The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals

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S O N E C O N

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Executive Summary

- This study examines the impact of authorized generic drugs on the introduction of other generic pharmaceuticals, and therefore on the potential benefits of generic drugs for U.S. consumers. The analysis focuses on the incentives and disincentives of generic companies to challenge the patents of brand products, in order to qualify for a special, 180-day period of market exclusivity, when their generic product still faces potential competition in that period from generics authorized by the original developer.

- A review of the literature and new analysis conducted for this study establish that the prospect of competition from authorized generics during the 180-day exclusivity period, on balance, benefits American consumers.

- The availability of generic pharmaceuticals reduces prices and increases the therapeutic use of treatments, benefiting consumers.

- Competition from a generic that successfully challenges the patent of a brand product produces lower prices, even during the 180-day exclusivity period; and the FDA and independent analysts, including the Congressional Research Service, have found that additional competition from authorized generics in that period produces even lower prices.

- The literature contains no empirical evidence that the prospect of competition from authorized generics has reduced either patent challenges by other generic manufacturers or the development of new generic products.

- Even without competition from an authorized generic, a generics manufacturer that successfully challenges a patent may face competition during the 180-day period from other generic manufacturers offering the same molecule in different dosages.

- The ability of drug developers to market or license authorized generic versions of their products also increases their R&D investments, leading to more new drugs.

- Concerns have been expressed that if heightened competition reduces generic profits, it might also reduce R&D and drug development by those generic firms. Those concerns are misplaced: New research conducted for this study suggests that competition from authorized generics does not reduce R&D by generic manufacturers, and therefore should not reduce or delay the introduction of future generic products. A theoretical explanation for this result is also provided.

The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals

Kevin A. Hassett and Robert J. Shapiro[1]

I. Introduction

In 1984, Congress took important and far-reaching steps to encourage the production of generic versions of original drugs. Under what is commonly known as the Hatch-Waxman Act, a pharmaceutical manufacturer can secure approval from the FDA to market a generic version of an original drug by demonstrating that its version is the bioequivalent of the approved drug, without providing separate evidence of its safety and effectiveness from clinical data or scientific literature, and that the active molecule in its version is not protected by patents.[2] To establish the second condition, Hatch-Waxman requires that original developers identify the specific patents that would be infringed if a generic version were marketed before those patent expired, listed in the "Orange Book". Generic manufacturers can secure FDA approval for their versions of drugs listed in the Orange Book on four possible bases: 1) the original developer has failed to file the required patent information on the drug; 2) the listed patent has expired; 3) the generic manufacturer will not market its version before the patent expires; or 4) the patent is listed and has not expired but is legally invalid.[3]

The fourth justification, commonly referred to as "paragraph IV" cases, has special circumstances. It raises the prospect of substantial consumer benefits from lower prices, since it would allow competition years before a patent is set to expire. However, it also requires that a generic company assume substantial expenses in order to demonstrate why and in what respects a developer's current patent is invalid. To provide additional incentives for generic manufacturers to assume these costs and risks, Hatch-Waxman also creates a 180-day "exclusivity period" for generic manufacturers that mount successful paragraph IV challenges, during which other generic manufacturers cannot market their own version of a patent-invalidated drug. However, generic versions of a drug produced or licensed by its original developer, called "authorized generics," are approved for marketing through other procedures and not subject to this 180-day exclusivity period.

Since Hatch-Waxman was enacted more than 20 years ago, its provisions have become significant factors in American health care. The Federal Trade Commission reports that generics' share of all prescriptions rose from 19 percent in 1984 to 47 percent

[1] This research was conducted with support from a grant from Prasco, LLC. The views and conclusions are wholly those of the authors.

[2] The law also created 505(b)(2) applications for generic market approval, in which the manufacturer can rely at least in part on published literature providing pre-clinical or clinical data.

