Pay-for-Delay:

How Drug Company Pay-Offs Cost Consumers Billions

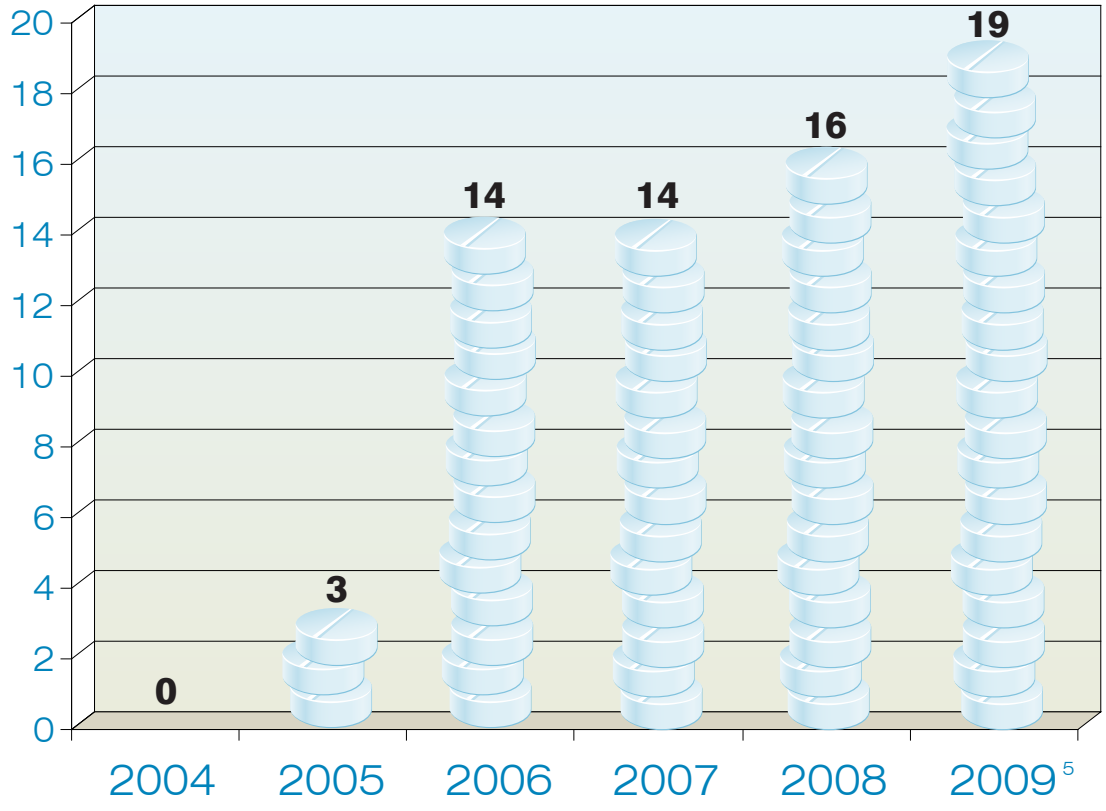
An FTC Staff Study
January 2010

Federal Trade Commission | ftc.gov

Summary

- Brand-name pharmaceutical companies can delay generic competition that lowers prices by agreeing to pay a generic competitor to hold its competing product off the market for a certain period of time. These so-called "pay-for-delay" agreements have arisen as part of patent litigation settlement agreements between brand-name and generic pharmaceutical companies.
- "Pay-for-delay" agreements are "win-win" for the companies: brand-name pharmaceutical prices stay high, and the brand and generic share the benefits of the brand's monopoly profits. Consumers lose, however: they miss out on generic prices that can be as much as 90 percent less than brand prices. For example, brand-name medication that costs $300 per month might be sold as a generic for as little as $30 per month.
- The Federal Trade Commission's (FTC) investigations and enforcement actions against pay-for-delay agreements deterred their use from April 1999 through 2004.[1] In 2003, an appellate court held that such agreements were automatically (or *per se*) illegal.[2]
- Since 2005, however, a few appellate courts have misapplied the antitrust law to uphold these agreements.[3] Following those court decisions, patent settlements that combine restrictions on generic entry with compensation from the brand to the generic have re-emerged.

