

# Cultivating the Genetic Commons: Imperfect Patent Protection and the Network Model of Innovation

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## TABLE OF CONTENTS

I.	INTRODUCTION .....	988
II.	PAST AND PRESENT: CULTIVATING THE GENETIC COMMONS.....	994
	A. <i>Assembling the Knowledge Base</i> .....	994
	B. <i>Parceling Out the Knowledge Base</i> .....	995
III.	ACCESS EXPANDED: PATENT PROTECTION AND INNOVATION NETWORKS.....	999
	A. <i>Basic Research and the Underinvestment Problem</i> .....	1002
	B. <i>The Incomplete Argument for Patent Protection</i> .....	1005
	C. <i>Completing the Argument for Incomplete Patent Protection</i> .....	1009
	1. <i>The Virtues of Incomplete Patent Protection</i> .....	1010
	a. <i>Patent Rights as Commitment Devices</i> .....	1012
	i. <i>Buyers' Commitment Costs</i> .....	1012
	ii. <i>Sellers' Commitment Costs</i> .....	1014
	b. <i>Innovation Networks as Risk-Distribution Mechanisms</i> .....	1015
	i. <i>Market Uncertainty</i> .....	1019
	ii. <i>Technical Uncertainty</i> .....	1020
	2. <i>The Vices of Complete Patent Protection</i> .....	1021
	a. <i>Managerial Risk Aversion</i> .....	1022

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	b. <i>Organizational Incompetencies</i> .....	1024
	c. <i>The Very Rational Fear of Cannibalism</i> .....	1026
	3. <i>Closing Argument: The Case for Imperfect Patents</i> .....	1028
	D. <i>Epilogue: Transcending the Schumpeterian Debate</i> .....	1031
IV.	ACCESS SUSTAINED: ANTITRUST CURES FOR PATENT CONSOLIDATION.....	1033
	A. <i>Why the Genetic Commons Needs Antitrust Scrutiny</i> .....	1034
	B. <i>Relaxed Treatment of Research and Production Joint Ventures</i> .....	1040
	C. <i>Compulsory Licensing and Innovative Efficiency</i> .....	1043
	1. <i>Innovation Markets and the Mini-Revival</i> <i>of Compulsory Licensing</i> .....	1044
	2. <i>Why Compulsory Licensing Can Sustain Innovation</i> .....	1051
V.	CONCLUSION .....	1054

## I. INTRODUCTION

The national parliament of Iceland recently approved a very unusual transaction: a \$200 million sale to a private corporation of an exclusive license to construct, manage, and commercially exploit a database that will include health and genetic information on every resident of Iceland.<sup>1</sup> This sale is a striking indicator of the extent to which courts, legislators, researchers, and corporations are rapidly converting the common pool of genetic resources<sup>2</sup> into a restricted-access field of proprietary entitlements. Recent developments in the legal, academic, and industrial communities have challenged the formerly uncontroversial assumption that genetic material, genetically modified organisms, and basic-science research techniques constitute an open-access information stock that falls outside the class of proprietary entitlements. Since the

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1. The homogeneity of Iceland's population means that its genetic data are a valuable prize for a biotechnology company. To address concerns about privacy and informed consent, the sale agreement provides that any Icelander can request to be excluded from the database. For a description of the transaction and responses in favor of and in opposition to Iceland's decision, see R.C. Lewontin, *People Are Not Commodities*, N.Y. TIMES, Jan. 23, 1999, at A19 (opposing the commodification of the human genome and lamenting the relaxed informed consent procedures regarding the licensee's use of personal information); Simon Mawer, *Iceland, the Nation of Clones*, N.Y. TIMES, Jan. 23, 1999, at A19 (questioning the public health utility of therapies based on genetic research). For a more recent update on the grant of the license, see Christopher Brown-Humes, *Icelandic Gene Group Up Sharply*, FIN. TIMES (LONDON), Jan. 25, 2000, at 29, available in LEXIS, News Library, Financial Times (London).

2. The Organisation for Economic Co-operation and Development (OECD), following the International Biodiversity Convention, defines "genetic resources" as "genetic materials of actual or potential value, containing functional units of heredity, and of microbial, plant, animal, or other origin." ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, INTELLECTUAL PROPERTY, TECHNOLOGY TRANSFER AND GENETIC RESOURCES 12 (1996).

early 1980s, the U.S. Patent and Trademark Office (“PTO”), the Supreme Court, and the Court of Appeals for the Federal Circuit (“Federal Circuit”) have granted patent protection to a variety of biotechnological innovations<sup>3</sup> and research techniques that historically have fallen outside the field of patentable products.

The explosive growth of the biotechnology industry and the commercialization of some basic-science research in the past two decades have coincided with, and may have relied closely upon, the patentability of certain types of genetic material and certain research techniques for genetic alteration.<sup>4</sup> This recent trend toward parceling out the genetic commons confronts policymakers with a novel variant of the familiar tradeoff between enhanced productivity and reduced accessibility that lies behind the extension of property rights to collectively held resources.<sup>5</sup> Patent rights in genetic resources encourage

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3. Several commentators in the patent and research and development (“R&D”) literature assign a special meaning to the term “innovation,” tending to situate innovation activities between more fundamental and less commercially oriented research (“invention”) and less fundamental and more commercially oriented research (“development” or “modification”). This Article uses “innovation” in the popular sense to encompass the full gamut of research and development activities designed to enhance existing products, develop new products, or investigate general areas of scientific inquiry. As needed, particular subsets of this general innovation category will be specified. For a detailed discussion of the distinction between fundamental and incremental types of innovation activities, see *infra* Part III.A.

4. The biotechnology industry covers a variety of technologies, including genetic and biochemical applications, recombinant DNA, monoclonal antibody protection, and tissue culture and cell fusion technologies. These techniques yield a wide range of products, including pharmaceutical, medical therapeutic, medical diagnostic, and agricultural products. This Article focuses on the pharmaceutical and medical product markets, which constitute the largest share of the biotechnology market. For a technical but accessible and up-to-date overview of biotechnological techniques and products, see Fredric M. Steinberg & Jack Raso, *Biotech Pharmaceuticals and Biotherapy: An Overview*, 1 J. PHARMACEUTICAL SCI. 48 (1998). For a description of the major biotechnological techniques from the perspective of patent law, see PHILIPPE G. DUCOR, PATENTING THE RECOMBINANT PRODUCTS OF BIOTECHNOLOGY AND OTHER MOLECULES 35-69 (1998). For overviews of the biotechnology industry, see generally ROHINI ACHARYA, THE EMERGENCE AND GROWTH OF BIOTECHNOLOGY: EXPERIENCES IN INDUSTRIALISED AND DEVELOPING COUNTRIES (1999); GARY P. PISANO, THE DEVELOPMENT FACTORY: UNLOCKING THE POTENTIAL OF PROCESS INNOVATION (1997); STEVE PRENTIS, BIOTECHNOLOGY: A NEW INDUSTRIAL REVOLUTION (1984).

5. The best articulation of this familiar dichotomy is found in Harold Demsetz, *Toward a Theory of Property Rights*, 57 AMER. ECON. REV. 347, 347-59 (1967). Under Demsetz’s well-known theory, property rights develop when the productivity gains from allocating private entitlements (e.g., increased incentives to invest private labor and capital) exceed the exclusion costs of preserving such entitlements (e.g., excluding trespassers from private land, litigating title disputes, purchasing title insurance). See *id.*

private investors to sink funds into uncertain biopharmaceutical projects that generate enormous development costs, take many years to yield a marketable product, and are often vulnerable to relatively low-cost imitators. There are some compelling and oft-voiced concerns, however, that patent protection may be a cure that is worse than the disease. Although patent rights may stimulate the commercial development of biopharmaceutical therapies, many academic and industrial researchers argue that these rights result in licensing, transaction, and litigation costs that significantly restrict access to the research tools and materials necessary for technological advance.<sup>6</sup>

This Article enters this debate and argues the following position. Assuming that antitrust authorities persist in certain strategies to impede patent consolidation, the recent introduction of patent rights for certain biotechnological innovations is likely to encourage private investment in the genetic commons and reduce (or, at least, not enhance) the accessibility costs that could stunt technological advance. To reach this conclusion, this Article shows that the two leading theories of patent protection, the “incentive” theory<sup>7</sup> and the “prospect” theory,<sup>8</sup> do not explain private industry’s willingness to sink significant investment capital into highly uncertain biopharmaceutical projects. These theories offer insufficient explanations because patent protection for biopharmaceutical innovations is substantially incomplete and generally covers only a small portion of a particular innovation’s technological yield. Both the incentive and prospect theories falsely predict that the appropriability gap would drive away private investors from biotechnology projects that appear to generate a large stream of unprotected, or “giveaway,” benefits. In contrast, this Article argues that this imperfect form of patent protection attracts private investment in uncertain research projects by reducing two information asymmetries that impede interfirm ventures capable of efficiently spreading the high risk of biopharmaceutical product development. At the same time, the imperfect character of patent protection reduces (or, at least, does not enhance) accessibility costs by encouraging individual firms to capture the unprotected portion of an innovation project’s expected yield by entering into interfirm research, marketing, or production alliances.

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at 350-53. If this is true, then any introduction of property rights necessarily involves a tradeoff between increased productivity benefits and increased exclusion costs.

6. See *infra* notes 32-36 and accompanying text.

7. For a description of the incentive theory, see Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 843 (1990).

8. See Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 267-71 (1977).

The incentive theory correctly states that patent protection stimulates private investment by warding off low-cost imitators and promising monopolistic profits that will at least cover product development costs. But this account does not explain how patent protection could encourage investors to divert funds from short-term, incremental innovation projects to long-term, breakthrough innovation projects that generate large inappropriable spillovers. The central thesis of this Article is that patent protection can most effectively induce investment in high-spillover innovations by providing incomplete coverage of the expected knowledge giveaways. Imperfect patent rights, and the resulting appropriability shortfall, may encourage patentholders to negotiate interfirm alliances that spread the development costs and capture the spillovers generated by fundamental research. This is not to say, however, that patents are superfluous. Without patent protection, potential research or production partners may face insurmountable costs in revealing private information, committing credibly to non-opportunistic behavior, and locating attractive investment opportunities. As a result, technological alliances do not go forward, and firms may shift investments to low-spillover research projects that do not require interfirm cooperation. By reducing the transaction costs of interfirm collaboration, imperfect patent protection may have nurtured the network structure<sup>9</sup> of the biotechnology market, which consists principally of collaborative ventures assigning research tasks to small biotechnology firms in the upstream market and distribution tasks to large pharmaceutical firms in the downstream market.

But this story of innovation networks may not have a happy ending. There is a reasonable chance that this network model will shift toward a vertically integrated hierarchy<sup>10</sup> that favors incremental

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9. "Network structure" or "innovation network" refers to the variety of collaborative relationships that small and large biotechnology or biopharmaceutical firms enter into to develop biotechnology products. This Article contrasts this network form of organization with a hierarchical or vertically integrated form of organization, where a large entity performs all of the steps that are required to fully develop a marketable product. This usage of the term generally follows that of the industrial economics literature and the economics of organization literature, which characterize a network form of organization as an agglomeration of loose relationships among small industrial actors. See *infra* notes 59, 79-81 and accompanying text.

10. "Hierarchy" is used in Oliver Williamson's sense of an internally self-contained or autarchic form of organization, which stands in contrast to market forms of organization where small, autonomous actors engage in short-term, contractually governed exchanges. See OLIVER E. WILLIAMSON, *MARKETS AND HIERARCHIES: ANALYSIS AND ANTITRUST IMPLICATIONS* 20-40 (1975).

over fundamental product innovation. Although imperfect forms of patent rights reduce some of the transaction costs of research collaboration, the contrary would be true if dominant firms could perfect effective patent coverage. This can be achieved by assembling broad patent portfolios through successive corporate control and intellectual property acquisitions. Biotechnological innovation may slow down as innovating firms merge, patents on fundamental discoveries or research techniques increasingly overlap, and a few industry participants acquire sweeping patent portfolios. Concentrated patent holdings constitute formidable entry barriers that may discourage a wide range of subsequent improvers and other potential entrants. Absent significant entry threats, incumbent firms may face serious disincentives to exploit intensively these intellectual property holdings and sustain significant levels of fundamental innovation. This is because dominant firms that foresee few potential entrants either: (1) may be reluctant to introduce pioneering innovations that would cannibalize existing product lines, or (2) tend to suffer from bureaucratic hierarchies and agency-cost distortions that stifle high-risk innovation projects.

Antitrust authorities may hold the key to foreclosing this unfortunate scenario. Merger enforcement can play a crucial role in preserving the disaggregated network structure of the biotechnology industry and this market's resulting innovative vitality. This structural concern best explains some of the Federal Trade Commission's ("FTC") recent applications of the "innovation market" approach<sup>11</sup> to several biopharmaceutical mergers. As presented by the Antitrust Division and the FTC, the innovation market approach treats research and development ("R&D") as a production output and assesses: (1) merged firms' ability to restrain the quantity of R&D output, and (2) whether that restraint on innovative output would have anticompetitive effects in the downstream product market.<sup>12</sup> Contrary to both "pro" arguments that this novel standard complements conventional merger analysis and "con" arguments that it is redundant or mistakenly targets efficient business combinations,<sup>13</sup> this Article contends that this approach

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11. The Antitrust Division and the FTC have enunciated this approach most explicitly in U.S. DEP'T JUST. & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY 10-13 (1995) [hereinafter INTELLECTUAL PROPERTY GUIDELINES]. For further illumination of this approach, see FED. TRADE COMM'N, ANTICIPATING THE 21ST CENTURY: COMPETITION POLICY IN THE NEW HIGH-TECH, GLOBAL MARKETPLACE 11-22 (1996) [hereinafter COMPETITION POLICY REPORT]. This report is based on two months of public hearings held by the FTC in October and November, 1995, to assess the economic effects of globalization and innovation. *See id.* at 1.

12. *See* INTELLECTUAL PROPERTY GUIDELINES, *supra* note 11, § 3.2.3.

13. For a full discussion of the innovation market approach and both sides of the

addresses innovative inefficiencies<sup>14</sup> that classical market power analysis is likely to overlook. Adapting antitrust concerns with consumer injury to science-based markets, the FTC has targeted biopharmaceutical mergers that are unlikely to result in supracompetitive pricing in the downstream products market but are likely to result in a reduced diversity and limited diffusion of technological inputs in the upstream market. Science-based markets require that antitrust authorities examine whether merging firms have the ability to injure the direction of R&D outputs by adopting an innovation portfolio that favors low-risk strategies of product improvement over high-risk strategies of breakthrough innovation. Although these combinations may not lead to allocative inefficiencies in the form of supracompetitive pricing, unilateral output restraints, or even reduced R&D expenditures, they may result in innovative inefficiencies in the form of a reduced incidence of fundamental product innovation.

To neutralize this danger, antitrust authorities can adopt, and to a large extent have adopted, a two-part regulatory strategy. First, antitrust authorities generally apply relaxed standards to research joint ventures, which facilitate information exchange among industry and academic researchers, spread development costs among several participants, and offer few plausible opportunities for cartel restraints on R&D or product output. Second, antitrust authorities have begun to apply licensing and divestiture remedies in approving mergers among dominant firms in the pharmaceutical and biopharmaceutical industries. The transaction-cost rationale for patent protection provides compelling grounds for this compulsory licensing strategy. Incomplete patent coverage of expected spillovers from basic-science innovation already encourages interfirm collaboration to capture a greater portion of those unprotected spillovers.

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debate, see Symposium, *A Critical Appraisal of the "Innovation Market" Approach*, 64 ANTITRUST L.J. 1 (1995). See also *infra* Part IV.C.1.

14. Innovative efficiency must be distinguished from allocative (and productive) efficiency. A market is *allocatively* efficient when it prices inputs and outputs equal to their marginal cost. If this is true, then the market must be allocating resources to the buyers who value them most, as measured by willingness to pay or willingness to forego other consumption alternatives. A market is *innovatively* efficient when it provides incentives for the private sector to invest funds in technological development that increases aggregate social wealth over the long term. For discussions of the distinction between innovative and allocative (and productive) efficiency, see Joseph F. Brodley, *The Economic Goals of Antitrust: Efficiency, Consumer Welfare, and Technological Progress*, 62 N.Y.U. L. REV. 1020, 1032-34 (1987); F.M. Scherer, *Antitrust, Efficiency, and Progress*, 62 N.Y.U. L. REV. 998, 998-1002 (1987). See also *infra* Part IV.C.

If this is true, then the threat of licensing or divestiture may further encourage interfirm alliances by further curtailing patent coverage and inducing large downstream firms to obtain innovation inputs by collaborating with, rather than acquiring, small upstream firms.

This Article proceeds as follows. Part II reviews governmental efforts to promote private investment in the biotechnology sector through federal funding of basic-science research and patent protection for certain genetic innovations. Part III examines critically the incentive and prospect rationales for patent protection and proposes a transaction-cost rationale that supplies a stronger basis for extending patent rights to the genetic commons. Part IV argues that dominant firms may accumulate socially excessive patent portfolios and suggests that antitrust authorities can maintain a wide diffusion of technological assets through relaxed treatment of R&D joint ventures and compulsory licensing remedies for certain biopharmaceutical mergers.

## II. PAST AND PRESENT: CULTIVATING THE GENETIC COMMONS

Any discussion of patent policy in the biotechnology sector requires some factual knowledge of the federal government's impressive efforts to stimulate private investment in this innovation market. Historically the federal government has allocated substantial resources to academic research that has generated the informational stock forming the basis for biotechnological development. Recently some governmental actors have sought to enhance private investment incentives by assigning patent protection to certain products or processes that researchers extract from the pool of genetic resources. This Part describes the historical development of each of these incentive-correcting policy devices.

### A. *Assembling the Knowledge Base*

Since World War II, the federal government has supplied basic-science research both directly, by maintaining government laboratories, and indirectly, through research grants or procurement programs that extend funds to universities, nonprofit research institutes, and private industry.<sup>15</sup> In the biotechnology sector, the National Institutes of Health ("NIH") has played an especially important role as a financing source.<sup>16</sup>

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15. See Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1667 (1996). Currently, there are over 600 federal laboratories employing well over 100,000 scientists and engineers. See ALAN S. GUTTERMAN & JACOB N. ERLICH, *TECHNOLOGY DEVELOPMENT AND TRANSFER: THE TRANSACTIONAL AND LEGAL ENVIRONMENT 2* (1997).

16. See Michael J. Malinowski & Maureen A. O'Rourke, *A False Start? The*

Most recently, the federal government has been funding the three billion dollar Human Genome Project.<sup>17</sup> Federal funding reduces the start-up cost of innovation projects in the biotechnology sector by supplying a knowledge base that opens up a broad prospect of potential advances for subsequent improvers. Government funding also provides training experience for research personnel who later move to a commercial environment. Much of the current growth in the biotechnology industry relies on scientific knowledge garnered through academic research or through industrial researchers who gained experience through federally funded projects.<sup>18</sup>

### B. Parceling Out the Knowledge Base

In the biotechnology sector, Congress and the federal courts took two significant steps that extended patent protection to basic-science research.<sup>19</sup> In 1980, Congress passed the Bayh-Dole Act,<sup>20</sup> which gives universities, small businesses, and nonprofit institutions the right to patent inventions developed through federally funded research.<sup>21</sup> Also in

*Impact of Federal Policy on the Genotechnology Industry*, 13 YALE J. ON REG. 163, 203-04 (1996) (stating that the NIH provides billions of dollars of research funding annually and that "the NIH is to the genotech industry what NASA has been to the space mission").

17. For a comprehensive description of this mammoth project, see the U.S. Dep't of Energy website devoted to this topic at Oak Ridge National Laboratory, *Human Genome Project Information* (visited Sept. 11, 2000) <<http://www.ornl.gov/hgmis/project/budget.html>>.

18. See Walter W. Powell, *Inter-Organizational Collaboration in the Biotechnology Industry*, 152 J. INSTITUTIONAL & THEORETICAL ECON. 197, 200 (1996) (stating that university researchers commonly take their sabbaticals at biotech firms and senior scientists move back and forth between universities and biotech firms); Gina A. Kuhlman, Comment, *Alliances for the Future: Cultivating a Cooperative Environment for Biotech Success*, 11 BERKELEY TECH. L.J. 311, 319 (1996) (stating that alliances between industry and universities, funded by federal grants, have facilitated capital-intensive and long-term biotechnological projects).

19. For a historical review of the federal government's policies toward granting patent rights for government-funded research, see Eisenberg, *supra* note 15, at 1663.

20. Bayh-Dole Act of 1980, Pub. L. No. 96-517, 94 Stat. 3015-3028 (codified as amended at 35 U.S.C. §§ 301-307 (1994 & Supp. IV 1998)).

21. See 35 U.S.C. § 202 (1994). The Bayh-Dole Act provides abundant opportunities for research participants to obtain patents for federally funded innovations. If a contractor fails to retain title to an invention within a certain period, the funding agency may seek a patent; if neither the contractor nor the agency seeks a patent, then the individual researcher may do so. See 35 U.S.C. § 202(a), (c)(2), (d). Several other statutes encourage the transfer of technology from federally funded procurement programs to the private sector. See, e.g., Stevenson-Wydler Technology Innovation Act

1980, the Supreme Court's ruling in *Diamond v. Chakrabarty*<sup>22</sup> extended patent protection to a genetically engineered microorganism which would break down crude oil, on the grounds that the patentee had significantly altered a naturally occurring organism.<sup>23</sup> As a result of the *Chakrabarty* decision, the PTO now grants patents to innovators who genetically modify a naturally occurring, non-human, multicellular organism<sup>24</sup> or, in some cases, to innovators who isolate whole genes or even gene fragments and sufficiently identify their biological function.<sup>25</sup>

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of 1980, Pub. L. No. 96-480, 94 Stat. 2311 (codified at 15 U.S.C. § 3710a (1994) (mandating that the federal government and its affiliated laboratories may transfer technology to the private sector through a variety of methods, including disseminating information about federal products and processes)); Federal Technology Transfer Act of 1986, Pub. L. No. 99-502, 100 Stat. 1785 (codified at 15 U.S.C. §§ 3710-3714 (1994 & Supp. IV 1998) (giving federal agencies the authority to conduct cooperative research with outside parties and negotiate patent licenses and chartering the Federal Laboratory Consortium for Technology Transfer)).

