Statement of Commissioner Pamela Jones Harbour
Genzyme Corporations's Acquisition of Novazyme Pharmaceuticals Inc.
File No. 021-0026

When I joined the Commission, it was already in the final stages of considering the complex issues raised by the acquisition of Novazyme Pharmaceuticals, Inc. by Genzyme Corporation. Given these circumstances, I chose not to participate in the vote regarding whether to close the investigation of this merger. As the statements issued by Chairman Muris and Commissioner Thompson attest, the decision to close was not an effortless one. Although I did not vote, I would like to take this opportunity to express some of my views on the relationship between competition and innovation, an important antitrust policy issue raised by this case.

Innovation, in the sense of "research and development directed to particular new or improved goods or processes,"[1] is critically important to the increased productivity and competitiveness of domestic firms and economic growth. Competition drives innovation, a crucial element in increasingly global markets. Firms in a competitive market generally have greater incentives to innovate than a monopolist facing no realistic threat of immediate entry.[2] Diversity of research and development efforts is also an important element of innovation, as firm rivalry plays a direct role in stimulating product development and improvements.[3] Moreover, in the innovation context, diversity is perhaps uniquely valuable in the same way that federalism

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[1] *See* U.S. Dep't of Justice and Fed. Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property*, § 3.2.3 (Apr. 9, 1995), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,406 [hereinafter *IP Guidelines*].

[2] *See* Kenneth J. Arrow, *Economic Welfare & the Allocation of Resources for Invention, in* THE RATE AND DIRECTION OF INVENTIVE ACTIVITY 609, 619 (1962). *Cf.* Fed. Trade Comm'n Staff Report, *Anticipating the 21st Century: Competition Policy in the New High-Tech, Global Marketplace*, Volume I, Ch. 7, 2 (May 1996) [hereinafter *Anticipating the 21st Century*] (noting that "Congress, the courts, and the antitrust agencies have consistently applied antitrust law to maintain a 'competitive level' of innovation.").

[3] *See, e.g.*, Kenneth J. Arrow, U.S. Dep't of Justice and Fed. Trade Comm'n, *Hearings on Competition and Intellectual Property in the Knowledge-Based Economy* [hereinafter *Hearings on Competition and I.P.*], Feb. 25, 2002, at 58-59 (transcript of oral remarks); Daniel L. Rubinfeld, *id.* at 19 ("...if you have fewer innovators [and] less diversity, you are likely to have less innovation or higher prices or lower quality products").

values the so-called laboratories of the States[4] – that is to say, different perspectives and approaches proceeding in parallel often yield greater benefits and insights than those dictated by unitary pursuits.[5]

Innovation competition is especially important in markets, such as pharmaceuticals, where frequent reliance on patents to protect the fruits of research and development is the norm;[6] where the increased profits that flow to the first firm to patent and market a new drug or treatment promote races to innovate; where entry barriers – most notably the costly and prolonged requirements of the regulatory approval process – are exceptionally high; and where the products of innovation can often be monopolized for significant periods of time.[7] The preservation of innovation competition in such circumstances is especially important to consumers and is, therefore, an important goal for antitrust enforcement.

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[4] *See* United States v. Lopez, 514 U.S. 549, 581 (1995) (Kennedy, J., concurring) ("...the theory and utility of our federalism are revealed, for the States may perform their role as laboratories for experimentation to devise various solutions where the best solution is far from clear."); New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) ("It is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country").

[5] Diversity of research will also benefit consumers on those occasions it leads to effective competition in the product market following innovation.

[6] *See* Wendy H. Schacht & John R. Thomas, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act")*, CRS Report for Congress (Dec. 18, 2000), at 5 ("Patents are perceived as critical in the drug and chemical industries."); Richard C. Levin et al., *Appropriating the Returns from Industrial R&D*, BROOKINGS PAPERS ON ECONOMIC ACTIVITY 783, 795-96 (1987) (finding, in a survey of publicly traded firms in 130 lines of business, that drugs were one of only five industries where product patents were regarded as "highly effective").

[7] This latter concern is especially acute where the law, such as in the case of products subject to the Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified as amended at 21 U.S.C. § § 360aa-360ee (1988)), provides the winner of the race to innovate with an even greater protection from competition than it typically provides patent holders.

Although one may question whether we have yet reached the point where a general presumption of anticompetitive effects in highly concentrated innovation markets is applicable,[8] in the extreme case of a merger to monopoly that eliminates all competition and diversity in the innovation market, such a presumption seems appropriate.[9] Indeed, applying this presumption of anticompetitive effects is especially appropriate in the pharmaceutical industry, which bears the characteristics described above. The creation of innovation monopolies in such an industry eliminates the all important race-to-innovate aspect of innovation competition, diminishes important diversity in research approaches, and, in light of high entry barriers, increases both the likelihood and the likely duration of a product market monopoly following successful innovation.[10] This concern, moreover, is especially acute where a firm has acquired, over time,

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[8] *See Anticipating the 21st Century, supra* note 2, Ch. 6, at 12 (noting that participants in the hearings on which the report is based "were in agreement only on the general proposition that economic empiricism and analysis have not conclusively demonstrated - *one way or the other* - whether there is a causal link between increased concentration and decreased innovation") (emphasis in the original). *But see Anticipating the 21st Century, supra* note 2, Ch. 6, at 12 -13 ("Business participants who addressed this issue were emphatic that competition is a primary incentive for innovation, and that continuous innovation is critical for success in increasingly global markets."); Section of Antitrust Law, American Bar Association, *The Economics of Innovation: A Survey* 22-28 (2002) (surveying various economic models indicating that competition can encourage innovation in specific circumstances).

