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**The Misapplication of Innovation Market Analysis to Biotechnology
Mergers**

Alvin R. Chin

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The Misapplication of Innovation Market Analysis to Biotechnology Mergers[†]

Alvin R. Chin*

I. Introduction

1. Pursuant to section 7 of the Clayton Act,¹ federal antitrust enforcement agencies have traditionally reviewed mergers in the context of the actual goods and services provided by the merging firms. The agencies, however, are increasingly using innovation market analysis in reviewing proposed mergers, particularly in research-intensive, technology-driven markets.

2. Innovation market analysis evaluates the merging firms' research and development ("R&D") capacity as distinct from the market for existing goods and services.² Because technology-driven markets are characterized by high rates of innovation, "purely static forms of economic analysis . . . will fail to describe adequately their competitive processes."³ The Department of Justice and the Federal Trade Commission ("enforcement agencies") propose to account for such dynamic competition by making an additional inquiry into the "market" for

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* Associate, Sidley & Austin. B.S., 1992, Massachusetts Institute of Technology; J.D., 1996, Northwestern University. Special thanks to Professor Keith Hylton of Boston University School of Law.

¹ Clayton Act § 7, 15 U.S.C. § 18 (1994). Section 7 of the Clayton Act prohibits a merger or acquisition whose effect "may be substantially to lessen competition, or tend to create a monopoly." *Id.*

² See U.S. Department of Justice and Federal Trade Commission Antitrust Guidelines for the Licensing of Intellectual Property, 4 Trade Reg. Rep. (CCH) ¶ 13,132, § 3.2.3, at 20,738 (1988) [hereinafter Licensing Guidelines].

³ Richard T. Rapp, *How Economists See Competition Problems in High-Technology Industries*, C137 A.L.I.-A.B.A. 139, 145 (1995) [hereinafter Rapp, *How Economists See*].

innovation.⁴

3. In reviewing a proposed merger, the enforcement agencies perform an innovation market analysis by: (1) defining the relevant market for innovation; and (2) examining the proposed merger's potential to reduce competition to innovate.⁵ To define the relevant innovation market, the enforcement agencies identify the merging firms' specialized R&D assets that are "directed to particular new or improved goods or processes, and the close substitutes for that research and development."⁶ Close substitutes are those R&D efforts, technologies, and goods that would "significantly constrain the exercise of market power with respect to the relevant research and development, for example by limiting the ability and incentive of a hypothetical monopolist to retard the pace of that research and development."⁷ Firms with the incentive and capability to engage in closely substitutable R&D would be considered market participants. After delineating the relevant innovation market, the enforcement agencies then determine the merger's potential anticompetitive effects on innovation, such as the post-merger firm's market power and its ability to cancel promising R&D tracks.⁸

4. Commentators have criticized the enforcement agencies' adoption of innovation market analysis.⁹ Because of the uncertainty in defining relevant markets for innovation, the highly speculative nature of assessing innovation for the purpose of evaluating market power, and inconsistencies with established antitrust case law, this article concludes that innovation market analysis is inappropriate for reviewing mergers in the biotechnology industry. Accordingly, the enforcement agencies should limit the scope of their merger analyses to existing product markets. By failing to do so, the enforcement agencies risk intervening in mergers that

⁴ See Licensing Guidelines, *supra* note 2, at 20,738.

⁵ See *id.* at 20,739.

⁶ *Id.* at 20,738.

⁷ *Id.*

⁸ See Christine A. Varney, *Innovation Markets in Merger Review Analysis*, ANTITRUST, Summer 1995, at 16.

⁹ See, e.g., Robert J. Hoerner, *Innovation Markets: New Wine in Old Bottles?*, 64 ANTITRUST L. J. 49 (1995) (arguing that innovation markets cannot legally be considered in antitrust analysis); Robert H. Lande & Sturgis M. Sobin, *Reverse Engineering of Computer Software and U.S. Antitrust Law*, 9 HARV. J. L. & TECH. 238 (describing the practical difficulties in applying innovation market analysis to software cases); Richard T. Rapp, *The Misapplication of the Innovation Market Approach to Merger Analysis*, 64 ANTITRUST L.J. 19 (1995) (criticizing the use of innovation market theory since the relationship between market structure, R&D, and innovation has not been proven) [hereinafter Rapp, *Misapplication*].

actually speed the arrival of new treatments to the market and thus to society.

5. Part II of this article briefly reviews the role of innovation and mergers in economic growth and the biotechnology industry. Part III discusses the enforcement agencies' underlying policy and approach to using innovation market analysis. The article presents a theoretical critique of innovation market analysis in Part IV, drawing, where appropriate, on examples from the biotechnology industry. Finally, the article concludes in Part V that innovation market analysis is an inappropriate tool for biotechnology antitrust analysis.

II. Biotechnology Industry Background

6. Biotechnology is the manipulation of the processes of life at the molecular level to yield new products and applications.¹⁰ Unlike traditional medical approaches, biotechnology seeks to understand disease on a genetic and molecular level and to apply this newly discovered knowledge. Accordingly, the research-intensive biotechnology industry is driven by innovation -- the actual use and application of technology for the first time.¹¹

7. Biotechnology-related products generated annual sales of \$7.7 billion in 1995 -- up 10% from the previous year.¹² The number of biotechnology drugs that have reached the market, however, is relatively small compared to the number of treatments under development.¹³ Nevertheless, successful biotechnology products provide significant benefits to society. For example, Amgen, the world's largest biotechnology company, has produced very effective drugs based on genetically

¹⁰ Biotechnology has been defined in many different ways, reflecting the breadth of its applications. Biotechnology includes "any process in which organisms, tissues cells, organelles, or isolated enzymes are used to convert biological or other raw materials to products of greater values." See J. COOMBS, *DICTIONARY OF BIOTECHNOLOGY* 41 (1986); see also Rochelle K. Seide & Frank A. Smith, *Intellectual Property Protection and Biotechnology*, N.Y. ST. BAR J., May-June, 1995, at 52, 52 (defining biotechnology as "the use of living organisms to make commercially valuable products and processes, including . . . therapeutic compositions and agricultural and industrial products.").

¹¹ See James M. Utterback, *Innovation in Industry and the Diffusion of Technology*, 183 *SCIENCE* 620, 621 (1974).

