[1] "An innovation market consists of the research and development directed to particular new or improved goods or processes, and the close substitutes for that research and development." U.S. Department of Justice and the Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property*

One important feature of the *Horizontal Merger Guidelines* is that they establish a rebuttable presumption of competitive effects for mergers if the change in, and resulting level of, market concentration is significant.[6] I see 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.

The facts in this case further illustrate this point.

Genzyme's Acquisition of Novazyme Is Anticompetitive

The evidence gathered in this investigation establishes that: (1) the market should be defined as the market for the innovation of Pompe enzyme replacement therapies; (2) the

---

Guidelines"), *available at* http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf.

[6] U.S. Department of Justice and Federal Trade Commission, *Horizontal Merger Guidelines*, § 1.51 (April 2, 1992; revised April 8, 1997), *available at* http://www.ftc.gov/bc/docs/horizmer.htm. A merger to monopoly creates an HHI of 10,000; mergers that increase the HHI by more than 100 points to a post-merger HHI exceeding 1800 points are presumptively anticompetitive. The *Horizontal Merger Guidelines* address market power that adversely affects innovation: "Sellers with market power also may lessen competition on dimensions other than price, such as product quality, service, or *innovation*." *Horizontal Merger Guidelines*, § 0.1 (emphasis added). Because the presumption is rebuttable, merging parties may be able to overcome the presumption by presenting evidence relating to such issues as entry, effects, and efficiencies to the Commission. *See Horizontal Merger Guidelines*, § 1.51 c).

[7] *See Horizontal Merger Guidelines*, § 1.51.

[10] The pace of biotechnology research and development is sometimes difficult to predict; therefore, we cannot determine exactly how fast Novazyme could have progressed should it have chosen not to merge with Genzyme. What is clear, though, is that the development schedule of the Novazyme product has fallen four to six years behind Novazyme's pre-acquisition estimates and even behind Genzyme's initial projections.

Novazyme, before the acquisition, projected reaching clinical trials during "the

mover advantage.

[12] Genzyme Press Release, *supra* n.10.

[13] *See supra* n.10.

[14] "Don't it always seem to go that you don't know what you've got till its gone?" JONI MITCHELL,

anticompetitive conduct following its acquisition of a competitor in an actual goods market:

> If a demonstration that no anticompetitive effects had occurred at the time of trial

[17] *U.S. v. General Dynamics Corp.*, 415 U.S. 486 (1974) (footnote omitted); *see also FTC v. Consolidated Foods Corp.*, 404 U.S. 592, 598 (1965) ("[T]he force of § 7 is still in probabilities, not in what later transpired.").

[18] FTC Staff Report, *Anticipating the 21st Century: Consumer Protection Policy in the New High-Tech, Global Market Place*, Chapter Seven at 20 (Volume I, May 1996).

power during the period of time that its merger was under investigation.[19]

Second, several arguments might also be raised that in essence assert that the benefits of competition could be provided through a market incentive or other mechanisms that would regulate corporate behavior.[20] For example, it could be argued that the revenues Genzyme would have hoped to gain by completing its R&D and selling a Pompe ERT product on the market would have been a powerful incentive. This market incentive, the argument provides, would alone have prevented Genzyme from slowing the pace of innovation whether it became a monopolist or not. This claim fails because the evidence collected in this investigation showed that pre-merger competition did in fact bring an additional incentive to race in this particular innovation market.[21] It might also be argued that contingent payment provisions contained in the merger agreement would prompt former Novazyme shareholders in post-merger Genzyme positions to monitor Genzyme's efforts to develop the Novazyme product, thus thwarting any anticompetitive effects on innovation. But these $87.5 million payments, which are contingent upon receiving U.S. Food and Drug Administration approval to market products employing

---

[19] *Horizontal Merger Guidelines,* § 0.2.

[20] Although it is not necessary to reach a conclusion that these arguments are not cognizable as a matter of law, I certainly have my doubts whether the Commission or any reviewing court would ever hold that these mechanisms could fully protect an innovation market from the adverse impacts of a merger to monopoly.

