

Merger Enforcement in Innovation Markets: The Latest Chapter—Genzyme/Novazyme

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The Federal Trade Commission has been challenging pharmaceutical mergers for a decade based upon their impact on “innovation markets.” Until this year, all of these challenges have been resolved by consent decree with little explanation of the economic rationale for concern over loss of “innovation” competition. The Commissioners have now provided new insights into their views on the proper approach to merger enforcement in innovation markets.

On January 13, 2004, by a vote of 3–1–1, the Commission closed its investigation of Genzyme’s previously completed acquisition of Novazyme. Three Commissioners issued separate statements explaining their respective views. In this article, we summarize the rationale for the Commission’s decision and provide additional information we believe may have been important to the Commission’s decision not to take action against the transaction.

Past Merger Enforcement in “Innovation Markets”

Over the past decade, the Commission has obtained consent orders in nearly a dozen matters based on the view that the merger would have eliminated competition to develop a new pharmaceutical product.¹ Yet the Commission has never given formal guidance as to its enforcement philosophy concerning mergers that involve “innovation markets.” The 1992 Horizontal Merger Guidelines² do not speak to innovation markets.³ The Antitrust Guidelines for Collaborations Among Competitors do set forth a simple, “number of competitors” approach as an initial screen in considering whether to challenge joint ventures that may cause the loss of innovation competition.⁴ These Collaboration Guidelines, however, make clear that the “antitrust safety zone does not apply to . . . competitor collaborations to which a merger analysis is applied.”⁵ Further, because there had been no previous Commission decisions on merger innovation cases, other than by consent, the Commission had never formally set forth its views.

¹ While innovation concerns were mentioned in other FTC, and DOJ, cases, those allegations seemed primarily aimed at buttressing concerns in existing product markets, rather than referring to specific products whose development might be inhibited as a result of the merger.

² U.S. Department of Justice and Federal Trade Commission, Horizontal Merger Guidelines (1992; revised 1997) [Merger Guidelines], available at <http://www.ftc.gov/bc/docs/horizmer.htm>.

³ The Merger Guidelines talk about “products” or “groups of products.” See, e.g., *id.* § 1.0.

⁴ “Absent extraordinary circumstances, the Agencies do not challenge a competitor collaboration on the basis of effects on competition in an innovation market where three or more independently controlled research efforts in addition to those of the collaboration possess the required specialized assets or characteristics and the incentive to engage in R&D that is a close substitute for the R&D activity of the collaboration.” Federal Trade Commission and U.S. Department of Justice, Antitrust Guidelines for Collaborations Among Competitors § 4.3 (2000) [Collaboration Guidelines], available at <http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf> (footnotes omitted).

⁵ *Id.*

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Examining the Commission's previous merger enforcement actions in innovation markets, we believe that the Commission's decisions to bring those actions rested on two premises: (1) competition in future goods markets would be harmed by the merger; and (2) development of new products would be harmed by a reduction in the competition to innovate. The Commission's first premise—harm to future product markets—is based on traditional merger enforcement principles applied to existing product markets and, at least initially, seems reasonable.⁶ If two firms with the only products in development for a particular disease were to merge only days before they both receive FDA approval, should that merger escape scrutiny simply because no products are yet on the market?

The Commission's enforcement activities, however, have ventured far beyond that fact pattern, reaching potential products that were years away from coming to market, if ever. For instance, in the Commission's 1997 decision in *Ciba-Geigy, Ltd.*⁷ the Commission challenged the merger of Ciba-Geigy and Sandoz, both of which had gene therapy R&D programs. The Commission speculated that the first gene therapy products would not be available until the year 2000 but that the market for gene therapy products could grow to \$45 billion by the year 2010.⁸ As of 2004, there is still no human gene therapy product approved for sale.⁹

The Commission's second basis for enforcement action offered a rationale for reaching early-stage R&D efforts, where any product was years away from reaching the market. The Commission reasoned that absent competition to innovate, competitors would be less likely to expend the resources and energy to do so, or would undertake innovation at a much slower pace. Thus, it was the competition to innovate, in addition to competition in the ultimate end-goods market, that the Commission has viewed as worthy of protection.