¹² See *Ernst & Young Biotech '95: Reform, Restructure, Renewal Fact Sheet* (visited Mar. 20, 1997) <http://www.biospace.com/industry/e%26y_factsheet.cfm>.

¹³ Approximately 10% of biotechnology drugs that enter clinical trials and 50% of the drugs that proceed through final testing are actually approved. See Joan O'C. Hamilton, *Biotech: An Industry Crowded with Players Faces an Ugly Reckoning*, *BUS. WK.*, Sept. 26, 1994, at 84, 87 [hereinafter Hamilton, *Biotech*].

engineered copies of naturally occurring proteins.¹⁴ Amgen's drug Neupogen, which increases the body's production of infection-fighting white blood cells, has been used to treat more than 190,000 cancer patients; cancer patients undergoing chemotherapy are at high risk of infection because chemotherapy destroys white blood cells.¹⁵ Genentech's anti-clotting agent Activase -- also known as tissue plasminogen activator -- is used to treat 135,000 heart attack patients annually.¹⁶

8. The biotechnology industry is predominantly comprised of small entrepreneurial firms centered around the R&D of a single product or family of related products.¹⁷ Unfortunately, biotechnology products are exceptionally expensive to develop.¹⁸ The isolation and manipulation of genetic material required for researching biotechnology products results in extended development times and escalated development costs.¹⁹ Biotechnology firms are also confronted with a lengthy patent application process²⁰ and administrative review of their products.²¹ Such costs and time delays are formidable obstacles for an industry populated by start-up firms lacking any sales revenue from established product lines.²²

¹⁴ See Larry Armstrong, *Amgen Could Use a Little Growth Factor*, BUS. WK., Oct. 31, 1994, at 122, 122.

¹⁵ See *id.* Amgen is also currently seeking FDA approval to expand Neupogen's uses to fighting infections in AIDS and pneumonia patients. See *id.* at 124.

¹⁶ Ralph T. King, *Genentech's Clot-Dissolving Drug, TPA, Found Major Aid in Treatment of Stroke*, WALL ST. J., Dec. 14, 1995, at A3.

¹⁷ See Dan L. Burk, *An Introduction: A Biotechnology Primer*, 55 U. PITT. L. REV. 611, 628 (1994).

¹⁸ See U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, BIOTECHNOLOGY IN A GLOBAL ECONOMY 6 (1991); see also Hamilton, *Biotech*, *supra* note 13, at 85 (explaining that biotechnology companies generally need seven to ten years and between \$100 million and \$150 million to bring a new drug to market).

¹⁹ See Hamilton, *Biotech*, *supra* note 13, at 85.

²⁰ See Teresa Riordan, *Regulators Brace for Spirited Testimony from Biotechnology Companies on Application Delays*, N.Y. TIMES, Oct. 17, 1994, at D2 (reporting that biotechnology patent applications are often delayed or even rejected because Patent and Trademark Office ("PTO") examiners hold patents to a higher standard than other types of inventions).

²¹ See Phillip J. Hilts, *Gain Cited in Approval of New Drugs*, N.Y. TIMES, Jan. 20, 1995, at A18 (reporting that the FDA took an average of 23.4 months to approve a new biotechnology product in 1993, but managed to reduce that time to 12.2 months in 1994); *F.D.A. is Eliminating Special Restrictions on Biotechnology Drugs*, N.Y. TIMES, Nov. 10, 1995, at D8 (reporting that some special regulatory restrictions on biotechnology drugs have been lifted to speed drug development and reduce development costs).

²² See Kevin Hamilton, *Biotech an Industry of 'Haves' and 'Have Nots' Says Institute's Study*,

9. Therefore, while biotechnology plays a very promising role in increasing social welfare, the industry is also populated by struggling firms fighting for financial survival.²³ As in other industries, mergers in biotechnology allow smaller firms to pool their strengths into a larger, more stable, unified firm.

10. Mergers traditionally provide a variety of efficiency benefits, and production and distribution economies. A merger can provide social welfare benefits by placing assets under superior management, which in turn puts those assets to more efficient and highly-valued uses.²⁴ Where a merger occurs pursuant to a takeover bid, it also disciplines and removes inefficient management.²⁵

11. In technology-driven markets, mergers and acquisitions promote technological transfers that might otherwise be unavailable to firms operating on a stand-alone basis.²⁶ Mergers allow firms to combine complementary skills, knowledge, or assets. Firms in biotechnology and other research-intensive industries can therefore combine their separate solutions to different parts of the same R&D puzzle.²⁷

12. Mergers can help avoid the duplication that necessarily accompanies competition. This is especially important because duplication in R&D activity is more wasteful than the duplication in a competitive market for an existing product.²⁸ Competitors in an existing product market may invest in the same types

BIOTECH. NEWSWATCH, May 1, 1995, at 12, *available in* 1995 WL 2196486 (predicting that of the 1,200 or so biotechnology firms in the United States, no more than 40 are expected to have products on the market or product royalties by the year 2000).

²³ See *US Biotech on the Brink of a Golden Age?*, BIOTECH. BUS. NEWS, Dec. 6, 1995, at 3, *available in* 1995 WL 769426 (reporting that approximately 60% of the United States biotechnology sector has less than two years cash).

²⁴ See ECONOMIC REPORT OF THE PRESIDENT, THE ANNUAL REPORT OF THE COUNCIL OF ECONOMIC ADVISORS 197 (1985).

²⁵ See RICHARD A. POSNER, *ANTITRUST LAW: AN ECONOMIC PERSPECTIVE* 96 (1976).

²⁶ See Hamilton, *Biotech*, *supra* note 13, at 299.

²⁷ See *Panic in the Petri Dish: The Free-Spending Biotechnology Industry May at Last Have Got Caught in a Cash Crunch It Cannot Easily Escape*, ECONOMIST, July 23, 1994, at 61, 62 ("Too many small biotech firms have only one piece of [the] R&D puzzle. By joining them together and stripping out the duplicate parts, a ruthless bioconglomerateur might be able to assemble a whole that was greater than the sum of its parts.").

