Nicolas Charbit Carolina S. Malhado Ellie Yang *Editors*

Douglas H. Ginsburg

An Antitrust Professor on the Bench *Liber Amicorum* Volume I

Alden F. Abbott, Margaret Artz, Anıl Acar, Gary Born, Michelle M. Burtis, John DeQ. Briggs, Terry Calvani, James Cooper, Daniel Crane, Susan Creighton, David S. Evans, Eric M. Fraser, Jamillia P. Ferris, Damien Geradin, Ilene Knable Gotts, Gönenç Gürkaynak, John Harkrider, Joshua Hazan, Thu Hoang, Keith N. Hylton, Jonathan M. Jacobson, Bruce H. Kobayashi, Gregor Langus, Marina Lao, Vilen Lipatov, Ryan S. Maddock, Danielle Morris, Damien Neven, Barak Orbach, James F. Rill, Katarzyna Sadrak, Jana I. Seidl, Hal S. Scott, D. Daniel Sokol, Jacques Steenbergen, Richard M. Steuer, Pablo Trevisán, Esra Uçtu, Nils Wahl, Joshua D. Wright



DOUGLAS H. GINSBURG An Antitrust Professor on the Bench

Liber Amicorum - Volume I

Foreword by Joshua Wright

Editors

Nicolas Charbit Carolina Malhado Ellie Yang

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Foreword

JOSHUA WRIGHT

It is our great honor and privilege to present this Liber Amicorum to Judge Douglas H. Ginsburg. I admit I also introduce this volume with some hesitation. For one usually introduces a volume such as this to mark the end of a distinguished career. And a distinguished career it has been. But as a significant beneficiary of Judge Ginsburg's scholarly endeavors at Scalia Law School, his guiding hand at the Global Antitrust Institute at George Mason University, and his friendship, I am particularly fond of the status quo.

Judge Ginsburg received a Bachelor of Science degree from Cornell University and his JD from the University of Chicago Law School. He then served as a clerk for Judge Carl McGowan on the D.C. Circuit and for Justice Thurgood Marshall on the Supreme Court. Following his clerkships, Judge Ginsburg began his career in academia at Harvard Law School in 1975.

Judge Ginsburg later became the Administrator of the Office of Information and Regulatory Affairs (OIRA) and then the Assistant Attorney General for the Antitrust Division of the Department of Justice. In 1987, he was nominated to the Supreme Court of the United States. Judge Ginsburg served on the D.C. Circuit Court of Appeals for more than 30 years, including as Chief Judge from 2001 to 2008. During this time, he also taught part-time at George Mason University School of Law. After taking senior status on the D.C. Circuit, Judge Ginsburg continued his career in academia teaching full time at NYU Law in 2012. He later returned to Scalia Law School at George Mason University, where he continues to serve as a Professor of Law and as the Chairman of the International Advisory Board of the Global Antitrust Institute.

A robust and full Liber Amicorum could focus exclusively upon Judge Ginsburg's impactful role as a jurist, or his contributions as legal scholar, or his commitment to public service, or his mentorship as a teacher. This challenge in fully capturing Judge Ginsburg's contributions in such a volume is to explore these dimensions of achievement individually as well as to take this opportunity to reflect upon their interactions.

The essays in this Liber Amicorum take up this challenge admirably. Practitioners, economists, and legal scholars explore the multiple dimensions of the footprint Judge Ginsburg has left in antitrust's landscape. Some explore in depth the impact Judge Ginsburg's opinions and scholarship have had in specific areas of antitrust jurisprudence: horizontal restraints, the intersection of intellectual property rights and antitrust, and international antitrust. Others focus more broadly upon how we should think about Judge Ginsburg's intellectual legacy and public service. The Liber Amicorum ties together these multiple dimensions of production and service to recognize and appreciate the full fruits of Judge Ginsburg's labors in the domestic and global antitrust community.

Judge Ginsburg is remarkably generous with his time and his wisdom with colleagues, students, legal academics, clerks, and practitioners alike. He is a source of advice and counsel for those who need it, of substantive intellectual feedback for those who seek it, and of mentorship for those fortunate enough to cross his path. The beneficiaries of his generosity range from antitrust luminaries and agency leadership around the world to aspiring law students. I would be remiss if I did not acknowledge the tremendous intellectual and personal debt I owe Judge Ginsburg as a colleague, co-author, co-venturer, and friend. I intend to run that debt even deeper in the years to come as I further benefit from Judge Ginsburg's continued dedication and commitment to his work. And so I hope selfishly – but no doubt joined by the international antitrust community that benefits from Judge Ginsburg's insights and wisdom – this Liber Amicorum is necessarily incomplete and leaves room for contributions yet realized.

Contributors

Alden F. Abbott The Heritage Foundation

Margaret Artz WilmerHale

Anil Acar ELIG, Attorneys-at-Law

Gary Born WhilmerHale

Michelle M. Burtis CRA International

John DeQ. Briggs Axinn

Terry Calvani Freshfields Bruckhaus Deringer

James C. Cooper George Mason University Antonin Scalia Law School

Daniel A. Crane University of Michigan Law School

Susan A. Creighton Wilson Sonsini Goodrich & Rosati

David S. Evans Global Economics Group

Eric M. Fraser Osborn Maledon

Jamillia P. Ferris Wilson Sonsini Goodrich & Rosati

Damien Geradin EUCLID Law

Ilene Knable Gotts Wachtell, Lipton, Rosen & Katz **Gönenç Gürkaynak** ELIG, Attorneys-at-Law

John D. Harkrider Axinn

Joshua Hazan Wachtell, Lipton, Rosen & Katz

Thu Hoang Wilson Sonsini Goodrich & Rosati

Keith N. Hylton Boston University School of Law

Jonathan M. Jacobson Wilson Sonsini Goodrich & Rosati

Bruce H. Kobayashi George Mason University Antonin Scalia Law School

Gregor Langus European Commission

Marina Lao Seton Hall University School of Law

Vilen Lipatov Compass Lexecon

Ryan S. Maddock Wilson Sonsini Goodrich & Rosati

Danielle Morris WilmerHale

Damien Neven Graduate Institute of International and Development Studies

Barak Orbach University of Arizona James E. Rogers College of Law James F. Rill Baker Botts

Katarzyna Sadrak EUCLID Law

Jana I. Seidl Baker Botts

Hal S. Scott Harvard Law School

D. Daniel Sokol University of Florida Levin College of Law

Jacques Steenbergen Belgian Competition Authority

Richard M. Steuer Mayer Brown

Pablo Trevisán Comisión Nacional de Defensa de la Competencia

Esra Uçtu ELIG, Attorneys-at-Law

Nils Wahl Court of Justice of the European Union

Joshua D. Wright George Mason University Antonin Scalia Law School

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Judge Douglas H. Ginsburg Biography

Career

Senior Circuit Judge Douglas H. Ginsburg was appointed to the United States Court of Appeals for the District of Columbia in 1986; he served as Chief Judge from 2001 to 2008. After receiving his B.S. from Cornell University in 1970, and his J.D. from the University of Chicago Law School in 1973, he clerked for Judge Carl McGowan on the D.C. Circuit and Justice Thurgood Marshall on the United States Supreme Court. Thereafter, Judge Ginsburg was a professor at the Harvard Law School, the Deputy Assistant and then Assistant Attorney General for the Antitrust Division of the Department of Justice, as well as the Administrator of the Office of Information and Regulatory Affairs in the Office of Management and Budget. Concurrent with his service as a federal judge, Judge Ginsburg has taught at the University of Chicago Law School and the New York University School of Law. Judge Ginsburg is currently a Professor of Law at the Antonin Scalia Law School, George Mason University, and a visiting professor at University College London, Faculty of Laws.

Judge Ginsburg is the Chairman of the International Advisory Board of the Global Antitrust Institute at the Antonin Scalia Law School, George Mason University. He also serves on the Advisory Boards of: Competition Policy International; the Harvard Journal of Law and Public Policy; the Journal of Competition Law and Economics; the Journal of Law, Economics and Policy; the Supreme Court Economic Review; the University of Chicago Law Review; The New York

University Journal of Law and Liberty; and, at University College London, both the Center for Law, Economics and Society and the Jevons Institute for Competition Law and Economics.

Education

Judge Ginsburg obtained his B.S. degree from Cornell University in 1970 and his J.D. from the University of Chicago Law School in 1973.

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Innovations Market Analysis: Twenty Years On

SUSAN A. CREIGHTON JAMILLIA P. FERRIS THU HOANG RYAN S. MADDOCK^{*} Wilson Sonsini Goodrich & Rosati

Abstract

Concerns about innovation are often front-and-center in merger review and are regularly expressed by regulators, policy makers, and other stake-holders. However, the antitrust agencies have provided little guidance on how they define and examine innovation *markets* as distinct from a lessening of innovation competition in traditionally-defined product markets. It has been over 20 years since the FTC last explicitly addressed innovation markets in a policy statement and 13 years since then-Chairman Muris's influential closing statement in Novazyme/Genzyme explained how mergers could enhance innovation. With a new administration beginning its work at the FTC and DOJ—and innovation concerns continuing to be an area of policy focus around the globe, it is the right time for a reexamination of innovation market analysis and the latest economic thinking. In this article, we review the FTC's findings on innovation markets expressed in there 1996 report

^{*} The authors practice antitrust law at Wilson Sonsini Goodrich & Rosati. The views expressed are their own, and not those of the firm or any firm client.

on competition policy in high-tech markets, the subsequent United States and European Union innovation markets cases, recent developments in economic literature about how mergers influence innovation, and ultimately argue that the time is ripe for agencies to clarify their thinking on this important issue.