Genzyme

Against this backdrop of past enforcement, the Commission was faced with Genzyme's completed acquisition of Novazyme.¹⁰ Genzyme is a large biotech company with thousands of employees and sales of nearly \$1 billion at the time of the acquisition. Novazyme, in contrast, was a small privately held research company. Novazyme had no products on the market, no products in clinical trials, and no clinical-scale or commercial-scale manufacturing facilities. Genzyme was the only company with an approved product for lysosomal storage disorders (LSDs), a group of forty-one diseases. The science involved in developing drugs to treat LSDs is complex. Genzyme's first LSD product took over ten years to develop.

Pompe, the LSD disease at issue in this matter, is a painful and debilitating disease that is always fatal; many of its victims are infants who die before their first birthday and children who die before adolescence after spending most of their lives dependent upon ventilators and wheelchairs. Pompe is an extremely rare disease, affecting fewer than five to ten thousand people worldwide. Although it has been more than sixty years since Pompe disease was first identified, there are still no approved drugs to treat Pompe on the market.

⁶ But see *infra* pp. 6–7 (discussing whether, as a matter of statutory interpretation, Clayton Act § 7 even applies to mergers that occur prior to the existence of a relevant market in the goods being developed).

⁷ 123 F.T.C. 842 (1997).

⁸ *Id.* at 845.

⁹ See <http://www.fda.gov/cber/gene.htm>.

¹⁰ The transaction was not reportable under the Hart-Scott-Rodino Act.

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Because Pompe is such a rare disease, efforts to develop pharmaceutical products for its treatment are covered by the Orphan Drug Act.¹¹ An “orphan drug” is a pharmaceutical product that treats a disease affecting fewer than 200,000 patients in the United States. To provide incentives for pharmaceutical companies to develop products to treat such rare diseases, the Orphan Drug Act was enacted in 1983. The most important incentive that Congress provided is marketing “exclusivity.” A company that obtains FDA approval of an orphan drug is given the assurance that FDA will not approve another company’s application for the “same drug” for seven years from the date of FDA approval.¹² In short, Congress grants a seven-year monopoly to orphan drugs that obtain FDA approval. The overriding purpose of the Orphan Drug Act is to bring drugs to market that otherwise would never be developed and marketed because the costs of developing such drugs could never be recouped without such exclusivity. Congress provided a set of narrow circumstances in which marketing exclusivity for an orphan drug could be broken by another drug considered “the same drug” under the Orphan Drug Act.¹³

At the time of the acquisition in September 2001, Genzyme and Novazyme were the only two companies attempting to develop a treatment for Pompe. The merger left Genzyme as the only entity performing R&D to develop Pompe treatments.

After a lengthy investigation, the Commission voted to close its investigation of Genzyme’s acquisition of Novazyme.¹⁴ Chairman Muris issued a detailed statement explaining his views as to why the investigation should be closed.¹⁵ Although Commissioners Leary and Swindell joined in the vote to close the investigation, they did not join in the Chairman’s statement or issue their own statements. Commissioner Thompson voted against closing the investigation and issued a statement explaining why he believed the Commission should have pursued an enforcement action against Genzyme.¹⁶ Finally, although Commissioner Harbour did not vote on the matter because she had only recently joined the Commission, she issued a statement setting forth her general views on “innovation markets.”¹⁷

¹¹ 21 U.S.C. §§ 360aa–ee.

¹² *Id.* § 360cc.

¹³ First, if a subsequent product is clinically superior to the original orphan drug, it can be brought to market during the exclusivity period. Second, a subsequent product can be brought to market if the orphan drug manufacturer either consents to “shared” exclusivity with the new product or is unable to supply sufficient quantities of the product to meet the patient demand for the orphan drug. The exclusivity is inapplicable where the second product is not the “same drug.” The Orphan Drug Act provides a fairly broad definition of the “same drug” for macromolecules (such as proteins). *See* 21 C.F.R. § 316.3(b)(13)(ii). Finally, a subsequent product may be marketed to treat a different disease than the disease for which the orphan drug was approved. In all other circumstances, the marketing exclusivity granted to the first orphan drug is absolute.

