.⁸

Dynamic Effects of Competition Policy towards Patent Settlements

⁷ Even the FTC appears to have endorsed a “safe harbor” where payments less than or equal to the cost of litigation are allowed.

⁸ Dickey, Bret, Jonathan Orszag, and Laura Tyson, “An Economic Assessment of Patent Settlements in the Pharmaceutical Industry,” *Annals of Health Law*, Vol. 19, pp. 367-400. See also Willig, Robert D. & John P., Bigelow, “Antitrust Policy toward Agreements that Settle Patent Litigation,” *The Antitrust Bulletin*, Fall 2004, pp. 655-698 for the formal development of the economic model.

While there is an extensive literature on the potential competitive effects of settlements with consideration and the appropriate policy treatment of them, the debate has generally focused on static effects of such settlements – to what extent these settlements facilitate or impede entry of generic versions of the drug that is at issue in the patent dispute. Yet a key factor that is often ignored in the policy debate is the dynamic implications of these settlements – to what extent do they affect incentives of branded and generic pharmaceutical manufacturers and therefore the availability of future branded and generic drugs. As explained by Frank Easterbrook, Chief Judge for the U.S. Court of Appeals for the Seventh Circuit:

An antitrust policy that reduces prices by 5 percent today at the expense of reducing by 1 percent the annual rate at which innovations lower the costs of patent introduction would be a calamity. In the long run a continuous rate of change, compounded, swamps static losses.⁹

There are two aspects of innovation that are important in the pharmaceutical industry. First, patent protection is an important component of branded manufacturers' incentives to invest substantial sums researching and developing new medicines. To the extent that limits on patent settlements reduce branded manufacturers' incentives to invest in pharmaceutical R&D, consumers may suffer significant adverse effects in the long-run, in the form of a smaller number of new medicines that become available.

Second, competition policy towards patent settlements will also affect generic manufacturers' incentives to develop new generic drugs and challenge branded patents. Patent litigation can be expensive and risky, particularly for small firms. All else equal, restricting the options for settling patent litigation reduces the ability of generic manufacturers to settle these cases and increases the cost and risk of challenging branded patents. Restricting the range of settlement options, therefore, will reduce generic manufacturers' incentives to bring these types of drugs to market and could lead to underinvestment in patent challenges. Even if the effect on a particular generic

⁹ Frank H. Easterbrook, *Ignorance and Antitrust*, in *Antitrust, Innovation, and Competitiveness* 119, 122—23 (Thomas M. Jorde & David J. Teece eds., 1992).

manufacturer's decision is relatively small, the collective impact on future generic competition could be substantial.

This effect has gotten little attention by economic and legal scholars. Judge Posner briefly pointed to it in one of his opinions.¹⁰ Dickey & Rubinfeld (2010) described the theoretical effect that restrictions on settlements with consideration could have on generic manufacturers' investment decisions.¹¹ It described a basic economic model of generic manufacturers' investment decisions as a function of the net present value of future profits from selling the generic drug, the cost of bringing the generic drug to market, and the risk associated with the investment. It described how restricting settlement options could increase the uncertainty of bringing a generic drug to market and lower the expected risk-adjusted returns. We, however, are not aware of any empirical evidence that examines the importance of a settlement option in this investment decision.

Survey and Results

Survey. As a first step in filling this gap, we conducted a survey of manufacturer members of GPhA. The survey asked various questions about manufacturing and development portfolios, experience with ANDA filings and patent challenges, and the importance of factors affecting their decisions to invest in a particular drug. We received survey responses from a majority of GPhA members sent surveys. These companies collectively represent nearly \$1 billion in annual R&D spending.

Costs of bringing a generic drug to market. Consistent with previous evidence, the results of our survey confirm that bringing a generic drug to market can be an expensive process. According to the survey, the typical range of cost per drug includes:¹²

- R&D costs of \$800,000 to \$3,250,000 per drug.

¹⁰ *Asahi Glass Co., Ltd. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994; N.D. Ill., 2003.

¹¹ Dickey, Bret M. and Daniel L. Rubinfeld, "Would the Per Se Illegal Treatment of Reverse Payments Settlements Inhibit Generic Drug Investment," *Journal of Competition Law & Economics*, 8(3), 615-625.

¹² We define "typical" as the interquartile range of costs, which is the range between the 25th and 75th percentile of the distribution. (Many respondents gave a range of costs, so the range reported is from the 25th percentile of the lower end of these ranges to the 75th percentile of the highest end of these ranges). Some respondents also indicated substantial additional costs as well.

- ANDA filing costs of \$76,250 to \$250,000.
- Patent litigation costs of \$2,000,000 to \$5,250,000.