22. 447 U.S. 303 (1980).

23. See *id.* at 303, 310 (holding that the patentee had created a "new bacterium with markedly different characteristics from any found in nature"). Federal law requires that all patent applications show that the claimed innovation is "nonobvious," which means that it constitutes a significant advance over previously discovered information existing at the time that the invention was made, or alternatively, that it represents something more than what would have been considered obvious to one of ordinary skill in the art at the time the invention was made. See 35 U.S.C. § 103 (1994 & Supp. IV 1998). The *Chakrabarty* Court focused on the nonobviousness requirement and sought to distinguish the case from previous decisions that had ruled that naturally occurring products were obvious, and hence, not patentable subject matter. See *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948). But see *In re Bergy*, 596 F.2d 952, 973-75 (C.C.P.A. 1979) (holding that a biologically pure bacterial culture is patentable because the culture did not exist in nature in its pure form and could only be produced in a laboratory under precisely controlled circumstances). For a full description of the statutory patentability requirements, see *infra* notes 67-69 and accompanying text.

24. See *Nonnaturally Occurring Non-Human Animals Are Patentable under § 101*, 33 PAT. TRADEMARK & COPYRIGHT J. (BNA) 664, 664 (Apr. 23, 1987) (stating that "non-naturally occurring non-human multicellular living organisms, including animals, are patentable subject matter"). For an example of a patent protection issued under this policy, see U.S. Patent No. 4,736,866, issued April 12, 1988, granting patent protection to Harvard University for an "oncomouse," a mouse genetically engineered to be unusually susceptible to cancer. See *Transgenic Non-Human Mammals*, United States Patent No. 4,736,866 (Apr. 12, 1988), available in Delphion Intellectual Property Network, US4736866: *Transgenic Non-Human Mammals* (visited Aug. 22, 2000) <[http://www.patents.ibm.com/details?&pn=US04736866\\_&s\\_all=1](http://www.patents.ibm.com/details?&pn=US04736866_&s_all=1)>. Even before the Court's decision in *Chakrabarty*, two federal statutes had extended limited patent-like protection to new plant organisms. The Plant Patent Act of 1930, 46 Stat. 376 (codified at 35 U.S.C. §§ 161-164 (1994 & Supp. IV 1998)), extends patent protection to asexually reproducing plant types. The Plant Variety Protection Act of 1970, Pub. L. No. 91-577, 84 Stat. 1542 (codified at 7 U.S.C. §§ 2321-2582 (1994)), directs the Department of Agriculture to extend patent-like protection to "inventors" of sexually reproduced plant types.

25. The extent to which a researcher must isolate a particular genetic sequence in order to obtain patent protection has recently been the subject of much controversy. In 1991, the NIH sought patents on complete gene sequences on the basis of scientific documentation of partial gene sequences (expressed sequence tags or ESTs) whose

In the gene therapy sector, most of the patents the PTO has granted are process patents on “research tools” that contain techniques for genetic alteration or for the delivery of altered genetic material to patients.<sup>26</sup> During this same period, the Federal Circuit, created in 1982, generally has adopted a patent-friendly stance that has resulted in more favorable rulings for patent infringers, higher infringement damage awards, and greater average patent scope.<sup>27</sup>

The Bayh-Dole Act and the *Chakrabarty* decision have sparked a technology transfer industry that has enabled private industry to acquire

function NIH researchers had not yet ascertained. The PTO initially denied the application on some of the claims because the NIH had not specified the function of the claimed genetic sequence. The NIH later withdrew the remaining claims in the face of public controversy from researchers and industry representatives. For a retelling and analysis of the controversy, see Rebecca S. Eisenberg, *A Technology Policy Perspective on the NIH Gene Patenting Controversy*, 55 U. PITT. L. REV. 633, 633-34 (1994). Currently, the PTO occasionally grants patent protection to complete or even fragmentary gene sequences provided the specifications are sufficiently narrow and the patent application documents the sequence’s function. Whether more extensive protection will become available remains unclear. See Rebecca S. Eisenberg, *Intellectual Property at the Public-Private Divide: The Case of Large-Scale DNA Sequencing*, 3 U. CHI. L. SCH. ROUNDTABLE 557, 563 (1996). Recently, the PTO has released new proposed utility guidelines which, if adopted, would raise the patentability threshold for patent applications on gene sequences. See Revised Interim Utility Guidelines and Revised Interim Written Description Guidelines, 64 Fed. Reg. 71441 (1999). These interim guidelines require that applicants credibly show a specific function or use to which the claimed gene sequence can be applied and, therefore, would exclude gene sequences whose function could only be potentially revealed by extensive additional research. See *Gene Patents on Other Genomic Inventions: Oversight Hearing Before the U.S. House Subcomm. on Courts and Intellectual Property*, 106th Cong. 1 (July 13, 2000) (statement of Q. Todd Dickinson, Chairman, PTO) [hereinafter *Gene Patents*]. See also Martin Enserink, *Patent Office May Raise the Bar on Gene Claims*, 287 SCI. 1196 (Feb. 18, 2000) (stating that the PTO has decided that “patent applicants must demonstrate a more substantial, real-world utility; not some throwaway utility”).

26. See John K. Flanagan, *Gene Therapy and Patents*, 80 J. PAT. & TRADEMARK OFF. SOC’Y 739, 739-40 (1998). The most well-known example of a patented research tool in the biotechnology sector is the pair of Cohen-Boyer patents, U.S. Patents 4,237,224 and 4,468,464, issued in 1980 and 1984, respectively, which were licensed for nominal fees on a nonexclusive basis by Stanford University throughout the term of the patents. See *Gene Patents*, *supra* note 25, at 6. These patents cover some of the fundamental techniques used in recombinant DNA research. See *id.*

27. See JEAN O. LANJOUW & JOSH LERNER, *THE ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS: A SURVEY OF THE EMPIRICAL LITERATURE* 8-9 (National Bureau of Econ. Research Working Paper No. 6296, 1997). See also SAMUEL KORTUM & JOSH LERNER, *STRONGER PROTECTION OR TECHNOLOGICAL REVOLUTION: WHAT IS BEHIND THE RECENT SURGE IN PATENTING?* 8-9 (National Bureau of Econ. Research Working Paper No. 6204, 1997) (stating that, from 1982 to 1990, the Federal Circuit affirmed 90% of district court decisions holding patents to be valid and infringed, and reversed 28% of judgments of invalidity and non-infringement).

licenses to the fruits of university research and encouraged academic researchers to pursue commercial applications for some of their scientific discoveries.<sup>28</sup> This extension of patent rights has catalyzed the biotechnology industry by opening up the federally funded genetic commons to dispersed ownership and commercial exploitation by academic institutions and large and small industry participants. Since the passage of the Bayh-Dole Act, universities have opened up technology transfer departments, filed for a significantly higher number of patents, and collaborated more frequently with private industry.<sup>29</sup> In a remarkable departure from academic norms that generally disdain commercial entanglements, numerous researchers have curtailed or abandoned their university-related endeavors and founded start-up firms specializing in biomedical research.<sup>30</sup> These small scientist-founded

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28. See Eisenberg, *supra* note 15, at 1708 (noting that “the Bayh-Dole Act has been consistently hailed as an unqualified success in stimulating the commercial development of discoveries emerging from government-sponsored research in universities”); Gale R. Peterson, *Introduction to the Field of Biotechnology Law*, in UNDERSTANDING BIOTECHNOLOGY LAW: PROTECTION, LICENSING, AND INTELLECTUAL PROPERTY POLICIES 1, 5 (Gale R. Peterson ed., 1993) (stating that the Bayh-Dole Act “was largely responsible for the expansion of existing [technology transfer] programs” at many universities and nonprofit research institutions). See also Kenneth Sutherland Dueker, *Biobusiness on Campus: Commercialization of University-Developed Biomedical Technologies*, 52 FOOD & DRUG L.J. 453, 461-66 (1997) (relying on empirical data to show that patent law reforms, and changes in federal law that encourage universities to obtain patents on federally funded research, have fueled the rise of the biotechnology and biopharmaceutical industries); REBECCA HENDERSON ET AL., UNIVERSITIES AS A SOURCE OF COMMERCIAL TECHNOLOGY: A DETAILED ANALYSIS OF UNIVERSITY PATENTING 1965-1988, at 8-9 (National Bureau of Econ. Research Working Paper No. 5068, 1995) (stating that university technology transfer offices reported in 1992 that they received royalties totaling about \$230 million on about 3000 patents).

29. See HENDERSON ET AL., *supra* note 28, at 1 (finding that number of university patents increased 15-fold since 1965 while university spending on research income increased only 300%); Kuhlman, *supra* note 18, at 345-46 (noting that universities were awarded 1324 patents in 1991, an increase of 200% over the 437 granted in 1980). It is true that technology transfer and patent licensing do not bring universities income that is significant relative to the size of a large university’s operating budget. See Lita Nelsen, *Identifying, Evaluating, and Reporting Innovative Research Developments at the University*, in UNDERSTANDING BIOTECHNOLOGY LAW: PROTECTION, LICENSING, AND INTELLECTUAL PROPERTY POLICIES 25, 28-29 (Gale R. Peterson ed., 1993) (stating that “even a fully developed licensing program will yield royalty income no more than 2 to 5% (at most) of . . . [a university’s] total annual research budget”). Nevertheless, universities have strong incentives to attract industry sponsorship that provides “unrestricted” funding (as opposed to dedicated federal funds) and insures against volatile swings in the availability of federal funding. See *id.*

30. See Henry Etzkowitz, *The Norms of Entrepreneurial Science: Cognitive Effects of the New University-Industry Linkages*, 27 RES. POL’Y 823, 823-33 (1998) (noting that universities are currently undergoing a shift toward a commercial ethos, where academic scientists have repeated interactions with private industry); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1018 (1989) [hereinafter Eisenberg, *Progress of Science*] (noting that the

biotechnology companies have played a crucial role in transferring scientific research from universities to the commercial marketplace.<sup>31</sup> Together, *Chakrabarty* and the Bayh-Dole Act have instituted a patent regime that has shifted significant portions of the academic knowledge base to private firms that apply this knowledge to develop commercially viable biopharmaceutical applications.

### III. ACCESS EXPANDED: PATENT PROTECTION AND INNOVATION NETWORKS

Discussions in the legal, industrial, and scientific communities on the introduction of patent rights into the genetic commons often speak of an intractable tradeoff between enhanced productivity and diminished accessibility.<sup>32</sup> On the one hand, patent grants offer a monopoly reward that encourages private investors to endure the high development costs and long gestation period of basic biopharmaceutical research. The full development of a biotechnology product usually takes more than a decade,<sup>33</sup> and development costs typically total over \$200 million.<sup>34</sup> On the other hand, any enhanced innovation incentives come at the price of

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“biotechnology revolution has accelerated the commercial development of basic research,” blurred the distinction between basic and applied research, and led academic scientists to patent commercially valuable research discoveries); Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 195-97 (1987) (suggesting that industrial sponsorship of biomedical research and availability of patent protection have blurred the traditional distinction between basic and applied research in this sector).

31. See ACHARYA, *supra* note 4, at 33.

32. See *Report of the National Institutes of Health (NIH) Working Group on Research Tools* (1998) (visited July 1, 2000) <<http://www.nih.gov/news/researchtools/index.htm>> [hereinafter *NIH Report*]; COMPETITION POLICY REPORT, *supra* note 11, chs. 6 & 8; Eisenberg, *Progress of Science*, *supra* note 30, at 1017. For an important exception to this general tendency, see Janusz A. Ordover, *A Patent System for Both Diffusion and Exclusion*, 5 J. ECON. PERSP. 43 (1991). Ordover shows that, in the Japanese patent system, legal constraints on available forms of patent protection induce firms to internalize spillovers through cross-licensing and other forms of collaboration. See *id.* at 44-54. On a more general level, Ordover uses the Japanese example to argue that much policy discussion in the patent literature relies on overly crude dichotomies between the exclusion/diffusion and short-term/long-term characteristics of patent protection. See *id.*

33. See Joshua Lerner, *Venture Capitalists and the Decision to Go Public*, 35 J. FIN. ECON. 293, 294 (1994).

34. See PISANO, *supra* note 4, at 73-74. As of 1993, published estimates report that average “out of pocket” R&D costs for a new biotechnology-based drug are \$125 million and average “facility” costs (“cash outlays on new plant and equipment required to manufacture a new chemical entity”) are \$99 million. *Id.*

reduced access to certain genetic discoveries or research techniques that cover a broad field of subsequent applications. Today academic and industrial researchers commonly lament the ballooning costs of navigating around proliferating clusters of patent claims,<sup>35</sup> and some commentators contend that patent claims ultimately will result in upstream strangleholds on basic-research discoveries that will significantly impede downstream technological applications.<sup>36</sup>

This Part offers a revised argument for granting patents to biotechnological discoveries, suggesting that this cost-cost tradeoff is not inevitable. That is, policymakers can purchase enhanced appropriability for biotechnological innovators without paying *any* price in the form of reduced accessibility. To show how this may be possible, this Article reviews and casts some doubt on the well-known incentive and prospect theories of patent protection.<sup>37</sup> Incentive theories correctly

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35. See COMPETITION POLICY REPORT, *supra* note 11, at 5-6 (stating that “especially with respect to new technologies such as biotechnology and computers, there is concern that overbroad grants and enforcement of intellectual property rights may increase incentives for anticompetitive conduct such as illegal patent pooling or sham litigation”); NIH Report, *supra* note 32, at 5-16 (exploring the extension of patent rights to “research tools” and noting that many scientists are frustrated about restricted access to research techniques and believe that this is impeding technological advancement). See also Jackie Hutter, Note, *A Definite and Permanent Idea? Invention in the Pharmaceutical and Chemical Sciences and the Determination of Conception in Patent Law*, 28 J. MARSHALL L. REV. 687, 724-25 (1995) (noting that research joint ventures rush to protect investment funds by patenting discoveries before commercial application is clearly defined and, as a result, these patents are vulnerable to litigation).

36. See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998) (arguing that excessive patenting in genetic research can lead to an “anticommons” where multiple property rights holdings impede the progress of unified research efforts). For a strong response to these arguments, see John J. Doll, *The Patenting of DNA*, 280 SCI. 689 (1998). The author argues that fears that patent rights for gene sequences will impede downstream technological advance simply repeat unfounded fears expressed 30 years earlier with respect to the granting of patent rights for the building blocks of basic polymers (a key component of certain insulation products). See *id.* Just as some commentators now argue that patent rights for DNA fragments will impede downstream research that relies on applying those fragments to subsequent discoveries, commentators once argued that patent rights for the building blocks of basic polymers would have a similar adverse effect. See *id.* As it turns out, these fears did not materialize because the Patent Office employed the patentability requirements to grant patent protection to subsequent investors who invented similar copolymers of the same type. See *id.* at 689-99. As the author suggests, the Patent Office has discretion to employ the same legal tools to foster downstream research in the biotechnology industry. See *id.*

37. For a review of these (and other) standard theories of patent protection, see Merges & Nelson, *supra* note 7, at 839-916. For current surveys of the vast literature on the economics of innovation, see generally CHRIS FREEMAN & LUC SOETE, *THE ECONOMICS OF INDUSTRIAL INNOVATION* (3d ed. 1997); RICHARD R. NELSON, *THE SOURCES OF ECONOMIC GROWTH* (1996); *HANDBOOK OF THE ECONOMICS OF INNOVATION AND TECHNOLOGICAL CHANGE* (Paul Stoneham ed., 1995); *THE HANDBOOK OF INDUSTRIAL INNOVATION* (Mark Dodgson & Roy Rothwell eds., 1994); F.M. SCHERER & DAVID ROSS, *INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE* 613-60

imply that, since biopharmaceutical innovations are high-cost projects that are vulnerable to low-cost imitation, patent protection is required to eliminate the free-rider threat that may prevent investors from recouping development costs and capturing the knowledge spillovers of a breakthrough invention. But this theory does not explain how, given a wide distribution of low-risk/low-spillover and high-risk/high-spillover innovation possibilities, patent rewards could encourage private investment in the most fundamental and uncertain types of innovation projects. Prospect theory recognizes this shortfall and prescribes “mineral claim” patents, which cover all, or most, of an innovation’s technological yield, to induce investment in R&D projects that fall at the high end of the risk/spillover spectrum.

Neither the incentive theory nor the prospect theory, however, leads to correct policy conclusions in biotechnology or other heavily science-based industries. This is because broad patents are not required to induce, and may even discourage, high-risk/high-spillover types of R&D investment in these areas. Widespread collaborative behavior in the biotechnology sector indicates that patent rights may function primarily as a facilitator mechanism that reduces the transaction costs of negotiating and sustaining interfirm R&D alliances. To play this role, however, patents must offer *no more than incomplete protection*. That enables investors to recoup development costs but does not cover the expected spillovers of a completed innovation. Imperfect patent coverage encourages patentholders to form technology-sharing alliances that allow participating firms to internalize a large portion of the expected spillovers by combining intellectual property holdings and research, marketing, or distribution capabilities. These interfirm ventures allow patent holders to minimize knowledge giveaways by erecting barriers to second-mover imitators through enhanced patent coverage and scale-efficient distribution and marketing facilities. By bringing together potential biotechnology rivals, these industry-industry or industry-university collaborations may reverse the tradeoff between accessibility and productivity that commentators routinely attribute to patent protection. Current technology-sharing practices in the biotechnology industry suggest that this imperfect form of patent protection has enhanced accessibility to *and* cultivation of the government-funded base of biotechnological knowledge.

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(3d ed. 1990).

### A. Basic Research and the Underinvestment Problem

A firm contemplating an innovation project must assess the net present value of the proposed R&D investment. To do so, it must consider the extent to which it expects to: (1) recover projected development costs and (2) appropriate the innovation's projected revenues (including revenues derived from subsequent applications). If patent protection is not available, the extent to which the firm can expect to recover development costs depends on the post-invention costs of production and marketing, expected consumer demand, and, crucially, rivals' costs of imitating the innovation. Imagine that firm *A*, after several years of expensive R&D, is the first to invent and produce a nuclear-powered toothbrush and initially acquires a monopoly share in the nuclear-powered toothbrush market. Firm *B*, however, may free-ride on firm *A*'s extensive development efforts, design a cheaper production method or more attractive brand image at relatively little cost, and diminish *A*'s market share before *A* can recoup development costs.<sup>38</sup> If firm *A* expects to suffer this first-mover disadvantage, it may delay investment and wait to exploit a second-mover opportunity. Thus, potential innovators are caught in a waiting game and technological advance slows as a result.

The incentive problems under a no-patent regime are not, however, completely insuperable. If first-movers can erect imitation barriers through technological opacity, trade secrecy, brand image, distribution efficiencies, or network effects, then there may be a *second*-mover penalty, and the waiting game may preclude only a portion of innovative output.<sup>39</sup> But these non-patent imitation barriers only partially solve the underinvestment problem. Even if non-patent imitation barriers are effective and firm *A* believes it can recoup development costs (plus a reasonable return) before imitative products erode its market share, it may not develop the nuclear-powered toothbrush if this breakthrough

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38. An empirical study of imitation costs finds that, although there is considerable interindustry variation, imitation costs are generally significantly lower than innovation costs. See Edwin Mansfield et al., *Imitation Costs and Patents: An Empirical Study*, 91 *ECON. J.* 907, 909-10 (1981) (reporting that the ratio of imitation costs to innovation costs is 0.65, and the ratio of imitation time to innovation time is 0.70).

39. The non-patent-based first-mover advantage is most pronounced for network technologies where each consumer who has already purchased the technology experiences increasing returns as more consumers adopt the technology. Thus, where two substitute and novel technologies are competing to garner consumer loyalty, the first technology to enter the market may enjoy an unbeatable lock-in effect, since even a superior but latecomer technology may not induce consumers to incur the switching costs of abandoning the old but inferior technology. See W. Brian Arthur, *Competing Technologies, Increasing Returns, and Lock-In by Historical Events*, 99 *ECON. J.* 116, 116-17 (1989).

innovation may open up other innovation possibilities to competitors. If these innovation possibilities include technological advances that could render firm A's well-established product line of electric toothbrushes obsolete, it may have little incentive to introduce the nuclear-powered toothbrush. Even if the nuclear-powered toothbrush is difficult to imitate perfectly, and thus, the firm can maintain its monopoly share in the product market, this innovation may indicate design principles for which the firm cannot charge a user's fee in the innovation market. Thus, the firm earns a short-term return on its toothbrush but gives away the design principle for all nuclear-powered handheld appliances. For this reason, firm A may prefer to develop an electric toothbrush with kiwi-flavored toothpaste that introduces marginal improvements to existing technologies and has little spillover value for subsequent improvers.

As this simplified example indicates, a no-patent world is bad public policy primarily because competing firms may fail to generate a socially adequate direction, rather than rate, of innovative output. This result has a sound theoretical explanation: the more fundamental the type of innovation, the more closely it resembles a public good that an unregulated market tends to produce in socially inadequate quantities.<sup>40</sup> A public good exhibits two characteristics: (1) it is impossible (or extremely costly) to exclude other people from using that good (the non-exclusivity condition), and (2) each additional user of that good does nothing (or very little) to diminish the value of that good (the non-rivalrousness condition).<sup>41</sup>

Whether or not biopharmaceutical innovations usually satisfy substantially the nonrivalrousness condition is disputable, since any particular scientific discovery opens up a broad but finite prospect<sup>42</sup> of commercially marketable applications. Thus, each additional researcher who improves upon an initial innovation reduces the limited therapeutic yield that remains for subsequent improvers to extract. Biopharmaceutical innovations, however, largely satisfy the non-exclusivity condition, since these are informational goods that third

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40. On the concept of public goods (and related concepts), see generally RICHARD CORNES & TODD SANDLER, *THE THEORY OF EXTERNALITIES, PUBLIC GOODS, AND CLUB GOODS* (2d ed. 1996).