¹⁴ FTC Press Release, FTC Closes Its Investigation of Genzyme Corporation’s 2001 Acquisition of Novazyme Pharmaceuticals, *available at* <http://www.ftc.gov/opa/2004/01/genzyme.htm>.

¹⁵ Statement of Chairman Timothy J. Muris in the Matter of Genzyme Corporation/Novazyme Pharmaceuticals, Inc., *available at* <http://www.ftc.gov/os/murisgenzymestmt.pdf>.

¹⁶ Dissenting Statement of Commissioner Mozelle W. Thompson, Genzyme Corporation’s Acquisition of Novazyme Pharmaceuticals Inc., *available at* <http://www.ftc.gov/os/2004/01/thompsongenzymestmt.pdf>.

¹⁷ Statement of Commissioner Pamela Jones Harbour, Genzyme Corporation’s Acquisition of Novazyme Pharmaceuticals Inc., *available at* <http://www.ftc.gov/os/2004/01/harbourgenzymestmt.pdf>.

There Is No Basis for Presuming Anticompetitive Effects in Innovation Markets

The Views of the Commissioners. Perhaps the most fundamental disagreement among the Commissioners was the appropriate analytical framework to use in assessing the merger, in particular, whether there should be any presumptions concerning “anticompetitive effects.” Chairman Muris advocated a fact-based approach to considering innovation mergers. The Chairman relied heavily upon a 1996 report of the Commission staff,¹⁸ which, he noted, acknowledged that “economic theory and empirical investigations have not established a general causal relationship between innovation and competition.”¹⁹

The Chairman summarized his views as follows:

[N]either economic theory nor empirical research supports an inference regarding the merger's likely effect on innovation (and hence patient welfare) based simply on observing how the merger changed the number of independent R&D programs. Rather, one must examine whether the merged firm was likely to have a reduced incentive to invest in R&D, and also whether it was likely to have the ability to conduct R&D more successfully.²⁰

In contrast, Commissioner Thompson suggested that innovation mergers, like other mergers, should be subject to a “rebuttable presumption of competitive effects for mergers if the change in, and resulting level of, market concentration is significant.”²¹ Commissioner Thompson pointed to the Antitrust Guidelines for Collaborations Among Competitors as support for his position. Although Commissioner Thompson did not refer to empirical support for the presumption in innovation cases, he stated that he saw “no compelling reason why innovation mergers should be exempt from the Horizontal Merger Guidelines or the presumption of anticompetitive effects for mergers to monopoly and other mergers as discussed therein.”²² Moreover, Commissioner Thompson pointed to testimony of business witnesses in the investigation that competition had affected other companies' innovation efforts.²³

Commissioner Harbour struck a middle ground. She noted that “[a]lthough one may question whether we have yet reached the point where a general presumption of anticompetitive effects in highly concentrated innovation markets is applicable, in the extreme case of a merger to monopoly that eliminates all competition and diversity in the innovation market, such a presumption seems appropriate.”²⁴

Economics Literature. Unlike traditional oligopoly theory as applied to markets for existing products, there is no firm grounding in economic doctrine for presuming an anticompetitive reduction in innovation from a reduction in the number of competitors attempting to innovate. The 1996 Global Marketing Report cited by Chairman Muris noted the lack of economic consensus that

¹⁸ FTC Staff Report, *Anticipating the 21st Century: Competition Policy in the New High-Tech, Global Marketplace* (May 1996) [Global Marketplace Report].

¹⁹ Muris Statement, *supra* note 15, at 2–3.

²⁰ *Id.* at 5–6.

²¹ Thompson Statement, *supra* note 16, at 3.

