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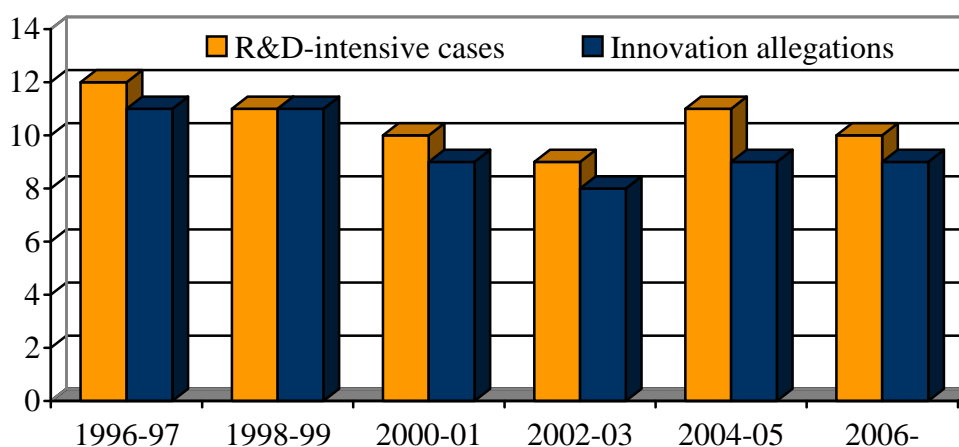
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## Innovation Markets after Genzyme/Novazyme

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The U.S. Federal Trade Commission (“FTC”) alleged adverse effects on innovation in about forty percent of all merger challenges between 1996 and mid-2008. The percentage was much higher for challenges in industries with unusually high research and development (“R&D”) intensity, such as pharmaceuticals (excluding generics), chemicals, software, instruments, high-tech manufacturing, defense, and aerospace. The FTC challenged sixty-three proposed mergers or acquisitions in these industries and alleged adverse innovation effects in fifty-seven cases, or about ninety percent of the challenged transactions.<sup>1</sup> The percentage of merger challenges in R&D-intensive industries that alleged adverse effects on innovation has been high throughout the past decade (see Figure 1).

**Figure 1. Merger challenges by the FTC in R&D-intensive industries that alleged adverse innovation effects**



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<sup>1</sup> Merger challenges that allege adverse innovation effects were less frequent at the U.S. Department of Justice (“DOJ”), in part because a smaller fraction of the transactions reviewed by the DOJ were in R&D-intensive industries. See, e.g., Richard Gilbert & Willard Tom, *Is Innovation King at the Antitrust Agencies? The Intellectual Property Guidelines Five Years Later*, 69 ANTITRUST L.J. 43 (2001).

Innovation is not determinative of the decision to challenge a merger when the merger raises independent concerns about higher prices. These are transactions that fall in cells (1) or (2) in Figure 2. Transactions in cell (2) raise prices, but may also promote innovation. Whether consumers benefit on balance from such transactions requires a weighing of costs and benefits. Innovation also could be pivotal to decisions to challenge transactions that fall in cell (3). These transactions do not raise prices, but may result in less innovation.

**Figure 2. Competitive effects from mergers**

	<b>Less Innovation</b>	<b>Greater Innovation or No Effect</b>
<b>Higher Prices</b>	(1) Clearly anticompetitive	(2) Unclear competitive effects
<b>Lower Prices or No Effect</b>	(3) Unclear competitive effects	(4) Clearly not anticompetitive

Neither the FTC nor the U.S. Department of Justice has challenged a proposed merger *solely* because the agency concluded that the transaction posed a likely harm to innovation.<sup>2</sup> The acquisition of Novazyme Pharmaceuticals, Inc. by Genzyme Corporation raised potential concerns about adverse effects on innovation, but not concerns about effects on prices. The public statements by FTC Chairman Muris and

<sup>2</sup> Innovation concerns have figured prominently in agency decisions to challenge several mergers and in the design of certain remedies. *See, e.g.,* Gilbert & Tom (2001), *id.* and Michael Katz & Howard Shelanski, *Mergers and Innovation*, 74 ANTITRUST L.J. 1 (2007). However, these cases presented independent concerns about price competition in existing markets or in markets in which one of the merging firms was a likely potential entrant. (In one case the price competition occurred outside the United States. *See* General Motors/ZF Friedrichshafen, U.S. v. General Motors Corp., No. 93-530 (D. Del. Nov. 16, 1993).)