41. *See id.*

42. "Prospect" refers to the potential applications and innovations that subsequent improvers may develop on the basis of an initial, more fundamental innovation. *See* Kitch, *supra* note 8, at 266.

parties may be able to imitate at low cost. The high costs of excluding imitators may prevent the innovator from earning a reasonable return or even recouping development costs. Even if imitation costs are high enough that the innovator can expect to recoup development costs, there may be few barriers to subsequent improvers and, thus, the first-mover innovator gives away research methods or design principles that it cannot internalize as profitable return.

In the absence of some form of state intervention, the market is likely to underinvest in fundamental innovation projects that generate a large stream of inappropriable spillovers. High-appropriability, low-spillover activities include intermediate and advanced product development, such as quality-enhancing modifications to existing products, cost-reducing modifications to existing processes of production, and cost-neutral modifications that enhance product differentiation and brand image.<sup>43</sup> Low-appropriability, high-spillover activities include radical product and process innovations that derive from basic research and some forms of applied research.<sup>44</sup> Without patent protection, private investors are likely to bias their R&D portfolios toward incremental improvements and away from more basic and applied research efforts.<sup>45</sup>

Even if exclusion costs are low enough to allow first-mover innovators to realize significant profits by moving ahead on the learning curve, cultivating a brand image, and establishing a dominant market share, innovators still may have strong incentives to pursue small, rather than breakthrough, inventions. This is because less fundamental types of product research are more likely to yield a technically feasible and commercially marketable product. Furthermore, they are less likely to generate knowledge spillovers that benefit competitors. Even if the lure of a first-mover advantage leads some innovators to pursue breakthrough inventions, subsequent improvements are likely to proceed slowly since the initial innovator minimizes spillover losses by concealing the knowledge that lies behind the breakthrough invention. Reinventing the

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43. See FREEMAN & SOETE, *supra* note 37, at 242-85.

44. See *id.* Basic research is roughly what goes on in most university and government laboratories; it expands the common stock of scientific knowledge, but does not point toward any practical application in a reasonable time horizon. See SCHERER & ROSS, *supra* note 37, at 616. Applied research covers much of what takes place in industry laboratories or, more recently, in collaborative ventures between private firms and university departments. See *id.* at 619.

45. There is a consensus among economists that, absent state intervention, private expenditures on basic research are likely to take place at socially suboptimal levels. See FREEMAN & SOETE, *supra* note 37, at 268-72. This consensus derives from two classic papers. See Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in NATIONAL BUREAU OF ECONOMIC RESEARCH, *THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS* 609 (1962); Richard R. Nelson, *The Simple Economics of Basic Scientific Research*, 67 J. POL. ECON. 297 (1959).

wheel every so often is not the best path toward technological advancement.

*B. The Incomplete Argument for Patent Protection*

This hypothetical no-patent world illustrates the basic lesson of the incentive theory. Namely, patent awards encourage innovation by supplying a rational profit motive to invest privately held resources in uncertain R&D projects. Since certain intellectual assets are often vulnerable to low-cost imitation, many innovations would not take place without patent rights that mitigate the first-mover penalty by promising monopoly profits for some limited duration. Patent duration must be carefully constrained, however, because a monopoly grant results in two significant social costs: (1) distributive costs (consumer surplus is transferred to the patent holder through supracompetitive pricing), and (2) allocative costs (deadweight loss results because monopoly power leads to output distortions).<sup>46</sup> Although deadweight loss tends to constitute a small portion of a monopolist's total sales, it can lead to more significant efficiency losses. This is because monopoly shares may: (1) encourage dominant-firm managers to allow costs to rise significantly above competitive levels (thus wasting social resources), or (2) induce firms to incur rent-seeking expenses to acquire or preserve monopoly shares (thus dissipating monopoly profits).<sup>47</sup> To minimize these indirect, and possibly very significant, allocative costs of monopoly shares, incentive theories usually hold that patent grants should generate profits that, ideally, cover no more than the innovator's expected development expenses plus a reasonable rate of return. These social costs of monopoly grants are worth incurring because either (1) distributive costs do not alter aggregate wealth, and thus are irrelevant for efficiency purposes, or (2) the direct and indirect allocative costs are less than the opportunity cost of not having the innovation at all.

In contrast to most other industries, where there is weak empirical support for incentive-based efficiency arguments for patent protection,<sup>48</sup>

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46. For a fuller discussion of the social costs of monopoly, see WALTER E. NICHOLSON, *INTERMEDIATE MICROECONOMICS AND ITS APPLICATION* 298-305 (7th ed. 1997).

47. See Scherer, *supra* note 14, at 998-1000.

48. Several empirical studies cast some doubt on incentive-based arguments for patent grants by showing that firm managers in most industry sectors believe they can raise imitation costs significantly through non-patent devices such as brand image, trade

pharmaceutical firm managers report that they would not undertake most innovation projects if patent protection were not available.<sup>49</sup> Notwithstanding this finding, however, an incentive theory of patent protection does not satisfactorily explain R&D behavior in the biopharmaceutical industry. The reason is straightforward: although an incentive theory explains how patents may encourage biopharmaceutical firms to invest in innovation projects generally, it does not explain how patents could encourage these firms to select high-risk/high-spillover projects in particular. Even if patent protection enables firms to recoup product development costs, it does not correct firms' rational tendency to bias their R&D portfolio toward incremental research that generates low knowledge spillovers. Even if patent protection is available, investors are likely to gravitate toward short-term, low-risk projects that

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secrecy, and "learning by doing." See WESLEY M. COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS: APROPRIABILITY CONDITIONS AND WHY U.S. MANUFACTURING FIRMS PATENT (OR NOT) (National Bureau of Econ. Research Working Paper No. 7552, 2000) (surveying in 1994 R&D lab managers randomly drawn from a sample of all R&D labs located in the U.S. conducting R&D as part of a manufacturing firm, receiving responses from 1478 labs, and finding that most industries viewed patents as the least effective mechanism for directly appropriating the economic returns from an investor); Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, in 3 BROOKINGS PAPERS ON ECONOMIC ACTIVITY: SPECIAL ISSUE ON MICROECONOMICS 783, 783-88 (Martin Neil Baily & Clifford Winston eds., 1987) (surveying manager expectations and showing that managers often view patents as ineffective mechanisms to protect intellectual property from imitators, and that managers use alternative devices to appropriate returns from R&D); Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173 (1986) (surveying R&D executives of 100 randomly chosen U.S. firms from 12 industries and finding that, in all industries other than chemicals and pharmaceuticals, corporate managers believed that less than 30% of the inventions their firms developed during 1981 to 1983 would *not* have been developed without patent protection).

49. See Levin et al., *supra* note 48, at 796-97. See also Mansfield, *supra* note 48, at 175 (finding that pharmaceutical firms' managers believed that 60% of all new products during 1981 to 1983 would not have been developed without patent protection). This result is not surprising because pharmaceutical products are expensive to develop but inexpensive to imitate perfectly, and thus few nonpatent devices can erect an adequate imitation barrier. See Mansfield et al., *supra* note 38, at 913 (assessing the imitation costs of copying patented and nonpatented innovation relative to the original invention costs and finding that the ratio of imitation costs to invention costs is especially skewed in the pharmaceutical industry where investors must incur enormous development costs but most products can be imitated at fairly low cost). It is important to add that the Food & Drug Administration ("FDA") approval process considerably enhances the first-mover disadvantage for pharmaceutical firms since this lengthy process doubles development costs for the initial innovator (and, under recent legislation, generally does not apply to generic drugs). See Malinowski & O'Rourke, *supra* note 16, at 205-10. Although 1984 federal legislation relieves generic drug manufacturers from undergoing a full approval process, this legislation also amended the patent law to allow drug manufacturers to request patent term extensions up to seven years to make up for the delay caused by the FDA approval process. See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 156, 355 (1994 & Supp. IV 1998)).

have a lower potential return but a higher certainty of cost and profit realization.<sup>50</sup> Numerous empirical studies demonstrate that most large firms employ incremental R&D strategies that rely on product modification to maintain brand image, sustain market share, and ensure readiness to react to technological innovations by existing or potential competitors.<sup>51</sup> This conventional investment pattern would impede significant progress in the biopharmaceutical sector, because biomedical innovation characteristically consists of a large portion of basic research that is highly capital-intensive and tends to generate numerous spillover applications.

Edmund Kitch sets forth a proposal that explains how a patent system might correct this selection bias. Kitch argues that policymakers should define patents in broad, property-like terms, so that patent claims extend over a wide prospect of subsequent applications and encourage first-mover inventors to exploit a wide range of possible improvements.<sup>52</sup> As Kitch suggests by analogizing patents to mineral claims,<sup>53</sup> this "prospect" patent is effectively a form of perfect or complete patent protection that covers development costs and many, or even most, of the expected spillovers. Most economists and academic lawyers have expressed serious doubt as to whether this policy recommendation would result in net social benefits.<sup>54</sup> It is easy to see why commentators might reach this conclusion. Broadly defined patents appear likely to exacerbate considerably the accessibility costs that attend any system of property rights. Extending any form of patent protection to biotechnological innovations obviously increases development costs for subsequent researchers and, depending on patent scope and duration, may reduce or eliminate some researchers' incentives to improve upon existing innovations. This danger grows as patent size increases. If

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50. See FREEMAN & SOETE, *supra* note 37, at 263-64 (stating that an unregulated market will tend toward underinvestment in long-term R&D projects and overinvestment in short-term R&D projects aimed at product differentiation).

51. See *id.* at 255.

52. See Kitch, *supra* note 8, at 267-71.

53. See *id.* at 271-75.

54. See Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 1044-51 (1997) (arguing that Kitch's proposal would probably retard subsequent innovation because of high licensing costs, including identifying suitable licensees and negotiating licensing terms); Merges & Nelson, *supra* note 7, at 843-44 (criticizing Kitch's proposal and arguing that pioneering patents should be limited in scope so as to encourage potential innovators to compete for patents on improvements of the initial innovation).

broad patents sufficiently inflate subsequent improvers' accessibility costs, patent protection would fail a net social benefit test, since it would reduce the total stream of innovative output that would exist in a world without any patent protection.

There is little determinative empirical evidence to settle theoretical speculation over the optimal scope and duration of patent protection.<sup>55</sup> Intuition, however, points strongly against Kitch in the biotechnology sector, since an innovator would require a very broad definition of patent rights to internalize the entire set, or even a substantial portion of the set, of innovation possibilities generated by certain research techniques. If this is true, then current patent coverage is substantially incomplete. Current forms of patent protection for biotechnology innovations cover only a small portion of the foreseeable prospect of subsequent applications and courts often use various doctrinal instruments to narrow further the scope of patent claims.<sup>56</sup> Under Kitch's theory, we would expect few firms to invest in high-spillover innovations under this relatively meager level of patent protection. But the real world operates to the contrary. In spite of (or rather, as we shall soon see, because of) these insufficient forms of patent protection, private industry has invested heavily in fundamental biotechnology research. This result suggests that private industry must be employing non-patent devices to internalize some of the knowledge spillovers that these imperfect patents

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55. See Merges & Nelson, *supra* note 7, at 868-70 (stating that most economic models of patent scope and duration focus on the relation between breadth, duration, and incentives to innovate, without giving serious consideration to the social costs of greater duration and breadth in the form of retarded subsequent improvement); Donald J. Wright, *Optimal Patent Breadth and Length with Costly Imitation*, 17 INT'L. J. INDUS. ORG. 419, 426-32 (1999) (noting that policy recommendations as to patent breadth or length depend on controversial assumptions as to market structure, the number of actual or potential entrants, and the costs of imitation).

56. See Merges & Nelson, *supra* note 7, at 840-42 (stating that the PTO and the courts generally have resisted granting broad prospects to biotechnological innovations and that courts have considerable discretion in patent infringement litigation to narrow the scope of a patent to enable subsequent improvements to go forward). *But see* COMPETITION POLICY REPORT, *supra* note 11, ch. 8, at 13 (noting that "the scope of patents issued has become increasingly broad, with some patent claims apparently designed to cover an entire area of research or even basic research, particularly in the biotechnology industry"). For an instance where a court has narrowed the scope of a biotechnology patent, see *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997). In *Eli Lilly*, the Federal Circuit examined a patent for a method of producing human insulin through a recombinant DNA process. *See id.* at 1562. Although the patent claimed that the method could be applied to the isolation of the insulin gene from higher mammals generally (including humans), it only specified the nucleotide sequence for rats. *See id.* The court held that the enablement doctrine, and the related requirement of a minimally specific description, narrowed the patent's scope to the isolation of the insulin gene from rats. *See id.* at 1567-69. For a critical discussion of this decision, see Harris A. Pitlick, *The Mutation on the Description Requirement Gene*, 80 J. PAT. & TRADEMARK OFF. SOC'Y 209, 217-26 (1998).

do not cover. As will be shown, the currently incomplete forms of intellectual property coverage have led the biotechnology industry to construct network forms of organization that make up for the appropriability shortfall.

### C. *Completing the Argument for Incomplete Patent Protection*

This Section presents the following claim. For the purposes of determining the socially optimal level of patent coverage for biotechnological innovations, it would not matter if empirical studies could show that broad patents would pass a social cost-benefit test by generating productivity benefits that would exceed accessibility costs. This is because imperfect patents, covering no more than development costs, adequately encourage firms to conduct basic research and improve accessibility to that research. Relative to a regime of perfect patents, a regime of imperfect patents does at least as well, and in fact probably better, at encouraging basic research and does far better at sustaining accessibility to the genetic commons. This insight carries an important implication. Contrary to common assumptions, extending patent rights to the genetic commons does not necessarily trigger a tradeoff between productivity benefits and accessibility costs.

To demonstrate this point, this Section will complete the argument for introducing patent rights into the biotechnology sector. As has already been shown, the incentive theory can explain how patents induce a certain rate, but not a certain direction, of innovative output. Incentive theory can explain how patents encourage firms to innovate generally, but it cannot explain how patents might encourage firms to select the most fundamental and uncertain types of innovation projects. This Section shows that imperfect patent rights can close the appropriability gap between low-spillover and high-spillover R&D investments by supplying a contracting device that reduces two important transaction costs of interfirm collaboration.<sup>57</sup> These transaction costs, each of which

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57. For an argument that insecure, divided entitlements may sometimes facilitate efficient bargaining more effectively than secure, undivided entitlements, see Ian Ayres & Eric Talley, *Solomonic Bargaining: Dividing a Legal Entitlement to Facilitate Coasean Trade*, 104 *YALE L.J.* 1027 (1995). The authors argue that undivided property rights sometimes inhibit efficient bargaining outcomes by allowing private parties to act strategically by concealing private information. *See id.* at 1058-61. By contrast, uncertainty as to which party owns a particular entitlement (effectively resulting in a divided entitlement in the context of negotiation) may induce parties to act cooperatively by revealing private valuations of the contested item. For the ensuing debate, see Ian

corresponds to a particular informational asymmetry, include: (1) downstream firms', or buyers', costs of credibly committing to non-opportunistic behavior, and (2) upstream firms', or sellers', costs of credibly representing the value of intellectual assets. This transaction-cost analysis detours around the tradeoff between productivity and accessibility by showing that an imperfect form of patent protection enhances productivity and accessibility by facilitating collaborative networks that close the appropriability shortfall and disseminate the genetic information stock among a wide community of competent users. As shall be shown, the real world appears to confirm this theory. The introduction of patent rights into the genetic commons has facilitated a trading and licensing network that has substantially accelerated the dissemination of the genetic knowledge stock and, as a result, the pace of technological advance.

### 1. *The Virtues of Incomplete Patent Protection*

Since the judicial and statutory initiation of patent rights for basic research findings in 1980, biotechnological product development generally has taken place through collaborative networks that involve multiple research agents and industry participants. These alliances typically match up a small biotechnology firm, which primarily attends to basic research and early product development, and a large pharmaceutical firm, which primarily attends to clinical testing, marketing, and distribution.<sup>58</sup> In contrast to classical models of autarchic innovation, such as the corporate R&D department or the individual inventor, the biotechnology sector relies on a network form of organization that brings together the technological capabilities of several firms and institutions.<sup>59</sup> This network innovation structure reduces the

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Ayres & Eric Talley, *Distinguishing Between Consensual and Nonconsensual Advantages of Liability Rules*, 105 YALE L.J. 235 (1995); Louis Kaplow & Steven Shavell, Comment, *Do Liability Rules Facilitate Bargaining? A Reply to Ayres and Talley*, 105 YALE L.J. 221 (1995).

58. See *infra* Parts III.C.1.b.i & ii.

59. See FREEMAN & SOETE, *supra* note 37, at 225 (discussing historical models of product innovation and reviewing the rise of the networking model in the late twentieth century); P.R. Beije & J. Groenewegen, *A Network Analysis of Markets*, 26 J. ECON. ISSUES 87, 87-88 (1992) (stating that a network analysis focuses on the complex interdependencies between firms and, unlike conventional market analysis, does not assume the perfect independence of firms); Paul L. Robertson & Richard N. Langlois, *Innovation, Networks, and Vertical Integration*, 24 RES. POL'Y 543, 549-50 (1995) (describing the "innovative network" and, specifically, the information exchange and task specialization that exist among start-ups and venture capitalist firms in Silicon Valley in California and Route 128 in Massachusetts). For more general discussions of the relation between innovation and relatively hierarchical or non-hierarchical forms of organization, see Mark Dodgson, *Technological Collaboration and Innovation*, in THE

funds that each participant risks and enables each participant to capture a greater portion of the spillovers that result from radical product innovation. These multiple-agent, disaggregated organizations replicate much of the appropriability advantages of a hierarchical, large-firm organization without exhibiting the same degree of resource integration and bureaucratic inflexibility. Because patent awards for biotechnological innovations generally cover only part of each innovation's spillover applications, and sometimes only part of the development costs, biotechnology innovators may have strong incentives to enter into collaborative ventures that pool the development costs and capture the spillover applications of a fundamental research project.

This argument raises the obvious question of why, prior to 1980, industry and academic actors did not enter into collaborative ventures in the absence of patent protection. If research agents and industrial actors can appropriate most of the rents generated by a particular innovation through the nonpatent device of a collaborative alliance, why did these research joint ventures only emerge on a significant scale after the introduction of patent protection? Patent rights certainly appear to play some role in encouraging biotechnological innovation, since empirical surveys find that biopharmaceutical firms highly value patent protection and, in its absence, probably would not undertake most R&D projects.<sup>60</sup> To resolve this puzzle, a transaction-cost rationale is offered for extending patent rights to the biotechnology sector. Patent rights for biotechnological innovations primarily serve as a means of reducing commitment costs that potential contractual partners incur in negotiating the terms of cooperative research or production ventures. By reducing the informational asymmetries between biotechnology start-ups and pharmaceutical multinationals, patent rights have facilitated the widespread formation of strategic alliances between the upstream and downstream sectors of the biopharmaceutical industry. At the same time, the imperfect coverage of currently available patent entitlements strongly encourages firms to execute innovation projects through technology-sharing structures that reduce the stream of knowledge giveaways. As shall be seen, these cooperative alliances offer upstream

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HANDBOOK OF INDUSTRIAL INNOVATION 285-92 (Mark Dodgson & Roy Rothwell eds., 1994); Gerard Fairtlough, *Innovation and Organization*, in THE HANDBOOK OF INDUSTRIAL INNOVATION 325-35 (Mark Dodgson & Roy Rothwell eds., 1994).

60. See *supra* note 49 and accompanying text.

and downstream firms a highly efficient mechanism for distributing the technical and market uncertainties of fundamental innovation projects and have become the preeminent mechanism for product development and distribution in the biotechnology sector.

*a. Patent Rights as Commitment Devices*

In a world without patent rights, upstream innovators may seek to erect a nonpatent imitation barrier and internalize knowledge spillovers by entering into technology-sharing alliances with downstream buyers that offer scale-efficient distribution and clinical testing capacities. But both upstream sellers and downstream buyers of R&D inputs face commitment difficulties that may frustrate the realization of any cooperative venture. This Section shows that patent entitlements, even in their currently incomplete form, may offer a partial solution to this commitment dilemma and thus cultivate the formation of interfirm innovation structures.

*i. Buyers' Commitment Costs*

As a potential participant in a product development venture with a large pharmaceutical firm, a biotechnology start-up has limited information as to whether its downstream partner will behave opportunistically during the course of their proposed collaboration. This threat of midstream opportunistic behavior characterizes almost any long-term relational agreement where it is too costly to: (1) write ex ante a complete contract that covers all possible contingencies, (2) monitor in midstream whether parties' performance is satisfactory, and (3) prove ex post the damages from parties' inadequate performance.<sup>61</sup> These transaction costs mean that potential partners in a long-term alliance may not be able to rely solely on even the most carefully drafted contractual obligations—and judicial enforcement of those obligations—to deter midstream opportunism. This dilemma may be especially severe in technological alliances where the researcher, or start-up, often has a single valuable intellectual asset<sup>62</sup> and the large firm has either a well-diversified R&D portfolio or may be contributing to production and marketing competencies rather than R&D assets in the joint project.<sup>63</sup>

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61. See Charles J. Goetz & Robert E. Scott, *Principles of Relational Contracts*, 67 VA. L. REV. 1089, 1092-93 (1981) (stating that ongoing, interactive relationships are characterized by incomplete contractual agreements due to parties' inability to identify all possible contingencies at the outset or adequately design complex adaptations even if any contingencies are identifiable).

62. See ACHARYA, *supra* note 4, at 21.

63. See generally Joanne E. Oxley, *Appropriability Hazards and Governance in*

Because the large firm invests far fewer transaction-specific, nonsalvageable assets in the joint innovation project, it incurs a far smaller loss if the project fails or if either party decides to abandon the project. If an upstream start-up firm fears that its downstream partner might reduce its financial commitment to the project, abandon the project, or even duplicate the start-up's only significant intellectual asset without reasonable compensation, it may be reluctant to reveal private information to any potential large-firm partners.<sup>64</sup>

Patent rights may mitigate this commitment problem by attaching a severe legal penalty that opportunistic firms will have to pay for improper conversion of intellectual assets. Although the high cost of infringement litigation certainly constrains patent rights' effectiveness in neutralizing midstream opportunism, these property-like entitlements may alleviate a litigant's burden of showing that it is the source of an improperly converted intellectual asset. Provided that patent rights increase a large firm's expected costs of opportunistic behavior to a level that equals or exceeds the expected benefits of such behavior, patent rights may encourage upstream researchers to reveal valuable intellectual assets to potential downstream partners. Even if patent rights do not entirely solve large firms' commitment problem, these firms can make up the difference by employing nonpatent devices—an equity stake in the joint project or a long-term reputation as a nonopportunistic partner—that expose them to further predetermined losses if they act opportunistically.<sup>65</sup> Together with these nonpatent

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*Strategic Alliances: A Transaction Cost Approach*, 13 J.L. ECON. & ORG. 387, 388-89 (1997) (stating that “appropriability hazards” which derive from the difficulty of specifying payoff-relevant activities, monitoring the execution of prescribed activities, and enforcing contracts in court, are a “well-accepted characteristic of technology contracts”).