²⁸ See William F. Baxter, *The Definition and Measurement of Market Power in Industries Characterized by Rapidly Developing and Changing Technologies*, 53 ANTITRUST L.J. 717, 721 (1985). *But see* George W. Dent, Jr., *Unprofitable Mergers: Towards a Market-Based Legal Response*, 80 NW. U. L. REV. 777, 793 (1986) (arguing that duplicative research is more likely to yield some success).

of production and marketing assets.²⁹ Where a merger produces economies of scale and eliminates some competitors, the remaining competitors' multiple investments are still additive and contribute to the needed flow of that product. Hence most of the duplication does not constitute waste.³⁰

13. In contrast, duplication in R&D is highly inefficient. The firm that innovates first gives society the new idea.³¹ The "public goods" character of the R&D end product -- information -- is such that other firms' investments will turn out to be largely redundant.³² By streamlining multiple R&D tracks with complementary strengths and assets into a single effort, mergers allow firms to avoid such duplicative inefficiencies.

14. Like mergers, joint ventures also allow firms to combine complementary R&D assets. The enforcement agencies treat joint ventures more leniently because their limited scope and duration reduce the potential for lasting anticompetitive effects.³³ On the other hand, joint ventures can fail to enhance co-venturer profitability and technological innovation.³⁴ Joint ventures have multiple owners who might otherwise compete with one another.³⁵ Accordingly, the participating firms often have differing objectives or opinions regarding the venture.³⁶ The joint venture is also "vulnerable to efforts by participants to free ride on coventurers by withholding their most advanced technological (or human) assets from the venture."³⁷

15. The problems that beset joint ventures can largely be mitigated by mergers. Mergers yield a centralized R&D effort subject to direct control by a single

²⁹ See Baxter, *supra* note 28, at 721.

³⁰ See *id.*

³¹ See *id.*

³² See *id.*

³³ See Joseph Kattan, *Antitrust Analysis of Technology Joint Ventures: Allocative Efficiency and the Rewards of Innovation*, 61 ANTITRUST L.J. 937, 947 (1991) (noting that a joint venture allows the participants to remain independent competitors outside of the collaborative effort). Cf. Joseph F. Brodley, *Joint Ventures and Antitrust Policy*, 95 HARV. L. REV. 1521, 1529 (1982) (discussing disadvantages of joint ventures).

³⁴ See Kattan, *supra* note 33, at 944.

³⁵ See *id.* at 945.

³⁶ See *id.*

³⁷ *Id.*

management.³⁸ A unified management is likely to do a better job than the bureaucratic and political mechanisms used to control a joint research effort.

16. The duration and uncertainty of potential antitrust litigation, however, often dissuade firms from completing a deal because mergers are time-sensitive transactions.³⁹ Confronted with the prospect of a merger stalled over a research project with an uncertain future payoff, firms considering a merger could be tempted to enter into consent decrees requiring divestiture or compulsory licensing.

III. Innovation Market Analysis

17. As noted above, section 7 of the Clayton Act prohibits those mergers that may substantially lessen competition or tend to create a monopoly in any line of commerce.⁴⁰ Any merger that threatens competition in the form of higher prices or reduced output should be found unlawful.⁴¹ Accordingly, the enforcement agencies will challenge a merger that might result in higher prices or lower output because of a reduction in innovation competition.

A. Policy

18. The theory underlying innovation market analysis is that firms compete in R&D.⁴² A firm that successfully develops a new or improved product could increase its profits either by capturing more of the existing product market or by meeting new demand. Innovation market analysis is meant “to introduce dynamic efficiency considerations into merger enforcement, to recognize the importance of innovation as a means of nonprice competition and a source of welfare gains, and to prevent mergers that would reduce competition in innovation.”⁴³ The enforcement agencies are particularly concerned with innovation competition, fearing that merging firms with competing R&D tracks will cancel one of the tracks after

³⁸ See Dent, *supra* note 28, at 793.

³⁹ Rapp, *Misapplication*, *supra* note 9, at 47; see also Steven C. Sunshine & Charles E. Biggio, *Antitrust Investigations Can Delay or Kill Deals*, NAT'L L.J., Apr. 15, 1996, at C20 (arguing that enforcement action and antitrust investigations can cause delay and increase costs).

⁴⁰ 15 U.S.C. § 18 (1994).

⁴¹ See *id.*

⁴² See Bryan R. Dunlap, *A Practical Guide to Innovation Markets*, ANTITRUST, Summer 1995, at 21, 21-22.

⁴³ Rapp, *Misapplication*, *supra* note 9, at 20.

combining.⁴⁴ Alternatively, the enforcement agencies are concerned that a firm with an existing product may acquire a firm that has a superior competing product still under development.⁴⁵ The acquiring firm would then have little incentive to pursue R&D on the target firm's forthcoming product. The acquiring firm could even cancel that R&D program altogether, thereby abandoning promising alternative technological approaches and suppressing innovation.⁴⁶

B. Approach

19. In using innovation market analysis to review a proposed merger, the enforcement agencies must first define the relevant market. Under the Licensing Guidelines, an innovation market "consists of the research and development assets directed to particular new or improved goods or processes, and the close substitutes for that research and development."⁴⁷ The agencies will evaluate what specialized R&D assets the merging firms possess, and include in the relevant market other firms that have the capability and incentive to undertake closely substitutable R&D.⁴⁸ Accordingly, the relevant market embraces: (1) firms that currently sell products developed from R&D tracks similar to that of the merging firms; (2) firms without a product on the market but that conduct R&D directed towards an existing, competing product or product under development; and (3) firms not embarked on similar R&D tracks but that have the capability and incentive to do so in the future.⁴⁹

20. After defining the relevant innovation market, the enforcement agencies evaluate the potential anticompetitive innovation effects of the merger. The Licensing Guidelines suggest allocating market share by evaluating for each firm those assets and characteristics upon which innovation depends, such as R&D expenditures, and related products and assets, such as intellectual property rights.⁵⁰

⁴⁴ See Varney, *supra* note 8, at 16.

⁴⁵ See *id.*

⁴⁶ See *id.*

⁴⁷ Licensing Guidelines, *supra* note 2, at 20,738.

⁴⁸ See *id.*

⁴⁹ See Dunlap, *supra* note 42, at 22.

⁵⁰ Licensing Guidelines, *supra* note 2, at 20,738.