Commissioners Thompson and Jones Harbour regarding this acquisition offer a rare glimpse into an enforcement agency's evaluation of innovation concerns.<sup>3</sup>

Genzyme acquired the assets of Novazyme in September 2001. Genzyme and Novazyme were the only two companies with significant research progress directed to enzyme replacement therapies to treat Pompe disease. Because of the rarity of the disease, Pompe therapies, if approved by the U.S. Food and Drug Administration ("FDA"), will be subject to the Orphan Drug Act ("ODA"). The ODA provides seven years of market exclusivity to the first innovator to obtain FDA approval, although the FDA may break that exclusivity if a subsequent therapy is clearly superior.

The acquisition did not exceed the Hart-Scott-Rodino ("HSR") reporting thresholds and was not reviewed prior to its completion. The FTC ultimately reviewed the concluded transaction and reported its findings in January 2004. According to Commission statements, the belief at the time of the FTC review was that Novazyme's research path as an independent company was more likely to result in a superior therapy, but Genzyme was more likely to be the first to win FDA approval. If correct, this would give Genzyme seven years of market exclusivity, unless an independent Novazyme could convince the FDA that it has a superior therapy. The FTC did not address price effects from the acquisition, presumably because there would be no competition during the period of exclusivity under the ODA and it is uncertain that the FDA would break exclusivity by approving a superior drug. What was left was a pure innovation case.

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<sup>3</sup> The Commission voted 3-1 not to challenge the acquisition, with one abstention.

Superficially, the Genzyme/Novazyme acquisition is a merger to monopoly in an innovation market. In their public statements, Commissioners Thompson and Jones Harbour support a presumption of anticompetitive effects for a merger to monopoly in an innovation market, while Chairman Muris said that there should be no such presumption. I explore different facts and show that the merger has no effect on incentives for innovation under some plausible assumptions. Under other plausible assumptions, the merger can increase or decrease incentives. Whether a presumption of an anticompetitive effect is appropriate or not, it is clear that competitive effects depend on the facts of the transaction.

In all scenarios I assume that Genzyme acting independently would develop a first-generation Pompe therapy with some probability in 2006 and that Novazyme acting independently would develop a superior second-generation therapy in 2010. The precise dates of the discoveries are unimportant, although the assumption that a superior Novazyme therapy, if successful, would occur after the Genzyme therapy with or without the merger is central to my analysis. I also assume that the probabilities of success for both therapies depend on research effort.

Relevant questions are whether the FDA would allow an independent Novazyme to sell a superior second-generation therapy in competition with the first-generation Genzyme therapy and, if so, how competition would affect their profits. Suppose that the FDA would allow Novazyme to sell a second-generation therapy. Furthermore, suppose that the second-generation therapy would displace the first-generation therapy and earn a

private benefit for Novazyme equal to its incremental value relative to the Genzyme therapy.

The merger does not affect the payoff from investment in the first-generation Genzyme therapy before 2010 because there is no competition prior to that date. After 2010, the Genzyme therapy has no value if the Novazyme therapy is successful. Therefore, the return to R&D after 2010 for an independent Genzyme is equal to the value of the Genzyme therapy multiplied by the probability that it succeeds and the Novazyme therapy fails. The value of R&D investment in the first-generation therapy is the same for the merged company and for an independent Genzyme. The merged company would market only the second-generation therapy if it is successful, and therefore, the value to the merged company of the first-generation therapy after 2010 also equals the value of the therapy multiplied by the probability that it succeeds and the Novazyme therapy fails. The return to R&D for an independent Novazyme is its full value if Genzyme's therapy fails, and is the incremental value relative to the Genzyme therapy if it succeeds. Again, this is the same payoff from R&D for the merged company. The merger does not affect incentives to invest in R&D for either therapy if the FDA would approve a second-generation therapy which would displace the first-generation therapy and earn a private benefit for Novazyme or the merged company equal to its increment in value relative to the Genzyme therapy.

The merger could decrease incentives to invest in R&D under other assumptions about how Genzyme and Novazyme would compete as independent companies if the

FDA approves both therapies. Suppose that the value of the second-generation therapy is not much larger than the value of the first-generation and the two companies would roughly split the value if they compete. The merged company would have no use for the first-generation therapy if the second-generation therapy is successful, whereas the profits that an independent Genzyme would earn in competition with Novazyme give the independent company an extra incentive to invest in the first-generation therapy compared to the merged company. Furthermore, the merged company would have a smaller incentive to invest in the second-generation therapy because its incremental value is low, yet an independent Novazyme can earn significant profits by sharing the value with an independent Genzyme. Thus, under these assumptions, the merger decreases incentives to invest in R&D for Pompe enzyme replacement therapies.<sup>4</sup>