[3] The provisions of Hatch-Waxman are described by John R. Thomas in "Authorized Generic Pharmaceuticals: Effects on Innovation," CRS Report to Congress, August 8, 2006.

in 2002, and that share reached 63 percent in 2006.[4] For drugs that are widely used, relatively simple to manufacture and involve small risks in administering them, generic competition is very strong and can rapidly claim much of the market: When competition from generic versions of Prozac began in 2001, for example, the share of all prescriptions filled by the original developer, Lilly, plummeted 73 percent in just two weeks.[5] The benefits for consumers have been very large: In 2006, for example, generics accounted for 63 percent of all prescriptions filled at drug stores but just 20 percent of those stores' sales revenues from all prescriptions.[6] For all of these reasons, pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed "authorized generics."

The issue of how the marketing of authorized generics may affect paragraph IV applications also has become important. For one, the incidence of paragraph IV demonstrations has increased substantially. From 1984 to 1989, only 2 percent of applications by generic manufacturers received paragraph IV certification; this share increased six-fold to 12 percent from 1990 to 1997, and then rose again to 20 percent of generic submissions from 1998 to 2000.[7] Moreover, the incentive to market or license an authorized generic is particularly strong when a drug developer faces potential competition from a generic manufacturer mounting a paragraph IV challenge, because the authorized generic can then take advantage of the higher generic prices associated with the constraints on generic competition during the 180-day exclusivity period.

In recent years, some analysts and generic manufacturers have voiced increasing objections to the marketing of authorized generics during these exclusivity periods. While competition with a brand product from a generic with a 180-day exclusivity arrangement should benefit consumers by producing lower prices, additional competition from an authorized generic during the exclusivity period should also benefit consumers by resulting in even lower prices. The question is whether the prospect of competition from an authorized generic during the exclusivity period discourages other generic manufacturers from mounting costly paragraph IV challenges and so ultimately results in higher by delaying general generic competition.[8] Based on both a review of the literature, the answer is no. Moreover, our own research, detailed here, shows that competition from authorized generics during the 180-day exclusivity period does not reduce investment by generic drug manufacturers, and therefore does not reduce or delay the entry of other generics in markets for successful original drugs.

[4] Cited in Edward Tuttle, Andrew Parece and Anne Hector, "Your Patent Is About to Expire: What Now?" *Pharmaceutical Executive*, Nov 2004; IMS NPA Plus, IMS National Sales Perspectives, December 2006:
[5] Ernst R. Berndt, Richard Mortimer, Andrew Parece, Edward Tuttle and , Ashoke Bhattacharjya, "Authorized Generic Drugs, Price Competition and Consumers' Welfare," Draft October 2005.
[6] IMS NPA Plus, *op. cit.*
[7] Berndt, *et. al., op cit.*
[8] Aidan Hollis, "The Anti-Competitive Effects of Brand-Controlled "Pseudo-Generics" in the Canadian Pharmaceutical market," *Canadian Public Policy – Analyse de Politiques*, Vol. XXIX, No. 1, 2003.

II. The View of Economists and the State of Current Research

A review of the literature does not support the critics of authorized generics. Perhaps the most prominent critic, Aiden Hollis of the University of Calgary, has argued that the profits from a monopoly generic for those 180 days are so great that they produce more paragraph IV challenges and thus earlier generic competition.[9] Yet, Hollis and a colleague, Brian Liang of Pepperdine University, found that the savings or discounts off brand prices from generics were only 0.6 percent less in markets with authorized generics than in those without them (weighted by sales revenues).[10] Similarly, David Reiffen, an attorney with the U.S. Treasury Department, and Michael Ward of the University of Illinois have written that the introduction of a branded or authorized generic could reduce the profits of a successful paragraph IV challenger so much as to "dramatically change the incentives of generic firms, perhaps eliminating the incentive to litigate the validity of patents in some cases." However, they do not provide direct empirical evidence to justify the claim.[11] And in July 2004, the FDA noted that "[m]arketing of authorized generics increases competition, promoting lower prices for pharmaceuticals, particularly during the 180-day exclusivity period in which the prices for generic drugs are often substantially higher than after other generic products are able to enter the market."[12]

Ernst Berndt of MIT and the National Bureau of Economic Research has conducted the most exhaustive analysis of these issues, along with three economists from the Analysis Group, Inc. and an analyst from Johnson & Johnson.[13] Their analysis of whether consumers gain or lose from the combination of greater short-term competition from authorized generics and their potential adverse effect on incentives for earlier generic competition is rigorous and objective. They conclude that "on balance authorized generics are unlikely to harm competition and can indeed benefit consumers." [14]