I. Introduction

Megan Crowley was just fifteen months old when she was diagnosed with Pompe disease, a rare genetic disorder. Her doctors believed she would not live to see her sixth birthday. John Crowley, determined to save his daughter Megan, started a company called "Novazyme" that focused on developing a treatment for this fatal disease. Although Novazyme's enzyme never made it to market, it became part of a company (Genzyme) that ultimately developed a treatment for Pompe disease that saved Megan's life. Now, almost twenty years later, she is a junior at Notre Dame University (and an avid blogger),¹ and among those whose encouraging life stories were noted by President Trump during an address to a joint session of the United States Congress in early 2017.

The Crowleys' story helps to illustrate the important real-world dimensions that can lie behind the seemingly-abstract innovation competition issues that can arise in antitrust merger reviews, such as those that were at issue in the Federal Trade Commission's (FTC or Commission) 2004 review of Genzyme's acquisition of Novazyme. At the time of the merger, Genzyme and Novazyme were the only two companies active in the development of an enzyme replacement therapy for Pompe disease. In closing the post-merger investigation of the transaction, a majority of the FTC's commissioners determined that the merger was likely to increase the chances of the parties successfully and quickly developing a drug, "and thus patients' lives [we]re more likely to be saved by this merger than to be put at risk."² With the happy coda of Megan Crowley's success, we now know that what seemed

¹ Megan Crowley, HIGH HEELED WHEELS, https://highheeledwheels.com.

² Timothy J. Muris, Chairman, Fed. Trade Comm'n, Statement in the Matter of Genzyme Corp. and Novazyme Pharm., Inc., FTC File No. 021-0026 (Jan. 13, 2004), https://www.ftc.gov/ system/files/attachments/press-releases/ftc-closes-its-investigation-genzyme-corporations-2001-acquisition-novazyme-pharmaceuticals-inc./murisgenzymestmt.pdf.

like no more than a distant hope at the time of the FTC's analysis ultimately became a life-saving reality.

With concerns about innovation competition playing a front-and-center role in the review of recent transactions both in the United States and the European Union, it is perhaps a good time to review antitrust law's experience with analyzing innovation competition in the context of "innovation markets"—a concept first introduced into antitrust merger review in the mid-1990s, which was front and center in the FTC's *Novazyme/Genzyme* review. The consideration of an "innovation market" was, and is, different from analysis of a merger's effect on innovation *competition*. Harm to innovation competition is alleged when there is evidence that the merging firms' drive to innovate or introduce new or improved products will be reduced, resulting in harm to a specific relevant product market.³ An analysis of innovation competition thus focuses on competitive harm in an identifiable *product* market.⁴ In contrast, the cases and doctrine which are the focus of this article examine merger challenges that specifically allege harm to *innovation or R&D* markets—that is, the proposed merger would reduce the number of entities engaged in a development or R&D activity, which in turn would harm competition.

This article will begin by discussing the FTC's 1995 hearings and subsequent report titled, *Anticipating the 21st Century: Competition Policy in the New High-Tech, Global Marketplace* (1996 Report), which summarized the then-current economic understanding of issues relating to "innovation and the assessment of competitive effects" in innovation markets—an idea that was introduced into U.S. antitrust analysis in the *Antitrust Guidelines for the Licensing of Intellectual Property* (IP Guidelines) issued in 1995. *Second*, this article will discuss United States and European Union merger cases in which antitrust enforcers have found or appear to have considered competitive harm in innovation markets in sectors

³ Gilbert and Greene studied FTC and DOJ merger challenges from 2004-2014 and found that the agencies cited innovation concerns in approximately 34% of the challenges. The authors also found that the agencies are more likely to cite innovation concerns when challenging a merger in an R&D intensive industry. Richard J. Gilbert & Hillary Green, *Merging Innovation into Antitrust Agency Enforcement of the Clayton Act*, 83 GEO. WASH. L. REV. 1919 (2015).

⁴ Terrell McSweeny, Comm'r, Fed. Trade Comm'n, Competition Law: Keeping Pace in a Digital Age, Keynote Remarks at 16th Annual Loyola Antitrust Colloquium, at 3-5 (Apr. 15, 2016), https://www.ftc.gov/system/files/documents/public_statements/945343/mcsweeny_-loyola_ antitrust_colloquium_keynote_4-15-16.pdf (citing recent merger challenges examples of harm to innovation in merger analysis).

where R&D is secret (which is the case in most industries). *Third*, this article will examine how innovation market analysis is applied to pharmaceutical mergers, which is a special case because pharmaceutical manufacturers have uniquely transparent R&D pipelines. *Finally*, this article will examine recent economic analysis of innovation markets and argue that the time is ripe for the antitrust agencies to update the FTC's 1996 Report in light of the agencies' experience in applying innovation market analysis as well as economic learning gained in the twenty years since the report was issued.

II. The FTC's 1996 Report

In late 1995, the FTC held twenty-three days of hearings "on whether there [had] been broad-based changes in the contemporary competitive environment that warrant[ed] any adjustments in competition and consumer protection policy[.]"⁵ During the extensive hearings, more than 100 witnesses testified on a broad range of topics. These witnesses were some of the most important antitrust thinkers of the day and included three future FTC Commissioners, Tim Muris, Bill Kovacic, and Tom Rosch, as well as Joseph Stiglitz, Steve Salop, Herbert Hovenkamp, and numerous other scholars, economists, and business leaders. The hearings resulted in the extensive, 304-page, 1996 Report.

One of the most influential chapters in the FTC's report addressed "innovation and the assessment of competitive effects" and discussed innovation markets, their role in merger analysis, and how they differed from the "potential competition doctrine."⁶ The IP Guidelines, when introducing the concept of innovation markets in 1995, defined an innovation market as "the research and development directed to particular new or improved goods or processes, and the close substitutes for that research and development."⁷ In a speech describing the IP Guidelines, then-Deputy Assistant Attorney General Richard Gilbert explained "[u]sing an innovation

⁵ U.S. FED. TRADE COMM'N, ANTICIPATING THE 21ST CENTURY: COMPETITION POLICY IN THE NEW HIGH-TECH, GLOBAL MARKETPLACE, Appendix B (1996) [hereinafter 1996 REPORT].

⁶ See id. ch. 7.

⁷ U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY (1995), reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,132, https://www. justice.gov/sites/default/files/atr/legacy/2006/04/27/0558.pdf [IP GUIDELINES].

market to analyze competitive effects is appropriate if the competitive effects of an arrangement cannot be adequately analyzed in conventional product markets."⁸

When the FTC issued the 1996 Report, the idea of an "innovation market" and the method by which to assess anticompetitive reductions in competition in such markets remained uncertain and controversial.⁹ In particular, as explained in the report, innovation market analysis is "somewhat unusual" because it requires consideration of anticompetitive conduct that "would take place in the current market in which innovation competition is occurring, but the anticompetitive effects would only become manifest in the future, and then only as 'non-events,' rather than 'events.'"¹⁰ The FTC explained that these "non-events" could take several forms, the most obvious of which would be the loss of an innovation that would have occurred but-for the merger; however, competitive harm could also arise if the innovated product was inferior to the product that would have been introduced but-for the merger world.¹¹ The report cautioned that when assessing competitive harm, antitrust analysis should focus on anticompetitive conduct.¹²

Further, the 1996 Report addressed two "basic categories of objections" to the analysis of innovation markets in antitrust cases: (a) whether there was a relationship between concentration and innovation, and (b) whether any firm could monopolize innovation. With respect to the first category, the FTC reported that several hearing participants concluded that there was insufficient economic evidence to determine that there was a correlation between market concentration and reductions in innovation and therefore antitrust "cannot predict with any confidence specific individual circumstances in which increased concentration would be likely to lead

- 11 Id.
- 12 Id. at 15.

⁸ Richard J. Gilbert, Deputy Assistant Att'y Gen., U.S. Dep't of Justice, The 1995 Antitrust Guidelines for the Licensing of Intellectual Property: New Signposts for the Intersection of Intellectual Property and the Antitrust Laws, Address at the ABA Section of Antitrust Law Spring Meeting (Apr. 6, 1995), https://www.justice.gov/atr/speech/1995-antitrust-guidelineslicensing-intellectual-property.

^{9 1996} REPORT, *supra* note 5, ch. 7, at 1-2.

¹⁰ Id. at 14.

to competitive effects on innovation."¹³ Richard T. Rapp, President of National Economic Research Associates, opined that "[a] decrease in the number of firms engaged in related or overlapping R&D projects does not reliably signal whether total R&D activity or innovation output in the market will either increase or decrease as a result."14 Some experts at the hearings further argued that without robust economic theory behind agency enforcement actions, the FTC would risk harming innovation through over-enforcement.¹⁵ For example, it is unquestionably procompetitive if a merged firm could produce the same innovation for less investment than the two firms operating independently. Even though the total R&D dollars on the project decreased, consumers still receive the same innovation and the postmerger firm is free to use that excess capital in other procompetitive ways.¹⁶ In this example, a regulator may be tempted to simply look at the reduction in R&D expenditures and conclude that the proposed transaction harmed innovation, rather than evaluate whether the merger was actually pro-competitive through a more efficient allocation of R&D spending. With respect to the second objection, multiple witnesses argued that it is extremely difficult to monopolize innovation, and thus "the use of innovation market analysis to assess a merger's competitive effects is unnecessary."¹⁷ Witnesses argued that a firm's attempts to monopolize innovation would fail because "there are likely many other technologies from which alternatives to current innovation efforts could develop" and that there was little evidence to support the theory that "research [was] being anticompetitively suppressed."¹⁸

The FTC addressed both arguments but ultimately concluded that the agency should consider innovation markets where the facts dictate it. The FTC acknowledged that "it may be difficult to distinguish between procompetitive and anticompetitive combinations of innovation efforts" and further agreed that "antitrust enforcers should not equate R&D expenditures" with a "fail-safe measure" of a merger's effect on innovation.¹⁹ Nonetheless, the report asserts that economics,

- 15 Id. at 17.
- 16 Id.
- 17 Id. at 20.
- 18 Id. at 20-21.
- 19 Id. at 19.