²² *Id.*

²³ *Id.* at 9 n.21 and accompanying text.

²⁴ Harbour Statement, *supra* note 17, at 3 (citations omitted).

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reduced competition leads to less R&D or to fewer new products.²⁵ In a 2001 article, Richard Gilbert and Willard Tom concluded that the basis for a belief that competition enhances R&D efforts is “largely anecdotal,”²⁶ and that “[e]conomic theory does not provide that more competition is better for R&D and [that] statistical studies do not support that conclusion either.”²⁷ Indeed, economic theory—as well as empirical evidence—supports the view that collaboration may be preferable to competition in terms of furthering innovation. As Dennis Carlton & Robert Gertner noted in a 2003 paper, “[s]ince competing R&D expenditures may be duplicative, a merger that eliminates redundancy may lead to the same knowledge produced at lower costs, or even greater knowledge at lower costs.”²⁸ Another efficiency that can result from combined R&D efforts is “an enhanced interchange of ideas and sharing of resources.”²⁹ As Carlton & Gertner explain, “It is incorrect to conclude that any reduction in R&D is necessarily bad for consumers.”³⁰ Their view, therefore, is that “neither theory nor empirical work provides any general justification for an antitrust merger policy aimed at preserving competition in R&D markets.”³¹

The Views of the Courts. It is of interest that all the Commissioners’ Statements appeared to assume that the antitrust laws could bar a merger that adversely affected an “innovation” market, even if no market for the sale of goods existed yet, despite the fact that no court has ever held a transaction unlawful solely because of effects solely on “innovation,” in the absence of an existing product market. Indeed, since Section 7 Clayton Act requires a lessening of competition “in any line of commerce,”³² there are significant questions whether Section 7 is implicated at all when no product is being sold and thus no commerce is currently affected, as prior cases have recognized. Yet the several Statements of the Commissioners did not address that case law.

The most directly relevant case authority is *SCM Corp. v. Xerox Corp.*,³³ in which the plaintiff alleged that Xerox had violated the antitrust laws by buying up patents for plain-paper copier technology. However, the acquisitions occurred several years before Xerox marketed the first plain-paper copier. In short (as in the *Genzyme* case), the relevant product market did not exist at the time of the acquisitions. The court ruled that acquisitions of patents could not violate the antitrust laws if the relevant product market did not exist at the time of the acquisitions, even though the “probable effect” of the patent acquisitions was to substantially lessen competition once the relevant market did exist.³⁴ Rather, the court construed the “line of commerce” requirement to mean that an acquisition (at the time it occurs) must have probable anticompetitive effects in an “existing” line of commerce.³⁵

²⁵ See Dennis W. Carlton & Robert H. Gertner, *Intellectual Property, Antitrust and Strategic Behavior*, UNIVERSITY OF CHICAGO, NATIONAL BUREAU OF ECONOMIC RESEARCH (Abstract, May 2002) at 13, reprinted in ADAM JAFFE & JOSHUA LERNER, 3 INNOVATION POLICY AND THE ECONOMY 13 (2003).

²⁶ Richard Gilbert & Willard Tom, *Is Innovation King at the Antitrust Agencies? The Intellectual Property Guidelines Five Years Later*, 69 ANTITRUST L.J. 43, 83 (2001).

²⁷ *Id.*

²⁸ Carlton & Gertner, *supra* note 25, at 10.

²⁹ *Id.* at 11.

³⁰ *Id.*

³¹ *Id.* at 14.

³² 15 U.S.C. § 18.

³³ 645 F.2d 1195 (2d Cir. 1981).

³⁴ *Id.* at 1210.

³⁵ *Id.* at 1211.