Professor Berndt and his co-authors show first that most small molecule drugs with medium or large markets attract intense competition, which produces substantial price discounts off the brands regardless of whether or not there is an authorized generic. The only issue is the profits that a generic manufacturer might earn during the six-month exclusivity period following a successful paragraph IV challenge. Yet as Brendt, *et. al.* note, if the profits during an exclusivity period are large, an authorized generic's entry is likely to discourage a patent challenge only in cases where they are already least likely to succeed (that is, those with low expected profits). They further point out that a successful paragraph IV challenge does not guarantee total exclusivity, even apart from authorized generics. For one, the FDA grants such exclusivity on a dosage basis, so that, for example, Sandoz successfully challenged the patent for Prozac and won 180-exclusivity

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[9] Aidan Hollis, "How Do Brands' "Own Generics" Affect Pharmaceutical Prices?", *Review of Industrial Organization*, 2005, 27:329-250.

[10] Aidan Hollis and Bryan Liang, "An Assessment of the Effect of Authorized Generics on Consumer Prices," July 31, 2006

[11] David Reiffen and Michael Ward, ""Branded Generics" As a Strategy to Limit Cannibalization of Pharmaceutical Markets," May 2005, www.uta.edu/faculty/mikeward/brandedgenerics.pdf.

[12] FDA, *FDA Supports Braoder Access to Lower Priced Drugs*, FDA Talk paper, July 2, 2004.

[13] Berndt, *et. al., op .cit*

[14] *Ibid.*

for the 10 mg dose while Barr Labs won simultaneous exclusivity for the 20 mg dose. In addition, under the Medicare Modernization and Improvement Act of 2003, more than one patent challenger can secure the exclusionary period if they file substantially complete applications for certification on same day.

Without evidence that authorized generics or their prospect actually reduce or delay other generic competition which would otherwise occur, the chief demonstrated effect of the marketing of authorized generics during an exclusivity period is the additional competition and the consequent lower prices for consumers and higher overall generic share. Moreover, the Brendt study also documents that among all drugs with generic versions, a successful paragraph IV challenge and the attendant exclusivity period has no effect on the long-run generic-to-brand price ratios and generic shares. Two years out, there are no discernable differences in these ratios and shares between those drugs that were successfully challenged under with paragraph IV and those that were not.[15]

There is also no question that the marketing of authorized generics is lawful. In response to direct challenges from generic manufacturers, the FDA has upheld competition from authorized generics awarded the 180-day exclusivity period, holding that the practice produces lower prices that benefit consumers without impairing the incentive for generic manufacturers to challenge patents.[16] Like the Brendt study, the FDA noted that competition from authorized generics is no different from cases in which two generic manufacturers shared exclusivity because they filed paragraph IV challenges on the same day or filed challenges for different dosages of the same original drug, concluding that "the marketing of an authorized generic during the 180-day exclusivity period is a long standing, pro-competitive practice."[17]

The literature also shows that the strategy is commercially successful for drug developers and authorized generic firms, especially when targeted at consumers who prefer brands over generics if they can purchase them at a discount. One analysis of 32 drugs in which a first generic manufacturer faced competition from an authorized generic, for example, found that the authorized generics accounted for nearly 35 percent of the generic market in these drugs.[18] There is also a reasonable symmetry in the competitive advantages of generic manufacturers and original drug developers that further supports the practices of authorized generics. Generic manufacturers have enormous cost advantages over a drug's original developer, since a generic manufacturer that can demonstrate that its version is the bioequivalent of an approved original drug does not have to develop independent evidence of its safety and effectiveness from clinical tests or the scientific literature. At the same time, a drug developer can market or license authorized generics at less cost than other generic manufacturers, since the latter

[15] Brendt, et. al., *op cit.*

[16] The holding came in response to appeals from generic manufacturers Mylan Pharmaceuticals and Teva Pharmaceuticals to prohibit the marketing and distribution of authorized generics until end of first generic applicant's 180-day exclusivity period.