¹³ Id. at 16.

¹⁴ Id. at 17, n.51.

most notably Kenneth Arrow's seminal work *Economic Welfare and the Allocation* of *Resources for Invention*,²⁰ had identified a number of specific circumstances where a monopolist would have a disincentive to invest in future innovation or would be incentivized to end or reduce current innovation efforts. In particular, this is the case if the innovation could result in a product that would likely "cannibalize sales of the monopolist's current product."²¹ The key to balancing concerns about under- and over-enforcement in innovation markets, the report argues, is "a careful, intense factual investigation" to determine whether reductions in R&D would generate procompetitive efficiencies or harm consumers through reductions in innovation.²²

The FTC also asserted that while there may be several situations where it is unlikely that a firm could monopolize innovation, there are other examples where a merger could significantly harm consumers and reduce innovation. To illustrate their argument, the FTC hypothesized a merger of two pharmaceutical firms:

[S]uppose a proposed merger would combine two innovation efforts competing toward the development of drugs for the same indication, and each innovation effort was within two years of FDA approval, with a third effort about seven years away from FDA approval. In such circumstances, the merged firm could slow innovation efforts for as much as five years before any other firm could catch up.²³

Several of the witnesses at the hearings argued that antitrust agencies should use the more-developed potential competition doctrine²⁴ to assess a merger's impact on innovation—an argument the FTC rejected because it would likely lead to over-enforcement by assuming that the post-merger firm would eliminate or reduce

23 Id. at 21.

²⁰ Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention, in* Essays IN THE THEORY OF RISK-BEARING 144, 157 (3d ed. 1976).

^{21 1996} REPORT, *supra* note 5, ch. 7, at 19.

²² Id. at 20.

²⁴ The report noted that there are two distinct iterations of the potential competition doctrine: (1) "actual potential competition," which asks "whether a potential merger might prevent the deconcentration of already concentrated market," and (2) "perceived potential competition," which "focuses on whether a potential merger might eliminate a "perceived potential entrant" whose presence already has a procompetitive effect on the market." However, the FTC focused its analysis on arguments related only to actual potential competition. *Id.* at 23.

one of the parties' innovation efforts.²⁵ For example, a post-merger firm could have the incentive to continue both firms' pre-merger innovation efforts or could combine those efforts but actually increase their R&D investments or, through the consolidation, increase the likelihood that their investment will yield a marketable product.²⁶ Potential competition analysis does not consider either of these alternatives because it addresses an *existing* product rather than a *future* product improvement or an entirely new product. Questions about how a merger will impact a firm's incentives to innovate are inherently fact-specific and, the FTC argued, require their own unique analytical doctrine.²⁷

Lastly, the FTC offered guidance on how and when agencies should employ the innovation market analysis. *First*, the report noted that a merger is only likely to generate innovation market concerns where there are a "very small number of innovation competitors."²⁸ Referencing the IP Guidelines, the 1996 Report noted that it may be advisable to determine that the presence of a certain number of competitors creates a safe harbor where agencies will assume that the merger will not harm the innovation market.²⁹ *Second*, the FTC tackled how exactly antitrust law should define an innovation market. The report explained that some commentators have argued that agencies should look to "specialized assets" to determine whether different firms' innovation efforts are substitutable.³⁰ However, the Commission ultimately concluded that even this analysis required the identification of an ultimate goods market. Thus, the FTC concluded that the IP Guidelines' focus on "research and development directed to particular new or improved goods

²⁵ Id. at 27-29.

²⁶ For example, the actual potential competition doctrine does not "reveal whether the merged firm would have increased abilities or incentives to eliminate the existing widget innovation effort. It might or it might not, depending on facts such as the size of its market share in the current widget market (which would indicate the extent to which it was already earning monopoly profits) and the likely competitive significance of the improvement targeted by the widget innovation effort." *Id.* at 37.

²⁷ Id. at 32.

²⁸ Id. at 33.

²⁹ However, the report also cautioned that "the usual caveats should apply -- that is, extraordinary circumstances might warrant a challenge even in "safe harbor" circumstances, and the secrecy of R&D might preclude an application of the safe harbor criteria." *Id.*

³⁰ Id. at 34.

or processes' seem[ed] most useful."³¹ Third, the FTC addressed and rejected arguments that the innovation market analysis should only apply to unilateral effects theories and explained that while unilateral effects issues were substantially more likely, "coordinated interaction regarding innovation is clearly not impossible."³² Fourth, the agency provided guidance on how to apply the 1992 Horizontal Merger Guidelines entry analysis in the context of an innovation market; that is, whether entry would be "timely, likely, and sufficient,"³³ and thus could alleviate any anticompetitive concerns. The Commission noted that there was insufficient research into what incentivizes firms to invest in new innovation efforts to adopt "general standards specifically tailored to entry into innovation markets[.]"³⁴ Nonetheless, the FTC stated that in markets where innovation is "typically secret and unobservable," there is no reason to expect entry to mitigate anticompetitive effects because neither the potential entrants nor the post-merger incumbent can observe the other's innovation efforts, and thus those efforts will not alter their incentives or behavior. However, in markets where competitors can obverse each other's R&D efforts, as in pharmaceutical markets, the entry analysis should ask whether there are firms that have:

(1) "core competencies" (and the ability to acquire specialized assets) that give them the ability to enter into competing R&D efforts, and (2) the incentive to enter into competing R&D in response to post-merger reductions in innovation efforts.³⁵

³¹ The report further noted that "in asking whether a firm possessed 'specialized assets,' one would need to ask: 'specialized assets necessary to produce what types of goods?'" *Id.*

³² *Id.* at 35 ("For example, effective punishment may be available if the parties are in repeat relationships or if there is an ability to punish in a goods market. Therefore, although the agencies may find that anticompetitive effects are primarily unilateral, the possibility of coordinated interaction should not be ruled out until there has been a factual analysis of the particular situation.").

³³ The 1992 Merger Guidelines instruct agencies to determine whether "entry would be timely, likely, and sufficient in its magnitude, character and scope to deter or counteract the competitive effects of concern." U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDE-LINES § 3.0 (1992, rev. 1997), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 20,573-9 to -11.

^{34 1996} REPORT, *supra* note 5, ch. 7, at 38.

³⁵ Id. at 39.

Finally, the FTC noted that mergers could produce efficiencies by allowing the post-merger firm to reduce duplicative R&D efforts but cautioned against classifying reductions in procompetitive research efforts as efficiencies.³⁶

III. Innovation Market Cases Involving Non-Public R&D

While merger challenges that allege harm involving innovation markets are relatively uncommon, there have been a few such cases, both in the United States and the European Union. For the most part, the analyses in these cases have tracked the FTC's suggestions in the 1996 Report. Certain of these cases, described below, involved R&D that are not observable in the marketplace but arise in highly concentrated markets that require specialized assets to compete and possess exceptionally high barriers to entry.³⁷

1. ZF Friedrichshafen / General Motors

Among the earliest of the innovation market cases (which in fact preceded the 1996 Report) was the U.S. Department of Justice (DOJ) challenge in 1993 to the proposed merger of ZF Friedrichshafen, AG (ZF) and the Allison Transmission Division (Allison) of General Motors Corporation.³⁸ The DOJ alleged that the transaction would harm price competition in the markets for automatic transmissions for transit buses and heavy refuse route trucks. In addition, the DOJ asserted that the merger would harm competition in the market for "technological innovation in the design, development, and production of medium and heavy automatic transmission for commercial and military vehicles (Innovation Market)."³⁹ The

39 Id. at 6, 9-10.

³⁶ Id. at 39-40.

³⁷ The 1996 Report noted the different entry analysis called for based on whether R&D efforts are secret or observable. Benjamin Kern, an economist who authored an innovation market study, described later in this article, also has distinguished between innovation market cases involving "unobservable" versus "observable" R&D. See Benjamin R. Kern, Innovation Markets, Future Markets, or Potential Competition: How Should Competition Authorities Account for Innovation Competition in Merger Reviews?, 37 WORLD COMPETITION: L. & ECON. REV. 173 (2014).

³⁸ Complaint, United States v. Gen. Motors Corp. (D. Del. 1993) (No. 93-530).

complaint further alleged that the two firms had a history of vigorously competing on innovation; specifically, Allison made substantial investments to improve its existing products and to develop a new line of transmissions in response to ZF's entry into the U.S. market.⁴⁰ Moreover, the DOJ asserted that entry was unlikely because a firm would need, "among other things, a full scale automatic transmission production facility" to successfully compete in the Innovation Market. Finally, the DOJ asserted that the parties had a combined 89% share of that market.⁴¹ The parties abandoned the transaction after the DOJ filed its complaint.