C. Application

21. In the Licensing Guidelines, the enforcement agencies have hinted that they might apply innovation market analysis sparingly -- only where "competitive effects on innovation . . . cannot be adequately addressed through the analysis of goods or technology markets."⁵¹ Nevertheless, a review of recent complaints and consent agreements reveals that the enforcement agencies have intervened in numerous biotechnology mergers on the basis of innovation competition, and will likely continue to do so.⁵²

22. When Hoechst and Marion Merrell Dow ("MMD") sought to merge in 1994, the FTC permitted the merger contingent on Hoechst not exerting control over MMD's operations before the conclusion of the antitrust investigation.⁵³ The consent order ultimately settling the antitrust charges centered on the market for four treatments for arteriosclerosis, tuberculosis, hypertension, and gastrointestinal inflammation.⁵⁴ For only one of the four treatments did Hoechst have a drug on the market expected to compete with a drug *still under development* by MMD.⁵⁵ Nevertheless, in three of the cases, the consent order required Hoechst to divest either the rights to the existing drug or the R&D rights to the experimental drug.⁵⁶

⁵¹ *Id.*

⁵² Even before announcing innovation market analysis in the 1995 Licensing Guidelines, the enforcement agencies had applied innovation market analysis to intervene in Roche Holding's acquisition of Genentech. *See Roche Holding Ltd.*, 55 Fed. Reg. 38,153 (FTC 1990) (proposed consent agreement). Both Roche and Genentech were engaged in R&D for a treatment for AIDS/HIV infection based on the CD-4 human protein. *See id.* There were no CD-4-based products on the market at the time of the merger, nor were Roche and Genentech the only firms conducting CD-4 R&D. *See id.* The consent agreement required Roche to license its CD-4-based U.S. patents to anyone who requests a license. *Id.*

⁵³ *See Hoechst Settles FTC Charges of Reducing Competition for Four Drugs in Connection with MMD Merger*, FTC News Release, Sept. 18, 1995, available in 1995 WL 549000 [hereinafter FTC Release].

⁵⁴ *See Hoechst AG*, 60 Fed. Reg. 49,609 (FTC 1995) (proposed consent agreement).

⁵⁵ *See id.* at 49,615-16.

⁵⁶ In the fourth case, Hoechst and Biovail Corp. were co-developing Tiazac, a hypertension and cardiac drug, that was expected to compete with MMD's Cardizem CD. Anticipating an antitrust challenge to its merger with MMD, Hoechst returned to Biovail all the rights to Tiazac. The FTC alleged that Hoechst's actions still left Tiazac a less competitive product and that Hoechst had access to sensitive information on Tiazac. The consent agreement required that Hoechst return, and refrain from using, any confidential information obtained from Biovail during the course of their relationship, and provide Biovail with technical data necessary for Tiazac's continued development. *See* FTC Release, *supra* note 53.

For another recent case where one firm had an existing product and the other was conducting R&D, see *Glaxo plc.*, 60 Fed. Reg. 16,139 (FTC 1995) (proposed consent agreement).

23. In the complaint threatening to halt American Home Products' 1994 acquisition of American Cyanamid, the FTC alleged that the combination would harm competition in the market for the R&D of a rotavirus vaccine.⁵⁷ At the time of the merger, neither of the merging firms (nor any other firm) had manufactured a vaccine for rotavirus -- a diarrheal disease that causes thousands of children's deaths annually. In the consent agreement, American Home Products agreed to license on a nonexclusive basis American Cyanamid's research in rotavirus vaccines and to provide technical support to a purchaser approved by the FTC.⁵⁸

IV. Theoretical Critique

24. Innovation market analysis inevitably relies on speculative assessments of innovation and inaccurate definitions of the relevant market. The enforcement agencies have created a vague standard. Vague standards in market definition make it difficult for firms to gauge which transactions will bring costly and lengthy antitrust scrutiny.⁵⁹ The unreliable conclusions drawn from innovation market analysis create the risk of preventing mergers with substantial pro-competitive and social welfare benefits when regulatory intervention is actually unwarranted.

25. While innovation plays a vital role in economic development, it is characterized by speculation and unpredictability.⁶⁰ Innovation involves uncertainty, risk-taking, continual experimentation, and testing.⁶¹ As innovation itself is inherently speculative, a particular innovation's performance in the marketplace is equally uncertain. In the United States and other capitalist economies, the uncertainty is largely attributable to national, evolutionary

According to the FTC complaint, Glaxo 's acquisition of Wellcome would eliminate competition between the two firms in the R&D of a non-injectable drug for migraine headaches, known as 5HT_{1D} agonist. *See id.* at 16140. At the time of the merger, Wellcome did not have any 5HT_{1D} agonist migraine drugs on the market, though Glaxo did. *See id.* The consent agreement required Glaxo to divest Wellcome's 5HT_{1D} agonist R&D assets and provide technical assistance to the purchaser. *See id.* at 16,141.

⁵⁷ *See* American Home Products Corp., 59 Fed. Reg. 60,807 (FTC 1994) (proposed consent agreement).

⁵⁸ *See id.* at 60,812.

⁵⁹ *See* Andrew C. Hruska, *A Broad Market Approach to Antitrust Product Market Definition in Innovative Industries*, 102 YALE L.J. 305, 314 (1992).

⁶⁰ *See* Thomas M. Jorde & David J. Teece, *Innovation and Cooperation: Implications for Competition and Antitrust*, J. ECON. PERSP., Summer 1990, at 76.

⁶¹ *See id.* ("It is an activity in which 'dry holes' and 'blind alleys' are the rule, not the exception.").

frameworks for innovation.⁶² The United States system for innovation is driven by private profit incentives, such that multiple, independent sources of new technology compete for market share.⁶³ Ultimately, the system relies heavily on market forces to select innovations as well as the firms themselves.⁶⁴ Accordingly, corporate R&D on the national level is largely unplanned and uncoordinated.⁶⁵ This translates, on the firm and industry level, into innovation uncertainty based both on technical uncertainty and continually fluctuating market forces.