64. See generally Kitch, *supra* note 8, at 277-78 (noting that, absent patent rights, innovators may not be able to seek business partners since “[d]isclosure of the secret imperils its value, yet the outsider cannot negotiate until he knows what the secret is”). This is related to a point made by Kenneth Arrow, who observed that the holder of a valuable piece of information will lose his monopoly on that information to the first purchaser, since that purchaser can reproduce the information at little cost. See Arrow, *supra* note 45, at 615.

65. See Goetz & Scott, *supra* note 61, at 1093 (stating that partners in relational contracts might rely on bonding or monitoring arrangements to overcome the deficiencies of uncertain contractual enforcement). See also Oxley, *supra* note 63, at 406 (stating that firms participating in cooperative R&D alliances may overcome the threat of opportunistic behavior by taking equity stakes or exchanging valuable assets as “hostages”); Gary P. Pisano, *Using Equity Participation to Support Exchange: Evidence from the Biotechnology Industry*, 5 J.L. ECON. & ORG. 109, 111-12 (1989) (suggesting

bonding devices, the threat of judicial damage awards for patent infringement may enable large firms to commit credibly to nonopportunistic behavior.

## ii. Sellers' Commitment Costs

While the upstream start-up may have little credible information about the large firm's opportunistic inclinations, the large firm may have little credible information about the commercial and scientific value of the researcher's intellectual assets. Thus, there is a commitment problem on the seller's side. If the upstream firm cannot commit credibly to the commercial value of its intellectual assets, then the downstream firm may incur unsustainable costs in ascertaining high-quality sellers with whom to enter into a collaborative relationship.<sup>66</sup> These informational asymmetries may create a pooling equilibrium where low-quality researchers can imitate, at a low cost, the impressive claims of high-quality researchers.

Patent rights can mitigate this signaling problem by erecting two obstacles that low-quality sellers may not be able to overcome. First, the patent examiners require that applicants demonstrate that their innovation meets a certain specificity threshold ("utility" requirement),<sup>67</sup> does not repeat "prior art" ("novelty" requirement),<sup>68</sup> and represents a significant technical advance ("nonobviousness" requirement).<sup>69</sup> Second, the patent courts attach a heavy legal penalty to the nonconsensual imitation of properly patented intellectual assets. If low-

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that some biotechnology firms may welcome the fact that large pharmaceutical firms purchase an equity stake because this aligns the two firms' incentives and mitigates the possibility that the large firm may abandon the project in midstream).

66. See GUTTERMAN & EHRlich, *supra* note 15, at 70 (stating that "[s]electing appropriate partners for licensing agreements or technology-based joint ventures is one of the toughest problems for technology managers at research laboratories, universities, and private firms"). See also David J. Teece, *Firm Organization, Industrial Structure, and Technological Innovation*, 31 J. ECON. BEHAV. & ORG. 193, 199 (1996) (stating that "[i]nvestors have obvious problems in evaluating the prospects for new products and processes, and the best investees have problems, though less serious, in identifying the best investors").

67. See 35 U.S.C. § 101 (1994). This requires that the applicant show that the invention presently offers a specific and concrete practical application (as opposed to a mere principle or concept that lacks any direct and immediate technological embodiment). See *Brenner v. Manson*, 383 U.S. 519, 534-35 (1996).

68. See 35 U.S.C. § 102 (1994). This requires that the applicant show that the invention does not replicate any "prior art"—i.e., that the invention was not known or used by others prior to the invention by the applicant. See *id.*

69. See 35 U.S.C. § 103 (1994 & Supp. IV 1998). This requires that the applicant show that the invention is not "obvious" and constitutes a significant advance over previously discovered information existing at the time that the invention was made. See *id.*

quality input suppliers cannot meet the patent examiners' requirements, or cannot sustain the litigation penalty for patent infringers, then patent rights may allow high-quality sellers to send a credible signal that they possess reasonably defensible legal title to a novel and well-developed innovation product.

*b. Innovation Networks as Risk-Distribution Mechanisms*

If patent rights reduce buyers' and sellers' credible commitment costs, it is plausible to believe that they may have facilitated the cooperative structures between university researchers, upstream start-ups, and downstream manufacturers that constitute the primary vehicle for biopharmaceutical product development. These collaborative ventures cover a range of innovation structures including research sponsorship agreements between universities and large firms' in-house R&D departments, cross-licensing agreements between holders of blocking patents or complementary technologies, manufacturing agreements, marketing agreements, and, most notably, "strategic alliances"<sup>70</sup> between small biotechnology firms and large pharmaceutical firms.<sup>71</sup> The

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70. A strategic alliance may be defined as "any arrangement in which two or more firms combine resources outside of the market in order to accomplish a particular task or set of tasks." SHARON M. OSTER, *MODERN COMPETITIVE ANALYSIS* 229 (2d ed. 1994). See also David Lei et al., *Building Cooperative Advantage: Managing Strategic Alliances to Promote Organizational Learning*, 32 J. WORLD BUS. 203, 203 (1997) (stating that "all strategic alliances may be thought of as coalignments between two or more firms in which the partners seek to learn and acquire from each other products, skills, technologies, and knowledge that are not available to other competitors"). For general explorations of strategic alliances from the management literature, see generally JOSEPH L. BADARACCO, JR., *THE KNOWLEDGE LINK: HOW FIRMS COMPETE THROUGH STRATEGIC ALLIANCES* (1991); PETER LORANGE & JOHAN ROOS, *STRATEGIC ALLIANCES: FORMATION, IMPLEMENTATION, AND EVOLUTION* (1992).

71. For a general discussion of these strategic alliances and research joint ventures in the biotechnology industry, see generally Dueker, *supra* note 28; Eisenberg, *supra* note 15; Kuhlman, *supra* note 18. For a detailed case study of the negotiation and evolution of a typical strategic alliance in the biopharmaceutical industry, see LORANGE & ROOS, *supra* note 70, at 124-47. For empirical studies of strategic alliances and other forms of interfirm R&D cooperation, see Srinivasan Balakrishnan & Mitchell P. Koza, *Information Asymmetry, Adverse Selection and Joint-Ventures: Theory and Evidence*, 20 J. ECON. BEHAV. & ORG. 99, 99-117 (1993) (examining investor reaction to announcements of joint ventures between public companies during 1974-1977 and finding that shareholders of parent companies enjoyed significantly larger abnormal returns when the parents were engaged in dissimilar businesses, and concluding that a joint venture is a mechanism for achieving synergistic gains by pooling complementary assets); John Hagedoorn, *Understanding the Rationale of Strategic Technology Partnering: Interorganizational Modes of Cooperation and Sectoral Differences*, 14

international downstream market for biopharmaceutical products has been tending toward increasing concentration and now consists of about twenty major firms that have global capacities for distribution, marketing, and manufacture.<sup>72</sup> Some of the largest companies currently have more than twenty collaborative projects ongoing with small biotechnology firms<sup>73</sup> and alliances with downstream firms have become the largest source of equity financing for biotechnology firms.<sup>74</sup> The upstream market currently consists of about 1300 biotechnology firms, which include primarily small firms that specialize in early product development but also a handful of larger more established firms that have some distribution and manufacturing capacities.<sup>75</sup>

Although strategic alliances in the biotechnology industry can take a variety of more or less closely integrated forms, they typically involve a large, downstream firm supplying product development capital to a small, upstream firm in exchange for a license, usually exclusive,<sup>76</sup>

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STRATEGIC MGMT. J. 371, 371-74 (1993) (examining sample of over 4000 strategic technology alliances in several industries and arguing that most R&D sharing arrangements are motivated either by technological complementarity, reduction of the innovation time-span, and market access or influence over market structure); Oxley, *supra* note 63, at 387-89 (examining sample of all horizontal technology transfer alliances between public U.S. manufacturing firms during the 1980s and finding that the degree of integration between participating firms often reflected several types of contracting hazards); Gary P. Pisano, *The R&D Boundaries of the Firm: An Empirical Analysis*, 35 ADMIN. SCI. Q. 153, 153-54, 162-73 (1990) (examining sample of R&D project-level procurement choices (that is, whether to procure R&D inputs internally or externally) in 1982 among world's top 50 pharmaceutical companies and finding that decisions to procure R&D internally often appeared to be motivated by concentration of R&D suppliers in the upstream market and a consequent fear of a "small-numbers" bargaining problem).

72. See Gregory B. Abbott, *Pharmaceutical and Biotechnology Licensing and Joint Ventures*, 514 P.L.I/PAT. 37, 42-43, 45-46 (1998). See also ACHARYA, *supra* note 4, at 21 (stating that the pharmaceutical industry exhibits strong market concentration and consists of a small number of very large firms).

73. See Powell, *supra* note 18, at 204.

74. See JOSH LERNER & ROBERT P. MERGES, *THE CONTROL OF STRATEGIC ALLIANCES: AN EMPIRICAL ANALYSIS OF BIOTECHNOLOGY COLLABORATIONS* 4-5 (National Bureau of Econ. Research Working Paper No. 6014, 1997).

75. See ACHARYA, *supra* note 4, at 20-21. The number of biotechnology firms appears to have stabilized at this figure, although there is still significant exit and entry. See *id.* at 34. One of the largest such firms, Genentech, has 10 marketing and distribution partnerships with larger firms, 20 licensing arrangements, and 15 formal research collaborations with small and large partners. See Powell, *supra* note 18, at 205.

76. See Abbott, *supra* note 72, at 53-57. The product license is usually a contested negotiation topic since the biotechnology company often wants to attach field-of-use and target restrictions if the product has multiple uses or multiple therapeutic targets. See *id.* at 54. At the same time, the pharmaceutical company often wants to include improvements in the license in order to strengthen its intellectual property rights as a licensee. See *id.* at 56-57. An intermediate solution sometimes involves granting the pharmaceutical company a right of first refusal if the biotechnology company develops some kind of similar improvement. See *id.* If the contractual agreement awards the

to market and/or manufacture the ultimate product.<sup>77</sup> Thus, the biotechnology firm performs most of the applied research and early product development and the large pharmaceutical firm usually is responsible for marketing, distribution, and clinical testing to meet regulatory requirements.<sup>78</sup> A strategic alliance is a hybrid and relatively novel organizational form that is structurally distinct from the small, single-product corporation, and the large, multi-product, vertically integrated corporation.<sup>79</sup> Although this hybrid form is widespread in

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larger firm an exclusive license, the exclusivity clause may be conditioned on whether or not the licensor expends a certain amount on marketing or is able to meet certain market share or revenue milestones. *See id.* at 55-56. The licensee also often agrees to refrain from using the licensed technology to manufacture or distribute new products that may compete with the licensed products or to act as a manufacturer or distributor of competing products of third parties. *See id.* Biotechnology companies that offer research tools rather than therapeutic or diagnostic products tend to offer nonexclusive licenses or limited exclusivity licenses, coupled with a "most favored nation" clause that ensures uniform terms to all licensees. *See id.* *See also* GUTTERMAN & EHRLICH, *supra* note 15, at 130-31.

77. *See* Abbott, *supra* note 72, at 51. These capital investments often take the form of equity purchases, which sometimes include representation on the board of directors as well as rights or obligations to participate in future rounds of equity financing. *See id.* Financing usually consists of a set of staggered payments, where only the initial payment (sometimes in the form of an equity purchase) is guaranteed, later payments are conditioned upon meeting certain performance milestones, and payments progressively increase for later-stage milestones. *See id.* at 57. Typically, there is an initial period when the licensee cannot cancel (usually three years) and an additional period where it has an option to continue on a year-by-year basis (usually five years). *See id.* at 59. Contractual agreements usually also provide for a management committee that reviews general project progress and sets budget constraints and a research committee that keeps track of scientific progress and determines future research tracks. *See id.* at 52-53.

78. *See* PISANO, *supra* note 4, at 69. *See also* Paul Y. Mang, *Exploiting Innovation Options: An Empirical Analysis of R&D-Intensive Firms*, 35 J. ECON. BEHAV. & ORG. 229, 231 (1998) (stating that a biotechnology firm that decides to partner with a larger downstream firm typically conducts research on the innovation until the product is ready for clinical trials, at which point responsibility for testing, marketing, and distribution is transferred to the downstream partner).

79. *See* Arnold Picot et al., *The Fading Boundaries of the Firm: The Role of Information and Communication Technology*, 152 J. INSTITUTIONAL & THEORETICAL ECON. 65, 65-66 (1996) (stating that the classical definition of the firm as a discrete and independent entity no longer describes the structure of many corporate operations, which more typically take the form of interdependent alliances among several market actors); Powell, *supra* note 18, at 197 (stating that the "canonical large corporation" is being replaced by more flexible forms of corporate organization, including networks, hybrids, and various symbiotic arrangements); Teece, *supra* note 66, at 207 (stating that the metaphor of the firm as an "island" needs to be modified because "firms commonly need to form strategic alliances, vertically (both upstream and downstream), laterally, and sometimes horizontally in order to develop and commercialize new technologies").

several research-intensive industries, it is widely recognized that the biotechnology industry relies especially heavily on this form of organization.<sup>80</sup> Unlike a corporate merger that integrates completely the resources of two firms, a strategic alliance involves a partial integration of common resources and allows each participating firm or institution to retain a substantial degree of independent decisionmaking capabilities. Industrial economists categorize an alliance as a network form of organization that confounds the conventional dichotomy between the hierarchical relations of a vertically integrated corporation and the market interactions that exist between independent contracting parties.<sup>81</sup> Unlike market interactions between organizationally independent actors, an alliance avoids the high coordination costs and monitoring costs of a contractual relationship through partially integrated research facilities and management personnel. As an entity that is not fully integrated, however, an alliance also avoids the bureaucratic inflexibility and high dissolution costs of a merged hierarchical firm.

Network innovation structures offer an attractive vehicle for private investment in fundamental R&D because they reduce the project risk to which any individual firm is exposed while maintaining the organizational independence of each participating entity. The imperfect character of currently available patent protection encourages innovating firms to enter into these technology-sharing alliances to make up the appropriability shortfall and capture a greater portion of a research project's knowledge spillovers. But these cooperative ventures are hardly a second-best organizational choice: strategic interfirm alliances

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80. See Powell, *supra* note 18, at 198.

81. See Beije & Groenewegen, *supra* note 59, at 103-04. See also LORANGE & ROOS, *supra* note 70, at 3-4 (locating different types of strategic alliances along a continuum ranging from hierarchies or total integration to markets or no integration); Balakrishnan & Koza, *supra* note 71, at 100-01 (showing that a joint venture has some characteristics of a hierarchical organization and some characteristics of a market-mediated contractual arrangement); Hagedoorn, *supra* note 71, at 371 (stating that "transaction cost economics inspired contributions . . . have theorized interfirm partnering as an economic phenomenon in between market transactions and hierarchies" (internal citation omitted)); Oxley, *supra* note 63, at 388-92 (proposing a market-hierarchy continuum as the basis for classifying the large variety of interfirm alliances and distinguishing between three rough alliance categories, including unilateral contract agreements, bilateral contract agreements, and equity-based alliances); Picot et al., *supra* note 79, at 66 (stating that strategic alliances do not conform to the "traditional differentiation between firms and markets [which] suggests that hierarchical mechanisms are used within firms and market mechanisms between firms"); Pisano, *supra* note 65, at 109 (stating that "[i]nterfirm arrangements are often viewed as intermediate or hybrid forms along an institutional continuum of markets to hierarchies"); Teece, *supra* note 66, at 207 (comparing the structure of a strategic alliance between two or more firms to contractual arrangements among individual firms and a hierarchy within a single corporation). For the classic articulation of the basic distinction between market-based and hierarchical forms of organization, see WILLIAMSON, *supra* note 10, at 20-40.

are a highly efficient mechanism for spreading two types of risks inherent in fundamental innovation projects. If this is true, then imperfect patent rights may attract private investment in biotechnology product development by fostering the formation of cooperative ventures that efficiently spread the high risks of developing and marketing a biotechnology product.

*i. Market Uncertainty*

Small firms or academic researchers involved in network innovation projects contract out the market uncertainty<sup>82</sup> of advanced product development and product distribution to large firms. There are several reasons why small firms may be eager to do so. These firms have difficulty maintaining financing during the advanced stages of product development, which is often a lengthy process for pharmaceutical and medical-therapeutic products that must pass through the FDA clinical trial and approval regimen.<sup>83</sup> Relative to small firms, large companies can reduce the costs of the approval, clinical testing, and marketing stages of product development through established facilities and significant economies of scale.<sup>84</sup> Furthermore, because small firms have few established distribution relationships and little market experience, and cannot afford maintaining idle production and distribution capacity, they may not maximize profits (or the probability of successful entry) if they underestimate consumer demand for a new product.<sup>85</sup> Distribution

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82. Some commentators distinguish between two forms of uncertainty. *Market uncertainty* refers to the fact that innovators may be uncertain as to whether there will be sufficient demand for the planned product and whether the input costs of production will lie at cost-effective levels. See FREEMAN & SOETE, *supra* note 37, at 242-45. *Technical uncertainty* refers to the fact that innovators may be uncertain as to whether the project will result in a technically feasible application. See *id.* at 243. For explanations of this distinction, see *id.* at 242-64; MORTON I. KAMIEN & NANCY L. SCHWARTZ, MARKET STRUCTURE AND INNOVATION 109-10 (1982).

83. See LERNER & MERGES, *supra* note 74, at 12-14 (surveying sample of 200 strategic alliances between biotech firms and larger pharmaceutical manufacturers, and finding that two-thirds of these alliances were arranged when the biotech start-ups were in poor financial health and had not yet begun preclinical development through animal studies).

84. See Pisano, *supra* note 71, at 155 (stating that large pharmaceutical firms have an advantage over smaller biotechnology firms because they have years of commercial experience and existing organizational capabilities to commercialize products and product distribution).

85. See *id.* (stating that young firms with novel technologies frequently lack the resources or expertise to market their product effectively). See also GUTTERMAN &

of pharmaceutical products is highly labor intensive, and major companies employ thousands of salespersons to approach physicians and hospitals directly.<sup>86</sup> Additionally, small firms may not be able to withstand protracted patent litigation and are vulnerable to sham infringement suits.<sup>87</sup>

*ii. Technical Uncertainty*

Technology-sharing alliances also enable large firms to contract out the technical uncertainty<sup>88</sup> surrounding basic research to universities and start-ups. This fact may seem puzzling, since larger, deep-pocket firms would seem to have superior ability to carry out expensive and uncertain research projects and strong incentives not to contract out potentially lucrative research projects to possible market entrants. However, a large firm may find that it can maintain a well-diversified innovation portfolio at lower cost by partnering with smaller firms to conduct basic and applied research than by directly bearing the risk and development costs of uncertain R&D projects.<sup>89</sup> Given the high probability of failure for basic research projects, large-firm managers may prefer offering

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EHRlich, *supra* note 15, at 93-94 (stating that, for a new entrant “a licensing agreement with an experienced distributor will facilitate rapid market entry and allow the licensor to generate revenue from sales in a new market without the need to commit any significant new capital to the development of a direct sales force in the market”).

86. See LERNER & MERGES, *supra* note 74, at 18 (noting that almost all pharmaceutical firms have large sales forces, “which engage in the time-consuming process of developing personal relationships with doctors and hospital administrators”). But see John W. Campo, Jr., *Strategies for Exploiting Biotechnology Patent Rights*, 382 *PLI/PAT* 495, 511-12 (1994) (stating that this distribution pattern may change because managed health care and other reforms are generating centralized purchasing entities for pharmaceutical products).

87. See LANJOUW & LERNER, *supra* note 27, at 1 (stating that the costs of litigation fall most heavily on small firms, which may be forced to settle because they cannot obtain financing for a long-term litigation).

88. See *supra* note 82.

89. See Margaret Meyer et al., *Organizational Prospects, Influence Costs, and Ownership Changes*, 1 *J. ECON. & MGMT. STRATEGY* 9, 16-17 (1992) (stating that larger firms may prefer alliances over mergers because small high-technology firms often engage in high-risk development projects and project failure could affect adversely the health of the acquirer). See also P.A. GEROSKI, *MARKET DYNAMICS AND ENTRY* 220 (1991) (stating that “a pattern that one might expect to observe is that of innovations undertaken by outsiders and then taken over by insiders [that is, incumbent firms] who would be only too happy to pay the present discounted value (to the outsider) of the innovation in the not too infrequent situations where it is worth more to the insider than to the outsider”). For a more general behavioral analysis of the considerations that managers of large pharmaceutical firms face in deciding whether to enter into an alliance with a small biotech firm, see generally Ashish Arora & Alfonso Gambardella, *Evaluating Technological Information and Utilizing It: Scientific Knowledge, Technological Capability, and External Linkages in Biotechnology*, 24 *J. ECON. BEHAV. & ORG.* 91 (1994).

financing to a small firm to conduct a risky R&D project that, if unsuccessful, could adversely affect the large firm's stock performance and the manager's job security. This economic calculus makes even more sense in today's economic climate, where large pharmaceutical firms face steeply declining pricing flexibility and falling profit margins due to patent expirations, large-volume buying from managed-care programs, and strong competition from generic drugs.<sup>90</sup>

## 2. *The Vices of Complete Patent Protection*

Industry-industry and industry-university alliances in the biotechnology sector facilitate innovative development by exploiting the specific types of risk-bearing capacities that are peculiar to small-firm and large-firm organizations. Imperfect forms of patent protection may have catalyzed these innovation networks by: (1) reducing the commitment costs faced by potential partners in negotiating the terms of strategic alliances, and (2) encouraging firms to enter into cooperative networks that enable participants to capture an innovation product's knowledge spillovers. The innovative vitality of these innovation networks, and the relative absence of such alliances prior to the introduction of patent rights in 1980, strongly suggest that patent rights may be crucial transaction-cost-reducing devices that facilitate private investment in highly uncertain R&D projects. But if this is true, then should we not prefer the most complete forms of patent protection to the currently incomplete forms of patent protection? This Section rebuts this intuitive response by showing that a regime of perfect patent coverage is unlikely to induce private industry to invest in fundamental project innovation at socially optimal levels.