[17] Quoted in Karl R. Karst, "Authorized Generics – Historical Overview and Current Issues," *Regulatory Affairs Focus Magazine*, March 2005.

[18] Cited in Aidan Hollis (2003), *op. cit.*

have to submit evidence to the FDA showing that their product is bio-equivalent in molecular structure, potency, purity and stability to the original while the authorized generic can secure FDA approval based on the developer's certification that it is identical to the original.

The literature also shows that the advantages of being first and winning a period of exclusivity go beyond the higher prices a paragraph IV challenger can charge for the 180-day period in the absence of competition from other generics. In addition, pharmacies and other outlets often stock only one generic version of a drug, in order to reduce their administrative costs, so the first generic on the market can win long-term contracts to supply them.[19] This advantage is also not constrained by initial competition from authorized generics, since the latter attract consumers eager to purchase the brand.

A recent study by the Congressional Research Service confirms these conclusions.[20] Citing the Berndt analysis as well as other studies, the CRS analysts found that authorized generics introduce price competition that can reduce the average price of a drug, and that potential competition from authorized generics should not substantially affect decisions by generic manufacturers to file paragraph IV challenges or generally develop new generic products.

The CRS analysis identified three other benefits of authorized generics. First, it cites cases in which patent infringement disputes between generic firms and drug developers were settled by agreements to allow the generic maker to produce an authorized generic version, benefiting consumers by permitting the introduction of a lower-priced generic before the disputed patent was set to expire. Second, the CRS found that the lower prices produced by the competition from authorized generics can increase the market penetration of useful pharmaceuticals, improving overall health outcomes. Third, the study noted that the ability to market authorized generics enables brand name firms to take greater advantage of their investments in manufacturing facilities, justifying greater investment in the research and development that produced the original drug, and provides additional revenue that can support research and development for subsequent original drugs.

Our own research, described below, provides evidence pertinent to another critical aspect of this debate: The capacity to market authorized generics during 180-exclusivity periods does not reduce investment by other generic firms. Therefore, competition from authorized generics, with its documented benefits, does not reduce or delay the entry of other generics in markets for successful original drugs.

III. Authorized Generics and Incentives to Invest: Recent Data

The economics of investment in research and development is different for generic pharmaceutical firms than for firms in other industries, in a number of important ways.

[19] *Ibid*

[20] John R. Thomas, "Authorized Generic Pharmaceuticals: Effects on Innovation," CRS Report to Congress, August 8, 2006.

First, the efficient scale of generic pharmaceutical production is large enough that small numbers of firms produce most of the industry's products and, indeed, generally dominate the industry. Thus, barriers to entry appear to be quite significant in the industry. One likely reason is that the plant and equipment investments required to produce a marketable generic pharmaceutical are relatively large and uncertain. To some degree, this reflects the imperfect competition that characterizes much of the health-care sector, so that the prices that firms collect for their generic products are not necessarily driven to their marginal costs.

The benefit of a 180-day exclusivity period for firms that are first to launch a product under a paragraph IV challenge is another factor in the imperfect competitiveness of this market. As noted earlier, during this period a generic firm generally faces no competition from other generic companies, and so effectively participates in a duopoly with the branded company or, when an authorized generic version is also marketed, in competition limited to three participants.

Since the equilibrium price in patented pharmaceutical markets must include a rate of return that compensates firms for the research and development spending on not only a given product but also on failed products, the price for successful products must be significantly higher than their marginal cost of production. Patent protection, of course, is designed to ensure that firms undertaking such research and development investments will be able to recoup those investments, plus a market rate of return. Generic firms do not engage in such risky research, and their presence in a market with imperfect competition creates the prospect of pure rents.

There is no basis in economic theory to expect that a reduction in such a rent will affect the investments required to secure that rent. It is a well known result in tax theory, for example, that a tax on a pure rent has no impact on investment decisions. This observation is important, because the introduction of an authorized generic product during the 180-day exclusivity period is the effective equivalent of a tax on the pure rents of a generic company. If we observe that a generic firm earns $2 in additional profit (above a competitive rate of return) without competition from an authorized generic, and only $1 in additional profit above the competitive rate of return when an authorized generic firm also competes, we should still expect the generic firm to produce the product that will generate the remaining $1 in additional profit.