Although the case pre-dates the 1996 Report, the DOJ complaint is consistent with the analysis that the FTC recommended. In particular, the DOJ alleged high concentration in the Innovation Market, the need for specialized assets to compete, and that timely and effective entry to mitigate the loss of innovation competition was unlikely. In fact, the 1996 Report cited to this case as an example of where the specialized assets requirement was built into the innovation market analysis. Finally, although the complaint did not expressly address efficiency issues, the DOJ appeared to imply that the deal would not generate substantial efficiencies by highlighting evidence that ZF proposed the merger for the specific purpose of eliminating the threat of competition from Allison.⁴²

2. Lockheed Martin / Northrop Grumman

A few years later, in 1998, the DOJ sought to enjoin the proposed acquisition of Northrop Grumman Corporation (Northrop) by Lockheed Martin Corporation (Lockheed). Both firms are manufacturers of military electronics systems and aircrafts and their only other meaningful competitor was Boeing. The complaint alleged that the transaction would result in the elimination of horizontal competition in specific product markets as well as vertical foreclosure.⁴³ But the complaint also

⁴⁰ *Id.* at 11-13 (arguing that the merger "would result in the elimination of competition in the Innovation Market and harm 'purchasers of automatic transmissions' through the loss of the fruits of the innovation").

⁴¹ The complaint used "the number of units produced worldwide" as a proxy for market share in the Innovation Market because of "the importance of production and customer experience in the innovation process." *Id.* at 12-13.

⁴² The DOJ alleged that ZF chose to acquire Allison "to counter the attack of Ally [Allison] against the European market and the rest of the world." *Id.* at 11.

⁴³ Complaint at 1-4, United States v. Lockheed Martin Corp. (D.D.C. 1998) (No. 1:98-CV-00731(EGS)).

made clear that DOJ was concerned about the loss of innovation competition, stating that with respect to high performance fixed-wing military aircraft

[t]he loss of Northrop as an independent entity will reduce the number of companies to which the DoD [Department of Defense] can turn to design, develop, and produce high performance fixed-wing military aircraft from three to two. The DoD relies on a competitive process to develop and produce aircraft for our nation's military defenses Competition is vital to maximize both the innovative ideas associated with each military aircraft program, as well as the quality of the processes used to turn innovative ideas into cost-effective, technically sound, and efficiently produced aircraft. The acquisition will lessen competition at all phases of the process that DoD employs to procure military aircraft, including the early phases where many innovative ideas are born.⁴⁴

While the complaint identified specific product markets and concerned the loss of price and innovation competition, the DOJ appeared most focused on the loss of defense technology innovation generally. In a subsequent speech, John M. Nannes, then-Deputy Assistant Attorney General of the Antitrust Division, explained that, in the context of defense markets it is "very easy to articulate the ways in which a decline in innovation could have an adverse effect . . . reduction in the pace of innovation could literally have life-and-death implications for our servicemen and women."⁴⁵ Nannes also indicated that, after a fact-intensive review, the DOJ concluded that in defense markets "technological breakthroughs have often been made, not by the dominant supplier of military systems, but by niche players or leading firms working outside their main areas of specialization," and thus one competitor was not enough to ensure a competitive market—even when that market was "characterized by lumpy purchases and high research-and-develop expenditures."⁴⁶

Likewise, Constance K. Robinson, then-Director of Operations and Merger Enforcement at the DOJ, noted that "while the complaint alleged significant price effects, [it is] fair to say the principal driver of [the DOJ's] challenge was the

46 Id.

⁴⁴ Id. at 26-27.

⁴⁵ John M. Nannes, Deputy Assistant Att'y Gen., U.S. Dep't of Justice, Address at the National Institute on Representing High Technology Companies: Antitrust in an Era of High-Tech Innovation (Oct. 22, 1998), https://www.justice.gov/atr/speech/antitrust-era-high-tech-innovation.

merger's effect on innovation.^{"47} Specifically, Robinson noted three distinct reasons that the DOJ was concerned about the merger's impact on innovation. *First*, the Pentagon's acquisition cycle creates a situation where "most of the critical competitive events occur at a very early stage, when costs and prices are extremely uncertain," and thus it is beneficial to have several firms attempting an innovation.⁴⁸ *Second*, "innovation is often achieved in response to external military threats that change rapidly and are unpredictable, requiring that we maintain a number of firms with the capability of innovating to meet future national security challenges."⁴⁹ *Third*, the nation's defense requires firms to undertake risky and "cutting-edge innovations," and entrenched incumbents are less likely to take those risks absent considerable innovation competition.⁵⁰ To underscore her point, Robinson noted that in 1990 there were eight U.S. military aircraft companies and by 1999 that number had dropped to three, two of which were attempting to merge.⁵¹

The DOJ may not have explicitly used the innovation market analysis with respect to any single product market; however, the competitive concerns enumerated in the complaint track with the analytical framework the FTC laid out in the 1996 Report. Unsurprisingly, the development of defense technology requires specialized assets including "advanced technology, skilled engineers, testing facilities, and specialized equipment."⁵² The complaint also noted that the product markets were characterized by high barriers to entry and few market incumbents.

3. Applied Materials / Tokyo Electron

Innovation markets were also center stage in the DOJ's announcement on April 27, 2015 that Applied Materials, Inc. (Applied Materials) and Tokyo Electron Ltd. (Tokyo Electron) had abandoned their plans to merge after the DOJ rejected their remedy proposal. At the time, Applied Materials and Tokyo Electron were the first

- 49 Id.
- 50 Id.

52 Complaint at 23, United States v. Lockheed Martin Corp. (D.D.C. 1998) (No. 1:98CV00731(EGS).

⁴⁷ Constance K. Robinson, Dir. of Operations & Merger Enf't, U.S. Dep't of Justice, Address before the American Bar Association 12-13 (June 10, 1999), https://www.justice.gov/atr/ file/518626/download.

⁴⁸ Id. at 13.

⁵¹ Id. at 13-14.

and fourth largest manufacturers of semiconductor manufacturing equipment, respectively.⁵³ The parties had publicly stated that they were not concerned about regulatory clearance because their businesses were highly complementary with only a few overlapping product lines.⁵⁴ Where the parties directly competed, combined shares were estimated to be unproblematic.⁵⁵ In fact, at least two competition agencies, the German *Bundeskartellamt* and Competition Commission Singapore, agreed that the transaction did not raise significant competition concerns and cleared the transaction.

⁵³ BUNDESKARTELLAMT, Case Summary: Clearance of Merger between Tokyo Electron and Applied Materials (Nov. 24, 2014), http://www.bundeskartellamt.de/SharedDocs/Entscheidung/EN/ Fallberichte/Fusionskontrolle/2014/B5-138-13.pdf?_blob=publicationFile&v=2.

⁵⁴ Financial News Release, Applied Materials, Applied Materials and Tokyo Electron to Combine, Creating a New Global Innovator to Serve the Semiconductor and Display Industries, (Sep. 24, 2013), http://investors.appliedmaterials.com/phoenix.zhtml?c=112059&p=irolnewsArticle&ID=1857330&highlight ("This combination, which has been unanimously approved by the Boards of Directors of both companies, brings together complementary leading technologies and products to create an expanded set of capabilities in precision materials engineering and patterning that are strategically important for customers."); TOKYO ELECTRON, Investor Relations: FY2015 Earnings Release Conference Q&A, http://www.tel.com/ir/library/report/2015/fy2015q4. htm ("There is little overlap with Applied Materials in our product mix so we did not expect this business combination to fall under antitrust regulations. However, it seems that regulators also looked at products under development which are not subject to competition, and this was beyond our expectations."); see also BUNDESKARTELLAMT, supra note 53 (noting that "[t]here are only overlaps in the activities of Tokyo Electron and Applied Materials on nine individual markets" and only closely examining the dielectric etch (including bump) market where it found no competitive concern); COMPETITION COMMISSION SINGAPORE, Grounds of Decision Issued by the Competition Commission of Singapore: In relation to the notification for decision of the proposed merger between Applied Materials, Inc. and Tokyo Electron Limited pursuant to section 57 of the Competition Act (Sept. 23, 2014), https://www.ccs.gov.sg/~/media/custom/ccs/files/public%20 register%20and%20consultation/public%20consultation%20items/proposed%20merger%20 between%20applied%20materials%20inc%20and/grounds20of20decision2020proposed20merger-20between20applied20materials20and20tokyo20electronpublic202320sept2014.ashx (noting overlap in seven markets where only one-i.e., dielectric etch (including bump)-had sales in Singapore and finding that the transaction will not lead to competition concerns).

⁵⁵ Doyle, Barlow & Mazard PLLC, Mergers that Diminish Innovation Present Deal Risk, ANTITRUST LAWYER BLOG (May 7, 2015), https://www.antitrustlawyerblog.com/2015/05/mergers-that-raisefuture-competition-concerns-present-deal-risk.html; Yigal Grayeff, Applied Materials optimistic that deal will be approved, SEEKINGALPHA (Sep. 25, 2013), https://seekingalpha.com/ news/1297612-applied-materials-optimistic-that-deal-will-be-approved (Executive Chairman Mike Splinter stating that "[w]here we actually compete, there is very, very little overlap."); Pallavi Guniganti, DoJ causes Applied/Tokyo deal collapse on innovation markets, GLOBAL COMPETITION REVIEW (Apr. 27, 2015), http://globalcompetitionreview.com/article/1062071/ doj-causes-applied-tokyo-deal-collapse-on-innovation-worries (noting that Applied Materials CFO stated that the parties spent a lot of time looking at their overlaps, which were nominal).