The court in *Crucible, Inc. v. Stora Kopparbergs Bergslags AB*³⁶ reached a similar result. As in *SCM*, the court ruled that “the absence of a relevant [product] market . . . at the time of patent acquisition precludes the applicability of Section 7.”³⁷

Thus, Genzyme argued to the Commission that there is no economic or legal foundation for a presumption that a merger of two innovators, even if they are the only ones, is anticompetitive. To state simply that the merger is a “merger to monopoly” in some area of R&D says nothing about what the merger means for the pace, amount, quality, or—most importantly—likely outcome of the innovation efforts. Only a detailed examination of the facts can answer those questions. In the case of Genzyme’s acquisition of Novazyme, Genzyme pointed to facts that indicated that no harm to innovation was likely, thus demonstrating that any presumptions would be inappropriate.

The Commission Neither Found (Nor Discussed) Risks of Harm in Future Product Markets

As noted above, one premise of prior enforcement actions was the possible effect of a merger on future product markets. For there to be an adverse effect on actual competition, however, the Commission would have had to demonstrate that there would in fact have been competition between Genzyme and Novazyme in a future product market absent the transaction. Genzyme pointed to an absence of any basis for believing that both products were likely to be successfully developed, especially in light of the legal impediments established by the Orphan Drug Act.

Successful development of a treatment for LSDs is exceedingly difficult. There are more than forty such diseases, and to date in the United States there are only four products for three LSD diseases, all made by Genzyme. Even though Orphan Drug exclusivity ended over two years ago for Genzyme’s Gaucher products, Genzyme faces no competition. A theoretical concern that additional patients might have benefited from the development of different products misses the point that patients can only be helped if effective and approved products actually emerge. It would have been highly speculative to predict that both Genzyme and Novazyme would have developed products, and received FDA approval, particularly in light of the Orphan Drug Act. Perhaps for this reason, the Commission statements do not discuss the theory of potential harm in a future products market from the transaction.

Procompetitive Benefits of the Combination Outweighed the Speculative Harm of a Reduction in Innovation Competition

The second premise underlying prior enforcement actions has been potential adverse effects on “competition to innovate.” The Statements of Chairman Muris and Commissioner Thompson considered various potential effects of the Genzyme/Novazyme transaction on such competition and reflect mainly a divergence of views as to whether any adverse effects were likely to arise from the transaction.

³⁶ 701 F. Supp. 1157 (W.D. Pa. 1988).

³⁷ *Id.* at 1162–63. *See also* *Fraser v. Major League Soccer, L.L.C.*, 97 F. Supp. 2d 130, 140–41 (D. Mass. 2000) (“Where there is no existing market, there can be no reduction in the level of competition. . . . Competition that does not exist cannot be decreased”), *aff’d*, 284 F.3d 47, 71 (1st Cir. 2002) (“Even advocates of a broader reading of section 7 concede that striking down a combination that does not threaten present competition could be justified . . . only in already concentrated markets.”).

A “Race” to Innovate? The first theory of anticompetitive harm Chairman Muris considered was “whether Genzyme and Novazyme would have engaged in a ‘race to market’ absent the merger.”³⁸ He said that for such a race to exist “at least one of them would have had to believe that altering its expenditures on R&D would significantly change its probability of beating the other company to the market with a therapy for Pompe.”³⁹ The Chairman concluded that the evidence showed that Genzyme and Novazyme did not view themselves as being in a “race” to innovate. Novazyme believed it was developing a better drug, not a drug that would come to market first. “Under these circumstances,” the Chairman stated, “the competition between Genzyme and Novazyme would not have had a substantial effect on the amount or timing of Genzyme’s or Novazyme’s R&D spending on Pompe, or on when the first Pompe therapy would reach the market.”⁴⁰ He explained that “regardless of Novazyme’s program, Genzyme’s incentive was to get a Pompe therapy to market sooner rather than later to earn profits on sales of its enzyme.”⁴¹ The same was true for Novazyme. Thus, absent the merger, “there would not likely have been a ‘race to market.’”⁴² Commissioner Thompson, however, believed the evidence indicated that a race existed between Genzyme and Novazyme to develop a Pompe product and that the race increased the pace of innovation.