Frequency of settlements. The results of our survey also highlight the importance of settlements in the resolution of patent litigation between branded and generic pharmaceutical manufacturers. On average, respondents reported resolving 64% of patent suits (165 of 256 resolved patent suits) by settlement. At least three manufacturers resolved all of their (non-outstanding) suits by settlement and a third settled more than 85% of the time.

Strength of brand patents. As discussed above, the competitive effects of patent settlements depend importantly on the so-called strength of the underlying patent. If the brand patent is thought to be strong (*i.e.*, likely to be found valid and infringed) then settlements with entry even a short time before patent expiration can benefit consumers through earlier entry of generic drugs. If the brand patent is thought to be weak (*i.e.*, unlikely to be found valid and infringed) then settlements can harm consumers by delaying entry of generic drugs. Survey respondents report that when patent litigation went to judgment, the generic respondent lost two out of every three times. Only one respondent reported winning more patent cases than it lost (and that respondent won two and lost one). Such evidence may suggest that branded patents were relatively strong, and where patents are strong, settlements with consideration are more likely to benefit consumers.¹³

Factors affecting investment decisions. We asked each manufacturer to rate the importance of various factors on their generic investment decisions on a scale of 1 (least important) to 5 (most important). The results are shown in Table 1:

¹³We recognize that cases litigated to judgment *may* be fundamentally different from the cases that settled with or without reverse payments. Indeed we have criticized the FTC for making unwarranted assumptions along these lines in previous papers (see Dickey, Bret, Jonathan Orszag, and Robert Willig, “A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on Reverse Payment Settlements”). Thus, we are not claiming here that reverse payment settlements are all likely procompetitive because the underlying patents were likely to be “strong.” Rather, we are simply observing that the cases that went to judgment (*i.e.*, the parties were unable to settle) tended to be won by the branded manufacturer.

Table 1: Importance of Factors Affecting Generic Manufacturers' Investment Decisions			
Factor	Average Importance (Simple)	Average Importance (Weighted)*	Manufs. Rating As Most Important
First Filer Opportunity	4.29	4.61	8
Expected Number of Entrants	4.29	4.56	9
Patent Strength	4.14	4.36	6
Patent Type	3.86	4.05	3
U.S. Market Size	3.79	4.03	4
Manufacturing Complexity	3.64	3.90	3
Uncertainty of Future Market Size	3.07	3.46	0
Remaining Patent Life	3.64	3.19	2
Dosage Form	3.93	3.16	4
Similarity to Existing Drug Portfolio	3.21	3.06	0
Distribution Channel (Retail/Hospital/Etc.)	3.21	3.06	2
Ability to Settle Litigation	2.93	2.63	2
Number of Patents	2.71	2.59	0
Litigation Uncertainty	2.79	2.58	0
Condition Treated (Chronic/Acute)	2.21	1.97	0
International Market Size	2	1.86	0
Expectation of Authorized Generic	1.71	1.44	0

* Weighted by number of generic products currently marketed by manufacturer

Consistent with the model presented in Dickey & Rubinfeld, the most important factors affecting investment decisions are (a) those that substantially affect a drug's expected revenue stream including the opportunity to be the first ANDA filer (and obtain a 180-day exclusive marketing window), the number of other generic entrants that are expected to launch versions of that drug, and the size of the available market, and (b) those that substantially affect the probability of winning the patent litigation, including patent strength and patent type.

The ability to settle patent litigation was also recognized as important. It received an average score of roughly 3 and was ranked as 5 (most important) by two of the respondents. Respondents also identified trends that will make the ability to settle reliably patent litigation more important in the future. These include the increasing trends towards

multiple first filers (resulting in increased uncertainty and decreased profit opportunities as profit opportunities from the exclusive period are shared among multiple generic manufacturers) and fewer numbers of blockbuster branded drugs facing patent challenges in the near future (again resulting in decreased profit opportunities from successfully challenging the branded patent).

Conclusion

Competition policy should put substantial weight on dynamic (long-run) not just static (short-run) competitive effects. This is particularly true for an industry like the pharmaceutical industry which is driven so importantly by innovation (both branded and generic development). An important aspect to consider in formulating the appropriate policy towards settlements with consideration is the importance of the ability to settle on generic manufacturers' incentives to invest in development of generic drugs. Our survey results suggest that (i) generic respondents lost more than half of the cases that they litigated to judgment, suggesting that branded patents in these cases were relatively strong and (ii) the ability to settle patent litigation is a factor considered by generics in deciding whether and how much to invest in drug development. Since the entry of a generic has significant benefits to consumer welfare, the creation of disincentives to invest in new generic medicines may make consumers worse off over the long haul. In determining the appropriate policy framework for evaluating settlements with consideration, policymakers should heed Judge Easterbrook's warning to focus on both the short-run, static effects and the long-run, dynamic effects, which could ultimately be even more important to consumer welfare than any short-run effects for any particular drug.