The DOJ, however, stated that the transaction "would have combined the two largest competitors with the necessary know-how, resources and ability to develop and supply high-volume non-lithography semiconductor manufacturing equipment."⁵⁶ The DOJ found that the parties' undisclosed remedy proposal was "insufficient to protect competition and future innovation"⁵⁷ for the "development of equipment for next-generation semiconductors."⁵⁸ The parties "strongly disagreed with the DOJs conclusions" stating that the merger was more likely to accelerate innovation, through the combination of complementary research and development, rather than slow it down.⁵⁹

Without a published complaint, it is unclear whether the DOJ followed the approach articulated in the 1996 Report. While the market for future innovation in semiconductor manufacturing equipment requires specialized assets and has potentially high barriers to entry, the industry was not concentrated.⁶⁰ The merged entity would have had less than a 30% share of the worldwide market for such equipment.⁶¹

- 59 Guniganti, supra note 55.
- 60 Notably, the Competition Commission Singapore found that "barriers to entry are not insurmountable but significant resources and time would have to be invested by any new potential entrant before they can be considered a significant competitive constraint." COMPETITION COMMISSION SINGAPORE, *supra* note 54.
- 61 COMPETITION COMMISSION SINGAPORE, *supra* note 3; Press Release Gartner Inc., Worldwide Semiconductor Manufacturing Equipment Spending Declined 16% in 2012, According to Final Results (Apr. 22, 2013), http://www.gartner.com/newsroom/id/2441915.

⁵⁶ Press Release, U.S. Dep't of Justice, Applied Materials Inc. and Tokyo Electron Ltd. Abandon Merger Plans After Justice Department Rejected Their Proposed Remedy (Apr. 27, 2015), https://www.justice.gov/opa/pr/applied-materials-inc-and-tokyo-electron-ltd-abandon-mergerplans-after-justice-department.

⁵⁷ Hearing on Oversight of the Enforcement of the Antitrust Laws Before the Subcomm. on Antitrust, Competition Pol'y & Consumer Rights Comm. on the Judiciary U.S. S. (March 9, 2016) (statement by Bill Baer, Assistant Att'y Gen., U.S. Dep't of Justice, Antitrust Div.), https:// www.justice.gov/opa/file/831686/download ("For example, two of the largest makers of semiconductor manufacturing equipment, Applied Materials Inc. and Tokyo Electron Ltd., abandoned their \$10 billion merger after we rejected settlement offers that were insufficient to protect competition and future innovation for the development of machinery used to make the memory and logic chips that power smartphones, tablets, computers, and many other products.").

⁵⁸ Press Release, *supra* note 56 ("The semiconductor industry is critically important to the American economy, and the proposed remedy would not have replaced the competition eliminated by the merger, particularly with respect to the development of equipment for next-generation semiconductors.").

4. Dow / Dupont

The European Commission (EC), for its part, appears to have relied on an innovation market analysis in its challenge to the merger between The Dow Chemical Company (Dow) and E. I. du Pont de Nemours and Company (DuPont). In addition to finding horizontal overlaps for existing products, the EC also found that the merger would reduce "innovation competition for pesticides."⁶² Before approving the transaction in March of 2017, the EC imposed divestiture remedies, including the divestiture of DuPont's global R&D organization.

The EC alleged that that there were only five manufacturers who were globally active throughout the entire R&D process for the innovation of pesticides, both to improve existing products and to develop new active ingredients.⁶³ With respect to the parties' incentive to reduce innovation post-merger, the EC found that Dow's and DuPont's pipelines competed head-to-head in a number of herbicide, insecticide, and fungicide innovation areas, and that post-merger, the combined entity would "have an incentive to discontinue some of these costly development efforts." The EC also concluded that the merger would harm innovation competition by removing the parties' incentive to develop new pesticides. The EC's press release mentioned that it had found "specific evidence" to this effect, and also that the merged entity would have a lower ability to innovate than Dow and DuPont separately. The press release also noted that the parties would have reduced R&D spending post-merger, which may have been a factor in that conclusion.

The EC's decision in this case closely tracks the 1996 Report in a number of ways. For example, the press release noted that there were "very high barriers to entry" in the industry; it is almost certain that those barriers involve at least some specialized assets. Interestingly, the EC also alleged that, in addition to the merging parties, there were three other global innovation competitors as well as some smaller ones—a number high enough that it could arguably trigger the 1996 Report's suggested safe harbor of four or more independent and closely substitutable innovation efforts. However, without more information than what is available in

63 Id.

⁶² European Commission Press Release IP/17/772, Mergers: Commission clears merger between Dow and DuPont, subject to conditions (Mar. 27, 2017), http://europa.eu/rapid/press-release_IP-17-772_en.htm.

the press release,⁶⁴ it is impossible to determine whether the EC deviated from 1996 Report's contention that innovation markets are generally only problematic when there are very few competitors, or if there was some unique characteristic about this innovation market or the two parties in this case.

5. Transparent R&D: Spotlight on Innovation Markets in Pharmaceutical Mergers

The cases described above arose in a variety of industries, but all involved R&D pipelines that were largely secret and undisclosed. In the pharmaceutical industry, by contrast, product pipelines are generally observable because companies must register certain clinical trials with the FDA on ClinicalTrials.gov (which is a public registry and clinical results database). Moreover, many pharmaceutical companies publish their pipeline development efforts on their company website and, for public companies, in annual reports. This identifiability of R&D competition in the pharmaceutical industry has allowed the FTC to more thoroughly evaluate competition in innovation markets than in other industries.

Here again it is important to remain mindful of the distinction between "innovation" or "research and development" competition in the context of a current or future product market and harm to competition in an innovation or R&D market. The FTC has alleged harm to actual competition or potential future competition that would likely result in higher prices in a current or future product market in many pharmaceutical cases.⁶⁵ However, the three cases described below—i.e., (1) the

⁶⁴ The EC has yet to publish a full decision in this case.

⁶⁵ See, e.g., Complaint, Glaxo Wellcome plc & SmithKline Beecham plc, F.T.C. No. 01-0088 (Dec. 15, 2000) (alleging likelihood of price increases by eliminating a potential entrant as well as reduction in product innovation in the markets for topical prescription herpes antivirals, prophylactic herpes vaccines, and topoisomerase I inhibitors for the treatment of ovarian, non-SCLC, colorectal, other solid tumor cancers, drugs for treatment of IBS, and triptan drugs for treatment of migraine headaches); Complaint, Amgen Inc. & Immunex Corp., F.T.C. No. 021-0059 (Sept. 3, 2002) (alleging harm to competition by eliminating potential competition in the TNF inhibitor and IL-1 inhibitor product markets as well as by reducing innovation competition in the research, development, and commercialization of TNF inhibitor and IL-1 inhibitor products); Complaint, Pfizer Inc. & Warner-Lambert Company, F.T.C. No. 001-0059 (July 27, 2000) (alleging that the reduction of four companies to three that are involved in human clinical testing of EGRr-tk inhibitors for the treatment of cancer increases the likelihood of reducing the number of drugs reaching the market and thus resulting in higher prices for consumers); Complaint at 2, Novartis AG & GlaxoSmithKline, F.T.C. No. 141-0141 (Apr. 8, 2015) (alleging that the elimination of future competition between GSK and Novartis in the development and sale of BRAF-inhibitors and MEK-inhibitors would likely result in higher

FTC's consent decree with respect to the merger of Ciba-Geigy Limited (Ciba-Geigy or Ciba) and Sandoz Inc. (Sandoz) to form Novartis, (2) the FTC's review of Genzyme's acquisition of Novazyme, and (3) the EC's decision regarding Novartis' acquisition of GlaxoSmithKline plc's oncology business—specifically consider harm to an innovation or R&D market.

Before considering these cases, it is worth reviewing the application of potential competition analysis in the context of pharmaceutical mergers. In a potential competition case, either (a) one party is in the market and the other is a likely and timely entrant, or (b) both parties are likely and timely entrants in the same future market. The U.S. antitrust agencies have generally considered entry within two to three years to be timely. Companies that have submitted a new drug application (NDA) or biologics license application (BLA) filing for a drug will be considered timely, as will companies in Phase III of development.⁶⁶ Products in Phase I or II of development often fall well outside of this range but are sometimes considered by the FTC as within the relevant product market.⁶⁷ The likelihood of a product in development obtaining approval from the Food and Drug Administration (FDA), which is a prerequisite to market entry, is also dependent upon the phase of the clinical trials. During the period 2006-2015, the average approval rates by clinical trial phase were as follows: Phase I to approval, 9.6%; Phase II to approval, 15.3%;

prices and reduce choices for cancer treatments although not explicitly alleging innovation markets); Complaint, Valeant Pharm. Int'l, Inc., F.T.C. No. 151-0236 (Feb. 8, 2017) (alleging elimination of actual competition in relevant markets for GP buttons used to produce lenses for orthokeratology, scleral, and general vision correction as well as the ability of the merged firm to exercise market power in the market for GP buttons, including by increasing prices and decreasing innovation). *See also* Analysis to Aid Public Comment, Ciba-Geigy Limited, et al., 62 Fed. Reg. 409, 411 (Jan. 3, 1997) (alleging harm to potential innovation competition and not a reduction in price competition in the future product markets).