A regime of perfect patent protection grants "prospect" patents that cover most, or all, of a particular innovation's therapeutic yield. A prospect patent allows its holder to recover most or all of the rents generated by the protected innovation. Because major biotechnological innovations are likely to cover a broad range of subsequent improvements, this regime probably tends to concentrate intellectual property rights to a wide array of fundamental research materials and techniques in the hands of a few large firms. Each of these large-firm patent holders would effectively have a dominant share within a particular innovation market and have the power to coordinate all

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90. See PISANO, *supra* note 4, at 57-64.

subsequent research in that market. Relying on several well-established strands in the innovation literature, this Section advances three reasons why this perfect patent regime, and the concentrated innovation market structure to which it leads, is unlikely to cultivate effectively the therapeutic potential of the genetic commons. These reasons include: (1) large firm managers' risk-averse tendencies to avoid costly and uncertain R&D projects, (2) a large firm's hierarchical tendencies that tend to stifle radically innovative activities, and (3) a dominant firm's rational interest in maximizing profits by postponing fundamental innovations that may cannibalize existing product lines. Together, these arguments show that a perfect patent regime is unlikely to stimulate biotechnological innovation at socially adequate levels because it concentrates essential scientific resources in large firms that have little ability, or incentive, to develop these resources independently.

*a. Managerial Risk Aversion*

A patent regime that concentrates genetic resources in the hands of a few large firms assigns valuable intellectual resources to large-firm managers who have comparatively weak incentives to conduct the high-risk R&D that is required to develop biopharmaceutical products. This incentive problem is a function of the separation of ownership and management within a large, publicly traded firm.<sup>91</sup> Large-firm managers have relatively weak incentives to endorse a risky R&D project since they expect to share in a small portion of the pecuniary gains if the project succeeds but a large portion of the reputational cost, up to and including job termination, if the project fails.<sup>92</sup> Even if a large firm has access to plentiful capital reserves to fund basic research, its risk-averse managers may prefer incremental innovations that improve cash flow and share prices in the short term, rather than big-ticket projects that

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91. There is a large literature on the "agency costs" that derive from the separation of ownership and management within publicly traded firms. For the classic sources, see Eugene F. Fama, *Agency Problems and the Theory of the Firm*, 88 J. POL. ECON. 288 (1980); Michael C. Jensen & William H. Meckling, *Theory of the Firm: Managerial Behavior, Agency Costs and Ownership Structure*, 3 J. FIN. ECON. 305 (1976).

92. See OSTER, *supra* note 70, at 303. See also OLIVER E. WILLIAMSON, *THE ECONOMIC INSTITUTIONS OF CAPITALISM: FIRMS, MARKETS, RELATIONAL CONTRACTING* 41-42 (1985) (stating that innovation incentives may be weak in a large firm because it is difficult to design a compensation scheme that reflects accurately responsibility for innovative output); David Hirshleifer & Yoon Suh, *Risk, Managerial Effort, and Project Choice*, 2 J. FIN. INTERMEDIATION 308, 308-09 (1992) (stating that "it is harder to motivate a manager to make the right decisions when projects differ in risk" and that "managers will avoid projects that are subject to early and conspicuous failure in order to maintain their reputations as good judges of project quality").

deplete cash flow and have a highly uncertain and deferred return.<sup>93</sup> Temporary share price fluctuations often accompany analysts' following of big-ticket research projects,<sup>94</sup> and visible project failure may injure the firm's future ability to access the capital markets.<sup>95</sup> Furthermore, many major innovation projects may be unlikely to reach completion during top managers' expected tenure.<sup>96</sup> All these factors drive large-firm managers to adopt a "fast-second" or an accommodation strategy where the firm allows new entrants to incur the initial development and debugging costs in a new innovation field and then uses its internal R&D capacities rapidly to design a superior product package.<sup>97</sup> This is precisely the strategy that many large pharmaceutical firms initially adopted toward the biotechnology industry, as they postponed large investments in internal biotechnology R&D while waiting to see if any start-up firms would successfully develop marketable therapies.<sup>98</sup>

Small biotechnology firms do not suffer substantially from these excessively risk-averse tendencies since management and ownership usually are not separated and only one quarter of these firms are publicly traded.<sup>99</sup> If owners and managers are not separated, or there is significant profit sharing, the owners/managers can expect to pocket a sizable portion of the gains from a successful innovation and thus have greater incentives to select high-risk/high-return R&D projects. Unlike large-firm managers, small-firm managers are exposed to significant portions of not only the downside risk but also the upside gain of a research project. This fact may remain true even as a biotechnology firm grows and ownership becomes more diffuse, since small-firm

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93. On the relation between agency costs, the choice of R&D projects, and investment horizons, see Bengt Holmstrom, *Agency Costs and Innovation*, in *THE MARKETS FOR INNOVATION, OWNERSHIP AND CONTROL* 131, 131-53 (Richard H. Day et al. eds., 1993). See also Jonathan B. Baker, *Fringe Firms and Incentives to Innovate*, 63 *ANTITRUST L.J.* 621, 638 (1995) (stating that risk-averse managers may reject R&D projects even if the proposed innovation has a greater expected return than alternative, safer investments).

94. See Bara Vaida, *Biotech Can Puzzle Best Analysts*, (visited Oct. 22, 2000) <[http://linkage.rockefeller.edu/wli/news/biotech\\_pick.html](http://linkage.rockefeller.edu/wli/news/biotech_pick.html)> (stating that biotechnology stocks are highly volatile and often suffer sharp price downturns, and that analysts have difficulty evaluating progress of firm research).

95. See Holmstrom, *supra* note 93, at 132-33 (stating that concerns for reputation in the capital markets lead large firms to act cautiously in selecting investment projects, since poor performance can constrain the future availability of affordable capital).

96. See Teece, *supra* note 66, at 202.

97. See Baker, *supra* note 93, at 638.

98. See ACHARYA, *supra* note 4, at 25.

99. See Abbott, *supra* note 72, at 46-47.

managers recognize that the firm's only comparative advantage, and its sole means of maintaining market share, relies on developing fundamental product innovations.

### *b. Organizational Incompetencies*

Even if the risk-aversion claim is untrue, and most large-firm managers strive valiantly to develop fundamental innovations, the argument against a perfect patent regime still stands. This is because large firms generally lack the organizational competence to develop fundamental product innovations. Some theories of organization view the firm as a collection of actors who rationally join together to maximize revenues by apportioning numerous tasks among agents with specialized skill sets.<sup>100</sup> Because each agent performs a single task repeatedly, it can execute that task more efficiently than an agent who operates alone and is responsible for performing several tasks. There is a tradeoff, however, between the returns to specialization achieved by cooperative action and the costs of communication within a large group.<sup>101</sup> As a firm grows in size, the simple fact of large numbers forces a large organization to develop a bureaucracy that distributes information among a large number of agents and to institute a multidivisional hierarchy that monitors the performance of each of those agents.<sup>102</sup> For this reason, although large numbers may result in impressive time savings and economies of scale in distribution and manufacture, large numbers may also hamper firms from achieving creative insights or investing rapidly in radical product innovations.<sup>103</sup> A

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100. See Patrick Bolton & Mathias Dewatripont, *The Firm As a Communication Network*, 109 Q.J. ECON. 809, 810 (1994). For other treatments of information processing capabilities, organizational structure, and innovation competencies, see Stephen J. DeCanio & William E. Watkins, *Information Processing and Organizational Structure*, 36 J. ECON. BEHAV. & ORG. 275 (1998); Teece, *supra* note 66.

101. See Bolton & Dewatripont, *supra* note 100, at 811.

102. See DeCanio & Watkins, *supra* note 100, at 287-88 (stating that a firm's choice of organizational structure often rests on a tradeoff between multiplying managerial levels to reduce informational overload and generating frictions that may result from an excess of hierarchical channels). See also WILLIAMSON, *supra* note 92, at 134 (stating that "[i]f any one manager can deal directly with only a limited number of subordinates, then increasing firm size necessarily entails adding hierarchical levels"); Teece, *supra* note 66, at 200 (stating that "[d]ecision making processes in hierarchical organizations almost always involve bureaucratic features").

103. See WILLIAMSON, *supra* note 10, at 200-01 (stating that "[s]ince innovation . . . tends to be untidy, innovation—which is a poorly structured, high-risk activity—may not be an activity which the large, mature bureaucracy is constitutionally well-suited to handle"). Interestingly, historical experience from the period up to 1980 demonstrates that when small, entrepreneurial Silicon Valley firms acquired large, vertically integrated firms, the organizational controls of the large corporation tended to destroy the entrepreneurial capacities of the smaller company. See Teece, *supra* note 66, at 212

hierarchical structure that channels information and responsibilities through numerous agents may diminish the speed with which the firm reacts to information about changed market conditions and the receptivity with which it contemplates new product concepts.<sup>104</sup>

Small firms do not face the large-numbers problem, and thus do not need to construct hierarchical communication and monitoring structures that may inhibit creative research and adaptive flexibility. Smaller, research-intensive firms tend to exhibit shallow hierarchies, low degrees of compartmentalization, and a higher concentration of decision-making authority in the founding individuals.<sup>105</sup> Although outside venture capital may impose resource constraints and creditor monitoring, this external pressure may lead small firms to pursue fundamental innovations that give them a comparative advantage over incumbent firms. Extensive empirical studies confirm this claim, showing that large firms do not engage in greater levels of R&D intensity than small firms and that small firms generate a disproportionate share of major innovations.<sup>106</sup>

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104. See DeCanio & Watkins, *supra* note 100, at 290 (stating that “an organization’s size may constrain its speed in adopting innovations”); Thomas M. Jorde & David J. Teece, *Innovation and Cooperation: Implications for Competition and Antitrust*, 4 J. ECON. PERSP. 75, 84 (1990) (stating that “one property of large integrated structures is that they have the potential to become excessively hierarchical and less responsive to market needs”); Teece, *supra* note 66, at 201 (stating that innovation is often “ill served” by bureaucratic structures since the “new and the radical will almost always appear threatening to some constituents” of the representative structure).

105. See Teece, *supra* note 66, at 213.

106. See GEROSKI, *supra* note 89, at 220-22. The author reviews a variety of studies that assess any possible correlation between firm size and the rate of innovative output. Although there is some interindustry variation, most studies report higher innovation rates in smaller firms. Thus, although the vast majority of total R&D expenditures derives from larger firms, smaller firms usually account for a major share of new innovations in most industries. See *id.* Furthermore, numerous studies find that large firms bias their R&D portfolio toward minor innovations and rely heavily on small firms for basic ideas that can serve as the basis for incremental commercial applications. See *id.* On some of the methodological difficulties that may undercut the results of these studies, see KAMIEN & SCHWARTZ, *supra* note 82, at 49-50. The authors observe that empirical efforts to correlate firm size, R&D expenditures, and monopoly share with rates of innovation are problematic because: (1) it is difficult to define an innovation, (2) it is difficult to categorize innovations as major or minor, (3) it is difficult to measure innovative output because not all innovations are patented and not all patents are commercialized, and (4) it is difficult to measure innovative input because R&D expenditures do not reflect the contributions of nonresearch personnel. See *id.* at 50. For some representative studies, see Zoltan J. Acs & David. B. Audretsch, *Innovation in Large and Small Firms: An Empirical Analysis*, 78 AM. ECON. REV. 678, 678-88 (1988) (examining data on innovations introduced to market in 1982 and showing that: (1) firms employing less than 500 workers produced almost half of all innovations in that period,

The current state of the biopharmaceutical industry backs up this general finding. Whereas pharmaceutical companies concentrate R&D resources on low-risk improvements to existing drugs and have a "thin product pipeline," biotechnology firms concentrate resources in fundamental innovation projects and, if successful, generally have many novel products in development.<sup>107</sup>

c. *The Very Rational Fear of Cannibalism*

Even if the risk aversion and organizational incompetence claims prove to be unfounded, the argument against perfect, broadly defined patents might still stand. Even a large firm that has the managerial incentives and the organizational competence to conduct fundamental R&D may have no rational profit incentive to develop or immediately introduce a fundamental product innovation that will displace an existing product line. If a large firm has a dominant market share and faces few potential entrants, it may be reluctant to undertake or accelerate development projects that may generate radical innovations that could cannibalize the existing profit stream of current products.<sup>108</sup> Relative to a

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(2) market concentration is *negatively* correlated with innovation activity, (3) large-firm composition is *positively* correlated with number of innovation products, and (4) small firms represent a disproportionate amount of innovative activity even in markets dominated by large firms); Welsey M. Cohen et al., *Firm Size and R&D Intensity: A Re-Examination*, 35 J. IND. ECON. 543 (1987) (examining data on R&D investment by large number of firms in various industries during period of 1974-1977 and finding that overall firm size has a statistically insignificant effect on R&D intensity).

107. Powell, *supra* note 18, at 203. Incidentally, small-scale operations are particularly well-suited to the technology of biopharmaceutical development, which has replaced traditional "mass testing" methods that rely on economies of scale with rational drug design that relies on highly specialized research personnel and can be accomplished effectively in small laboratories. See COMPETITION POLICY REPORT, *supra* note 11, § 1.B.3.a, at 22. Conventional development of pharmaceutical products generally requires scale economies since it relies on a "trial by error" method that consists of mass testing of a wide range of potentially therapeutic chemical compounds. See Powell, *supra* note 18, at 204. The company selects a disease market and then takes a group of chemical compounds and screens them for therapeutic efficacy against the disease. See *id.* Thus, the company achieves success through a laborious process and with little understanding of the reason for success. For a more detailed description of "random screening," see PISANO, *supra* note 4, at 55-56. By contrast, biopharmaceutical development has begun to rely on "genetic approaches" that investigate the biochemistry of a disease and then work backward to find a naturally occurring organic molecule or design a chemically synthesized organic molecule that will inhibit a chemical reaction involved in the disease. See COMPETITION POLICY REPORT, *supra* note 11, § 1.B.3.a.

108. See KAMIEN & SCHWARTZ, *supra* note 82, at 110 (stating that firm managers may face conflicting motives in contemplating developing a product innovation, since the "carrot" of extraordinary profits from the new innovation conflicts with the "stick" of existing profits on an existing product innovation); LERNER & MERGES, *supra* note 74, at 17 (stating that a pharmaceutical manufacturer may not want to develop therapeutic products for a disease where it has an existing product for fear that the new, superior

potential entrant, a dominant firm that already extracts monopoly profits from an existing product has lower incentives to introduce a fundamental innovation that will partially or entirely displace that product.<sup>109</sup> Whereas the potential entrant expects to gain the entire profit stream from the proposed innovation, the dominant firm expects to gain the new profit stream minus the displaced profit stream from existing products.<sup>110</sup> Depending on the expected profits from the new innovation, the current profits from the existing innovation, and the potential for preemptive development by known or unknown rivals, a dominant firm may find that delayed development is its profit-maximizing strategy.<sup>111</sup> By

product may cannibalize existing sales); Baker, *supra* note 93, at 636 (stating that a dominant firm will choose to accommodate entry where heavy R&D investment may generate products that will “cannibalize” existing products and yield fewer net returns).

109. Kenneth Arrow first made this point. See Arrow, *supra* note 45, at 619-22 (finding that a monopolist, which already extracts a monopoly profit, has less to gain from an innovation that would cannibalize its existing earnings than a firm in a competitive industry, which begins with zero economic profit). See also Jennifer F. Reinganum, *The Timing of Innovation: Research, Development, and Diffusion*, in 1 HANDBOOK OF INDUSTRIAL ORGANIZATION 849, 851 (Richard Schmalensee & Robert D. Willig eds., 1989) (stating that “[w]hen innovation is uncertain, a firm which currently enjoys a large market share will invest at a lower rate than a potential entrant, for an innovation which promises the winner a large share of the market”); Michael L. Katz & Carl Shapiro, *R&D Rivalry with Licensing or Imitation*, 77 AM. ECON. REV. 402, 402 (1987) (showing that postdevelopment dissemination of an invention, either through licensing or imitation, will cause noninnovating firms to benefit from the invention, and that this fact means that dominant firms will tend to develop minor innovations and will only develop major innovations if imitation is difficult).

110. This incentive problem can be illustrated numerically. If  $P_1$  (the firm’s pre-innovation profits) = \$5, and  $P_2$  (the firm’s expected postinnovation profits) = \$10, then the incumbent firm’s managers can only expect to yield \$5 (that is,  $P_2 - P_1$ ) from the proposed innovation. By contrast, a potential entrant who is seeking to develop the proposed innovation can expect to yield \$10 (the undiluted  $P_2$ ) in postinnovation profits if it succeeds. Thus, in the stylized example where the subsequent innovation entirely displaces the existing innovation, a small-firm manager has stronger profit-based incentives to innovate than the large-firm manager.

111. Admittedly, there are few documented examples of this type of behavior in the antitrust case law. A good illustration is found in the facts of *McDonald v. Johnson & Johnson*, 722 F.2d 1370 (8th Cir. 1983). The plaintiffs had developed an electronic pain control device and then sold out to Johnson & Johnson after having been given assurances that the acquirer would develop and promote the technology. See *id.* at 1372. The plaintiffs alleged that Johnson & Johnson effectively suppressed the acquired technology because it posed a threat to its over-the-counter and prescription drug business. See *id.* at 1372-73. Although the district court upheld the plaintiffs’ claim, the Eighth Circuit Court of Appeals vacated the antitrust claims due to lack of standing, proximate causation, and lack of cognizable injury under the antitrust laws (largely because the plaintiffs had voluntarily entered into the buy-out agreement). See *id.* at 1373.

The history of innovation also includes several possible instances where incumbent

postponing the development or introduction of a radical product innovation, a dominant firm that faces few potential entry threats may maximize the total profit stream it can gain from its existing products *plus* the new innovation (*minus* the opportunity cost of delaying the new innovation).

### 3. *Closing Argument: The Case for Imperfect Patents*

The introduction of patent protection for biotechnological innovations, coupled with federal funding of basic science research, has triggered the formation of network forms of organization to conduct high-spillover/high-risk innovation in the biopharmaceutical sector. The existence of a federally funded knowledge base reduces the start-up costs of fundamental research and supplies private industry with highly trained university researchers. At the same time, industry-industry or industry-university alliances enhance the ability of research partners to capture a greater portion of the broad prospect of knowledge spillovers either through shared patent holdings or nonpatent devices such as distribution and production efficiencies. Without these collaborative devices, firms would incur prohibitive development costs in “reinventing the wheel” and, consequently, substantial free-rider costs as the result of knowledge giveaways. As a result, fundamental product innovation would lie beyond the sustainable project horizon of all but the very largest firms. That is a socially undesirable outcome because large-firm managers have few incentives to divert internal cash flow toward these uncertain investments and poor organizational competencies to direct fundamental innovation projects.

Strangely enough, the key to the biotechnology sector’s vigorous investment in fundamental innovation lies in the insufficiency of currently available forms of patent protection. This is for two reasons. First, imperfect forms of patent protection that cover only a portion of expected spillovers encourage innovators to enter into collaborative interfirm relationships to cover the appropriability shortfall. Second, patent rights reduce dramatically buyers’ and sellers’ commitment costs in negotiating the terms of these interfirm development projects. Although it is certainly true that patent entitlements directly encourage

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firms sought to defend their monopoly share by suppressing new innovations that could displace existing products and trigger a competitive market. See Richard Dunford, *The Suppression of Technology As a Strategy for Controlling Resource Dependence*, 32 ADMIN. SCI. Q. 512, 514-16 (1987) (citing historical evidence that AT&T may have delayed the introduction of the automatic telephone because of “patent consolidation” concerns, and that General Electric delayed the introduction of fluorescent lighting because it wished first to saturate the market for incandescent lighting).

private investment in biotechnological R&D, an incentive theory of patent protection tells less than half the story about the role that patents play in encouraging such investment. Applied to the biotechnology sector, an unqualified incentive theory cannot explain how imperfect forms of patent protection ameliorate investors' rational bias against high-spillover innovation projects. A transaction-cost theory, which shows that patent rights mitigate buyers' and sellers' commitment difficulties in forming interfirm ventures, fills this theoretical gap.

This transaction-cost rationale shows why imperfect forms of patent protection dominate two alternative regulatory strategies to stimulate biotechnology innovation. A no-patents strategy would force innovators to incur insurmountable costs in negotiating collaborative arrangements that close the appropriability gap between incremental and fundamental innovation projects. A perfect patents strategy would consolidate broadly defined patents in the hands of a few large firms, impose substantial accessibility costs, and probably slow down the rate of radical innovation. While the no-patents strategy pays for high accessibility at the price of reduced productivity, the perfect patents strategy at best pays for high productivity at the price of low accessibility and, at worst, pays for low productivity at the price of low accessibility. In contrast to both of these alternatives, an imperfect patent strategy solves the spillover problem without reducing accessibility to fundamental innovations. Imperfect patent coverage encourages potential innovators to follow a two-step innovation process, where they incur the development costs of generating and patenting a valuable intellectual asset and then seek research partners to bring that product to the marketability stage. Because available patent awards fail to cover a large portion of the appropriability shortfall, buyers and sellers of innovative inputs have incentives to enter into network agreements that internalize expected spillovers. At the same time, imperfect patent entitlements operate as a facilitator mechanism that reduces the substantial costs which can prevent sellers from committing credibly to the value of their assets and can prevent buyers from committing credibly to nonopportunistic behavior. By stimulating the formation of interfirm ventures to carry out high-risk/high-spillover innovation projects, imperfect forms of patent protection ultimately may yield accessibility benefits.

It is possible to object that perfect forms of patent protection may not always inhibit the formation of technology-sharing interfirm structures.