26. The uncertainty in biotechnology innovation is reflected in the industry's performance in the capital markets and business world. The long delays between a firm's inception and the hoped-for marketing of a commercial product, coupled with high R&D expenditures, have forced biotechnology firms to turn to corporate alliances⁶⁶ and venture capital⁶⁷ in order to remain solvent during the start-up and development phases. Traditional financing through public stock offerings, on the other hand, has been an uncertain source of capital for the industry. Biotechnology stocks tend to fluctuate wildly with any hint of change in the outlook for a given firm's product.⁶⁸ Investors often become disenchanted with biotechnology stocks

⁶² See Richard R. Nelson, *Institutions Supporting Technical Change in the United States*, in TECHNICAL CHANGE AND ECONOMIC THEORY 312-14 (Giovanni Dosi et al. eds., 1988).

⁶³ See *id.* at 313.

⁶⁴ See *id.*

⁶⁵ See *id.*

⁶⁶ See, e.g., Udayan Gupta, *Small Biotech Companies Finding Eager Big Buddies*, WALL ST. J., July 21, 1993, at B2 (describing a wave of alliances among European, Japanese, and United States biotechnology firms); Scott Kiman & Peter Fritsch, *Monsanto Agrees to Buy Stake in DeKalb for Up to \$158 Million*, WALL ST. J., Feb. 2, 1996, at B4 (describing alliance between Monsanto and DeKalb providing DeKalb with needed funding and direction); Stephen D. Moore, *Ciba's Alliance With Chiron Is an Open Relationship*, WALL ST. J., June 21, 1995, at B6 (noting that the best biotechnology companies will benefit from forming an alliance with a big partner).

⁶⁷ See, e.g., Udayan Gupta, *Biotech Firms Get More Help From Venture Capitalists*, WALL ST. J., Aug. 15, 1994, at B2 (describing increasing venture capital funding for closely held biotechnology firms); Udayan Gupta, *Venture Capital Investment Soars, Reversing 4-Year Slide*, WALL ST. J., June 1, 1993, at B3 (noting that 1993 venture capital funding for biotechnology start-ups increased three-fold between 1991 to 1993 to \$209 million).

⁶⁸ See generally Shannon Brownlee, *On Wall Street, Amgen's Stock is a Whale of a Deal*, U.S. NEWS & WORLD REP., Aug. 7, 1995, at 47 (noting that Amgen's stock soared after several promising studies on the patented ob gene and protein leptin suggested a potential for anti-obesity treatment); Lawrence M. Fisher, *Synergen Halts Tests*, N.Y. TIMES, July 19, 1994, at D1 (reporting that Synergen's stock prices plunged nearly 50% in a single day after an announcement that the company would halt clinical trials of its unsuccessful anti-sepsis drug, Antril); Ronald Rosenberg, *Biogen Lost a Drug, Kept its Health, Reputation*, BOSTON GLOBE, Nov. 20, 1994, at A1 (noting that

because of the high risk and the long wait for an uncertain pay-off.⁶⁹

27. The "all-or-nothing" nature of innovation makes competition a very risky proposition.⁷⁰ A breakthrough by only a single firm is necessary to acquire an exclusive patent position.⁷¹ Innovation market analysis is also inconsistent with established antitrust case law that holds that there is no market for antitrust purposes unless and until there are actual commercial transactions.⁷² In *SCM Corp. v. Xerox Corp.*, for example, the Second Circuit held that it is impossible to monopolize a market that is not yet in existence.⁷³ Xerox had made several successively broader acquisitions of plain paper copying technology--the last one in 1956--before plain paper copiers reached the commercial market.⁷⁴ In holding for Xerox, the Second Circuit stated that "[t]he patent system would be seriously undermined . . . were the threat of potential antitrust liability to attach upon the acquisition of a patent at a time prior to the existence of the relevant market and,

when Biogen, Inc. announced it would abandon its development of Hirulog, an anti-clotting drug, its stock price dropped 25% within a few days).

⁶⁹ Cf. Gene Bylinsky, *Biotech Tries to Act Like a Business*, FORTUNE, Feb. 20, 1995, at 16 ("For biotech shareholders, 1994 was a disaster. As product after product failed in clinical trials, venture capitalists dumped shares into a declining market. One major investor, David Blech, left the field altogether, sinking a number of companies in a move one trade journal dubbed 'Blech Friday.'"); Douglas Frantz, *Blech Moves Its Accounts to Josephthal*, N.Y. TIMES, Sept. 24, 1994, at 33 (reporting that D. Blech & Co. agreed to transfer certain assets and customer accounts to Josephthal, Lynn & Ross due to a prolonged market decline in biotechnology stocks).

⁷⁰ See Baxter, *supra* note 28, at 722 (noting that in an innovation market where a single breakthrough innovation by a smaller firm can capture substantial market share, "[t]here is not an opportunity to sit there, restricting your output and watching some particular fringe firm grow . . ."); see also *Major Killers Continue to Dominate Biotech Research and Development*, BIOTECH. BUS. NEWS, June 23, 1995, at 16 ("The search is always on for treatments and cures for major killers such as cancer and Aids [sic], and any company that makes a breakthrough in one of these areas has not only a very large potential patient population, but will probably make huge profits into the bargain.").

⁷¹ See Baxter, *supra* note 28, at 722.

⁷² See, e.g., *Babcock & Wilcox Co. v. United Tech. Corp.*, 435 F. Supp. 1249, 1275 (N.D. Ohio 1977) (concluding that the independent analytical value of considering product design and development is de minimis, and that only sales or the prospects of sales need be examined); see also *American Medicorp, Inc. v. Humana, Inc.*, 445 F. Supp. 589, 600 (E.D. Pa. 1977) ("Courts have found existing transactions between buyers and sellers to be the appropriate measure of market power. The capacity to expand, or develop new facilities, has been taken into account within that market analysis by the assessment of changing market shares in the basic product market, considered in the light of overall market conditions.").

⁷³ 645 F.2d 1195, 1206 (2d Cir. 1981), *cert. denied*, 455 U.S. 1016 (1982).

⁷⁴ See *id.* at 1198-99.

even more disconcerting, at a time prior to the commercialization of the patented art."⁷⁵ Market analysis is therefore appropriate only where there is an existing line of commerce.

A. *Defining the Innovation Market*

28. To allocate market share, the enforcement agencies must define the relevant market. The following discussion demonstrates that defining an innovation market is a speculative task, unlikely to yield a reliable delineation of the relevant market. The enforcement agencies are forced to define relevant assets and close substitutes for the products at issue with limited information.