Genzyme contended that the facts supported a finding that the parties’ innovation efforts would have been no different whether or not they perceived themselves to be in a race. Both Genzyme and Novazyme each stated, both publicly and privately, that they were pushing their programs as quickly as possible. Moreover, the incentive to speed up—rather than withdraw from an unwinnable race to market—will occur only when the competing innovators’ programs are close to each other in development progress. Yet there was no evidence that Genzyme and Novazyme were close to each other in development progress. Nor was there evidence that Genzyme and Novazyme were close in the race to develop a Pompe product. Finally, and perhaps critically, the Commission apparently concluded that the actual benefits of the Genzyme-Novazyme collaboration—providing better products to patients—outweighed the minimal and highly speculative risk that Genzyme might develop a drug a few months later than it would have if R&D competition had existed.

Incentives to Delay Novazyme’s Development Program?

Chairman Muris also considered whether the merger might lead Genzyme to delay the Novazyme program.⁴³ He noted that such a concern was problematic only if the Genzyme product succeeded.⁴⁴ If the Genzyme program failed, Genzyme’s incentives would be to push the development of the Novazyme product.⁴⁵

³⁸ Muris Statement, *supra* note 15, at 11.

³⁹ *Id.*

⁴⁰ *Id.* at 12.

⁴¹ *Id.*

⁴² *Id.* at 12–13.

⁴³ *Id.* at 13.

⁴⁴ *Id.* at 14.

⁴⁵ The Chairman pointed to other facts suggesting that Genzyme was not planning to delay the program, including putting the Novazyme CEO, whose two children had Pompe disease, in charge of the merged company’s Pompe program, and entering into a merger agreement which provided significant milestone payments for stages of the Pompe program that substantial Novazyme shareholders headed up.

Genzyme raised a number of reasons why its incentives to continue R&D on the Novazyme technology are far greater than the incentives of a third party. First, Genzyme noted that it believes that the Novazyme technology, in conjunction with the existing Genzyme CHO product,⁴⁶ might be useful in the development of an improved second-generation Pompe product. No other company would have access to the Genzyme CHO product.

Second, if Genzyme succeeded with its internal CHO product, it would have market exclusivity under the Orphan Drug Act. In the hands of a third party, any product developed with Novazyme technology would have to be demonstrably better and would have to prove superior efficacy in head-to-head clinical trials. The need to break Orphan Drug exclusivity is a significant disincentive for a third party to develop the Novazyme Pompe preparation in light of the problems that have been uncovered. In contrast, Genzyme can bring a product with the Novazyme technology to market if (1) the product is only marginally better than the Genzyme product, (2) Genzyme believes the product is better but that fact would be very difficult to demonstrate or (3) the product is no better but results in cost savings.

Third, Genzyme believes that the Novazyme technology may have potential use in products for the treatments of other LSDs. A third party would not be able to apply the technology to those products.⁴⁷ For these reasons, Genzyme argued that it has greater incentives and is more likely to develop the Novazyme technology than a third party.

Commissioner Thompson, in contrast, believed that Genzyme's incentives to develop the programs aggressively could be adversely affected and that business incentives motivating Genzyme to develop a Pompe product were not a substitute for competition.⁴⁸ He suggested that Genzyme could develop a product that was not as good in the absence of a race to develop a product that would not lose Orphan Drug exclusivity. Yet the economic incentive to develop a better drug effective for more patients always existed. Moreover, Genzyme pointed to evidence that showed that, in other cases where Genzyme had market exclusivity, it has continued to improve its products.⁴⁹

Beyond the issue of incentives, Chairman Muris also concluded that "there is no evidence that the merger reduced R&D spending on either the Genzyme or the Novazyme program or slowed progress along either of the R&D paths."⁵⁰ To Commissioner Thompson's suggestion that the programs had been delayed, the Chairman countered that "there is no evidence . . . that the merger caused those delays. Rather, they appear attributable to overly optimistic early projections and subsequent unexpected problems."⁵¹ Indeed, Novazyme's documents repeatedly made the erroneous prediction that it was only months away from the beginning of clinical trials for Pompe and was within reach of the clinic for its other products. In an atmosphere of a start-up biotech company that had to convince investors to provide funding, such aggressive projections are commonplace. Nor is it surprising that Novazyme's CEO, trying desperately to find a cure for his

⁴⁶ "CHO" refers to Chinese Hamster Ovary cells, the cell line on which the Genzyme product is based.