Relying primarily on evidence from the copyright context, Robert Merges has argued that strong forms of intellectual property protection do not inhibit the dissemination of intellectual property because copyright holders form collective licensing associations that can overcome the costs of repeated licensing negotiations.<sup>112</sup> A transaction-cost theory of patent protection suggests that this argument certainly does not hold for patent protection in the biotechnology sector and, most likely, does not hold for patent protection generally. To see why this is the case, we need to return to the concept of public goods. One respect in which patentable assets differ from copyrightable assets is that patentable discoveries do not fully meet the nonrivalrousness condition of a public good. Whereas the value of a copyrighted song does not decline, and probably rises, with each additional user who purchases and plays the song, the value of a patented gene sequence declines dramatically as each additional improver reduces the patented innovation's remaining therapeutic yield. This means that a copyright holder has every incentive to license to as many users as possible, while a patent holder has incentives to license to a very limited number of users (or often, to no users at all).<sup>113</sup> Whereas the copyright holder preserves the value of the copyrighted asset by expanding the number of licensees, the patent holder preserves the value of the patented asset by constraining, or eliminating, the number of licensees. This insight explains why strong forms of patent protection are undesirable in the biotechnology sector. Whereas strong forms of copyright protection do not harm incentives for copyright holders to license, strong forms of patent protection may diminish incentives for patent holders to license. Because perfect forms of patent protection cover a broad prospect of subsequent applications, they enable a single innovating firm to capture independently a larger portion of the expected spillovers and, consequently, diminish its incentive to enter into collaborative ventures that may dilute its monopoly profits.

Even if empirical evidence were to cast doubt on the claim that perfect forms of patent protection generally will result in socially inadequate levels of fundamental innovation, the transaction-cost argument for imperfect patent protection still holds for the biotechnology sector. Even if perfect and imperfect forms of patent protection both would result in socially adequate levels of fundamental innovation, an

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112. See Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293, 1391-93 (1996).

113. See Nelsen, *supra* note 29, at 30 (stating that the licensing value of many commercially valuable biological materials "may decrease as the number of people having access to them increases, because the objective is to get a time advantage over competitive researchers").

imperfect regime still would be preferable because it enhances the accessibility of fundamental innovations. Because patent monopolies impose distributive and allocative costs,<sup>114</sup> it is always preferable—*ceteris paribus*—to minimize patent scope and duration that inflate those costs. Counterintuitively, imperfect patent rights stimulate socially adequate levels of fundamental R&D investment through innovation networks that preserve or enhance the accessibility levels which would exist if patent protection were less complete or if patent protection were nonexistent. Just as counterintuitively, incomplete patent protection probably results in a higher rate of fundamental innovation in the biotechnology sector than would exist if patent protection were more complete. By parceling out the genetic commons to a research community that has the organizational competence and profit-based incentives to cultivate that information base, incomplete patent protection triggers innovation networks that efficiently extract the therapeutic yield of the genetic commons.

#### *D. Epilogue: Transcending the Schumpeterian Debate*

The academic literature on innovation policy has often consisted of inconclusive debates over the so-called Schumpeterian hypothesis: namely, the claim that technological advance proceeds faster under concentrated, or even monopolistic, market conditions.<sup>115</sup> On the one hand, opponents of the hypothesis have argued that small-scale organizations or individual entrepreneurs have greater managerial freedom and behavioral incentives to conduct creative innovation

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114. See *supra* notes 46-47 and accompanying text.

115. For reviews of the debate over the Schumpeterian hypothesis, see GEROSKI, *supra* note 89, at 214-29; KAMIEN & SCHWARTZ, *supra* note 82, at 22-48; RICHARD R. NELSON & SIDNEY G. WINTER, *AN EVOLUTIONARY THEORY OF ECONOMIC CHANGE* 275-351 (1982). To be more precise, the Schumpeterian hypothesis actually covers two logically independent hypotheses: (1) the claim that market concentration correlates positively with R&D intensity, and (2) the claim that large firm size correlates positively with R&D intensity. Schumpeter roughly argued for both of these claims when he suggested that departures from perfectly competitive market structures—a category that could encompass large firm size and monopoly power—were most conducive to the development of innovative technologies. See JOSEPH A. SCHUMPETER, *CAPITALISM, SOCIALISM AND DEMOCRACY* 131-34 (5th ed. 1976). In his earlier work, Schumpeter appeared to embrace almost the contrary position by identifying the central catalyst of innovative development as the individual entrepreneur who “carries out new combinations” and disrupts the dominant position of incumbent firms. JOSEPH A. SCHUMPETER, *THE THEORY OF ECONOMIC DEVELOPMENT* 128-56 (Redvers Opie trans., Oxford Univ. Press 1963) (1934).

projects.<sup>116</sup> On the other hand, proponents have argued that large organizations exhibit economies of scale, cash flow reserves, and appropriability advantages that facilitate complex, expensive, and long-term innovation projects.<sup>117</sup> Extensive empirical testing of the Schumpeterian hypothesis has yielded few definitive conclusions.<sup>118</sup>

The market structure of the biotechnological sector suggests that it is sometimes possible to bridge the gap between each side of the Schumpeterian debate. The network forms of organization that link the concentrated downstream market and the diffuse upstream market in the biotechnology industry offer an innovation model that may, within this context, transcend the debate over the Schumpeterian hypothesis. Part of the key to the recent success and technological advances of the biotechnological sector lies in the coexistence of and interaction between “entrepreneurial” and “routinized” innovation regimes.<sup>119</sup> Each regime type exemplifies one side of the debate over the Schumpeterian hypothesis. The symbiotic network that links these two regimes appears to solve the tradeoff between economies of scale in clinical development, marketing, and distribution and small-scale organizational flexibility and production incentives in fundamental innovation.<sup>120</sup>

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116. See NELSON & WINTER, *supra* note 115, at 279-80.

117. *See id.*

118. See WILLIAMSON, *supra* note 10, at 176-77. On this point, Williamson writes: “An ‘optimum’ degree of competition, which holds across all industries and all times, for promoting technical progress cannot be established by appeal to either theoretical argument or empirical analysis.” *Id.*

119. Richard Nelson and Sidney Winter distinguish between “routinized” and “entrepreneurial” regimes of innovation activity. See NELSON & WINTER, *supra* note 115, at 275-351; Sidney G. Winter, *Schumpeterian Competition in Alternative Technological Regimes*, 5 J. ECON. BEHAV. & ORG. 287, 293-97 (1984). For a similar distinction, see Beije & Groenewegen, *supra* note 59, at 101-02 (distinguishing between “routinized” and “adaptive” forms of production). Firms that operate under a routinized regime have a dominant market share, attain a competitive advantage in innovative readiness by learning through doing, and concentrate on cumulative technological advances that maintain sales of existing products. Routinized innovation principally includes cost-reducing activities such as retailoring products to consumer preferences (debugging), process modifications, and imitative reverse engineering. *See id.* It also includes rent-seeking activities that seek to extend dominant market share through marginal improvements that enhance brand image and visibility. *See id.* Good examples are annual updates of textbooks or automobiles that bring little added quality value to the existing product but may inflate sales, either by attracting consumer attention or enticing consumers to exchange old product versions for the new version. By contrast, firms that operate under an entrepreneurial regime generally have little market share and concentrate on identifying and developing radical innovations that will permit successful entry into a concentrated market. *See id.* For some empirical data supporting this hypothesis, see Acs & Audretsch, *supra* note 106, at 688 (stating that “there is considerable support for Winter’s . . . hypothesis that different economic and technological regimes may account for at least some of the differences between the innovation activity of large and small firms”).

120. Interestingly, the bifurcated network structure of the biotechnology industry

On the one hand, an entrepreneurial regime in the R&D input market supplies most of the innovative breakthroughs that large-firm managers have weak profit incentives and poor organizational abilities to pursue. Downstream distributors are likely to produce far fewer radically innovative technologies in the absence of a competitive upstream market that supplies fundamental R&D inputs and provides indirect access to the academic knowledge stock. By relying on upstream start-ups for fundamental R&D inputs, risk-averse downstream managers avoid much of the uncertainty and negative cash flow of basic-science research projects. On the other hand, a routinized technological regime in the downstream market generates a manufacturing, debugging, and distribution apparatus that most upstream suppliers, who suffer from diseconomies of scale and market inexperience, cannot expect to replicate at competitive cost levels. Without a concentrated downstream market that reduces the cost of product manufacture and diffusion, outside creditors would hold back R&D financing for upstream suppliers. By establishing a pattern of nonopportunistic collaboration with upstream suppliers, a downstream distributor or a group of downstream firms may lead upstream firms (and their potential creditors) to expect that a reliable downstream partner will be available for an initially high-risk project. As a result, cash-starved biotechnology start-ups can obtain outside funding for the early research that leads to marketable product innovations and ultimately attracts scale-efficient distribution partners in the downstream market.

#### IV. ACCESS SUSTAINED: ANTITRUST CURES FOR PATENT CONSOLIDATION

Part II presented compelling grounds for believing that the extension of imperfect patent rights to the genetic commons, and the resulting rise of numerous innovation networks, may encourage fundamental product innovation in the biotechnology sector. An imperfect patent regime provides commitment devices that facilitate an innovation network that exploits commercially promising segments of the genetic information stock. But a hidden social cost lurks behind the imposition of even this

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partially conforms to an intuition advanced by Williamson that an efficient innovation system might consist of a two-stage process, where small firms dominate the early invention stage and their inventions are then acquired (either through licensing or merger) by larger firms which undertake development and marketing. *See* WILLIAMSON, *supra* note 10, at 205-06.

weak form of patent protection. Granting patent entitlements may generate not only allocative and distributive costs but, ultimately, innovative costs in the form of depressed levels of fundamental innovation. If a dominant firm or firms can assemble a broad patent portfolio that effectively perfects the imperfect coverage of any individual patent award, these firms may have reduced incentives to negotiate interfirm alliances and enhanced incentives to block potential entrants by refusing to license or imposing harsh licensing terms. These anticompetitive practices may effectively institute a regime of perfect patent protection that is likely to close off much of the genetic commons to the small firms that have been the indispensable catalysts of most fundamental innovation in the biotechnology sector.

There is an obvious role for antitrust regulators to play in this dilemma. Regulators must walk a fine line between ensuring that large firms do not assemble broad patent portfolios that stifle innovation incentives and facilitating the formation of interfirm ventures that spread the cost and uncertainty of fundamental research. Current antitrust policy aims to trace that fine line by pursuing two divergent policies. On the one hand, Congress, the agencies, and the courts provide relaxed antitrust treatment for research and production joint ventures. This generous stance encourages holders of complementary patents, blocking patents, or efficient distribution capacities to merge research, development, production, or diffusion processes to spread the cost of undertaking fundamental innovation. On the other hand, the FTC recently has applied unconventional compulsory licensing and asset divestiture remedies as an approval condition for several mergers in the biopharmaceutical sector.<sup>121</sup> If this licensing and divestiture threat discourages some larger downstream firms from acquiring smaller, upstream firms, it may maintain a widely diffused body of biotechnological patent holdings and sustain entry opportunities in the upstream R&D market.

#### A. *Why the Genetic Commons Needs Antitrust Scrutiny*

This Article has shown that innovation networks in the biotechnology sector rely on two reciprocal risk-distribution devices that allocate product distribution and product development to two symbiotic markets. Large firms tend to contract out basic research to an upstream market populated by small start-ups and university departments, while the upstream market tends to contract out product manufacture and diffusion to large pharmaceutical firms in the downstream market. Although this

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121. See *infra* notes 174, 177-81 and accompanying text.

model generally describes the current structure of the biotechnology market, the real world is slightly more complicated. Small firms sometimes attempt to market and manufacture a product independently to obtain the undivided profits on an R&D investment.<sup>122</sup> In particular, small biotechnology firms that wish to siphon off a pharmaceutical firm's market share in a particular disease market<sup>123</sup> may be more willing to risk undertaking product diffusion independently to establish a brand image and distribution relationships. Partly to counteract this entry threat from the upstream market, large firms engage in a considerable amount of internal biotechnology R&D and sometimes acquire upstream input suppliers. Thus, both downstream and upstream participants face the threat of entry through vertical integration and, in response, have strong incentives to maintain substantial internal research/development and marketing/manufacture capacities.

A plausible scenario, however, could upset this happy mix of innovation incentives. If large downstream distributors expect that small upstream suppliers may pose an entry threat in the downstream market, even managers with short-term performance horizons may have incentives to take aggressive counteractive measures. A dominant firm may adopt a predation strategy<sup>124</sup> that deters entry by inflating the minimum level of R&D investment required for market penetration. To do so, the dominant firm may choose to constrain monopoly profits and overinvest in excess R&D capacity through the acquisition of patent assets, research facilities, and star research personnel. This diversion of cash flow to R&D activities, and the resulting short-term decline in

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122. See LERNER & MERGES, *supra* note 74, at 17-18 (noting that small biotech firms are reluctant to completely concede manufacturing rights to a larger sponsoring firm and that many small firms are eager to develop marketing capabilities and thus often seek "co-marketing" rights). Many small biotech firms often waver between integrating downstream to market their therapeutic products independently or relying on an established downstream distributor. See Abbott, *supra* note 72, at 46-47. This may explain why pharmaceutical companies rarely are willing to grant "co-marketing" rights in product development projects with small biotech firms. See *id.* at 50. Pharmaceutical companies know that marketing is their comparative advantage and are not willing to give away that know-how to biotech firms. See *id.*

123. "Disease market" refers to the consumer market for therapeutic products that target a particular medical or psychiatric disorder or the diagnostic, surgical, or therapeutic equipment that physicians and other clinical personnel use to treat a particular disorder.

124. There is a large literature on predatory pricing and non-pricing strategies. For a useful source on exclusionary practices generally and non-price predatory strategies in particular, see generally Thomas G. Krattenmaker & Steven C. Salop, *Anticompetitive Exclusion: Raising Rivals' Costs to Achieve Power over Price*, 96 YALE L.J. 209 (1986).

monopolistic profits, may maximize long-term profits if the dominant firm can successfully threaten small firms that it will be able to catch up to and overtake quickly any new entrant.<sup>125</sup> To enhance the credibility of the catch-up threat, the dominant firm may establish a track record of awakening sleeping patents, or gearing up idle R&D capacities, by a disproportionately aggressive reaction to the first firm that makes an entry attempt.<sup>126</sup> By incurring this one-time belligerence cost, the dominant firm could reduce future expenditures on fundamental R&D and discourage further entry attempts by maintaining an asset portfolio of sleeping patents and semi-idle R&D facilities and defending that intellectual property portfolio through aggressive litigation strategies.

But the dominant firm can select a far simpler and far more effective strategy. Large, downstream firms could vertically integrate upstream by acquiring small firms in the R&D input market and, as a result, accumulating a patent portfolio that covers a broad prospect of subsequent improvements. This strategy effectively overcomes the imperfect scope of individual patent entitlements and obtains patent interests in a wide range of innovation resources. As an alternative to a collaborative venture with several smaller participants, a dominant downstream firm may achieve roughly the same degree of risk distribution and spillover internalization through a series of vertical acquisitions. Financing pressures from venture capitalists, who may want to cash out early, may give small firms strong incentives to accept above-market takeover bids from downstream acquirors. Through an aggressive litigation strategy that extends the effective scope of its patent warehouse, combined with a refusal to license basic research tools to potential upstream entrants on reasonable terms, a dominant downstream firm may hoard core scientific resources and raise significant entry barriers in the upstream R&D market.

Every corporate or intellectual asset acquisition by downstream firms increases development costs for smaller upstream firms by increasing the costs of inventing around the dominant firm's increasingly broader patent portfolio. Even if there are multiple, noncolluding competitors in the downstream market, the dominant firms' expanding patent portfolios mean that there are fewer safe harbors where small firms can engage in

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125. Dominant firms may have incentives to acquire but not exercise this expanded intellectual property inventory if any new product innovations may substitute for some of the firm's existing products and thus cannibalize existing sales. See Reinganum, *supra* note 109, at 869 (arguing that monopolist firms have an incentive to deter entry that would dissipate industry profits by acquiring patents and holding them as "sleeping patents").

126. See Baker, *supra* note 93, at 635 (stating that a dominant firm may attempt to deter actual entry by heavily investing in R&D, and to deter potential entry by setting a strong precedent that it will defend its market share through heavy R&D investment).

product development without fear of protracted and exorbitant infringement litigation.<sup>127</sup> If a production cartel or monopoly exists in the downstream market and no other markets offer, or reasonably threaten to offer, close substitute products, matters are even worse. A vertically integrating firm that has a monopoly in the downstream market may impose harsh cross-licensing terms on smaller firms that have developed innovation inputs and seek entry into the upstream or downstream markets.<sup>128</sup> This dominant firm may exert monopsonistic bargaining leverage in the input market, push down the price of innovation inputs, and divert potential innovation suppliers to alternative investment opportunities.

This is not a fantastic scenario, although it is certainly more likely if there is a single downstream firm (which is not uncommon in many disease markets). Several Supreme Court decisions hold that an aggressive strategy of patent acquisition may be a means to obtain or sustain dominant market share.<sup>129</sup> In *Hartford-Empire Co. v. United States*,<sup>130</sup> the district court had found that the defendant, the leading U.S. manufacturer of glass-making machinery, conspired with smaller glass manufacturers to acquire thousands of patents to enforce cross-licensing restrictions, production quotas, and territorial allocations that blocked potential entrants.<sup>131</sup> This large patent pool included numerous

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127. See Josh Lerner, *Patenting in the Shadow of Competitors*, 38 J.L. & ECON. 463, 465 (1995) (showing that firms with high litigation costs are likely to patent in research areas with relatively few other patent awards, and are even less likely to patent in areas dominated by firms with low litigation costs).

128. This type of behavior is roughly what the FTC alleged in its recently settled case against the Intel Corporation. See Intel Corporation: Analysis to Aid Public Comment, 64 Fed. Reg. 14, 246 (1999). The FTC alleged that Intel refused to provide advance technical information concerning its microprocessors to computer retailers and hardware developers who had patents that they were either trying to enforce against Intel or were refusing to license royalty-free to Intel. See *id.* In the consent order, Intel is prohibited from withholding certain advance technical information or assistance from existing customers who were involved in an intellectual property dispute with Intel. See *id.* at 14, 247-48.

129. See *United States v. Singer Mfg. Co.*, 374 U.S. 174, 175, 196-97 (1963) (finding that cross-licensing agreement between two holders of mutually infringing patents in various countries for sewing machine designs concealed violative conspiracy to acquire broad patent portfolio so as to institute infringement litigation against the remaining global competitor); *Kobe, Inc. v. Dempsey Pump Co.*, 198 F.2d 416, 422-23 (10th Cir. 1952) (finding that aggressive strategy of acquiring all patents for hydraulic pumps for oil wells and instituting frivolous infringement litigation against new entrant constituted a violative attempt to monopolize).

130. 323 U.S. 386 (1945).

131. See *id.* at 392.

improvement patents that the defendants never exploited and acquired solely to maintain control over the industry.<sup>132</sup> *Hartford-Empire* may be the patent law analogue to the *Terminal Railroad* case,<sup>133</sup> where a group of railroads acquired the central railroad terminal and bridge facilities in the St. Louis area, and the court ordered that the controlling group admit nonmembers to maintain competitive conditions.<sup>134</sup> Similar concerns about an innovation or access bottleneck<sup>135</sup> have motivated a number of the FTC's recent biopharmaceutical merger decisions, which address the possibility that reduced R&D incentives could result from a merger of the only two firms that are seriously developing therapies for the same disease market.<sup>136</sup>

One obvious response to these decisions, and the prospect of upstream vertical integration generally, is "so what?" If upstream vertical

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132. *See id.* at 395. Although the Court agreed with the lower court's assertion of the facts of the case, it considerably relaxed the district court's decree and ordered that the defendants must: (1) license their currently patented glass-making machinery at a reasonably royalty to any applicant, and (2) refrain from attaching restrictive territorial or grant-back provisions to its license contracts in the glassware industry. *See id.* at 434-35.

133. *United States v. Terminal R.R. Ass'n*, 224 U.S. 383 (1912).

134. *See id.* at 383-85. For related "duty to engage" and "essential facilities" cases, see *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985) (finding antitrust violation in refusal by owner of most skiing areas in Aspen area to participate in multi-area lift ticket package with only other ski area); *Otter Tail Power Co. v. United States*, 410 U.S. 366 (1973) (finding violation of Section 2 of the Sherman Act in electric utility's refusal to sell wholesale power to competing municipal utilities); *Lorain Journal Co. v. United States*, 342 U.S. 143, 152 (1951) (finding violation of Section 2 of the Sherman Act in newspaper's refusal to sell advertising space to customers that had also bought advertising from a new radio station that was the paper's main competitor); *Eastman Kodak Co. v. Southern Photo Materials Co.*, 273 U.S. 359, 375-76 (1927) (finding attempt to monopolize in Kodak's refusal to sell wholesale products to a retailer that Kodak previously had sought to acquire).

135. *See generally* William J. Baer, *Antitrust Enforcement and High Technology Markets* (visited Dec. 3, 1998) <<http://www.ftc.gov/speeches/other/ipat6.htm>> (noting that "the networking effects present in many high tech industries can lead to a winner-take-all market with very limited opportunity for any firm to compete with the dominant network").