⁶⁶ See BIO, BIOMEDTRACKER & AMPLION, CLINICAL DEVELOPMENT SUCCESS RATES 2006-2015, at 12 (June 2016), https://www.bio.org/sites/default/files/Clinical%20Development%20Success%20 Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf (noting that the average filing to approval time is 1.6 years); FDAReview.org, The Drug Development and Approval Process (2016), (citing Dimasi, Hansen, and Grabowski (2003)), http://www.fdareview. org/03_drug_development.php; U.S. FOOD & DRUG ADMIN., The Drug Development Process, Step 3: Clinical Research (2017), https://www.fda.gov/forpatients/approvals/drugs/ucm405622.htm.

⁶⁷ See, e.g., Complaint, Amgen Inc. & Immunex Corp., F.T.C. No. 021-0059 (Sept. 3, 2002) (including Amgen's TNF inhibitor in late Phase II trials as a potential competitor to Immunex's Enbrel and including Immunex's Phase I IL-1 inhibitor product as a potential competitor to Amgen's Kineret).

Phase III to approval, 49.6%; and NDA/BLA filing to approval, 85.3%.⁶⁸ While success rates for products in development vary by indication, these statistics suggest that products in Phase I and Phase II are not sufficiently likely to enter the market.

6. Ciba-Geigy/Sandoz

In 1997 the FTC challenged the merger of Ciba-Geigy and Sandoz, alleging likely harm to (a) potential competition in the future product markets for HSV-tk gene therapy for the treatment of cancer, HSV-tk gene therapy for the treatment of graft versus host disease, gene therapy for the treatment of hemophilia, and chemore-sistance gene therapy; and (b) competition in the R&D market for gene therapy technology with respect to the four specific gene therapy products listed above.⁶⁹ In each of the relevant future markets, Ciba (including Chiron, in which Ciba owned a 46.5% interest) and Sandoz were the only two companies capable of developing the product and in or near clinical development.⁷⁰ In addition, the FTC alleged harm to competition in the innovation market for gene therapy generally because the firms were among the "few entities capable of commercially developing gene therapy products."⁷¹

Unlike in other pharmaceutical merger consent decrees, the FTC did not allege that the transaction was likely to result in a price increase, even where it alleged harm to future markets for specific gene therapy products. Rather, the FTC focused on the ability of competitors to enter the market, particularly given IP barriers. The FTC did not require divestiture of the R&D assets, recognizing among other things, that a divestiture would "create substantial disruption in the parties" research

71 Complaint at 5, Ciba-Geigy Limited, et al., F.T.C. No. 961-0055 (Mar. 24, 1997).

⁶⁸ BIO, BIOMEDTRACKER & AMPLION, *supra* note 66, at 9.

⁶⁹ Complaint, Ciba-Geigy Limited, et al., F.T.C. No. 961-0055 (Mar. 24, 1997); see also Analysis to Aid Public Comment, Ciba-Geigy Limited, et al., 62 Fed. Reg. 409, 410 (Jan. 3, 1997) (stating "[t]he proposed complaint alleges that therapy technology and the research and development of gene therapies constitute relevant markets in which to analyze the effects of the proposed merger.").

⁷⁰ In the relevant product market for chemoresistance gene therapy, a third company was found capable of commercially developing a MDR-1 gene therapy for the treatment of chemoresistance, but only Ciba and Sandoz were found capable of developing an MRP gene therapy for the treatment of chemoresistance. *See* Analysis to Aid Public Comment, Ciba-Geigy Limited, et al., 62 Fed. Reg. 409, 410 (Jan. 3, 1997).

and development efforts."⁷² Instead, as part of the consent, the parties agreed (a) to license specific gene therapy technology and patent rights to Rhone-Poulenc in order to position Rhone-Poulenc to compete against the combined firm, and (b) to grant all gene therapy researchers and developers non-exclusive licenses to certain essential gene therapy technologies to address concerns with the overall gene therapy R&D market.

7. Genzyme/Novazyme

The FTC initiated an investigation into Genzyme's \$120 million acquisition of Novazyme shortly after the transaction closed in September 2001. The transaction remains distinctive in a number of ways. To begin with, it is the only instance, to our knowledge, in which an agency has applied an innovation market analysis to a *consummated* merger—and, hence, had any record regarding how the merging parties actually behaved with respect to their overlapping R&D efforts. In addition, it also appears to be the only innovation market case involving *only* an R&D overlap (rather than a merger involving harm to both R&D and actual or future product markets).

This case was also notable in that it involved a merger to monopoly—Genzyme and Novazyme were the only two companies engaged in early-stage research and development of enzyme-replacement therapy (ERT) for Pompe disease, a rare inherited neuromuscular disorder that typically was fatal and which had no known treatment at the time of the merger. Genzyme previously had acquired two other Pompe R&D programs: Pharming in 1998 and Synpac in 2000. By 2002, Genzyme had discontinued the development of the Pharming and Synpac enzymes, which were in Phase II clinical trials, because of production scale issues, leaving Genzyme's internal ERT program and Novayzme's ERT program, as the only ongoing R&D programs for Pompe disease at the time of the merger.

Finally, the *Novazyme/Genzyme* investigation resulted in a more complete record with respect to the agency's factual and legal analysis than is true in most other innovation market cases. The FTC stated that its investigation centered on "how the transaction would affect the pace and scope of research into pharmaceutical

⁷² Analysis to Aid Public Comment, Ciba-Geigy Limited, et al., 62 Fed. Reg. 409, 411 (Jan. 3, 1997).

products for [Pompe's disease]."⁷³ Specifically, the agency considered whether the post-merger firm would have a lower incentive to quickly develop the treatment and that consumers would miss out on multiple treatment options and face higher prices when a Pompe treatment became available.

In its 3-1-1 decision, the FTC concluded that the merger should not be challenged. Chairman Muris, as part of the majority, issued a long separate statement concluding that "on balance, rather than put patients at risk through diminished competition, the merger more likely created benefits that will save patients' lives."⁷⁴ He drew on the 1996 Report and argued that while innovation markets are worthy of antitrust scrutiny, the FTC had been properly "cautious" in applying that analysis because "economic theory and empirical investigations have not established a general causal relationship between innovation and competition."⁷⁵ The key, as explained in the 1996 Report, is a "careful, intense factual investigation is necessary" to "distinguish between procompetitive and anticompetitive combinations of innovation efforts."⁷⁶

According to Chairman Muris, the FTC staff's thorough factual investigation had "properly focused on how the transaction would affect the pace and scope of research," including "whether Genzyme and Novazyme would have engaged in a 'race to market' absent the merger" and whether "the merger might influence the [further development of the] 'Novazyme program' if Genzyme's internal program [to develop a treatment] succeeds."⁷⁷ Muris went on to note his conclusion that the investigation uncovered "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."⁷⁸ To the contrary, he found that there were "strong reasons to believe that the merger will benefit patients" and that "we are without a basis for concluding that the merger is likely to result in net harm to patients.

78 Id. at 17.

⁷³ Muris, *supra* note 2, at 1.

⁷⁴ Id.

⁷⁵ Id. at 2-3 (quoting the 1996 REPORT, supra note 5, ch. 7 at 16).

⁷⁶ Id. at 2-3 (quoting the 1996 REPORT, supra note 5, ch. 7, at 18, 20).

⁷⁷ Id. at 1, 11, 13.

On balance, the merger is likely to be procompetitive, and thus patients' lives are more likely to be saved by this merger than to be put at risk."⁷⁹

Finally, Chairman Muris rejected the position, taken by Commissioner Mozelle Thompson in dissent, that the presumption of anticompetitive effects that attaches to a merger to monopoly in product markets should be applied to innovation market analysis. Stating that he strongly disagreed with the dissent's "suggest[ion] that the Commission has found evidence that the merger already has caused, or is likely to cause, anticompetitive effects," Chairman Muris emphasized that "the adoption of presumptions without economic foundation would constitute a major step backward in antitrust law."⁸⁰

8. Novartis / GlaxoSmithKline Oncology Business

While the FTC has not publicly analyzed the effect of a pharmaceutical merger on an innovation market since *Genzyme/Novazyme*, the EC in 2015 conducted an innovation market analysis of a pharmaceutical merger between Novartis and GlaxoSmithKline plc (GSK) whereby Novartis acquired GSK's oncology business.⁸¹ In its decision concerning the merger, the EC analyzed two future market overlaps and an innovation market related to Novartis' and GSK's BRAF and MEK inhibitors, which are targeted therapies that inhibit specific proteins involved in cell reproduction.⁸²

First, the EC analyzed the future product market for pipeline targeted therapies for the treatment of advanced melanoma.⁸³ GSK had received approval from the European Medicines Agency (EMA) to sell its BRAF inhibitor, Tafinlar, and its MEK inhibitor, Mekinist, as a monotherapy for the treatment of unresectable or metastatic melanoma with a BRAF V600 mutation. GSK was conducting Phase III clinical trials of Tafinlar and Mekinist in combination for the same indication.⁸⁴

82 *Id.* ¶ 11.

83 *Id.* ¶ 33.

84 Id. ¶¶ 38-40.

⁷⁹ Id. at 20.

⁸⁰ Id. at 22, 25.

⁸¹ See EUROPEAN COMMISSION, Decision in Case M.7275: Novartis AG & GlaxoSmithKline Oncology Business (Jan. 28, 2015).