⁴⁷ Finally, Section 4.23 of the Agreement and Plan of Merger between Genzyme and Novazyme requires Genzyme to use "commercially reasonable and diligent efforts" to determine the development plan for the Novazyme programs.

⁴⁸ See Thompson Statement, *supra* note 16, at 9.

⁴⁹ Indeed, Genzyme introduced a second generation Gaucher product during the Orphan Drug exclusivity period for its first generation product.

⁵⁰ Muris Statement, *supra* note 15, at 17.

⁵¹ *Id.* at 23.

children's illness, used these timelines as aspirational documents to motivate his colleagues to find a cure.

Genzyme pointed out that Novazyme's aggressive timelines could never be met, for several reasons. First, Novazyme's projections were based on having the money it needed to do the R&D work, conduct clinical trials, and obtain FDA approval. Yet there was great uncertainty as to whether that money would ever materialize. Second, Novazyme was having difficulty making its preparation. Third, Novazyme simply had no plan for how to manufacture its preparation. It had no bioreactors, and such capacity is in short supply. It is important to realize that at the time of the acquisition only one animal trial had been conducted—with a drug that because of toxicity issues could never be used in humans.⁵²

Commissioner Thompson viewed with skepticism "post-acquisition evidence" regarding delays. He reasoned that because the merged firm controls its own behavior, any reduction or delay of innovation would be "inherently difficult to detect."⁵³ Yet Genzyme pointed to the absence of any evidence that Genzyme was delaying the Novazyme program and the fact that for two years after the acquisition, Genzyme was diligently continuing R&D and having extensive collaboration between the Genzyme and Novazyme programs. In his response to Commissioner Thompson's statement, Chairman Muris underscored that "[a]nticompetitive behavior . . . depends on incentives as well as ability. . . . When those incentives are evaluated, the specific facts of this case do not indicate any likely effect on Genzyme's effort to bring a second Pompe therapy to market."⁵⁴

Procompetitive Benefits. Chairman Muris next considered "whether the merger has made it more likely that the Genzyme program or the Novazyme program will produce a successful therapy, or will do so sooner."⁵⁵ He pointed to several benefits arising from the merger, such as allowing comparative experiments and information that "enabled the Novazyme program to avoid drilling dry holes."⁵⁶ Indeed, there were numerous examples presented to the Commission of merger-specific benefits to the Novazyme development program that in fact had been realized by the transaction. As Chairman Muris wrote, "We are not dealing with vague claims about uncertain benefits some time in the future."⁵⁷ These benefits included allowing the Novazyme product to use cell lines previously developed by Genzyme that were scaleable for a Pompe enzyme; access to a Genzyme assay; knowledge of how different patients reacted to previous Pompe products; and technology for measuring the clearance of glycogen. These benefits could not have been brought to the Novazyme development program by any party other than Genzyme, given Genzyme's unique history with development of Pompe treatment. No other company had a Pompe cell line. No other company had experience measuring glycogen reduction. No other company had a patient database of Pompe patient's reactions to different Pompe products. In sum, to the suggestion that other possible means of achieving efficiencies might exist, Chairman Muris said there was

⁵² Genzyme explained that the value of Novazyme to Genzyme was always in the promise of its technology, rather than the specific product it was trying to develop.

⁵³ Thompson Statement, *supra* note 16, at 8.

⁵⁴ Muris Statement, *supra* note 15, at 24.

⁵⁵ *Id.* at 17.