136. There are several recent rulings that illustrate this claim. In *Ciba-Geigy Ltd.*, the FTC expressed concern over the innovation incentives that would result from the merger of two dominant developers of a single gene-therapy treatment, where the merged firm would hold the patents to the two processes essential for conducting most existing types of gene therapies. *See Ciba-Geigy Ltd. et al.: Prohibited Trade Practices, and Affirmative Corrective Actions*, 62 Fed. Reg. 65,706 (1997). Similarly, in *Glaxo*, the FTC claimed harm to innovation incentives where the merger transaction would integrate the only two firms that had invested seriously in developing an oral drug to treat migraine headaches. *See Glaxo plc: Prohibited Trade Practices, and Affirmative Corrective Actions*, 60 Fed. Reg. 39,396 (1995). The FTC claimed that the merger would allow Glaxo to unilaterally curtail R&D investment in this innovation project and reduce the number of research tracks that firms were pursuing in this innovation market. *See id.* Ultimately, the firms entered into a consent order requiring the divestiture of one of the research projects to a competing third firm. *See id.*

integration results in economies of scale in R&D activities and monopsonistic buying power for the downstream supplier, it may push down the price of upstream innovation inputs, and, depending on competitive substitutes and demand elasticities in the downstream market, the consumer retail price for downstream outputs. Thus, it seems that certain vertical mergers in science-based markets may enhance, rather than diminish, consumer welfare. These arguments neglect to consider, however, the important distinction between allocative and innovative efficiency and the correspondingly different conceptions of consumer welfare.<sup>137</sup> Allocatively, or statically, efficient business combinations, which may push prices toward marginal cost and thus enhance consumer welfare in the short term, may engender innovative, or dynamic, inefficiencies that result in reduced fundamental innovation and thus reduce consumer welfare over the long term.<sup>138</sup> A process of upstream vertical integration, and the accompanying consolidation of patent portfolios, would perfect the current regime of imperfect patent coverage and effectively institute a regime of prospect-like patent protection that is likely to injure the innovative fitness of the biotechnology market. Patent-warehousing strategies threaten to undermine the network model of collaborative innovation that favors fundamental product development and set in its place the autarchic model of corporate R&D that favors incremental innovation. That would be an ironic result. Although the introduction of patent rights was designed to correct private underinvestment in radical biotechnology research, ultimately it could do little to remedy that problem or could even exacerbate it.

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137. On the distinction between allocative and innovative efficiency, see *supra* note 14. As Joseph Brodley notes, “consumer welfare” is one of the most commonly used terms in antitrust decisions and commentary, but, curiously, lacks any precise or settled definition. See Brodley, *supra* note 14, at 1020. Even if we equate consumer welfare with maximizing social wealth through efficient market structures (rather than equating consumer welfare with the redistributive goal of maximizing consumer surplus), we still must decide whether we are concerned about maximizing short-term social wealth (which points toward allocative efficiency) or long-term social wealth (which points toward innovative and productive efficiencies). For more on this problem, see *id.* at 1032-36.

138. See KAMIEN & SCHWARTZ, *supra* note 82, at 15 (stating that a dilemma “occurs in the formulation and enforcement of our antitrust laws, because to the extent that these laws are meant to achieve and maintain efficient allocation of resources in the short run, they may tend to inhibit invention”).

## B. *Relaxed Treatment of Research and Production Joint Ventures*

Although joint ventures<sup>139</sup> enable firms in high-technology markets to engage in long-term and uncertain innovation projects, these arrangements resemble horizontal agreements that traditionally trigger considerable antitrust scrutiny for anticompetitive effects.<sup>140</sup> Even upstream-downstream collaborations may fall under the horizontal category, since upstream input suppliers commonly harbor ambitions of forward integration and downstream distributors commonly harbor ambitions of backward integration. The courts have long viewed with suspicion information-sharing, patent and copyright licensing, and patent-pooling mechanisms that may allow horizontal competitors to mask cartel-like collusion over price or output or to erect an entry barrier to nonparticipants who cannot replicate the joint venture's efficient cost structure.<sup>141</sup> This antitrust bias against collaboration among holders of complementary intellectual property assets historically has posed a significant obstacle to the formation of efficiency-enhancing R&D alliances.<sup>142</sup>

Sound analysis of interfirm collaboration must consider that, although the restricted access character of a joint venture erects an entry barrier, it may be an essential prerequisite to the venture's welfare-enhancing production and research efficiencies.<sup>143</sup> Because science-based markets

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139. The Antitrust Division defines a joint venture as "essentially any collaborative effort among firms, short of a merger, with respect to R&D, production, distribution, and/or the marketing of products or services." *Antitrust Enforcement Guidelines for International Operations*, 4 Trade Reg. Rep. (CCH) ¶13,109, at 20,599 (1988).

140. For a current discussion of antitrust treatment of joint ventures, see Joseph F. Brodley, *Joint Ventures and Antitrust Policy*, 95 HARV. L. REV. 1521 (1981-1982); Howard H. Chang et al., *Some Economic Principles for Guiding Antitrust Policy Towards Joint Ventures*, 1998 COLUM. BUS. L. REV. 223; Joseph Kattan, *Antitrust Analysis of Technology Joint Ventures: Allocative Efficiency and the Rewards of Innovation*, 61 ANTITRUST L.J. 937 (1992); Gregory J. Werden, *Antitrust Analysis of Joint Ventures: An Overview*, 66 ANTITRUST L.J. 701 (1997).

141. In the intellectual property context, the Court has swung back and forth on the degree to which synergistic efficiencies may be considered in assessing the anticompetitive effects of patent pooling arrangements. Compare *Bement v. Nat'l Harrow Co.*, 186 U.S. 70 (1902) (exempting from antitrust scrutiny a pooling arrangement that effectively amounted to price-fixing), with *United States v. Line Material Co.*, 333 U.S. 287 (1948) (finding antitrust violation in agreement to pool blocking patents on ground that it masked price-fixing restraint), and *United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963) (finding that cross-license agreement was part of broader combination to exclude potential entrants).

142. See Jorde & Teece, *supra* note 104, at 75.

143. See Herbert Hovenkamp, *Exclusive Joint Ventures and Antitrust Policy*, 1995 COLUM. BUS. L. REV. 1, 7 (stating "[t]he difficult problem for antitrust policy is that the very same exclusions that facilitate anticompetitive behavior may have been essential to create the incentives to form the joint venture in the first place"). See also Carl Shapiro & Robert D. Willig, *On the Antitrust Treatment of Production Joint Ventures*, 4 J. ECON.

depend heavily on basic-research investments, they have a special need for vertical and horizontal joint ventures that spread the direct costs of early product development and the indirect costs of inappropriable knowledge spillovers.<sup>144</sup> If patent protection is imperfect and does not cover most of the expected spillovers of fundamental research, an innovating firm can only expect to recover a good deal of those spillovers by partnering with firms that have complementary intellectual assets or distribution capacities. For this reason, the private sector may be slow to develop certain product innovations in the absence of joint ventures and other collaborative opportunities.<sup>145</sup> Additionally, antitrust concerns about output restraints are not very compelling with respect to joint ventures that are confined to research activities, since it would be unusually difficult for research collaborators to commit to and enforce collusive agreements to restrain each participant's product output.<sup>146</sup>

Recognizing these considerations, Congress, antitrust agencies, and the courts have relaxed antitrust scrutiny for research and production joint ventures in high-technology markets. In 1984 Congress passed the National Cooperative Research Act<sup>147</sup> ("NCRA"), which offers special

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PERSP. 113, 116 (1990) (stating that research joint ventures may result in cost-saving efficiencies that outweigh any anticompetitive welfare losses).

144. See Jorde & Teece, *supra* note 104, at 78 (stating that "much innovation today is likely to require lateral and horizontal linkages" and that "[i]f innovating firms do not have the necessary capabilities in-house, they may need to engage in various forms of restrictive contracts with providers of inputs and complementary assets").

145. See Werden, *supra* note 140, at 702.

146. Some writers argue that confining collaboration to the research stage does not rule out price-fixing, since the joint venture could transfer research outputs to the participating firms at elevated prices, and then each firm could pass on the costs to consumers. See Shapiro & Willig, *supra* note 143, at 115. This argument is only compelling, however, if the research cartel is able to prevent cheating at the distribution and manufacturing stage. The cartel can only do so if the cartel participants are concerned about reputational effects, and sufficiently value further collaboration in the future. If short-term gains exceed long-term reputational harm, however, each cartel participant can undercut other participants once it obtains the know-how to manufacture the product independently. If this is true, then all cartel members charge competitive prices and the antitrust authorities have little to worry about.

147. 15 U.S.C. § 4302 (1994). For joint ventures that register with the Department of Justice, the Act reduces antitrust penalties to single damages and offers a more favorable attorneys' fee provision. See 15 U.S.C. § 4303 (1994). The Act also requires courts to apply rule-of-reason analysis to R&D joint ventures and forbids the application of per se rules of illegality. See 15 U.S.C. § 4302. Empirical studies are mixed as to whether the Act has stimulated a substantially higher number of newly formed research ventures. See Joseph F. Brodley, *Antitrust Law and Innovation Cooperation*, 4 J. ECON. PERSP. 97, 99 (1990) (observing that the Act has stimulated the formation of research joint ventures but noting single study showing that, during an 18-month period, joint ventures

treatment to registered research joint ventures, and in 1993 it enacted the National Cooperative Research and Production Act,<sup>148</sup> which extends relief granted under the NCRA to registered production joint ventures. Following Congress's lead, the agencies and the courts recently have accorded significant leeway to horizontal innovation agreements. The antitrust agencies have stated that they will consider whether licensing terms that are likely to have an anticompetitive effect are "reasonably necessary to achieve procompetitive efficiencies."<sup>149</sup> In its most recent statement in this area, the FTC and the Antitrust Division observed that most R&D competitor collaborations are procompetitive.<sup>150</sup> The courts have adopted a similarly generous approach. The widely criticized Supreme Court decision in *United States v. Topco Associates*,<sup>151</sup> applying a rule of per se illegality to a territorial restraint imposed by a joint venture that lacked dominant market share, has never been explicitly overruled. However, the Court's later decision in *Arizona v. Maricopa County Medical Society*,<sup>152</sup> as well as numerous lower courts' decisions, suggest that the per se rule no longer applies to joint ventures that demonstrate significant degrees of economic integration and exhibit plausible welfare-enhancing effects.<sup>153</sup>

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registered under the Act tended to operate in industries without serious appropriability problems); Jorde & Teece, *supra* note 104, at 87 (arguing that filings indicate that most firms that registered under the Act between 1984 and 1988 were modest endeavors and are "not of great competitive moment").

148. 15 U.S.C. §§ 4301-4306 (1994).

149. INTELLECTUAL PROPERTY GUIDELINES, *supra* note 11, at § 4.2. The Guidelines state:

If the Agencies conclude that the restraint has, or is likely to have, an anticompetitive effect, they will consider whether the restraint is reasonably necessary to achieve procompetitive efficiencies. If the restraint is reasonably necessary, the Agencies will balance the procompetitive efficiencies and the anticompetitive effects to determine the probable net effect on competition in each relevant market.

*Id.* It is important to note that numerous restraints imposed in joint ventures, such as exclusive distribution territories, may prevent members from appropriating a disproportionate share of the revenues and thus encourage participation in the collaborative arrangement. See Werden, *supra* note 140, at 707.

150. See FED. TRADE COMM'N & U.S. DEP'T JUST., ANTI-TRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS 14-15 (2000) [hereinafter GUIDELINES FOR COLLABORATIONS].

151. 405 U.S. 596, 608 (1972). For a review of the central arguments often offered against that decision, see Werden, *supra* note 140, at 709-11.

152. 457 U.S. 332, 357 (1982) (holding that agreements among seventy percent of area physicians to adhere to maximum fee schedule were per se violations of Section 1 of the Sherman Act, but stating that the arrangement was not a joint venture because it did not pool capital and investment uncertainty).

153. See *id.* at 356-57 (stating "[t]he foundations are not analogous to partnerships or other joint arrangements in which persons who would otherwise be competitors pool their capital and share the risk of loss"). See also Werden, *supra* note 140, at 713 (reviewing current case law and concluding that "[a]ny genuine economic integration

### C. Compulsory Licensing and Innovative Efficiency

A survey of current antitrust treatment of joint ventures suggests a happy story in which federal agencies have given adequate leeway for biotechnology firms to design interfirm arrangements that spread the costs of researching and developing the genetic terrain. This rosy picture is complicated, however, by the fact that the biotechnological sector in the 1990s has exhibited not only a high incidence of joint venture activity, but also a strong trend toward consolidation among firms in the downstream sector along with some incidence of upstream vertical acquisitions.<sup>154</sup> This latter phenomenon is worrisome since mergers, unlike joint ventures, consolidate patent portfolios of a range of fundamental innovations and, consequently, may slow down the pace of technological advance by erecting barriers to potential entrants and depressing the merged firms' incentives to innovate. Although interfirm collaboration with partial resource integration (joint ventures) generally facilitates radical innovation, there is reason to believe that interfirm collaboration with complete resource integration (mergers) will generally harm radical innovation. Antitrust authorities have not neglected this danger. In several merger decisions, they have employed

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that plausibly could confer nontrivial social benefits suffices to take a joint venture outside the purview of the per se rules applied to cartel activity"). This is not to say that research and production collaboration will not trigger some antitrust scrutiny. The agencies and the courts are not willing to extend relaxed treatment to collaborative agreements that result in supracompetitive prices, do not combine complementary inputs, do not pool investment uncertainty, or are not accompanied by significant production or research efficiencies. In *Summit Technology*, a 1998 administrative ruling, the FTC found that a patent pool between the only two FDA-approved manufacturers of lasers for treating certain vision disorders used an *ad valorem* (i.e., per unit) licensing fee effectively to set a price floor. See *VISX, Inc. et al.*, 5 Trade Reg. Rep. (CCH) ¶ 24,254-55. See also *Summit Technologies, Inc.*, 5 Trade Reg. Rep. (CCH) ¶ 24,490, at 24,336 (1999). The Commission found that the horizontal restraint (and, in particular, the effective price floor) was not reasonably tailored to any expected efficiency enhancement, since each competitor had sufficient intellectual property assets and capital resources to enter the market as independent competitors. See *id.* at 24,337. Thus, the most recent case law and administrative rulings indicate that industry participants in collaborative ventures have wide, but not unlimited, leeway to enter into arrangements that show significant degrees of economic integration. See also GUIDELINES FOR COLLABORATIONS, *supra* note 150, at 14 (noting that R&D joint ventures typically are analyzed under the rule of reason).

154. See ACHARYA, *supra* note 4, at 22-26. Although there were a number of vertical acquisitions of biotechnology firms by pharmaceuticals in the early 1990s, this trend has slowed and strategic alliances between upstream and downstream firms remain a far more frequent pattern of R&D acquisition for pharmaceutical firms. See *id.* at 22.

fairly burdensome divestiture and compulsory licensing remedies that may facilitate a wide diffusion of privately and publicly generated scientific knowledge.

There is an obvious argument that compulsory licensing may undermine the innovation incentives generated by the introduction of patent rights. If prospective patentees expect that compulsory licensing will probably suspend or curtail a patent monopoly, they may shift resources to other investment opportunities or choose not to patent and expend resources on maintaining secrecy over any product innovations. But these arguments view patents primarily as monopoly rewards that supply incentives for private innovation. In the biotechnology sector, this argument has decidedly mixed support. If biotechnology patents operate primarily as commitment devices that reduce the transaction costs of negotiating long-term contractual commitments, there are far less compelling grounds to fear that compulsory licensing will lead to diminished investment in risky innovation activities. Relying on this transaction-cost rationale for patent protection, this Article argues that the FTC's judicious application of compulsory licensing in merger enforcement will do little to discourage private investment in innovation, probably encourages participation in collaborative ventures, and may foreclose an undesirable regime of "perfected" patent protection.

### *1. Innovation Markets and the Mini-Revival of Compulsory Licensing*

In issuing compulsory-licensing remedies in science-based markets, the FTC relies on the novel innovation market approach to merger analysis.<sup>155</sup> The FTC employs this approach in executing its merger enforcement duties under three statutory provisions: Section 1 of the Sherman Act,<sup>156</sup> Section 7 of the Clayton Act,<sup>157</sup> and Section 5 of the

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155. This method of analysis is presented in the 1995 Federal Antitrust Intellectual Property Guidelines. See INTELLECTUAL PROPERTY GUIDELINES, *supra* note 11, at §§ 3.2.2, 3.2.3. The Guidelines define an innovation market as "the research and development directed to particular new or improved goods or processes, and the substitutes for that research and development." *Id.* at § 3.2.3. For a general presentation of the innovation market concept by two former Department of Justice staff members who originally conceived this approach, see Richard J. Gilbert & Steven C. Sunshine, *Incorporating Dynamic Efficiency Concerns in Merger Analysis: The Use of Innovation Markets*, 63 ANTITRUST L.J. 569 (1994). For a review of some of the FTC's recent applications of the innovation market concept in merger enforcement, see Andrew Chin, *Analyzing Mergers in Innovation Markets*, 38 JURIMETRICS J. 119 (1998); Thomas N. Dahdouh & James F. Mongoven, *The Shape of Things to Come: Innovation Market Analysis in Merger Cases*, 64 ANTITRUST L.J. 405 (1995).

156. 15 U.S.C. § 1 (1994). Section 1 claims challenge mergers or practices that constitute a "contract, combination . . . or conspiracy in restraint of trade." *Id.*

157. 15 U.S.C. § 18 (1994 & Supp. IV 1998). Section 18 claims challenge mergers

Federal Trade Commission Act.<sup>158</sup> The conventional market power approach to merger enforcement assesses whether the merged firm has the ability to sustain supracompetitive pricing or unilateral output restraints in a consumer goods market.<sup>159</sup> By contrast, the FTC's novel approach to high-technology mergers assesses: (1) whether the merged firm will be able unilaterally to restrain output in an upstream R&D market, and (2) whether that output restraint will result in competitive injury to the downstream products market.<sup>160</sup> This approach defines the R&D market in terms of either licensed intellectual property assets or R&D capacities to develop and manufacture certain high-technology products.<sup>161</sup> Just like conventional horizontal merger analysis under Section 7 of the Clayton Act, the innovation market approach proceeds by identifying the size of the relevant market and then measuring the pre-merger and post-merger levels of concentration in that market. If the merger significantly increases concentration in the relevant R&D market, the enforcement agency addresses whether there are procompetitive efficiencies that may result from this presumptively violative business combination and, if so, whether those procompetitive efficiencies outweigh any anticompetitive effects.

The innovation market approach allows antitrust authorities to assess whether a proposed merger will reduce or enhance incentives for the merged firms unilaterally to restrain innovative output, with a resulting downstream welfare effect in a consumer products market. In an innovation market, where firms require access to certain patented technologies to develop substitute products, an incumbent firm can erect entry barriers by acquiring a competitor's extensive patent portfolio and either refusing to license or dictating harsh licensing terms. If these barriers lock out most potential entrants, then the incumbent firm may be able unilaterally to reduce innovation output. Furthermore, if entry

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or business "in any line of commerce . . . in any section of the country" whose combined effect "may be substantially to lessen competition, or to tend to create a monopoly." *Id.*

158. 15 U.S.C. § 45 (1994). Section 45 claims challenge mergers or practices that constitute "unfair methods of competition." *Id.*

159. See U.S. DEP'T OF JUST. & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES 1-2 (1992 & Revised 1997).

160. See INTELLECTUAL PROPERTY GUIDELINES, *supra* note 11 at § 3.2.3. The notion of an R&D market made its first official appearance in 1984 in the language of the NCRA, which directs courts to review antitrust complaints against certain joint ventures for their "effects on competition in properly defined, relevant research, development, product, process, and service markets." 15 U.S.C. § 4302 (1994).

161. See INTELLECTUAL PROPERTY GUIDELINES, *supra* note 11, at §§ 3.2.2, 3.2.3.

relies on a substantial sunk-cost investment in project-specific R&D facilities and personnel, a firm may deter entry or compel withdrawal by acquiring a competitor's research assets and human capital. Highly specialized research personnel may be scarce in industries where firms acquire R&D cost efficiencies through "learning by doing" and where project-specific know-how is difficult to communicate to inexperienced personnel.<sup>162</sup>

It may appear that the agencies' application of the innovation market approach departs from conventional market power analysis only insofar as it examines a market for potential rather than existing products. This is why some commentators argue that it is not a necessary addition to the enforcement repertoire.<sup>163</sup> These critics argue that, in most cases where the FTC has applied the innovation market approach, it could have reached the same result under a conventional analysis of the incumbent's ability unilaterally to restrain output in the product market.<sup>164</sup> Furthermore, in the few cases where the FTC applied the innovation market approach and classical market power analysis would not have reached the same result, it is likely that the FTC wrongly targeted an efficient business combination. This latter criticism has two possible versions. First, these critics argue that the innovation market analysis unjustifiably assumes that market concentration is likely to result in reduced R&D output.<sup>165</sup> Second, and more crucially, these critics argue that the FTC misapplies the innovation market approach to business combinations that are likely to reduce R&D expenditures but are unlikely to result in supracompetitive pricing in the consumer products market. Although these mergers may result in a lower rate of innovative

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162. See Teece, *supra* note 66, at 196 (stating that "technology transfer is often difficult without the transfer of key individuals" and that "the diffusion of new technology often depends on the mobility of engineers and scientists").

163. See George A. Hay, *Innovations in Antitrust Enforcement*, 64 ANTITRUST L.J. 7 (1995); Robert J. Hoerner, *Innovation Markets: New Wine in Old Bottles?*, 64 ANTITRUST L.J. 49 (1995); Richard T. Rapp, *The Misapplication of the Innovation Market Approach to Merger Analysis*, 64 ANTITRUST L.J. 19 (1995). For a reply to critics of the innovation market approach, see Richard J. Gilbert & Steven C. Sunshine, *The Use of Innovation Markets: A Reply to Hay, Rapp, and Hoerner*, 64 ANTITRUST L.J. 75, 77-78 (1995) (recognizing that there is no incontrovertible evidence showing that innovative activity declines as R&D concentration increases, but arguing that the innovation market approach is legally tractable in certain business situations and captures a welfare loss from certain mergers that traditional market power analysis would overlook).