[21] Further, the investigation's witnesses pointed out three examples of other Orphan Drug Act markets where the presence or lack of competition affected the pace of innovation. In addition, a Federal district court recently observed that innovation competition occurred in yet another Orphan Drug Act market: "What ensued was a race for orphan drug approval since both Taxol and Paxene had been granted orphan drug designation; whichever drug was approved first would receive the seven-year period of market exclusivity." *Baker Norton Pharmaceuticals, Inc. v. U.S. Food and Drug Administration and Bristol-Myers Squibb Co.,* 132 F. Supp. 2d 30, 32 (D.D.C. 2001).

[22] Genzyme Press Release, *supra* n.10.

[23] *See supra* n.18. Moreover, I am not convinced that Genzyme or the shareholders believed that the payments were very likely and that Genzyme would have been concerned that one of its current executives would bring and win a breach of contract lawsuit.

[24] Geeta Anand, *Clinical Trials: For His Sick Kids, A Father Struggled to Develop A Cure,*

defense to an antitrust violation.[25]

The final argument that might be made in support of the merger is that the combination provides significant *merger-specific* efficiencies. Because we examined a consummated merger in this matter, we have the ability to evaluate specific claims of post-merger efficiencies and to determine whether there is in fact evidence to support such potential claims.[26] I believe that the evidence fails to support a determination that Genzyme's acquisition of Novazyme led to merger-specific efficiencies.

I do not believe that the merger provided any significant benefits to the Genzyme product in R&D. And, although I understand the argument that the merger may have been of some general benefit to the Novazyme R&D efforts, I found insufficient evidence of any *merger-specific* efficiencies because these benefits could have been created without the merger.[27] It is also possible that Genzyme and Novazyme would have achieved such benefits, while maintaining competition, if they had collaborated in a more narrow R&D joint venture.

---

[25] "A firm, however well-intended, that lacks meaningful rivalry in its market simply cannot replicate the results of competition. Thus, as the Supreme Court has made clear, 'good motives will not validate an otherwise anticompetitive practice.'" Brief for Plaintiff-Appellant at Section II.A., Federal Trade Commission v. Butterworth Health Corp., et al., 1997-2 Trade Cas. (CCH) ¶ 71,863, 1997 LEXIS 17422 (6th Cir. 1996) (No. 96-2440) (*quoting* NCAA v. Board of Regents, 468 U.S. 85, 101 n.23 (1984)), *available at* http://www3.ftc.gov/bc/bbrepf~1.htm.

[26] As previously discussed, the Commission may choose to discount certain post-merger evidence. Specifically, the Commission may discount post-merger evidence demonstrating that the merger had no competitive effects if the merged firm had the ability to control this evidence. On the other hand, post-merger evidence relating to efficiency claims may be quite revealing because a merged entity has the incentive both to create efficiencies for its own benefit and to demonstrate them to the Commission.

[27] *Horizontal Merger Guidelines*, § 4.

Moreover, Novazyme could have collaborated with,[28] or could have been acquired by, another biotech firm. However, none of these practical alternatives were pursued.

For all of these reasons, I am satisfied that the Commission had reason to believe that the acquisition violated the Clayton and FTC Acts.

The Exercise of Prosecutorial Discretion

Beyond the legal issues in this matter, I believe this matter raises substantial competition policy issues. It could be argued that the Commission should exercise its prosecutorial discretion and not challenge the Genzyme/Novazyme merger even if the Commission had found reason to believe that the transaction was unlawful. An argument would be that litigation could disrupt Genzyme's efforts and ultimately harm Pompe disease patients, all without creating offsetting benefits because no meaningful and timely remedy is possible.

I am mindful of this concern. Even if some R&D activity were disrupted, however, the disruption would likely be limited and certainly not outweigh the innovation competition that is presently extinguished or the consequences of future loss that the public may experience because innovation may now not occur. Indeed, the very basis of modern antitrust jurisprudence is that competition has value. Exercising discretion not to bring a case would seem to discount this value. Nonetheless, there are several reasons that the impact of administrative litigation would not unduly harm innovation (assuming *arguendo* that it is good antitrust policy to accept business disruption as a good reason to refrain from challenging a monopolist we have reason to believe violated the antitrust laws).

First, pharmaceutical and other companies routinely litigate while engaging in R&D but

---

[28] Crowley Interview, *supra* n.10.

[29] In addition to being investigated by the Commission (Pompe ERTs), Genzyme has recently been under investigation by the Office of Fair Trading in the United Kingdom (Cerezyme and other ERTs), and has been litigating a patent case against Transkaryotic