Novartis was conducting Phase III trials for (i) its B-Raf inhibitor, LGX818, as a monotherapy for the treatment of B-Raf mutated advanced melanoma, (ii) its MEK inhibitor, MEK162, as a monotherapy for the treatment of N-Ras mutated advanced melanoma, and (iii) LGX818 and MEK162 in combination for the treatment of B-Raf advanced melanoma. Roche was the only other company with a B-Raf inhibitor or MEK inhibitor on the market or in Phase III clinical trials.⁸⁵ The EC found that the transaction would "lead to a reduction of potential competition on the market for B-Raf and MEK inhibitors used in combination [or as a monotherapy] for advanced melanoma . . . by reducing the number of available B-Raf and MEK inhibitors from three to two."⁸⁶

Second, the EC analyzed the future product market for pipeline targeted therapies for the treatment of ovarian cancer.⁸⁷ GSK's Mekinist and Novartis' MEK162 were in Phase III clinical trials for a rare type of ovarian cancer called low-grade serous carcinoma.⁸⁸ The EC found that the only other competitor was AstraZeneca's MEK inhibitors, Selumetinib, which was in Phase II and concluded that the combination would "restrict competition through non-coordinate effects."⁸⁹

Third, the EC analyzed the market for innovation competition with respect to the development of the parties' MEK and B-Raf inhibitors for other therapeutic uses. GSK and Novartis had Phase I and Phase II clinical trials involving "the potential use of their MEK and B-Raf inhibitors, either as monotherapies or in combination, in a number of other types of cancer, notably colorectal cancer, nonsmall-cell lung cancer (NSCLC) and advanced melanoma brain metastases."⁹⁰ The EC recognized that "the effects of a concentration on competition in innovation . . . may not be sufficiently assessed by restricting the assessment to actual or potential competition in innovation is likely to reduce the number of new products that will be developed

- 86 Id. ¶ 57.
- 87 *Id.* ¶ 72.
- 88 Id. ¶ 62.
- 89 Id. ¶¶ 81-83.
- 90 Id. ¶ 84.
- 91 Id. ¶ 89.

⁸⁵ Id. ¶¶ 48-52.

for the same product market," which would have the effect of (a) reducing competition and causing higher prices in future product markets and (b) reducing the variety of therapies available to physicians and patients who may respond better to different drug products.⁹²

The EC provided guidance on defining the relevant innovation market—i.e., competing clinical research should be identified by the mechanism of action of the pipeline products concerns, the therapeutic use for which clinical trials are being conducted, and the phase of the clinical trials.93 The EC defined the relevant innovation market as "the development of MEK and B-Raf inhibitors for the treatment of colorectal cancer, NSCLC and advanced melanoma brain metastases."94 The EC's competitive assessment focused on "whether after the Transaction there [would] be a sufficient number of remaining clinical research programs," finding Roche to be the only company with the capability to compete with the parties' clinical research programs for the use of BRaf and MEK inhibitors to treat colorectal cancer, NSCLC, and advanced melanoma brain metastases.95 The EC expressed concern that Novartis had the incentive to prioritize the clinical research of GSK's Tafinar and Mekinist for other types of cancer and reduce the R&D efforts related to Novartis' LGX818 and MEK162 therapies or abandon such efforts altogether.96 The EC determined that the transaction was likely to result in a reduction in the variety of B-Raf and MEK therapies available to physicians and patients as well as the lessening of competition in the future markets for use of these products in colorectal cancer, NSCLC, and advanced melanoma brain metastases.⁹⁷ In order to remedy the EC's concerns, Novartis agreed to return its rights to MEK162 to its owner Array BioPharma and divest LGX818 to Array.98

The FTC also required Novartis to divest its rights and assets related to LGX818 and MEK162 to Array. The FTC, however, did not separately allege an innovation

- 94 Id. ¶ 94.
- 95 Id. ¶¶ 102-104.
- 96 Id. ¶ 106.
- 97 *Id.* ¶ 113.
- 98 Id. ¶¶ 279-282.

⁹² Id. ¶ 110.

⁹³ Id. ¶¶ 90, 94.

market. Instead, in its complaint, the FTC alleged relevant product markets for (i) the development and sale of BRAF inhibitors used to treat cancer, and (ii) the development and sale of MEK inhibitors used to treat cancer.⁹⁹ The complaint further alleged harm to future competition in these relevant product markets.¹⁰⁰ While the FTC only alleged harm to future competition for BRAF and MEK inhibitors generally as well as for treatment of metastatic melanoma patients, the FTC noted that the transaction "would also likely reduce the development of BRAF and MEK inhibitors to treat other types of cancer, because GSK and Novartis are currently developing their respective BRAF and MEK inhibitors for several of the same indications beyond melanoma," including for ovarian cancer, colorectal cancer, and NSCLC.¹⁰¹ Coupled with the fact that both parties' products were in early clinical trials (i.e., Phase I or Phase II) for colorectal cancer and NSCLC, at least in Europe, this suggests that, even though not specifically articulated in its complaint, the FTC considered harm to an R&D or innovation market as well as to a specific product market.

IV. Economic Literature

In the FTC's 1996 Report, the agency stressed that there were still several outstanding questions related to the economic theory of innovation markets.¹⁰² Economic thinking on how mergers can impact a firm's incentive to innovate has not stagnated in the over two decades since the FTC issued that report; indeed, recent economic work, either empirically or through invocation of other considerations, suggests that perhaps there is a relationship between concentration and innovation—although the nature of and how to measure that relationship remains an open question.

⁹⁹ Complaint at 2, Novartis AG & GlaxoSmithKline, F.T.C. No. 141-0141 (Apr. 8, 2015).

¹⁰⁰ Id. at 3.

¹⁰¹ Analysis of Agreement Containing Consent Orders to Aid Public Comment, Novartis AG, 80 Fed. Reg. 11202, 11204 (Mar. 2, 2015).

¹⁰² *See e.g.* 1996 REPORT, *supra* note 5, ch. 7, at 38 ("Before general standards specifically tailored to entry into innovation markets are framed, additional research into the mechanisms that induce firms to enter into new innovation efforts would be desirable.").

1. Grabowski and Kyle

Grabowski and Kyle published a paper in 2008 discussing the results of their empirical study on the relationship between pharmaceutical mergers and innovation.¹⁰³ The study used a database of more than 4,500 firms engaging in pharmaceutical R&D between 1990 and 2007, and measured R&D outcomes in terms of advancement through the various phases of drug research and market launch.¹⁰⁴ The study found that the effect of the firm size on innovation varied across development stages. The effect of size on success probabilities for firms that did not undergo a merger was relatively small for drugs in Phase I and Phase II, but there was a strong positive relationship between size and performance in Phase IIIsuggesting that large firms may be better equipped to shepherd a drug through Phase III.¹⁰⁵ The study also found that non-merging, very large firms, defined as firms with more than fifty projects, launched approximately 60% more of their Phase III projects than small firms, defined as firms with fewer than 5 projects per year.¹⁰⁶ As the authors recognized, these two results only showed correlation, not causation, which led them to suggest two alternative causes for the correlation between size and success at Phase III R&D: "The higher probabilities of success for phase III for the largest-scale firms are consistent with their comparative advantage at later stages of the R&D process hypothesis . . . or alternatively, with the hypothesis that large firms are better at weeding out unlikely successes earlier in the process[.]"¹⁰⁷

Interestingly, the study further found that projects initiated after a merger were much more likely to advance from each stage of development. For example, the authors determined that merging small firms were approximately 50% more likely to proceed through Phase III than their non-merging counterparts.¹⁰⁸ The difference, while not as profound, is apparent regardless of the size of the firm or the stage of

- 106 Id. at 280.
- 107 Id.
- 108 Id. at 279 fig.11.4.

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¹⁰³ Henry Grabowski & Margaret Kyle, Mergers and Alliances in Pharmaceuticals: Effects on Innovation and R&D Productivity, in THE ECONOMICS OF CORPORATE GOVERNANCE AND MERGERS 262 (Klaus Gulgler & Burcin Yurtoglu eds., 2008).

¹⁰⁴ Id. at 274.

¹⁰⁵ Id. at 276, 280.

development—all other things being equal, post-merger firms are more likely to proceed to the next stage in development.¹⁰⁹ The authors inferred from this finding that there was "a benefit to merging that is independent of size alone" and suggested that further research was necessary to identify what the benefit was.¹¹⁰

Grabowski and Kyle concluded that the results of their study were consistent with the results of studies on alliances between small biotech firms and larger pharmaceutical entities.¹¹¹ Studies of such alliances showed a positive correlation between a firm's experience in clinical development and the probability of successful outcomes. As the authors summarized, these results bolster the existing alliance literature and suggest "that very small firms with only a few projects in their R&D portfolio can gain the most benefits from mergers with more experienced firms in developing new drug indications."¹¹²

2. Comanor and Scherer

Subsequently, a 2012 study on the effect of pharmaceutical mergers between large firms on innovation published by Comanor and Scherer appears to contradict Grabowski and Kyle's finding that there is positive correlation between mergers and successful development.¹¹³ Comanor and Scherer argued that because technological innovation, including in the pharmaceutical industry, is characterized by uncertainty, progress is best achieved "when there is widespread dispersion of R&D initiatives both across companies and within them through the exploration of multiple technical paths."¹¹⁴ They argue that "pursuing more sequential approaches to research and development often leads to foregone payoffs during the period of probable delay." ¹¹⁵

115 Id. at 9.

¹⁰⁹ See id. at 277-79 figs.11.2, 11.3 & 11.4.

¹¹⁰ Id. at 282.

¹¹¹ Id. at 283.

¹¹² Id.