1. Defining Relevant R&D Assets

29. The enforcement agencies state that they will define an innovation market only when they can associate the ability to conduct the relevant research with "specialized assets or characteristics of specific firms."⁷⁶ However, it is unclear when "specialized assets and capabilities" exist.

30. The Licensing Guidelines provide an example that defines an innovation market in biodegradable plastics research.⁷⁷ Some of the assets required for R&D in biodegradable plastics are the appropriate chemical polymers, personnel, laboratory facilities, and even dirt. Although these are rather common research inputs, the enforcement agencies unrealistically define the example innovation market as consisting of only four firms when many firms have access to these materials.⁷⁸

31. The enforcement agencies have failed to grasp that, in the biological sciences, the assets and capabilities required for research are quite *unspecialized*. Equipment for even the most sophisticated research in molecular biology, such as devices for centrifugation,⁷⁹ electrophoresis,⁸⁰ and determination of DNA sequences, are basic to most laboratories. Thus, the technology needed to perform research on

⁷⁵ *Id.* at 1206.

⁷⁶ Licensing Guidelines, *supra* note 2, at 20,738.

⁷⁷ *See id.* at 20,739.

⁷⁸ *See id.*

⁷⁹ Centrifugation is the process of centrifuging -- using centrifugal force for separating substances of different densities. *See* MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 186 (10th ed. 1994).

⁸⁰ Electrophoresis is the movement of suspended particles through a fluid or gel under the action of an electromotive force applied to electrodes in contact with the suspension. *See id.* at 372.

an infectious disease such as AIDS could be present in the same facilities that are performing research on cancer.

2. Defining Close Substitutes

32. The agencies define as likely participants in an innovation market those firms that have the capability and incentive to undertake closely substitutable R&D.⁸¹ Identifying closely substitutable R&D in biotechnology proves to be elusive. It is very difficult to determine whether R&D directed towards a particular illness may yield a product that has application to other ailments, thereby broadening the innovation market for those "secondary" treatments. Accordingly, the enforcement agencies may perceive merging firms with related R&D efforts as possessing high degrees of market power when, in reality, innovation market power is quite diffuse because of unrecognized, substitutable R&D.

33. An example of the difficulties inherent in recognizing substitutable R&D is Genentech's highly successful TPA drug, Activase.⁸² Activase was originally developed to treat heart attack victims.⁸³ Recent clinical studies funded by the National Institutes of Health have indicated that TPA may also be the first effective treatment of acute ischemic stroke.⁸⁴ In addition, Immunex developed its drug Leukine to stimulate production of white blood cells during bone marrow transplants, and only secured FDA approval for that particular usage.⁸⁵ Amgen's Neupogen is also an immune system-boosting drug.⁸⁶ While the R&D efforts for Neupogen and Leukine could conceivably be considered close substitutes, Neupogen is actually used in significantly broader applications to treat cancer patients with weakened immune systems.

34. Targeted funding to spur research on orphan drugs--those for which there is an unprofitably small market--further illustrates the problems in identifying closely substitutable R&D. In 1983, Congress passed the Orphan Drug Act, creating financial incentives for firms to develop treatments for rare diseases with relatively

81 See Licensing Guidelines, *supra* note 2, at 20,737.

82 See King, *supra* note 16, at A3.

83 See *id.*

84 See *Tissue Plasminogen Activator For Acute Ischemic Stroke*, NEW. ENG. J. MED., Dec. 14, 1995, at 1581. "Ischemic stroke afflicts about 400,000 Americans annually. It is the leading cause of adult disability, resulting in paralysis, loss of vision and speech, and other permanent debilitation. It is also the nation's third-largest killer." *Id.* The study has demonstrated that as many as 11% of stroke patients, or 44,000 people, could avoid disability and fully recover. *Id.*

85 See Gail Dutton, *Biotech: Risky Business?*, MGMT. REV., Jan. 1995, at 36, 38.

86 See *id.*

small patient markets.⁸⁷ To come under the 200,000 patient limit and thereby qualify for those incentives, many biotechnology firms would declare research targeted at the rarest subcategory of a common disease, such as cancer. Only in retrospect did legislators discover that companies would then develop purported "orphan drugs" with treatment potential for large numbers of patients with widespread ailments.⁸⁸

35. Definition of the relevant market is complicated where innovations are applicable to an entire industry. "The scientific techniques of biotechnology are closely intertwined and remarkably similar in any sector whether agricultural, chemical, medical, or otherwise. A breakthrough or discovery in, for example, microbial molecular biology is likely to have an impact on similar research being conducted in animal or plant systems."⁸⁹ The biotechnology industry may be segregated in terms of product markets, yet is tightly bound by commonalities of business and research.⁹⁰

36. Definition of the innovation market is further complicated when research cannot be accurately categorized by its relation to a potential product's stage of development. That is, it is difficult to identify substitutable R&D efforts according to whether they constitute basic research or applied, commercially viable research. The distinction between basic and applied research is particularly difficult to maintain in biotechnology research.⁹¹ Commercial entities are conducting basic biotechnology research and academic researchers are making patentable, marketable discoveries.⁹² Indeed, biotechnology firms and academic scientists have formed hundreds of strategic alliances.⁹³

⁸⁷ Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983).

⁸⁸ See 138 Cong. Rec. E1042-03 (daily ed. Apr. 10, 1992) (statement of Rep. Waxman) (citing Genentech's \$600 million in sales from human growth Hormone and Amgen's \$900 million in sales of EPO as abuse of the Orphan Drug Act).

⁸⁹ Burk, *supra* note 17, at 631.

⁹⁰ See *id.* (noting close ties between commercial and academic biotechnology research allows academia to act as a natural conduit for the flow of information between industry sectors).

⁹¹ See PETER DALY, *THE BIOTECHNOLOGY BUSINESS* 54-56 (1985). Scientists in biotechnology firms simultaneously generate new knowledge and apply existing knowledge, thus the distinction between the two is not very clear. While one may construct a spectrum that extends from molecular biology of a purely basic nature -- with no immediately identifiable application or relevance -- to readily applicable research, there is in fact a substantial "gray area" of research between the two extremes. *Id.* at 55.

⁹² Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1018 (1989).