Agreements with Delay and Compensation[4]



- Agreements with compensation from the brand to the generic on average prohibit generic entry for nearly 17 months longer than agreements without payments, where the average is calculated using a weighted average based on sales of the drugs.[6] Most of these agreements are still in effect. They currently protect at least $20 billion in sales of brand-name pharmaceuticals from generic competition.[7]

- Pay-for-delay agreements are estimated to cost American consumers $3.5 billion per year – $35 billion over the next 10 years.[8]

Recommendation

Pay-for-delay agreements have significantly postponed substantial consumer savings from lower generic drug prices. The Commission has recommended that Congress should pass legislation to protect consumers from such anticompetitive agreements.

Background

Pay-for-delay agreements appear in some settlements of patent litigation between brand-name and generic pharmaceutical companies. That patent litigation usually takes place within the framework for generic entry established by the Hatch-Waxman Act.[9] Under that Act, a generic competitor may seek entry prior to expiration of the patents on a brand-name drug. Generic drug entry before patent expiration can save consumers billions of dollars. Generics have an incentive to challenge brand patents because the first generic to file its application can obtain 180 days of marketing exclusivity during which it is the only generic on the market. To seek FDA approval for entry before patent expiration, a generic must declare that its product does not infringe the relevant patents or that the relevant patents are invalid.

Typically, brand-name pharmaceutical companies challenge the generic's declaration, and litigation ensues between the brand-name and generic pharmaceutical manufacturers to determine whether the relevant patents are valid and infringed. For the brand to prevail and block entry, it must successfully defend the validity of its patents and demonstrate that the generic's product would infringe those patents. In 2002, the FTC issued a study showing that generics prevailed in 73% of the patent litigation ultimately resolved by a court decision between 1992 and June 2002.[10]

Given the costs and potential uncertainty of patent litigation, brand-name and generic pharmaceutical companies sometimes settle their patent litigation before a final court decision. For example, the parties may agree that the generic can enter at some time before the patent's expiration date, but not as soon as the generic seeks through its litigation. Absent compensation to the generic for the delay in its entry, such settlement agreements are unlikely to raise antitrust issues.

The FTC's 2002 study determined, however, that some brand-name and generic pharmaceutical companies had settled their patent litigation through agreements that compensated generics for substantial delays in generic entry. The FTC recommended that Congress pass legislation to require pharmaceutical companies to file certain agreements with the FTC. The intent of the legislation was "to put an end to this exploitation of the provision in Hatch-Waxman that grants a short-term protection from competition to the first manufacturer to bring a generic version of a brand name drug to market."[11]

Congress acted on the FTC's recommendation. Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"), pharmaceutical companies must file certain agreements with the FTC and the Department of Justice within ten days of their execution.[12]

Findings from Pharmaceutical Agreement Filings from FY2004 through FY2009

- **How Many Final Agreements Have Involved Compensation from the Brand to the Generic Combined with Restrictions on Generic Entry?**

  From FY2004-FY2009, 66 final agreements involved some form of compensation from the brand to the generic combined with a delay in generic entry.

- **Can Pharmaceutical Companies Settle Patent Litigation without Pay-for-Delay Agreements?**

  Yes. From FY2004-FY2009, pharmaceutical companies filed a total of **218 final settlement agreements** involving brand and generic companies. **Seventy percent of those patent settlements – 152 – did not involve compensation from the brand to the generic combined with a delay in generic entry.** This large number of settlements not involving compensation from the brand to the generic undermines brand and generic firms' arguments that compensation is the only way to settle patent litigation. In fact, there are a variety of ways to settle litigation that do not involve these payments.

- **Do Agreements with Compensation from the Brand to the Generic Postpone Generic Entry Significantly Longer than Other Patent Settlement Agreements?**

  Yes. Staff analysis of patent settlements restricting generic entry finds that agreements with compensation on average prohibit generic entry for nearly **17 months** longer than agreements without payments, where the average is calculated using a weighted average based on sales of the drugs.[13] This difference in time to entry is very unlikely to be caused by random variation in the agreements. In fact, there is less than a 1% chance that this large a difference in average time to entry would be observed if the amount of delay from the two types of agreements were drawn from the same statistical distribution.