Therefore, we should not expect to see any relationship between investment by other generic firms and the presence, or lack of it, of authorized generic versions of their products during 180-day exclusivity periods.

Again, this expected result reflects the rents and imperfect competition available to generic drug manufacturers, especially during a 180-day exclusionary period. In the apple industry, for example, we would expect to see a reduction in investments in apple trees if the government imposed a new tax on the profits of apple producers. In the market for most successful, pharmaceutical products, however, a generic firm knows that it can count on a significant markup if it builds a plant to produce a generic version of the

original drug. If the marginal cost of producing an additional dose is low, and the demand for the drug is relatively inelastic, the presence of competition during the 180-day exclusivity period from an authorized generic will reduce the rent received by the generic firm but not affect the firm's decision to invest in the plant.

Whether competition from authorized generics affects the development of new generic products is a key issue in the policy debates in this area. As the literature attests, to the extent that authorized generics increase the number of competitors in the generic space, they reduce the price of generic drugs and benefit American consumers. But authorized generics could reduce consumer welfare in the long run if, as some critics have claimed, the prospect of their competition during an exclusivity period discourages generic companies from entering the market (i.e., undertaking the investments to do so).

To examine this question, we gathered data from a number of sources on the financial characteristics of generic firms facing different levels of competition. In general, we found three competitive scenarios: Some generic firms face no competition from an authorized generic; others face competition throughout an exclusivity period; and others face competition during part of that period. We compared the investment and financial characteristics of generic companies that launched drugs under some form of exclusivity period, with those launching drugs without an exclusivity period, to identify the impact of the variations in the presence of an authorized generic on the investment and other financial decisions of generic firms.

For this analysis, we collected and analyzed data on 53 generic drugs launched by generic pharmaceutical companies, wholly owned subsidiaries, and publicly traded generic pharmaceutical firms.[21] Of that total, four generic drugs had uncontested exclusivity for more than one month, 17 generic drugs were launched simultaneously with an authorized generic or faced competition from an authorized generic within one month, and 32 drugs were launched without an exclusivity period.

We analyzed the data in two ways. First, we categorized the data from 2003-2005 by year and analyzed each company's investment and financial data depending on the level of competition that it faced in that year.[22] We label the results of this analysis "year-by-year." The second analysis covered the longer period from 1987 to 2005 and classified the companies based on whether in any year they secured exclusivity for a

[21] Our analysis only analyzed the publicly traded firms (on the U.S. stock exchange) as financial data would be limited for the independent companies and the wholly owned subsidiaries. We used the Yahoo Finance classification of the generic pharmaceutical industry, and cross referenced those companies with the Compustat (North America) database using the NAICS code 3254 and the keyword "generic". Therefore, this analysis includes only those companies that were presented in both sets of classifications. This cross-referencing produced a total of ten generic pharmaceutical companies that also had publicly-available financial data. Retrieved from http://biz.yahoo.com/ic/512_cl_all.html on March 5, 2007; and Compustat (North America) Database, Standard and Poor's, February 28, 2007.

[22] If a company's fiscal year data were classified as exclusive, the following fiscal year data were also defined as exclusive, even if the company did not have an exclusive period in the subsequent year. By doing so, we capture the full effects of the exclusivity period as profits and, in particular, R&D investment may be impacted by the exclusivity period of the prior year.

generic drug.[23] If the company had one year in which it had an exclusivity period, the company was considered "exclusive" for all years. Using these categories, we analyzed their variations in investment over time compared to firms that never had such exclusivity, and label these results "longitudinal." This comparison is useful if the impact of a particular level of competition diffuses over time while the firms that face that particular level of competition are different in a significant way from those that do not. Our caveat is that the incomplete state of the data on generic means that our conclusions must be considered tentative.

Year-by-Year Results

First, we classified generic manufacturers in two groups based on whether or not they enjoyed a period of exclusivity in any of the three years covered.