⁵⁶ *Id.*

⁵⁷ *Id.*

no reason to weigh equally the merger's actual benefits with the potential benefits of a joint venture that never occurred. Any number of factors . . . render the benefits in the hypothesized "but for" world more conjectural. These speculative gains cannot offset concrete gains that will translate into immense benefits for patients if the Genzyme internal Pompe program fails and the Novazyme program succeeds. Many lives would be saved and much suffering prevented.⁵⁸

While Commissioner Thompson suggested that the parties might have collaborated in a narrower R&D joint venture, he pointed to no evidence in support of the view that they might ever have done so. Nor did he provide any explanation as to why the parties would have had any incentive to do so if, as he alleged, the parties were in a race to innovate.

The Effect of a Challenge. Finally, Chairman Muris noted that "[n]either litigation nor a remedial order would likely benefit Pompe patients. To the contrary, litigation could adversely affect Genzyme's incentives to spend on R&D, and could disrupt the Novazyme research program" by diverting the attention of key scientists from research to courtroom testimony.⁵⁹

Chairman Muris also determined that finding an appropriate remedy "appears problematic. . . . unwinding the merger of preclinical research efforts on the particular facts of this case raises numerous issues."⁶⁰ For instance, a nonexclusive license to the Novazyme product would be unlikely to spur competition. Any value in the Novazyme product lay in its potential to break Orphan Drug Act exclusivity as a "superior" product; yet, if another competitor had a license to that product as well, there would be little incentive for either party to expend the money and effort to break Orphan Drug exclusivity. A forced divestiture would destroy the beneficial synergies that had already resulted from the combination. Because the Novazyme development program was using a Genzyme cell line, divestiture would mean going back to the drawing board in search of an effective cell line.

Commissioner Thompson rejected that argument as a basis for exercising prosecutorial discretion not to challenge the transaction. He contended that companies routinely litigate and engage in R&D simultaneously and that the costs, distractions, and other adverse effects of litigation can be avoided through settlement.⁶¹ While acknowledging that developing and implementing remedies for consummated mergers can provide challenges, he noted that "imprecise or otherwise imperfect remedies for consummated mergers may still be able to replace some or all of the meaningful competition lost due to the merger."⁶²

Lessons from Genzyme

In some respects, Genzyme's acquisition of Novazyme presented a unique fact situation. The early-stage nature of the drug programs at the time of the acquisition raised significant questions as to whether both products would ever reach the market. As a result, concerns that might otherwise have existed with respect to competition in the future goods market were lessened. There were significant factual questions as to whether the parties were really in any "race" to innovate given Genzyme's further advanced R&D program. Finally, because this was a consummated

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⁵⁸ *Id.* at 18.

⁵⁹ *Id.* at 20.

⁶⁰ *Id.* at 21.

⁶¹ Thompson Statement, *supra* note 16, at 12–13.

⁶² *Id.* at 13.

transaction, the Commission had post-acquisition evidence from which to judge the merger's effects.

Nevertheless, there are important lessons to be taken from the Commissioners' statements in connection with the termination of the investigation of the Genzyme/Novazyme merger. First, despite prior court rulings requiring an existing product market for an antitrust violation to be found and economic literature stating no clear effects of mergers on innovation or R&D, the absence of an "existing" goods market appears to be no impediment, in the Commission's view, to a challenge to mergers affecting innovation efforts. Such challenges are likely to continue.

Second, a majority of the Commissioners appear to believe that no "presumptions" of anti-competitive effect should govern "innovation market" mergers. Rather, mergers involving innovation markets should be subject to very specific factual analysis, and require a focused examination into whether innovation is likely to be adversely impacted (or enhanced) by consolidation. This was clearly illustrated in Genzyme, where evidence as to the likelihood of competition between the parties, R&D efficiencies, and alternatives to the merger were considered by both Chairman Muris and Commissioner Thompson.

Finally, evidence of procompetitive benefits will likely play an important role in the Commission's decision on whether to challenge mergers in innovation markets. Indeed, Chairman Muris underscored his view that the Genzyme/Novazyme transaction was more likely to benefit consumers than to harm them. ●