  A hypothetical consumer paying $300 per month for a brand-name drug, instead of a generic price as low as $30 per month, could pay as much as $270 per month more for prescription drugs. Over a 17-month period, this could total additional expenses of $4,590 resulting from the extra delay that occurs, on average and weighted for sales.

Is the First Generic to Seek Entry Prior to Patent Expiration Involved in Most of the Potential Pay-for-Delay Settlements?

Yes. Out of the 66 agreements that combined compensation from the brand to the generic with deferred generic entry, **51 agreements** (77%) were between the brand pharmaceutical company and the generic company that was the first to seek entry prior to patent expiration for the relevant brand-name drug.

Settlements with first-filer generics can prevent *all* generic entry. Those agreements place a "cork in the bottle" that typically ensures the brand-name drug's lock on the market. This cork-in-the-bottle effect occurs because every subsequent generic entrant has to wait until the first generic has been marketed for 180 days. [14]

Do All Pay-for-Delay Agreements Involve Dollar Payments from the Brand to the Generic?

No. Brand-name pharmaceutical companies have found a wide variety of techniques through which to compensate generic companies for delaying their entry.

Recently, brand-name pharmaceutical companies have sometimes compensated generics by agreeing not to compete through a so-called "authorized generic." Under the Hatch-Waxman Act, the generic that is first to file its approval application can be entitled to market its generic product for 180 days with no competition from other generics.[15] This rule, however, does not protect the first-filer generic from competition from an "authorized generic" or "AG" during those 180 days.

AGs are brand-name pharmaceutical products marketed as generics. AG competition can substantially reduce the revenues a first-filer generic earns during its 180 days of marketing exclusivity.[16]

About 25% of patent settlement agreements from FY2004-FY2008 that were with first-filer generics involved an explicit agreement by the brand not to launch an AG to compete against the first filer, combined with an agreement by the first-filer generic to defer entry past the date of the agreement.[17] In effect, by agreeing not to launch an AG, the brand agrees not to subtract from the generic's profits during the 180-day period.

Has the FTC Given Up Litigating Pay-for-Delay Cases under the Antitrust Laws?

No. The FTC has multiple investigations underway and currently is litigating two cases in the trial courts.[18] Over the past nine years, the FTC has invested substantial resources in investigating and, when necessary, litigating cases involving patent settlements in which brand-name pharmaceutical companies allegedly paid generic companies to stay off the market, thus depriving consumers of millions of dollars in cost savings that would otherwise have been available.[19]

Given the magnitude of consumer harm from pay-for-delay settlements – an estimated $35 billion over the next ten years – a legislative solution offers the quickest and clearest way to deter these agreements and obtain the benefits of generic competition for consumers.

Study Methodology

This study was prepared by staff from the FTC's Bureau of Competition, Bureau of Economics, and Office of Policy Planning.

This study is based on patent settlement agreements filed with the FTC between January 1, 2004 and September 30, 2009 pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, codified in relevant part at 42 U.S.C. § 1395w-101 note (section 110), 21 U.S.C. § 355 note (sections 1111-1118), 21 U.S.C. § 355(j)(5) (section 1102).

Staff identified agreements in which restrictions on generic entry were combined with compensation from the brand to the generic. The FTC has challenged some of these agreements as violating the antitrust laws, but the agency lacks sufficient resources to investigate and litigate the legality of all of these agreements.

How staff calculated the additional delay in generic entry associated with agreements that involved compensation from the brand to the generic.

To calculate how long (on average and weighted for sales) generic entry was delayed as a result of compensation from brand-name pharmaceutical companies to generic drug companies, staff compared agreements with and without compensation to the generic in terms of the sales-weighted average time between the date of the agreement's execution and the date of generic entry.

To avoid double counting multiple settlements on the same drug, only the settlement that establishes the earliest date for generic entry was used in this calculation.