- **Exclusive Group:** The "exclusive group" covers companies that launched a generic with an exclusivity period of more than one month in any of the three given years, either at the same time or within one month of the launch of an authorized generic ("simultaneous"), or not at the same or nearly the same time as an authorized generic ("non-simultaneous").[24]

- **Non-Exclusive Group:** The "non-exclusive" group covers companies' that did not launch a new generic product with an exclusivity period in any of the three given years.[25]

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[23] Under the classification for the first set, Par Pharmaceutical's 2004 financial data are defined as exclusive, as an authorized generic was launched simultaneously with Par Pharmaceutical's ribavirin 200 mg capsules in fiscal year 2004. However, under the first set classification, Par Pharmaceutical Inc.'s 2003 financial data are classified as non-exclusive. Under the classification for the second set, since Par Pharmaceutical Inc. had one year where a generic pharmaceutical was considered exclusive, Par Pharmaceutical is classified as exclusive for all years, including 2003.

[24] The exclusive grouping includes data from the following companies (in given years): (1) Barr Pharmaceuticals Inc. (2003-2005); (2) Impax Laboratories Inc. (2004-2005); (3) Mylan Laboratories Inc. (2004-2005); (4) Par Pharmaceutical Companies Inc. (2004-2005); (5) Teva Pharmaceutical Industries (2003-2005); and (6) Watson Pharmaceutical Inc. (2003-2004). Impax Laboratories Inc. did launch a simultaneous drug with an AG in 2004, but the Compustat (North America) database had no financial data for Impax Laboratories Inc. in that year or the following year. Mylan Laboratories Inc.'s and Par Pharmaceutical Companies Inc.'s financial data for the years 2004 and 2005 were classified as simultaneous. Watson Pharmaceutical Inc. was classified as simultaneous for 2003 and the following year 2004 as it had a 180-day exclusivity period in 2003. Barr Pharmaceuticals Inc.'s and Teva Pharmaceutical Industries' both settled litigation that resulted in exclusive periods for each company along with receiving exclusivity beyond that of the 180-days. Both Barr and Teva were classified as non-simultaneous for the all three year 2003-2005.

[25] Caraco Pharmaceutical Laboratories Ltd., Hi Tech Pharmacal Co. Inc., KV Pharmaceutical Co., and Taro Pharmaceutical Industries Ltd. were all classified as non-exclusive for all three years: 2003-2005. Impax Laboratories Inc., Mylan Laboratories Inc. and Par Pharmaceutical Companies Inc. were classified as non-exclusive in 2003 only. Additionally, Watson Pharmaceutical Inc. was classified as non-exclusive for the year 2005. Taro Pharmaceutical did not have financial data for fiscal year 2005.

As Table 1, below, shows, the overall generic pharmaceutical industry earned healthy (operating) profit margins averaging 23.8 percent over the period, 2003-2005. As expected, generic firms in the "exclusive group" earned higher returns, averaging 24.4 percent, than those that did not launch new products with an exclusivity period, averaging 21.1 percent (including those that did not launch any new products in this period). This difference likely reflects the higher prices and higher margins earned by companies launching with the 180-day exclusivity period, even when they competed with an authorized generic. The data also show, as expected, that those exclusives launching at the same time as authorized generics or nearly so ("simultaneous") earned lower returns than those launching without initial competition from authorized generics. This reflects the lower prices resulting from that competition. Still, the differences are small, with the exclusivity period lifting margins only 0.6 percent above the industry norm on average.

Table 1. Operating Profit Margins, Generic Pharmaceutical Firms, 2003-2005 [26]

	2003	2004	2005	Weighted Average
Industry	25.8%	22.8%	23.1%	23.8%
Non-Exclusive	29.2%	8.8%	14.6%	21.1%
Exclusive	24.0%	23.9%	25.4%	24.4%
Simultaneous	23.2%	21.0%	20.1%	21.2%
Non-Simultaneous	24.3%	25.6%	26.9%	25.8%

By way of comparison, all of these margins are quite impressive compared to other industries. The average margin between 2001 and 2005 for all generic drug manufacturers was 23.9 percent – nearly the same as 2003-2005 – and 24.1 percent for the entire pharmaceutical sector. These margins are significantly higher than those in other R&D intensive industries – for example, the average operating margin was 11.3 percent for makers of scientific instruments and 7 percent for the electronics industry.