⁹³ See David Blumenthal et al., *Relationships Between Academic Institutions and Industry in the*

3. Informational Deficiencies

37. Unlike analyzing existing goods markets in which price information and transactions can be documented, defining the relevant innovation market is complicated by the frequent lack of information with regard to who is actually innovating. Commercial research, comprising the predominant market share, cannot be adequately evaluated since it is generally conducted in secret. Patent information is an incomplete indicator of innovation, and pending domestic patent applications are not disclosed to the public. The sources of research are also numerous and widespread, and include university, extraterritorial, and nonprofit research.⁹⁴ Research and development secrecy, an increasingly globalized economy, and the ease with which information is transferred across national borders make definition of a relevant innovation market a resource-intensive, global review likely to be fraught with inaccuracies.

38. Firms may choose to publicize their R&D in order to generate consumer interest and demand for their innovations.⁹⁵ Because biotechnology firms often operate for years without a profit while developing their products, they may announce R&D advances to maintain investor interest.⁹⁶ While this may reveal which firms are engaging in certain types of research, it is not indicative of which innovative efforts are actually successful. What appears to be an innovative new treatment will often fail in late-stage clinical trials.⁹⁷

B. Assessing Innovation Market Power

39. "Innovation is intangible, uncertain, unmeasurable and often even

Life Sciences -- An Industry Survey, 334 NEW. ENG. J. MED. 368, 368 (1996); see also Yusing Ko, Note, *An Economic Analysis of Biotechnology Patent Protection*, 102 YALE L.J. 777, 794 (1992); Burk, *supra* note 17, at 629 ("The biotechnology industry also is characterized by exceptionally close ties to the academic community . . . [M]ost of the personnel in [biotechnology] companies, including officers and directors, were initially drawn from an academic setting, and key personnel in such companies will often continue to hold university appointments.").

⁹⁴ See generally Baxter, *supra* note 28, at 719 (explaining that the R&D market is most likely to be a world market that does not exhibit any measurable signs of concentration).

⁹⁵ See Varney, *supra* note 8, at 17.

⁹⁶ See Dutton, *supra* note 85, at 40.

⁹⁷ See, e.g., Lawrence M. Fisher, *Protein Labs' Stock Slides After Setback*, N. Y. TIMES, July 4, 1995, at 48 (reporting that Protein Design Labs Inc.'s lead drug, Zenapax -- a monoclonal antibody designed to prevent graft-versus-host disease in bone marrow transplant patients -- failed in advanced clinical trials).

unobservable except in retrospect."⁹⁸ There are no market transactions in innovation, only in its inputs and outputs. Perhaps recognizing this, the enforcement agencies have suggested that innovation may be measured in such terms.⁹⁹ The link between innovation and its inputs and outputs, however, is tenuous and cannot serve as a basis for evaluating the innovation market.

40. While R&D spending is a necessary input for innovation, it is neither sufficient for, nor a reliable indicator of, innovation market share. Theoretically speaking, more input implies more output, so that a firm that expends more in R&D should produce more innovation output. In reality, however, there is no correlation between R&D expenditure and innovation.¹⁰⁰ A small firm can carry out extremely efficient research despite its relatively few assets and low expenditures.¹⁰¹

41. The development of the Japanese biotechnology industry demonstrates the lack of probative value in using R&D expenditures to measure innovation. Congress was concerned that Japan would come to dominate biotechnology, much as it had come to dominate the electronics industry.¹⁰² Despite billions in Japanese investments in biotechnology, however, Japanese biotechnology firms failed to

⁹⁸ Rapp, *Misapplication*, *supra* note 9, at 27.

⁹⁹ See Licensing Guidelines, *supra* note 2, at 20,738. ("The Agencies may base the market shares of participants . . . on shares of research and development expenditures . . .").

¹⁰⁰ See Rapp, *Misapplication*, *supra* note 9, at 31 (noting that relative to their market share, larger firms do not develop a greater proportion of innovations as compared with smaller firms). For example, Amgen spent \$1.6 billion in R&D over five years without any significant research successes. See Barry Stavro, *Amgen Ready for Infusion*, L.A. TIMES, Oct. 19, 1996, at D1; see also Wesley M. Cohen & Richard C. Levin, *Empirical Studies of Innovation and Market Structure*, in 2 HANDBOOK OF INDUSTRIAL ORGANIZATION 1059, 1069 (Richard Schmalensee & Robert Willig eds., 1989) ("The most notable feature of this considerable body of empirical research on the relationship between firm size and innovation is its inconclusiveness.").

¹⁰¹ F. M. SCHERER, INNOVATION AND GROWTH, SCHUMPETERIAN PERSPECTIVES 237 (1984) (finding that while large industrial corporations conduct a substantially larger share of R&D than smaller firms, the smaller firms produce proportionally more innovations, contest-winning technical advances, and design patents); see also Roy Rothwell, *The Role of Small Firms in the Emergence of New Technologies*, in DESIGN, INNOVATION AND LONG CYCLES IN ECONOMIC DEVELOPMENT 231-34 (Christopher Freeman ed., 1986) (noting that smaller firms experience a higher rate of innovative efficiency -- innovations per unit of R&D expenditure).

¹⁰² See Joan O'C. Hamilton, *Measuring Biotech by Patents is Patently Absurd*, BUS. WK., Apr. 22, 1996, at 47 [hereinafter Hamilton, *Measuring Biotech*]. When the Japanese Ministry of Trade identified biotechnology as a major area of concentration for the 1990s and fostered its biotechnology industry by offering tax incentives and facilitating access to capital, some analysts believed the United States could lose its industry leadership to Japan. See Lawrence M. Fisher, *The Biotech Industry's Plight: A Shortage of Cash*, N.Y. TIMES, Dec. 3, 1988, at 47 (discussing Japanese biotechnology efforts). Prompted in part by these Japanese initiatives, the Biotechnology Competitiveness Act was introduced. See H.R. 4211, 103d Cong. (1994).

acquire any significant share of the market.¹⁰³ The modest performance of Japanese biotechnology has been attributed to the inapplicability of Japanese manufacturing efficiencies, the lack of global reach relative to United States drug companies, and the failure to attract top scientists to the industry.¹⁰⁴