To better reflect the amount of consumer savings held up by the delay, staff used weighted averages of sales.

This calculation established that, on average and weighted for sales, agreements with compensation from the brand to the generic delayed generic entry for nearly 17 months longer than agreements without compensation. Staff determined that the 17 month difference in time until generic entry was statistically significant at the 99% confidence level. Thus, this difference in time to entry is very unlikely to be caused by random variation in the agreements. In fact, there is less than a 1% chance that this large a difference in average time to entry would be observed if the amount of delay from the two types of agreements were drawn from the same statistical distribution.

How staff calculated the estimate of $3.5 billion annually that consumers lose due to pay-for-delay agreements.

The calculation below is a method of estimating the likely harm to consumers from the loss of competition when patent settlements delay generic entry.[20] The analysis estimates that under relatively conservative assumptions, the annual savings to purchasers of drugs that would result from eliminating "reverse-payment" settlements would be approximately $3.5 billion.

This calculation requires four factors:

1. the consumer savings that result from generic competition in any given month,
2. the likelihood that a generic manufacturer and brand-name manufacturer will reach a settlement that delays entry in return for compensation,
3. the length of entry delay resulting from such settlement, and
4. the combined sales volume of drugs for which settlements are likely.

(1) Consumer savings from generic competition.

When generic entry occurs, purchasers immediately begin to benefit from the savings associated with lower generic drug prices. Following an initial entry period, the generic market matures and consumers receive the full savings from generic competition. Thus, any delay in entry results in a longer period of purchases at the full brand price and correspondingly fewer purchases at the mature competitive prices.[21] This means that the costs to consumers (or what they would have saved but for the entry delay) are equal to the monthly savings from the mature generic market multiplied by the number of months of delay.

Publicly available information about recent generic launches suggests that a generic market typically matures about one year after the first entrant comes on the market. The generic penetration rate at that point is about 90% on average, i.e. pharmacists fill 90 of every 100 prescriptions for the molecule with an AB-rated (or bioequivalent) generic. Recent information also shows that in a mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug price.[22]

Using the above figures and assumptions, the average consumer savings from a mature generic market relative to pre-generic levels are approximately 77% (85% savings multiplied by 90% of market demand). If purchasers discount future savings at the same rate as they expect drug prices and quantities to increase, then all future savings can be expressed in terms of today's dollars without complicated net present value calculations. Thus, the costs of delay are the average discount (77%) times the length of the delay times the pre-generic entry revenues of the branded drugs that will reach a settlement with delay.

(2) Likelihood of Settlements with Payment to Delay, and the Length of Delay

It is more difficult accurately to estimate how much delay is likely to result from settlements that have not yet been reached, especially because future legislative or judicial actions could alter the types of settlements that are likely. Therefore, the calculation assumes that recent settlements provide the best information about what may happen in the future. Data on settlements reported to the FTC from FY2004 to FY2008 show that of all patent settlements resulting from a Paragraph IV (invalidity or non-infringement) challenge, approximately 24% included both restrictions on timing of generic entry and a payment to the generic firm.

The additional length of the delay that is attributed to the payments in these settlements can be calculated by taking the universe of Paragraph IV settlements that have restrictions on entry, then comparing the average number of months between the execution of the agreement and the date of generic entry in agreements with and without payments to the generic entrant. Agreements with payments on average allow entry nearly 17 months (1.42 years) later than agreements without payments.

This does not mean that we are assuming that all settlements with payments would "become" settlements without payments if the former were banned. Some would; others might involve litigation of the patent. But since settlements without payments will tend to reflect patent strength, they can provide a benchmark for the consumer impact of either alternative.

(3) Sales Volume of Drugs for which Settlements are Likely

Staff relied on recent history as a guide to the settlements likely to be seen in the future. The analysis starts with the FDA's list of all drugs that have received a Paragraph IV filing.[23] It then uses information from the FDA's Orange Book, IMS NPA retail sales data, and the settlement filings to determine whether there had been a generic version of a challenged drug launched before 2004. If a generic had entered, it was removed from the list of drugs that could have settled between FY2004 and FY2008. The analysis next uses the IMS data to determine the total dollar sales associated with those drugs remaining in the sample for each year. It adjusts these annual totals by removing drugs that reached a settlement or experienced generic entry due to a non-settlement event such as a court victory or patent expiration.