Critics of authorized generics also claim that the exclusivity period promotes the development of new products by generic firms, especially when there is no competition from authorized generics. The year-by-year data do not support this view. Table 2, below, shows the ratios of R&D to sales for these same groups of firms. In two of the three years, R&D was actually higher for firms without exclusivity than for those firms with it. Within the set of firms with exclusivity, the R&D ratios were higher for firms that faced simultaneous authorized generic competition in one year and lower in two other years. However, the figures for 2004, when the R&D ratio rose sharply for firms with exclusivity and without simultaneous competition from authorized generics, were inflated by a one-time charge of $584 million for in-process R&D by Teva Pharmaceutical Industries, arising from its acquisition of Sicor, Inc. on January 22, 2004.[27] Excluding this charge, the data show no clear evidence of a relationship in the generic industry between exclusivity and research and development.

[26] Compustat NorthAmerican Database, Standard & Poor's, February 28, 2007.

[27] Removing Teva Pharmaceutical Industries' one time charge of $584 million would lower the non-simultaneous R&D to sales ratio from 18.8% to 9.3%, below that of the simultaneous group. Retrieved from http://www.tevapharm.com/pr/2004/pr_449.asp on March 12, 2007.

Table 2. R&D to Sale for Generic Pharmaceutical Firms, 2003-2005[28]

	2003	2004	2005	Weighted Average
Industry	7.4%	15.4%	8.8%	10.8%
Non-Exclusive	7.7%	14.0%	10.6%	9.6%
Exclusive	7.3%	15.5%	8.3%	11.1%
Simultaneous	7.0%	10.0%	9.8%	9.3%
Non-Simultaneous	7.4%	18.8%	7.9%	11.8%

These data support the view that the prospect of a clear rent drives investment by generic firms, with or without exclusivity and competition from authorized generics.

Longitudinal Results

Next, we analyzed financial and investment data over a longer period, 1987-2005, using similar classifications:

- **Exclusive Group:** The exclusive group here includes companies that in any year covered had an exclusivity period of more than one month for a generic drug. This group is also divided into those that launched the generic simultaneously with or within one month of an authorized generic ("simultaneous") and those which launched without such immediate competition ("non-simultaneous").[29]

- **Non-Exclusive Group:** The non-exclusive group includes all companies that during this extended period neither had an exclusivity period of more than one month nor launched a generic pharmaceutical simultaneously with or within one month of an authorized generic.[30]

The generic pharmaceutical industry has earned healthy (operating) profit margins since 1987, ranging from about 8 percent in the early 1990s to 25.8 percent in 2003, and tending to rise over the period (Figure 1, below). In the most recent year for which data are available, 2005, generic pharmaceutical firms earned an average of 23.1 percent. Since most firms in the industry at some point have periods of exclusivity, the profit margins for firms with exclusivity nearly match those for the industry as a whole. Firms that never have had an exclusivity arrangement, however, have been significantly less

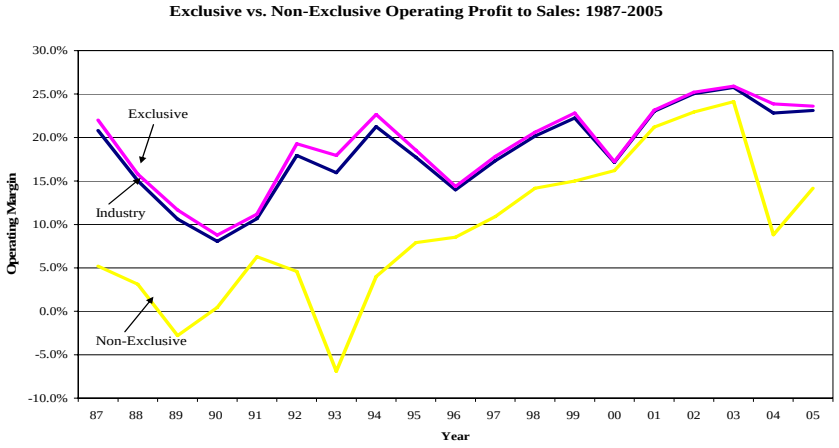
[28] Compustat NorthAmerican Database, Standard & Poor's, February 28, 2007.