42. Innovation also requires successful management and marketing.¹⁰⁵ The key factor in these elements is largely human, not physical.¹⁰⁶ Since quantifying the potential innovative contributions of any group or person is nearly impossible, innovation market analysis fails to account for a key element in innovation. R&D employment is essentially a subset of R&D expenditures, and is merely a measure of innovative effort, not of actual innovative output.¹⁰⁷

43. The significance of the failure of innovation market analysis to measure human innovative contribution is underscored by how biotechnology firms operate. The successful biotechnology firm identifies a molecule with commercial potential and develops it with a professional team possessing complementary scientific and business skills.¹⁰⁸ In light of the time delay, capital requirements, and technical challenges in developing a biotechnology product, the firm's success will depend upon the competence of its scientists and managers.¹⁰⁹

44. The enforcement agencies' reliance on R&D assets and expenditures also tends to distort traditional antitrust principles. As noted above, R&D expenditures are merely inputs and have no consistent bearing on innovation. By attributing innovation market power to firms with the greatest R&D expenditures, the enforcement agencies effectively equate market power with inefficiency.

45. The enforcement agencies will also evaluate innovation market share in

¹⁰³ See Hamilton, *Measuring Biotech*, *supra* note 102, at 47.

¹⁰⁴ See David Stipp, *Biological Warfare: How the U.S. Triumphed and Japan Beat Itself*, *FORTUNE*, Apr. 1, 1996, at 40.

¹⁰⁵ See Utterback, *supra* note 11, at 621 (discussing environmental factors that affect innovation).

¹⁰⁶ See Donald G. Marquis, *The Anatomy of Successful Innovations*, in *READINGS IN THE MANAGEMENT OF INNOVATION* 49 (1982) (stressing that "training and experience of the people in your own firm are the principle sources of information for successful innovations").

¹⁰⁷ See Richard J. Gilbert & Steven C. Sunshine, *Incorporating Dynamic Efficiency Concerns in Merger Analysis: The Use of Innovation Markets*, 63 *ANTITRUST L.J.* 569, 579 (1995) (while conceding that assessment of innovation is fraught with difficulties and uncertainties, the authors nevertheless argue for the continued application of innovation market analysis in merger review).

¹⁰⁸ See Aris Persidis, *Building Molecular Value*, *J. BUS. STAT.*, Mar.-Apr. 1996, at 18.

¹⁰⁹ See Dutton, *supra* note 85, at 38.

terms of a firm's relevant assets, including intellectual property.¹¹⁰ The scope of a merger participant's intellectual property rights, however, is a poor indicator of its share of the innovation market. Patents are indeed an observable manifestation of inventive activity, and the basic requirements for obtaining a patent--novelty, usefulness, and non-obviousness--suggest a close relationship with innovative capacity.¹¹¹ On the other hand, the majority of patents are of little or no value and confer no market power whatsoever.¹¹² As "one or two patents may be worth far more than a hundred minor patents,"¹¹³ there would still be no clear test for determining what is a significant innovation. If patents vary so much in their worth, their numbers cannot be informative of the extent of innovation that has taken place.¹¹⁴

46. The unreliability of using patents to indicate innovation market power capacity is demonstrated by an examination of patents on human DNA sequences. A recent study ranked the 13 companies with the most patents, worldwide, on human DNA sequences.¹¹⁵ Japan's Takeda Chemical Industries was ranked first with 63 such patents. However, Takeda has not developed any gene-related

110 See Licensing Guidelines, *supra* note 2, at 20,738 ("The Agencies may base the market shares of participants in an innovation market on their shares of identifiable assets or characteristics upon which innovation depends . . .").

111 35 U.S.C. §§ 101-103 (1994).

112 See E. THOMAS SULLIVAN & HERBERT HOVENKAMP, *ANTITRUST LAW, POLICY AND PROCEDURE* 664 (3d ed. 1994) ("Although we sometimes call the right created by a patent a 'monopoly,' the great majority of patents do not confer substantial power in a relevant market."); see also Rapp, *How Economists See*, *supra* note 3, at n.20 (citing a 1986 study of European patent renewals; based on the presumption that patents will only be renewed if the renewal fee is less than the value of maintaining the patent for another term, the study found that half of the French patents had a value of less than \$534, and only 2.5% had values greater than \$50,000).

113 PHILLIP AREEDA & DONALD F. TURNER, *ANTITRUST LAW* 189 (1980).

114 *But see* MANUEL TRAJTENBERG, *ECONOMIC ANALYSIS OF PRODUCT INNOVATION THE CASE OF CT SCANNERS* 187 (1990). The author suggests that as opposed to simply counting patents, patent *citations* may be a fairly accurate index of the innovative significance, using a weighted formula to account for the number of times a patent has been cited in subsequent applications reviewed by the PTO. *Id.* In reviewing patent applications, the PTO searches for and cites relevant prior patents whose subject matter may preempt or limit the scope of the pending application. If a document is cited in numerous patents, the technology revealed in that document is apparently involved in many developmental efforts. That document would presumably have particular innovative significance.

115 S. M. Thomas et al., *Ownership of the Human Genome*, 380 *NATURE* 387, 387 (1996).

drugs.¹¹⁶ In contrast, Amgen, the world's most successful biotechnology company, did not hold enough patents to be included on the list.¹¹⁷

V. Conclusion

47. Biotechnology continues to provide society with significant welfare benefits, particularly in the form of novel biomedical treatments. However, time delays, expensive R&D programs, and the uncertainty of innovation present formidable obstacles for the mostly smaller firms that comprise the biotechnology industry. Biotechnology mergers are an important way for firms to pool financial resources, lower operating costs, and enhance R&D efficiency by bringing together complementary pieces of a larger R&D solution.

48. In reviewing biotechnology mergers with innovation market analysis, the enforcement agencies are using a blunt instrument in a highly speculative search for anticompetitive effects. Innovation market analysis is unreliable because of the uncertainty in both the assessment of innovation in, and the definition of, a relevant market. It is also inconsistent with established antitrust case law. By failing to limit the scope of merger analysis to actual product markets, the enforcement agencies run the serious risk of needlessly preventing mergers that speed new treatments to the market and to society as a whole.

¹¹⁶ See Hamilton, *Measuring Biotech*, *supra* note 102, at 47.

¹¹⁷ See *id.* (noting that even with 1995 sales of \$1.9 billion Amgen did not make the list).