By the end of FY2008, the above method estimates that there were $90 billion of branded drug sales still facing a Paragraph IV challenge. Since the IMS data used does not cover all purchasing channels and excludes injectable drugs, $90 billion is a conservative estimate of the total branded dollars affected by possible settlements.

The next step is to look at the number of settlements per year as a percentage of all Paragraph IV-challenged drugs that could possibly settle. Over the FY2004 to FY2008 time period, the percentage of drugs that settled per year (not including injectables) increased from 7 percent to 18 percent, with most of the increase following the Eleventh Circuit's *Schering* decision. Since this post-*Schering* era is probably a better

reflection of likely future settlement patterns, it seems appropriate and conservative to use the 15 percent per year average from this period in the estimate calculations.

Multiplying $90 billion by 15 percent yields $13.5 billion in drug purchases that are predicted to be affected by settlements each year. Multiplying this $13.5 billion total by 24 percent (an assumption based on the percentage of past settlements with payment and delayed entry), leads to a prediction of $3.2 billion in drug sales that will be affected by reverse payment settlements in a given year.

(4) Final Estimate Calculation

The final steps in calculating the savings to be gained by eliminating pay-for-delay settlements are to factor in the discount consumers would receive from matured generic entry and the length of delay. From the 77 percent savings and 1.42 year delay figures above, the calculation is therefore:

77% savings
× $3.2 billion (15% per year settling)
× 1.42 years (median delay)

$3.5 billion of annual purchaser savings

In sum, the calculation yields a conservative estimate of $3.5 billion per year of potential savings from eliminating pay-for-delay settlements.

Results with Varied Assumptions

The $3.5 billion figure represents staff's best estimate of the effect based on what staff believes to be the most reasonable assumptions. Nonetheless, this estimate is sensitive to changes in the assumptions.[24] Reasonable estimates about the length of delay and the sales of drugs likely to be affected by the legislation can vary. The calculations below present high and low estimates of savings derived from the data ranges.

77% savings
× $3.9 billion (18% per year settling)
× 2.5 years (high of interquartile distribution of delay)

$7.5 billion of annual purchaser savings

77% savings
× $1.5 billion (7% per year settling)
× 0.5 years (low of interquartile distribution of delay)

$0.6 billion of annual purchaser savings

Endnotes

1 *See Generic Drug Entry Prior to Patent Expiration: An FTC Study*, Exec. Summary at viii (July 2002), *available at* **http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf**. This study covered the period through June 2002. The FTC began receiving patent settlement agreements in January 2004 pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Although there is a gap between July 2002 and December 2003, we are unaware that brand and generic firms entered into any pay-for-delay settlement agreements during this time period.

2 *See In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003).

3 *See Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056 (11th Cir. 2005); *see also In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008). *But see* Brief For the United States In Response To the Court's Invitation, *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, No. 05-cv-2851(L) (2d Cir. July 6, 2009), *available at* **http://www.justice.gov/atr/cases/f247700/247708.htm**.

4 These agreements were filed with the FTC pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified in relevant part 42 U.S.C. § 1395w-101 (2009) note (section 110), 21 U.S.C. § 355 (2009) note (sections 1111-1118), 21 U.S.C. § 355(j)(5) (2009) (section 1102)). All of these agreements involved patent settlements that combined restrictions on generic entry with compensation from the brand to the generic. The FTC has challenged some of these agreements as violating the antitrust laws, but the agency lacks sufficient resources to investigate and litigate the legality of all of the agreements represented in this chart.

5 These years represent fiscal years.

6 The 17-month delay attributed to payments was calculated by comparing the sales-weighted average time between the date of the agreement's execution and the date of generic entry for agreements with and without compensation to the generic.