¹¹³ William S. Comanor & F.M. Scherer, Merger and Innovation in the Pharmaceutical Industry (Am. Antitrust Inst. Working Paper No. 12-05, 2012), https://papers.ssrn.com/sol3/papers. cfm?abstract_id=2190201.

¹¹⁴ Id. at 5.

Comanor and Scherer described an economic model estimating a profit maximizing degree of parallelism in R&D efforts but noted that in actuality large pharmaceutical companies were not engaged in this theoretical degree of parallel innovation.¹¹⁶ The authors explored a number of explanations for this deviation, including that companies failed to "appreciate the full merits of parallel paths and or view[ed] parallelism as a form of wasteful 'duplication.""¹¹⁷ They argued that this perceived "duplication" could result in post-merger portfolio-pruning and cost-cutting.¹¹⁸ The paper then introduced the finding of Comanor and Scherer's study that following mergers between large pharmaceutical companies, the number of independent sources of R&D initiatives were reduced—*i.e.*, there were fewer instances of different firms pursuing parallel R&D paths towards the treatment of the same disease state regardless of whether such instances were too few or too many.¹¹⁹ The paper also cited to another economic study showing that following mergers between large pharmaceutical companies, the number of new drug approvals may have decreased rather than increase and argued such lessening of innovative diversity "mostly likely" caused the reduction in innovation.¹²⁰

The paper also argued that niche biotech companies have more expertise at the initial R&D stage, but would require the support of large pharmaceutical companies to complete the clinical trial process and bring the product to market.¹²¹ Accordingly, mergers between large pharmaceutical companies would reduce the number of larger pharmaceutical firms that smaller, niche firms can partner with to carry the R&D effort through to approval, thus resulting in the loss of new products.¹²² Ultimately the authors acknowledged that their conclusions were "suggestive rather than definitive" but stated that their analysis at least provided support for "the hypothesis that recent pharmaceutical mergers contributed to an observed decline in the rate of pharmaceutical innovation."¹²³

- 117 Id.
- 118 Id. at 12.
- 119 Id. at 14.
- 120 Id. at 14-15.
- 121 Id. at 15.
- 122 Id. at 16.
- 123 Id. at 21.

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¹¹⁶ Id. at 11.

3. Kern

Two years later, Benjamin R. Kern published an article considering the same question that the FTC asked in its 1996 Report: whether competition authorities should examine innovation competition through the lens of innovation markets, future markets, or potential competition.¹²⁴ After reviewing these three theories and the cases where they had been applied, Kern addressed what he perceives as the "shortcomings" of the innovation market analysis and proposed potential revisions. Specifically, he pointed to three critiques that have been raised against the innovation market analysis: (1) agencies struggle to identify competitors in innovation markets because "R&D activities are often subject to secrecy"; (2) the lack of a robust theoretical basis to conclude that market concentration impacts firms' incentives to innovate; and (3) the "missing theoretical basis" for the presumption that more innovation competition leads to more innovation.¹²⁵

Kern proposed four components of a revised approach to addressing and evaluating innovation markets. *First*, he argued that in cases where R&D is "unobservable," antitrust agencies should focus their analysis on whether the innovation in question requires "specialized assets" and that if an agency cannot identify any such assets then "the investigation should cease."¹²⁶ *Second*, he supported then-Chairman Muris' statement in *Genzyme/Novazyme* that agencies should undertake a fact-specific analysis about the parties' ability and incentives to innovate and ask how the proposed transaction alters those factors.¹²⁷ By insisting on a fact-intensive analysis, Kern argued, agencies will not be bound by the "ambiguous interrelationship between 'market concentration' and innovation."¹²⁸ *Third*, he argued that agencies should adopt a "weak" presumption that the reduction of innovation competition will harm innovation outcomes because that will shift the burden to the merging parties to demonstrate merger-specific efficiencies.¹²⁹ To support this presumption, Dr. Kern pointed to "evolutionary" economics' suggestion that

- 128 Id.
- 129 Id.

¹²⁴ Kern, supra note 37.

¹²⁵ Id. at 195-204.

¹²⁶ Id. at 204.

¹²⁷ Id. at 205.

innovation is inherently uncertain and different firms will invariably approach their R&D programs differently. Consequently, an increase in the number of firms attempting an innovation, and thus an increase in the number of approaches to achieve that innovation, should increase the likelihood that consumers benefit from the market's attempt to innovate.¹³⁰ *Fourth*, to avoid an overly restrictive merger regime, Kern argued that any revised framework should acknowledge that mergers could generate substantial innovation efficiencies.¹³¹

4. Haucap and Stiebale

Most recently, Haucap and Stiebale published a paper in 2016 discussing the effect of mergers on innovation in R&D-intensive industries; in particular, their study sought to determine how a merger impacted innovation by the post-merger firm's rivals.¹³² They noted that while existing economic research has largely found a negative correlation between mergers and innovation by the merged firms, there had been little research on the effect of a merger on innovation by non-merging competitors.¹³³ The authors argued that in addition to questions about how a merger will impact the post-merger firm's incentive to innovate, merger analysis should consider the merger's effect on innovation by non-merging competitors or the analysis risks underestimating harm to innovation.¹³⁴

Haucap and Stiebale examined all pharmaceutical mergers reported on the EC's website between 1991 and 2007 and analyzed how those mergers impacted marketwide innovation. The authors primarily looked at the number of patents granted¹³⁵ per year to measure innovation because this metric is readily available, unaffected by the "accounting manipulations" that can skew self-reported R&D expenditures,

133 Id. at 3, 5-6.

¹³⁰ Id.

¹³¹ Id. at 206.

¹³² Justus Haucap & Joel Stiebale, How Mergers Affect Innovation: Theory and Evidence from the Pharmaceutical Industry (Dusseldorf Inst. for Competition Econ., Discussion Paper No. 218, 2016), http://www.dice.hhu.de/fileadmin/redaktion/Fakultaeten/Wirtschaftswissenschaftliche_ Fakultaet/DICE/Discussion_Paper/218_Haucap_Stiebale.pdf.

¹³⁴ Id. at 26.

¹³⁵ The authors noted that while they only looked at granted patents they chose to "date them back to the application year," because that is the most effective way to measure a merger's impact on innovation. *Id.* at 13.

and is a "well-established indicator of innovation."¹³⁶ However, the authors acknowledged that even this metric is imperfect because not every innovation leads to a patent and firms are not uniformly aggressive in seeking patents. To improve their results and account for these nuances, the authors also examined R&D expenditures as a secondary data set.

Haucap and Stiebale found that both the post-merger firm and their rivals had substantial reductions in innovation directly following the transaction. Specifically, the authors found that post-merger firms' innovation output decreased by 20% in the four years following the consolidation when compared to their pre-merger output.¹³⁷ In addition, the study concluded that rival firms' innovation decreased by 16% after the merger—indicating that mergers can have a substantial impact on the innovation incentives of non-merging parties.¹³⁸ The study also determined that mergers have negatively impacted the size of firms' patent stocks¹³⁹ and found that "in the absence of a merger, the cumulative patent [portfolio] of merged entities would be 30% higher and those of competitors would be about 5% higher" than they were four years post-merger.¹⁴⁰

The authors observed several other trends that indicate consolidation has a negative impact on innovation for both the post-merger firm and its competitive rivals. Specifically, they determined that the post-merger firm's innovation output is 30% lower than other similarly situated firms, while its competitors' output is 7% lower, and that both the post-merger firm and its competitors reduce R&D expenditures while increasing profits after the transaction.¹⁴¹

Like Comanor and Scherer, Haucap and Stiebale concluded that mergers decrease the post-merger firm's innovation output. However, their results suggest that a merger can also impact rivals' innovation output. The authors ended their paper by urging agencies to examine how merger will impact the entire market's innovation incentives because "[f]ocusing only on the merged entity's innovation

¹³⁶ Id. at 11-13.

¹³⁷ Id. at 20.

¹³⁸ Id.

¹³⁹ The authors define "patent stock" as the number of patents a firm holds. Id. at 15.

¹⁴⁰ Id. at 20-21, fig.1.

¹⁴¹ Id. at 21.

activities may well underestimate the negative effects that mergers can have on innovation."¹⁴²

By focusing on rivals' innovation output, Haucap and Stiebale highlighted yet another facet of innovation market analysis, but certainly many questions remain, including the applicability of the studies and their conclusions outside of the pharmaceutical context.

V. Conclusion

Twenty-one years have passed since the FTC's report on innovation markets. Given the antitrust agencies' experience in a number of cases involving innovation markets since that time, and the ongoing legal and economic thinking on these issues, it would seem that it is appropriate for the FTC to revisit and update its analysis in this area.

As the late FTC Commissioner Rosch once noted, economics does not appear to have yet concluded under what circumstances it is "better to lock scientists from competing firms in a room and let intellectual fermentation occur," rather than to prevent such combinations from going forward.¹⁴³ As Megan Crowley's story reminds us, however, a great deal often may be at stake in the proposed combination of R&D efforts, and it is important that we make every effort to get our antitrust analysis right, even as we may need to remain humble about the current state of our understanding regarding the challenging issues often raised by these combinations.

¹⁴² Id. at 26.

¹⁴³ J. Thomas Rosch, Comm'r, Fed. Trade Comm'n, Remarks at the ABA Antitrust Intellectual Property Conference: Antitrust Regulation of Innovation Markets (Feb. 5, 2009), https://www. ftc.gov/sites/default/files/documents/public_statements/antitrust-regulation-innovationmarkets/090205innovationspeech.pdf.

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