The merger could increase incentives to invest in R&D under still other assumptions. Suppose the FDA would not allow Novazyme to compete with Genzyme during the exclusivity period. In this case, an independent Novazyme would benefit from R&D only if the Genzyme therapy fails. The merged company also would benefit from the second-generation therapy in this event, but, if the Genzyme therapy succeeds, the merged company also would benefit from the incremental value of the second-generation therapy relative to the first-generation therapy. This positive benefit from R&D would have to be balanced against lower incentives for the merged company to invest in the first-generation therapy. After 2010, the merged company benefits from investment in the first-generation therapy only if the second-generation therapy fails, whereas an

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<sup>4</sup> Whether these private incentives for R&D correspond to the social value of the R&D is a separate question that I do not address in this article.

independent Genzyme would benefit regardless of the success of the second-generation therapy if the FDA would not allow Novazyme to compete with Genzyme during the exclusivity period. Competition that occurs after the end of the exclusivity period in 2017 could have additional procompetitive effects that would partially offset the increased R&D incentives from the merger.

The combination of Genzyme and Novazyme has no competitive effect on incentives to innovate before 2010, because by assumption the two technologies do not co-exist before that date. After 2010, the competitive effects depend on assumptions and may increase or decrease incentives to innovate or leave innovation incentives unchanged. Chairman Muris emphasized that anticompetitive behavior depends on incentives as well as ability and concluded that there is no evidence that the acquisition significantly changed incentives to develop either the first-generation or the second-generation therapy. My analysis confirms that a merger to monopoly in an innovation market need not adversely affect incentives to innovate. In this respect, my analysis does not support a presumption of anticompetitive effects, but it also does not support a presumption that a merger to monopoly in an innovation market has no anticompetitive effects. There is no substitute for a careful evaluation of the facts.

Is it likely that an antitrust enforcement agency will challenge a merger or other business arrangement solely because the arrangement creates adverse incentives for innovation? Some would argue that insurmountable obstacles prevent antitrust enforcers from pursuing a pure innovation case, including the following:



1. With the exception of contract R&D, there is no market in which R&D is bought and sold.
2. R&D is an input to innovation and bears an uncertain relationship to innovative output.
3. There is no solid body of economic theory and empirical research on which to base predictions of the effects of changes in market structure or business conduct on innovation.

I discuss these potential obstacles in light of the Genzyme/Novazyme decision and recent economic developments pertaining to competition and innovation.

### **1. No Market for R&D**

Most R&D is internal to a firm and is not bought and sold like petroleum or computer displays. When transactions involve research and development, they typically take the form of patent or know-how licenses, sometimes with provisions such as grant-backs or cross-licenses. R&D expertise is often transferred through corporate acquisitions of R&D facilities, but this differs from a market sale of the products of a R&D laboratory.

Based on historical jurisprudence, the absence of trade in R&D may preclude a court from holding that R&D has been monopolized even if a merger combines the only two firms that could possibly engage in R&D directed to a particular product or process. Courts could rely on measures of R&D concentration beside transactions or expenditures, such as R&D assets directed to particular innovative efforts. Courts also could analyze the effects of a transaction in existing or future product markets, but product market

effects may not exist in a pure innovation case such as a transaction that slows the development of a new vaccine but does not affect its price.

The absence of trade in R&D does not prevent an enforcement agency from using measures of R&D assets to inform a decision to challenge a merger or acquisition based on likely effects on innovation. None of the public statements in the Genzyme/Novazyme case questioned the lack of a proper antitrust market as a reason not to challenge the acquisition. The Commissioners did not differ over the use of an innovation market as an analytical aid to guide merger enforcement, but rather over whether an innovation market analysis may justify a presumption that a merger will harm innovation. The Commission's public statements in the Genzyme/Novazyme case do not show that the agency is reluctant to pursue a pure innovation case because innovation is not a proper antitrust market, although how courts would react to a pure innovation challenge remains to be tested.

## **2. R&D Is an Input, Not an Output**

A second objection to the use of an innovation market to evaluate mergers is that measures of concentration in an innovation market are likely to be based on R&D expenditures or assets, which are *inputs* to innovation, not measures of innovative *output*. Expenditures on R&D or the accumulation of R&D assets provide no guarantee of successful innovation, as evidenced by many examples of generously funded corporate R&D laboratories that have produced less than stellar innovative performance.