7 This dollar amount represents the prior-year total sales of the brand-name pharmaceuticals that are currently covered by agreements with delay and compensation and thus indicates the order of magnitude of brand-name pharmaceutical sales for which generic competition (with lower prices) has likely been delayed.

8 *See* Jon Leibowitz, Chairman, Fed. Trade Comm'n, *"Pay-for-Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (The $35 Billion Solution)* at 8 (June 23, 2009), *available at* **http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf**.

9 The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (2009)) governs how generics may enter the marketplace to compete with brand-name pharmaceuticals.

10 *See supra* note 1.

11 *See* S. Rep. No. 107-147 at 4 (2002).

12 *See* Pharmaceutical Agreement Filing Requirements, *available at* **http://www.ftc.gov/os/2004/01/04106pharmrules.pdf**.

13 The delay attributed to payments was calculated by comparing the sales-weighted average time between the date of the agreement's execution and the date of generic entry for agreements with and without compensation to the generic. The distribution of annual sales figures for drugs covered by these pay-for-delay agreements is not discernibly different from the distribution of annual sales figures for drugs covered by agreements that restrict generic entry with no payment to the generic.

14 Later-filing generics cannot enter the market until they win their own patent litigation at the court of appeals level and the first filer generic either markets its product for 180 days or forfeits its right to do so. 21 U.S.C. § 355(j)(5)(D) (2009) (forfeiture provisions).

15 There may be more than one "first-filer" if more than one generic firm files its application on the same, "first" day.

16 *Authorized Generics: An Interim Report*, Fed. Trade Comm'n at 3 (June 2009); *available at* **http://www.ftc.gov/os/2009/06/P062105authorizedgenericsreport.pdf**.

17 *Id.*

18 *See Fed. Trade Comm'n v. Cephalon*, No. 08-cv-2141-RBS (E.D. Pa. May 8, 2008) (transfer order); *Fed. Trade Comm'n v. Watson*, No. 09-cv-00598 (N.D. GA Feb. 9, 2009) (transfer order).

19 *See In re Hoechst Marion Roussel Inc., Carderm Capital L.P. and Andrx Corp.;* 131 F.T.C. 927 (2001) (consent order); *In re Abbott Laboratories and Geneva Pharmaceuticals, Inc.*, C-3945, C-3946 (consent orders issued May 22, 2000); *In re Schering-Plough Corp., et al,* D. 9297, Initial Decision issued June 27, 2003; *rev'd* by Commission Decision and Order, December 8, 2003(136. F.T.C. 956 (2003)); *rev'd* 402 F.3d 1056 (11th Cir. 2005); *In re Bristol-Myers Squibb*, 135 F.T.C. 444 (2003) (consent order); *Fed. Trade Comm'n v. Cephalon*, No. 08-cv-2141-RBS (E.D. Pa. May 8, 2008) (transfer order); *Fed. Trade Comm'n v. Watson*, No. 09-cv-00598 (N.D. GA Feb. 9 2009) (transfer order).

20 This calculation first appeared as an Appendix to Chairman Leibowitz's speech. *See supra* note 8.

21 If one assumes some future end-point in the drug's life on the market, delayed entry means that, by that end-point, consumers will have had less time buying in the mature competitive market.

22 The calculation assumes that the total demand for the drug/molecule (market size in unit sales) remains the same after generic entry occurs. It also assumes that the brand's price stays the same after generic entry occurs. Data show that branded prices often rise following generic entry, but there are also instances when brand price declines. Assuming the price stays the same simplifies the analysis.

23 This is based on a version downloaded from the FDA's website on May 19, 2009.

24 In addition, a possible effect in the other direction could arise if a future legislative or judicial action made pay-for-delay agreements illegal. To the extent that such an action would reduce generic firms' incentives to file Paragraph IV challenges, it could reduce the sales volume of drugs facing such challenges. Any such deterrent effect would likely be very low, however. As noted above, only 24% of all cases settled with both payment and delay, so presumably generic drug firms do not assume that they will be able to settle their patent litigation through compensation for deferred generic entry. Moreover, a generic would still have a strong incentive to challenge a weak patent in a large market.