164. See Rapp, *supra* note 163, at 19-20.

165. See *id.* at 20. This argument relies principally on the assertion that economic analysis has not demonstrated any reliable or predictable relationship between market concentration and R&D output, R&D output and innovative success, and R&D expenditures and future output prices. For a rebuttal of this argument, see Gilbert & Sunshine, *supra* note 163, at 77-80.

output in the upstream market, they are unlikely to result in supracompetitive pricing in the downstream market, and thus do not trigger the type of welfare loss covered by the antitrust laws.<sup>166</sup>

These critics are absolutely right that the innovation market approach sometimes may largely overlap with the conventional analysis of consumer injury in terms of output restraints or supracompetitive pricing. These critics are also right in asserting that the agencies have not limited the innovation market approach to testing indirectly whether a merger may trigger competitive injuries in the downstream market. In those instances where the innovation market approach reaches a result that does not track the market power approach, the FTC appears to be implicitly relying on an alternative definition of competitive injury in terms of innovative, rather than allocative, efficiencies.<sup>167</sup> Under this alternative definition, competitive injury may result from business combinations that reduce the merged firms' incentives to sustain current R&D expenditures, or certain types of R&D expenditures, even if they do not enable the merged firms to engage in supracompetitive pricing of consumer goods.<sup>168</sup> Proponents of the innovation market approach insist that it is limited, by definition, to R&D output distortions that are likely to generate supracompetitive pricing in the downstream market.<sup>169</sup> Several recent FTC applications of this approach in the biopharmaceutical sector, however, address innovative output distortions that plausibly could only affect the variety and quality, rather than the pricing and quantity, of consumer goods in the downstream market.<sup>170</sup>

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166. See Hoerner, *supra* note 163, at 49-51 (arguing that the type of market behavior that the innovation market approach targets is not cognizable under Section 7 of the Clayton Act).

167. On the distinction between innovative and allocative efficiencies, see *supra* note 14.

168. See generally COMPETITION POLICY REPORT, *supra* note 11, at 1 (Executive Summary & Principal Conclusions) (noting that "in many markets, the basis for competition today includes not only the price at which a product is sold but the ingenuity, variety, and speed of development of new goods and services" and that "innovation contributes powerfully to our economy . . . generally more so than do cost savings gleaned in existing ways of doing business").

169. See Gilbert & Sunshine, *supra* note 163, at 80.

170. The FTC's pattern of application finds some textual support in the Intellectual Property Guidelines, which state that innovation market analysis may be necessary to determine whether licensing arrangements (and, presumably, all dispositions) with respect to intellectual property "are likely to affect adversely the prices, quantities, qualities, or varieties of goods and services either currently or potentially available." INTELLECTUAL PROPERTY GUIDELINES, *supra* note 11, at § 3.2 (emphasis added). See also GUIDELINES FOR COLLABORATIONS, *supra* note 150, at § 3.3 (stating that exercise of

These rulings primarily exhibit *qualitative* concerns with the effect of patent consolidation on the diversity of technological inputs or the diffusion of intellectual property holdings. These rulings rarely express *quantitative* concerns that the merged firm's dominant share in the upstream market will lead to supracompetitive pricing in the downstream market.

Although this structural application of the innovation market approach may appear unorthodox, it conforms closely to a trend in antitrust scholarship that emphasizes that antitrust enforcement should advance not only the goal of allocative efficiency but also, and even primarily, the goal of innovative efficiency.<sup>171</sup> Whereas allocative efficiency is concerned with setting prices equal to marginal cost in the consumer products market, innovative efficiency is concerned with ensuring that firms invest in R&D projects that maximize social wealth over the long term.<sup>172</sup> There is a strong basis for favoring innovative efficiency over allocative efficiency, since economic evidence shows that retarded innovation almost certainly injures aggregate social wealth far more than the deadweight loss from supracompetitive pricing.<sup>173</sup> Understanding market efficiency in innovative terms would result in a relaxation of antitrust concerns in some areas and an intensification of antitrust scrutiny in other areas. Thus, antitrust enforcement may be unjustified if it targets firms that enter into horizontal agreements that promote innovation efficiencies even if these agreements may result in allocatively inefficient pricing practices. This proposition obviously supplies a strong basis for the agencies' relaxed scrutiny for research joint ventures. Conversely, antitrust enforcement may be justified as a means of precluding market structures that threaten innovation efficiencies, even if the targeted parties are engaging in allocatively efficient market practices. This approach enables antitrust authorities to target a merger that is likely to result in reduced R&D output or a misallocation of R&D resources toward incremental, rather than fundamental, innovation but is unlikely to have any supracompetitive effect in the downstream market.

This broadened understanding of the innovation market approach

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market power by R&D joint venture may injure consumers by leading to lower innovation levels, fewer products for consumers, and lower quality products).

171. See, e.g., Brodley, *supra* note 14, at 1032-36; John J. Flynn, *Antitrust Policy, Innovation Efficiencies, and the Suppression of Technology*, 66 ANTITRUST L.J. 487, 493-97 (1998); Scherer, *supra* note 14, at 998-1002.

172. See Brodley, *supra* note 14, at 1032-33. See also Flynn, *supra* note 171, at 508 (stating that "[s]ome mergers and acquisitions that might not otherwise be challenged under Section 7 of the Clayton Act can become questionable when viewed in light of innovation efficiencies").

173. See Brodley, *supra* note 14, at 1025-26; Scherer, *supra* note 14, at 1001-02.

supplies the strongest theoretical basis for much of the FTC's recent scrutiny of biopharmaceutical mergers. Even if it were true that the innovation market approach has little added value under a conventional analysis of unilateral constraints on product output, it has significant added value under a less conventional concern with unilateral constraints on the rate or direction of R&D output. A structural concern with the innovative vigor of science-based markets best explains several recent FTC consent decrees that conditioned approval of mergers between large pharmaceutical firms on either divestiture or licensing of some of the firms' intellectual property assets.<sup>174</sup> Although compulsory licensing has been an uncommon remedy in U.S. antitrust enforcement since the 1970s,<sup>175</sup> it serves to break up growing patent portfolios that threaten to

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174. A non-exhaustive list of these consent decrees includes the following representative cases. In *In re Baxter Int'l Inc.*, 123 F.T.C. 904 (1997), the FTC conditioned approval of a merger between Baxter, a large pharmaceutical manufacturer, and Immuno International AG, an upstream biotechnology firm, on the licensing of a chemical agent (in development) for controlling bleeding in surgical procedures and divestiture to an FTC-approved buyer of one of only two existing technologies (the other being owned by Immuno) for certain hemophilia treatments. *See id.* at 910-12, 921. In *In re Upjohn Co.*, 121 F.T.C. 44 (1996), the FTC examined a merger in which neither company had FDA-approved, marketable assets, but both companies were far ahead of the few other companies that were developing drugs for colorectal cancer. *See id.* at 46. The settlement order required the acquired firm to divest some of its intellectual property assets. *See id.* at 50. In *In re Wright Med. Tech., Inc.*, 119 F.T.C. 344 (1995), the FTC examined a merger between Wright, the leading current manufacturer of orthopedic finger implants, and Orthomet, a firm that was developing finger implants, on the ground that the acquisition would reduce competition in the market for existing and potential finger-implants products. *See id.* at 346-47. Ultimately, the FTC issued a consent order prohibiting Wright for 10 years from acquiring any firm that conducts or intends to conduct R&D regarding finger-implant products. *See id.* at 354.

175. *See* Scherer, *supra* note 14, at 1017. The antitrust authorities and federal courts used compulsory licensing extensively during the 1940s and 1950s. *See id.* From 1941 to 1959, 107 antitrust settlements included a compulsory licensing order, and together these settlements covered an estimated 40,000 to 50,000 patents. *See id.* In the most noticeable instance, IBM and AT&T entered judgments requiring the licensing of more than 9,000 patents (usually without any royalty). *See id.* In the most recent, well-known instance, the FTC used the compulsory licensing remedy in a 1975 consent decree that ordered the Xerox Corporation to open up its portfolio of copying machine patents for licensing at a capped royalty rate. *See In re Xerox Corp.*, 86 F.T.C. 364, 374 (1975). That decree, however, established a weak precedent, since the FTC's next attempt at requiring licensing did not meet with success. In 1977, the FTC charged that the DuPont Corporation had engaged in predatory underpricing of a chemical product by exploiting its cost advantage as a result of a process it had developed and patented. *See In re E.I. DuPont de Nemours & Co.*, 96 F.T.C. 653 (1980). The agency asked for divestiture of two company plants and royalty-free licensing of the technology. On appeal, however, an administrative law judge issued an order to dismiss. *See id.* at 655-56, 751.

erect entry barriers, constrain the diffusion of intellectual property assets, and injure technological diversity within a particular innovative field.<sup>176</sup> The FTC occasionally has determined that licensing could not assure competitive conditions and has ordered that the acquiring firm or acquired firm divest itself of certain technologies.<sup>177</sup> In some instances, the FTC has even required the merged firm to supply the recipient of the divested or licensed technologies with technical assistance from personnel who developed the technology.<sup>178</sup>

All the biopharmaceutical mergers that the FTC has targeted under this approach since 1990 have involved firms which had formerly been the few competitors that were progressing seriously toward developing a therapeutic innovation for a particular disease market. In conventional market power terms, the merged firms were the dominant actors in a particular market for innovation goods. In all these rulings, the FTC evidenced a structural concern with the long-term innovative fitness of the relevant market, the continuation of the target firm's or acquiror

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176. Although these licensing remedies generally do not provide for a royalty, the consent order usually restricts the FTC-designated licensee to using the licensed technology to continue the development project initiated by one of the merged firms. A good example of this nuanced approach is the 1995 *American Home Products Corp.* ruling. See *In re American Home Prods. Corp.*, 119 F.T.C. 217 (1995). This ruling concerned a merger of two of only three competitors in the R&D market for development of a rotavirus vaccine. Reflecting concerns about the diversity of research inputs, the FTC imposed a restricted-use, royalty-free licensing remedy partly on the ground that the acquired firm employed a research route different from that of the acquiring firm and the single remaining competitor in the relevant disease market. See *id.* at 226.

177. To the author's knowledge, the first instance of this sort of remedy in the biotechnology sector was *In re Roche Holdings Ltd.*, 113 F.T.C. 1086 (1990). The FTC opposed the acquisition by Roche, a large pharmaceutical firm, of a controlling interest in Genentech, an established biotechnology firm. See *id.* at 1086. It alleged that the acquisition would lessen competition in the research, development, production, and marketing of vitamin C, human growth hormone, and certain CD4-based AIDS and HIV treatments. See *id.* At the time of the challenge: (1) Roche manufactured vitamin C, while Genentech had developed a new patented process for producing vitamin C but had not yet done so; (2) Genentech had a human growth hormone on the market, and Roche had a competing product in clinical trials; and (3) both firms were researching the same type of AIDS/HIV treatments, but neither had a product approved for sale. See *id.* at 1081-86. The consent decree required divestiture of Genentech's vitamin C interests and Roche's human growth-hormone businesses, including both existing technology and R&D assets. See *id.* at 1093-95.

178. See, e.g., *In re Roche Holdings, Ltd.*, File No. 971-0103 (F.T.C. 1998), available at *Agreement Containing Consent Order* (visited Oct. 2, 2000) <<http://www.ftc.gov/os/1998/9802/9710103.agr.htm>> (ordering that the acquired firm divest intellectual property assets related to cardiac thrombolytic agents, a market in which it is one of only a few competitors, and provide technical assets to the FTC-designated recipient of the assets); *In re Glaxo PLC*, 119 F.T.C. 815, 820-21 (1995) (requiring Glaxo to divest some of Wellcome's intellectual assets and then provide information, technical assistance, and advice to the recipient of those assets, including consultation with and training by Glaxo employees familiar with the project).

firm's parallel research efforts, and potential entrants' access to at least a portion of the merged firms' patent portfolio. The best example is the FTC's *Ciba-Geigy* ruling.<sup>179</sup> The merged firms were two global competitors that were among only a few firms engaged substantially in the development of gene therapies for a variety of disorders. The FTC expressed concern that the merged firm would relax innovative intensity in these disease markets and, most crucially, that it would hold a patent portfolio that consolidated the intellectual property rights to one of the two major techniques (the *ex vivo* process) for conducting gene therapy.<sup>180</sup> The FTC stated that this astonishingly broad patent portfolio could enable the merged firm to erect significant entry barriers to the gene therapy market, impose harsh licensing terms, refuse to license its patented technologies, or unilaterally reduce its R&D expenditures in the gene therapy market.<sup>181</sup> To remedy this threat to the innovative efficiency of the gene therapy market, the FTC required that the merged firm grant a nonexclusive license to certain patented technologies that were deemed essential for subsequent research in this innovation market.<sup>182</sup>

## 2. *Why Compulsory Licensing Can Sustain Innovation*

The threat of compulsory licensing means that firms may invest substantial resources in an innovation project and then generate large knowledge giveaways through a royalty-free license that antitrust authorities grant to actual or potential rivals. As this scenario suggests,

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179. *See In re Ciba-Geigy Ltd.*, 1996 WL 743359.

180. *See id.* The Commission stated that the merged firms "control crucial inputs into the development of gene therapy products and the merger creates an unmatched portfolio of intellectual property assets that are necessary to commercialize gene therapy products." *Id.* Furthermore, it found that the "combination changes the competitive incentives of the merged entity" and that "[i]t will likely lead to a reduction in development of gene therapy products, as the parties combine their research and development pipelines and eliminate or slow down their parallel development projects." *Id.*

181. *See id.* The Commission stated that, although several other companies are capable of conducting gene therapy research, "[w]ithout licenses to crucial intellectual property held by [the merged firms] . . . these other researchers would not be likely to continue development." *Id.* Additionally, the Commission concluded that, due to the breadth of the merged firm's consolidated portfolio, the firm "will have a disincentive to license intellectual property rights to or collaborate with other companies as compared to the pre-merger incentives of the independent competitors. . . ."

182. *See id.* The FTC ordered that the merged firm could receive sales-based royalties on some of these compulsorily licensed technologies.

it appears that compulsory licensing reintroduces, to some extent, the first-mover disadvantage and counteracts the incentive-correcting function of the patent system. Several commentators have raised these incentive-reducing concerns with regard to the widely criticized "essential facilities" doctrine<sup>183</sup> and argued that ordering a dominant firm to share certain assets with competitors may discourage firms from developing these welfare-enhancing facilities in the first place.<sup>184</sup> In the pharmaceutical industry, it appears plausible that compulsory licensing could lead some firms to reduce their anticipated flow of knowledge giveaways by reducing total investment in R&D or favoring incremental R&D that reveals few additional applications. Although these very sensible arguments often cast considerable doubt on specific instances of compulsory access remedies,<sup>185</sup> they do not offer a compelling case against the FTC's surgical use of compulsory licensing in the biopharmaceutical sector.

Even though compulsory licensing of essential patented technologies may appear to reduce firms' expected return on certain fundamental R&D projects, there is good reason to believe that it may not lead to *any* reduction in corporate investments in these high-risk innovation projects.<sup>186</sup> To the contrary, this regulatory device may sustain current levels of fundamental innovation by encouraging large firms to acquire R&D assets through collaborative ventures rather than upstream acquisitions. This is because large firms can avoid the expected knowledge giveaways as a result of compulsory licensing by favoring strategic alliances that diffuse patent holdings over mergers that concentrate patent holdings. Thus, the FTC's surgical use of compulsory licensing complements an imperfect patent regime and sustains private incentives to conduct fundamental innovation through network forms of organization. Just as incomplete patents encourage

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183. For an excellent review of the case law applying the essential facilities and related duty to deal doctrines, see James C. Burling et al., *The Antitrust Duty to Deal and Intellectual Property Rights*, 24 J. CORP. L. 527 (1999). For a list of some of the leading cases, see *supra* note 134.

184. On the incentive costs imposed by wide application of the essential facilities doctrine, see Phillip Areeda, *Essential Facilities: An Epithet in Need of Limiting Principles*, 58 ANTITRUST L.J. 841, 851 (1990).

185. For a list of some especially questionable requests for and judicial grants of compulsory access remedies, see *id.* at 843-47.

186. Incidentally, the only significant study (to the author's knowledge) to measure the economic effects of compulsory licensing found no support for the incentive-reducing hypothesis. See F.M. SCHERER, *THE ECONOMIC EFFECTS OF COMPULSORY PATENT LICENSING* (1977). Scherer found no support for the hypothesis that 44 companies operating under significant compulsory licensing decrees spent less on R&D per dollar of sales than 635 companies not operating under such decrees. See *id.* at 67-75.

patent holders to construct interfirm networks that internalize otherwise inappropriate spillovers of fundamental innovation projects, the threat of compulsory licensing encourages large firms to prefer collaborative ventures over vertical acquisition as a means of achieving that objective. We know that large-firm managers already have strong incentives to do so, given the adverse cash-flow effect of large-firm R&D investments and the organizational incompetencies of bureaucratized research environments. Compulsory licensing supplies an additional incentive, since any high-growth or dominant firm that anticipates future mergers may want to avoid exclusive ownership of a high-technology product that lacks any close substitutes. Thus, large-firm managers may prefer to enhance spillover internalization through interfirm collaborations rather than vertical acquisitions or internal R&D investments.

Phillip Areeda argues that courts should order compulsory access only if a single firm's facility is "both critical to the plaintiff's competitive vitality and the plaintiff is essential for competition in the marketplace."<sup>187</sup> Biopharmaceutical mergers are likely to satisfy both of these conditions. Certain intellectual assets may close off a broad prospect of subsequent applications and dominant-firm managers often require the stimulus of a credible entry threat to maintain at least moderate levels of R&D intensity. The threat of compulsory licensing may discourage downstream firms from pursuing upstream vertical acquisition strategies that harm the long-term innovative fitness of the relevant disease market. These acquisition strategies would likely result in a science-based market dominated by a few large competitors that would wield sweeping patent portfolios and might exert sufficient market power unilaterally to slow down the rate of fundamental innovation. By disaggregating the patent portfolios of merged firms, licensing and divestiture remedies ensure that small firms have access to the basic tools for successful entry into certain disease markets. At the same time, this persistent entry threat sustains large firms' incentives to maintain innovative readiness and to seek R&D partners in the upstream inputs market.

The FTC's concern with long-term innovative fitness, and the

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187. Areeda, *supra* note 184, at 852. For an example of a court ruling that imposes a duty to deal when a monopolist's essential facility is not easily duplicated, see *MCI Comm. Corp. v. AT&T*, 708 F.2d 1081, 1132-33 (7th Cir. 1983) (holding that AT&T obstructed MCI's connection to local telephone exchanges and thus impeded competitive conditions in the long-distance market, contrary to the federal government's deregulation policies in the telecommunications market).

resulting application of licensing and divestiture remedies to patent consolidation practices, has a distinctly structural aspect. These remedies may preserve the bifurcated industry structure of a downstream, largely routinized innovation regime, and an upstream, largely entrepreneurial innovation regime. This network model of innovation relies on a symbiosis between small-scale operations that breed breakthrough technologies and large firms that exhibit economies of scale in clinical testing, manufacture, and distribution. Licensing remedies sustain the innovative vitality of the upstream market by occasionally compelling dominant firms to disseminate fundamental research tools that actual or potential entrants require to compete for market share and cannot replicate independently at a reasonable cost. At the same time, licensing remedies either do not affect, or may even enhance, incentives for downstream firms to maintain distribution capacities and participate in interfirm alliances to develop new product innovations. This distribution capacity is important because it encourages small firms to incur the up-front costs of product development and enables these cash-starved firms, including new entrants, to obtain outside financing. Finally, sustaining competitive conditions in the upstream market preserves the threat of forward vertical integration, and thus encourages downstream firms to engage independently in substantial amounts of fundamental innovation.

## V. CONCLUSION

Current innovation policies in the biopharmaceutical sector consist of substantial cash transfers to university research, imperfect forms of patent protection, weak enforcement of the antitrust laws against research and production joint ventures, and occasional use of compulsory licensing and asset divestiture in merger approvals. In science-based industries, there is a strong argument for an antitrust enforcement strategy that periodically breaks up consolidated patent portfolios that are likely to stifle technological advance. Licensing and divestiture remedies may preclude upstream vertical integration strategies that would upset the happy mix of incentives that explains biotechnology's current success in cultivating, and maintaining access to, the genetic commons. Part of the key to this success lies in the structurally ambiguous status of small upstream firms. These small firms not only provide large downstream firms with R&D inputs but also threaten to integrate vertically downstream and enter the product development, marketing, and distribution markets. A competitive upstream market, coupled with a fairly concentrated downstream market, encourages large firms to engage in innovative product development,

allows small firms to bargain with downstream firms for competitively priced distribution contracts, and maintains an open knowledge base for university and small-firm entrants into the upstream market. By contrast, a patent regime that lacks the threat of compulsory licensing may allow large firms to integrate vertically upstream, acquire a patent portfolio that erects insurmountable entry barriers to small firms, and ultimately slows down the rate of fundamental innovation. This unhappy result would reduce competitive conditions in the upstream market, dampen incentives for incumbent firms to engage in fundamental innovation, and close off much of the genetic commons to biopharmaceutical scientist-entrepreneurs.

This Article has argued that the network model of innovative development that characterizes the biotechnology sector relies closely on the introduction of an *imperfect* regime of patent protection. This fact may carry some general implications for understanding the primary function of patent rights in stimulating private innovation in science-based industries. Incentive theories of patent rights focus on optimizing the scope and duration of monopoly awards to cover the development costs, and under some versions lost spillovers, that discourage private investment in high-risk/high-spillover innovation projects. Applied to the biopharmaceutical sector, these incentive-based theories would recommend broadly defined prospect patents that cover a wide range of subsequent improvements. The innovative vitality of the biotechnology sector suggests, however, that policymakers sometimes should design patent entitlements that provide *incomplete* coverage of the spillover losses that private investors expect to incur in product development. The availability of even an incomplete degree of patent protection for fundamental innovation products allows entrepreneurially inclined researchers and large-firm distributors to overcome the commitment costs that may prevent the formation of mutually beneficial alliances. At the same time, the incomplete coverage of these patent rights encourages individual patent holders to form technology-sharing, or competency-sharing, alliances that cover the appropriability shortfall and internalize much of the expected spillovers from an innovation project.

These upstream-downstream, industry-industry, or university-industry collaborative ventures form a network model of innovation that detours around the tradeoff between productivity benefits and accessibility costs that commentators generally associate with patent protection for biopharmaceutical innovations. Each alliance operates as an individual

network that allocates product development, distribution, and marketing costs among small-firm and large-firm managers who exhibit contrasting risk preferences, investment horizons, and organizational competencies. In turn, each individual network operates as a node in a higher-order innovation network, including biotechnology start-ups, multinational pharmaceutical manufacturers, and university departments, that transmits commercially promising units of the federally funded stock of genetic information from the academic to the industrial sector. Subject to antitrust monitoring of backward integration and patent consolidation strategies, this innovation network is likely to enhance diffusion of the genetic information base and accelerate the development of fundamental therapeutic innovations.