In some situations, expenditures on R&D can be inversely related to innovative output, not merely unrelated to innovative output. Suppose that ten firms compete in an industry and each of the firms invests in R&D to lower its production costs. Contrast this situation to investment in R&D for cost reduction by a monopolist in the same industry. The benefit from a reduction in cost is proportional to the firm's output. The monopolist would have a greater incentive to invest in cost-reducing R&D than does each of the ten firms, assuming that its output is larger than the output of each of the firms. Moreover, some of the R&D investment by the ten firms may be redundant. It could be better for a single firm to invest in R&D and share the knowledge with others in the industry than for each firm to replicate the same R&D. Total investment in R&D by the ten firms could exceed investment by the monopolist in the same hypothetical market, but this does not mean that total innovative output, as measured by the actual reduction in production costs, is larger in the more competitive industry. Indeed, the opposite could be true.<sup>5</sup>

### **3. Weak Theoretical and Empirical Foundation**

Some have argued that the theory of innovation competition is too complex and unsettled to provide a foundation for evaluating the likely effects of a transaction on innovation and lacks empirical verification. In his comments on the Genzyme/Novazyme transaction, Chairman Muris appeared to express both views when he stated that:

There is no reason to believe, a priori, that a particular merger is more likely to harm innovation than to help it—which is, of course, simply another way of

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<sup>5</sup> For a formal analysis of this argument, see Partha Dasgupta & Joseph Stiglitz, *Industrial Structure and the Nature of Innovative Activity*, 90 *ECON. J.* 266 (1980).

saying that there is no empirical basis for a presumption [that a merger to monopoly in an innovation market is anticompetitive].<sup>6</sup>

There are two main themes in the economic theory of the relationship between market structure and innovation. The first is the Schumpeterian argument that scale and market power promote innovation. According to this argument, large firms and the profits that flow from scale and market power provide a more stable platform for firms to weather the risks of R&D. Monopoly also promotes innovation by making it easier for a firm to appropriate the benefits of R&D, some of which may spill over to competitors. Under the Schumpeterian view, monopoly is both a consequence of innovation, because innovation creates temporary market power, and a driver of innovation.

Kenneth Arrow developed the second main theme in the theory of innovation and market structure. The incentive to innovate is the difference in the profit that a firm can earn with and without an expenditure of effort. The profits that a firm would earn if it did not exert innovative effort reduce the *net* return from the innovation. All else equal, competition reduces pre-innovation profits and hence increases the difference in profits with and without the innovation. There is a “replacement effect” that diminishes the incentive for a monopolist to innovate relative to a more competitive industry if the monopolist has a flow of profits from existing products. A competitor has a smaller replacement effect and a larger net return from innovation, assuming that the monopolist and the competitor would earn the same amount from the innovation.

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<sup>6</sup> Statement of Chairman Timothy J. Muris, In the matter of Genzyme Corporation / Novazyme Pharmaceuticals, Inc., File No. 021-0026 (Jan. 2004), at 23, *available at* <http://www.ftc.gov/os/2004/01/murisgenzymestmt.pdf>.

The theoretical predictions of Schumpeter and Arrow are at odds with each other. Schumpeter argues that monopoly promotes innovation whereas Arrow argues that monopoly lowers the incentive to innovate. Woven in-between the warp and weft of Schumpeter and Arrow are numerous other theoretical variants on the innovation theme. These include preemption, dynamic models such as patent races, and models that provide for managerial slack. The apparent contradiction between Schumpeter and Arrow stems from different assumptions about the ability of an innovator to capture the benefits of the innovation. Arrow assumes that an innovator can prevent unauthorized copying of her invention, perhaps as a result of an effective and long-lived patent. A consequence of this assumption is that the profit from innovation is independent of the market structure that exists before the innovation, and therefore, the net return from innovation is an increasing function of the amount of competition that would occur without the innovation.

The assumed facts in the Genzyme/Novazyme acquisition do not support a Schumpeterian theory that the transaction would promote innovation of Pompe enzyme replacement therapies. The facts do not presume that the merged company would better appropriate the benefits from innovation. The assumed payoff to innovation of a new therapy is the same, whether accomplished by the merged company or by Genzyme or Novazyme as stand-alone companies.

Whether an Arrow replacement effect argument applies to the Genzyme/Novazyme acquisition depends on the particular facts of the case. There is no replacement effect prior to the arrival of the second-generation therapy, because neither

the merged Genzyme nor an independent Genzyme has an existing product that would be replaced by the development of the first-generation therapy. For the second-generation therapy, any replacement effect would not act differently on the merged company and an independent Novazyme if they would benefit to the same extent from a successful second-generation therapy. This follows if the merged company and an independent Novazyme would benefit equally from the incremental value of the second-generation therapy relative to the first-generation therapy.