[29] The exclusive grouping includes data from the following companies: (1) Barr Pharmaceuticals Inc.; (2) Impax Laboratories Inc.; (3) Mylan Laboratories Inc.; (4) Par Pharmaceutical Companies Inc.; (5) Teva Pharmaceutical Industries; and (6) Watson Pharmaceutical Inc. The simultaneous group includes: (1) Impax Laboratories Inc.; (2) Mylan Laboratories Inc.'s; (3) Par Pharmaceutical Companies Inc.; and (4) Watson Pharmaceutical Inc. The non-simultaneous group includes: (1) Barr Pharmaceuticals Inc.; and (2) Teva Pharmaceutical Industries.

[30] Caraco Pharmaceutical Laboratories Ltd., Hi Tech Pharmacal Co. Inc., KV Pharmaceutical Co., and Taro Pharmaceutical Industries Ltd. were all classified as non-exclusive.

profitable. This likely reflects both the value of exclusivity and the high margins earned by larger firms that can invest substantial resources in complicated development projects.

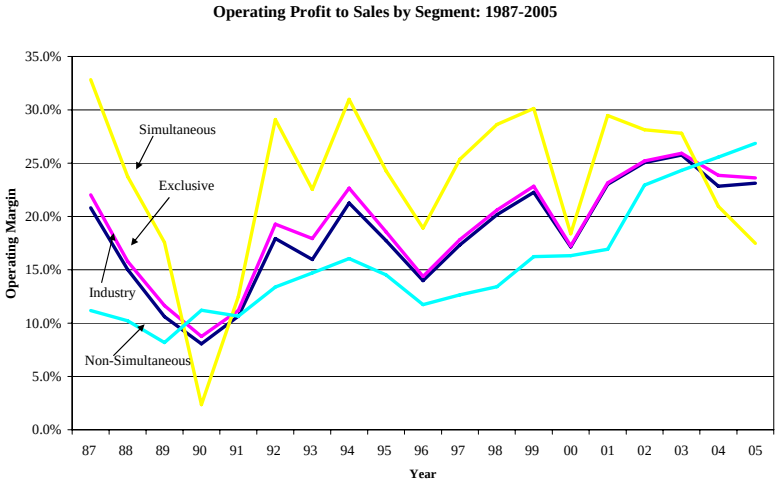
Figure 1. Ratio of Operating Profits to Sales, Generic Manufacturers, 1987-2005[31]



Source: Compustat (North America) Database, Standard and Poor's, February 28, 2007.

We further divided the firms with periods of exclusivity into those that faced simultaneous or nearly simultaneous competition from authorized generics and those that did not. The data show that those firms competing during the exclusivity period with authorized generics actually earned higher profits, relative to sales, than those that did not face such competition. (See Figure 2, below) To some extent, this may reflect the way the data are classified as "simultaneous" and "non-simultaneous." At a minimum, it appears to confirm the view that generic manufacturers with exclusivity periods earn substantial profits (and significant rents) when competing with authorized generics.

Figure 2. Ratio of Operating Profits to Sales, By Segment, 1987-2005[32]



Source: Compustat (North America) Database, Standard and Poor's, February 28, 2007.

[31] Compustat NorthAmerican Database, Standard & Poor's, February 28, 2007.
[32] Compustat NorthAmerican Database, Standard & Poor's, February 28, 2007.

Conclusion

While the high concentration of sales by a relatively small number of companies in the generic pharmaceutical industry makes the data somewhat limited, the evidence clearly shows that a period of exclusivity does produce higher profits, but that those higher profits do not necessarily lead to more intense investment and R&D. The data also support the view that competition from authorized generics during exclusivity periods leads to lower prices, and are wholly consistent with the view this competition does not reduce or slow the introduction of new generic pharmaceuticals.

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