[9] *See* William J. Baumol & Janusz A. Ordover, *Antitrust: Source of Dynamic and Static Inefficiencies?, in* ANTITRUST, INNOVATION, AND COMPETITIVENESS 85 (Thomas M. Jorde & David J. Teece eds., 1992) ("It is neither monopoly nor perfect competition that comes off with honors. It is intermediate-sized, not giant-sized, firms that are most propitious for R & D investment, while strong competitive pressures stimulate rapid dissemination and widespread adoption of successful innovative steps."). Indeed, a former Commissioner has already stated that a merger to monopoly of two, closely related, research and development tracks raises competitive concerns. After examining hypothetical facts that somewhat resemble the facts of the present investigation, Commissioner Varney stated that such a merger was likely to reduce an acquirer's incentive to continue its research of the more effective, but less developed product. Christine Varney, *Innovation Markets in Merger Review Analysis*, 9 ANTITRUST 16, 18 (Summer 1995) ("If, for example, a merging researching firm has a history of acquiring competitors with innovative and seemingly successful research projects and then terminating those projects, it may be likely to do so again.").

[10] Suzanne Scotchmer, *Competition Policy and Innovation: The Context of Cumulative Innovation, Hearings on Competition and I.P.*, Feb. 26, 2002, at 137 ("...typically,

all of the research and development tracks of its immediate rivals, and is unencumbered by the threat of timely and sufficient entry.

The suggested presumption of anticompetitive effects from a merger to monopoly in an innovation market could be rebutted by evidence of transaction-specific efficiencies that could not have been achieved in a less restrictive manner.[11] The merging firms, however, must present evidence of cognizable efficiencies that "are of a character and magnitude such that the merger is not likely to be anticompetitive in any relevant market" to rebut the presumption.[12]

Enthusiasm for justifiable enforcement must always be disciplined, however, by pragmatic considerations regarding the ability to achieve effective relief in a given case. Where such concerns are significant, as in some consummated merger settings, prosecutorial discretion might well be appropriate. Specifically, in the pharmaceutical industry case, the overall impact on the patient class, which would not benefit from an undue disruption of the remaining research and development efforts, should also be taken into account.

Nevertheless, I am concerned about the precedent set by the majority's decision to close this case based upon a factual background that appears straightforward: the pharmaceutical industry is extremely dependent on innovation, and races to innovate are common; the structure of this particular innovation market – only two known firms competing to find a cure for a rare

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the patent race will get us the product sooner, and may get us the product with higher probability."); Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEG. STUD. 247, 252 (1994) ("[I]nvestment in research and development is itself a major form of competition and leads directly to consumer benefits in the form of new products and lower prices.").

[11] *Cf.* U.S. Dep't of Justice and Fed. Trade Comm'n, *Horizontal Merger Guidelines*, § 4.0 (Apr. 2, 1992; as revised, Apr. 8, 1997), 4 Trade Reg. Rep. (CCH) ¶ 13,104 ("The Agency will only consider those efficiencies likely to be accomplished with the proposed merger and unlikely to be accomplished in the absence of either the proposed merger or another means having comparable anticompetitive effects. These are termed *merger-specific efficiencies*.") (emphasis in original).

[12] *Id.* ("When the potential adverse competitive effect of a merger is likely to be particularly large, extraordinarily great cognizable efficiencies would be necessary to prevent the merger from being anticompetitive.")

disease – is apparent; the winner of this Orphan Drug Act race would be granted seven years of market exclusivity; the barriers to entry are high; and there was no clear evidence of significant cognizable efficiencies. The decision to close an investigation under these circumstances is puzzling.

The absence of the suggested presumption is troublesome in this consummated merger where evidence of a slowdown in post-merger research exists.[13] In the present case, an unequivocal slowdown – which is inherently hard to detect – appears to have occurred during the course of the Commission's investigation.

Finally, the difficulties created by a presumption-free approach towards mergers to monopoly in innovation markets multiply in the common prospective merger case. Such cases, however, where the determination of effects is inevitably forward-looking, are the more frequent candidates for effective enforcement.

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[13] Prior to the acquisition, Novazyme projected reaching clinical trials at "the end of 2001." Interview of John Crowley, CEO, Novazyme, by International Pompe Association (May 21, 2001), available at http://www.worldpompe.org/internov.html. After the acquisition was consummated, Genzyme initially projected a Novazyme product launch of 2005 and then revised the projection to sometime between 2009 and 2011. Genzyme Corporation, *Form 10-K for the Fiscal Year Ended December 31, 2001,* U.S. Securities and Exchange Commission File No. 0-14680, at GG-24; Genzyme Corporation, *Form 10-K for the Fiscal Year Ended December 31, 2002,* U.S. Securities and Exchange Commission File No. 0-14680, at GG-28; Genzyme Corporation, *Form 10-Q for the Quarterly Period Ended March 31, 2003,* U.S. Securities and Exchange Commission File No. 0-14680, at 77.