A small change in the assumed facts could reverse this conclusion. Suppose that, absent the merger, upon discovery of the second-generation therapy the first-generation therapy would disappear from the market and exercise no competitive constraint on a stand-alone Novazyme. In this case, a stand-alone Novazyme would benefit from the entire value of a successful second-generation therapy, whereas a merged Genzyme/Novazyme would only benefit from the incremental value of the second-generation therapy relative to the first-generation therapy. Under these new assumed facts the merger would reduce the incentive to innovate as a consequence of the Arrow replacement effect. The facts are indeed important.

Chairman Muris was correct in his view that there is no basis to believe, a priori, that a particular merger is more likely to harm innovation than to help it. But it is not clear whether he was saying that the theory does not necessarily support such a presumption (which is true) or that the empirical evidence is not sufficient to support a presumption even if the facts of the case are clearly consistent with adverse innovation

effects, for example from an Arrow replacement effect. The purpose of this article is not to review the empirical literature on market structure and innovation, but readers can refer to other recent surveys.<sup>7</sup> The empirical evidence is not abundant, but it is improving in both quantity and quality and recent empirical studies that pay careful attention to the theoretical predictions are finding results that correspond with those predictions.<sup>8</sup>

### **Conclusions and Recommendations**

The FTC's review of the Genzyme/Novazyme acquisition provides a rare example of a detailed discussion by an antitrust enforcement agency of a transaction's likely effect on innovation. The fact that the FTC did not challenge the acquisition even though it combined the two major research programs for Pompe enzyme replacement therapies could be interpreted as a refusal to challenge a proposed transaction solely on the basis of its likely effects on innovation. Such a conclusion probably is not justified. A transaction's effects on innovation are highly fact-specific. The facts of the Genzyme/Novazyme acquisition, as described in public Commission statements, do not necessarily support a conclusion that the acquisition would diminish the incentives of the merged company to invest in research for Pompe enzyme replacement therapies.

A more relevant question is whether the agencies will ever challenge a merger based solely on its likely adverse effects on innovation. Empirical studies of the

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<sup>7</sup> See, e.g., Richard Gilbert, *Looking for Mr. Schumpeter: Where Are We in the Competition-Innovation Debate?*, in INNOVATION POLICY AND THE ECONOMY (Adam B. Jaffe, Josh Lerner & Scott Stern eds., Nat'l Bureau Econ. Res., 2006); Katz & Shelanski (2007), *supra* note 2; and Jonathan Baker, *Beyond Schumpeter vs. Arrow: How Antitrust Fosters Innovation*, 74 ANTITRUST L.J. 575 (2007).

<sup>8</sup> One example is a finding that business unit size is directly related to the propensity to patent innovations for which there is weak appropriability. This is consistent with the theory, because larger operations allow a firm to capture more of the benefits. See, e.g., Wesley M. Cohen & Steven Klepper, *Firm Size and the Nature of Innovation within Industries: The Case of Process and Product R&D*, 78 REV. ECON. & STATISTICS 232 (1996).

relationship between competition and innovation are unlikely to provide sufficient evidence to justify a challenge in a particular case. It is particularly difficult to find a “natural experiment” that informs the effects of a particular proposed transaction on innovation, because innovation effects are case-specific and one does not typically observe a pattern of R&D investment and innovative output corresponding to different structures of otherwise similar markets. Innovation tends to be a unique event with a multitude of reasons for success or failure. Indeed, the Commission observed that the time schedule for launch of the Novazyme therapy slipped by several years following the merger with Genzyme, but could not reject the usual problems of risky pharmaceutical research as the reasons for the delay.

A careful analysis of the incentives for investment in innovative effort will be an essential component of any merger challenge that is based on innovation effects. The question is whether the combination of a careful theoretical analysis along with empirical evidence that is not necessarily case-specific will ever be sufficient for an agency to challenge a merger based solely on its predicted adverse effects for innovation. Time will tell. We do know that economic theory is providing sharper evidence as to when an increase in market concentration may adversely affect innovation and the theory has some support in recent empirical studies.

The enforcement agencies should not presume that every merger that raises prices also harms innovation. It is certainly possible that a merger that raises prices also will enhance incentives to invest in innovation, and the agencies should give greater



consideration to innovation-efficiency defenses, particularly in industries with conditions that limit the ability to appropriate the benefits of innovative efforts. At the very least, the agencies should not routinely incorporate an allegation that a merger harms innovation whenever the agency concludes that the merger is likely to have an adverse effect on prices. The clear lesson from the FTC review of the Genzyme/Novazyme acquisition is that not every merger that increases concentration, whether measured in an innovation market or in a product market, also has an adverse effect on innovation.