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UNCERTAINTY AND THE STANDARD OF PATENTABILITY

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"I have suggested that, although 'it may be impossible to estimate the total benefits and costs of the patent system, one may attempt to analyze the marginal benefits and costs of particular moderate changes in the duration, scope, or strength of patented protection.' "—Fritz Machlup[1]

I. INTRODUCTION

To qualify for a patent, an invention must be more than an extension of what was known; it must represent a significant or "nonobvious" step in the art. This Article explains the economic function of the nonobviousness test. It thus extends other recent work on the economics of specific patent doctrines,[2] work which has been spurred in part by the recent explosion of interest in the patent system.[3]

The statutory[4] nonobviousness test serves a gatekeeping function; it seeks to reward inventions that, viewed prospectively, have a low probability of success. As explained below, this Article treats nonobviousness as a legal rule that influences behavior—specifically, the decisions of research and development (R&D) managers to pursue or ignore specific research projects. The nonobviousness standard encourages researchers to pursue projects whose success appears highly uncertain at the outset. The standard insists that only the results from uncertain research should be rewarded with a patent.

This approach has several benefits. First, it transcends particular doctrinal squabbles to clarify the overarching goal of the nonobviousness standard. The second advantage of an uncertainty-based conception of nonobviousness is that it fits nicely with one of several complementary theories often put forth to explain the patent system—the "compensation-for-disclosure" theory. The threshold nonobviousness requirement guarantees that a minimum quantum of information is disclosed in exchange for a patent. Indeed, the view taken here pushes this theory a measure further: it highlights the fact that research which overcomes uncertainty is precisely the sort society values, and hence rewards with a patent. Thus disclosure theory, often seen as embedded in doctrines

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1. FRITZ MACHLUP, THE ECONOMICS OF INFORMATION AND HUMAN CAPITAL 165 (1984).

2. *See, e.g.*, Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990); Robert P. Merges, *Economic Perspectives on Innovation: Commercial Success and Patent Standards*, 76 CAL. L. REV. 803 (1988).

3. *See, e.g.*, Norm Alster, *New Profits from Patents*, FORTUNE, Apr. 25, 1988, at 185; Edmund L. Andrews, *Patents: Courts Called Tougher on Infringement*, N.Y. TIMES, Sept. 16, 1989, at 34. *See generally* ROBERT P. MERGES, PATENT LAW AND POLICY (1992).

4. 35 U.S.C. § 103 (1988):

> A patent may not be obtained [even though the invention is novel under § 102 of the Act], if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains . . . .

requiring a full and adequate description of an invention, also plays a role in the threshold question of patentability.

An uncertainty-based view of nonobviousness also meshes well with other theories of the patent system, including the venerable incentive theory. This theory claims that inventions are socially valuable and that patents are needed to induce inventions that would not otherwise be made, due to the inability of inventors to recoup all the benefits of their inventions.[5] As informed by the incentive theory, the job of nonobviousness is to encourage invention while not over-rewarding it. A clear articulation of this view can be found in an influential 1966 article by Edmund Kitch. According to Kitch, nonobviousness tries to assure that patents will only be given for those inventions that would not have been made without the promise of a patent.[6] That is, society will reward only those who *require* a reward to do their work. This article builds on Kitch's basic insight in an attempt to explain *when* an inventor would need the extra stimulus of a patent, i.e., *which* inventions are likely to be patent-induced.

The uncertainty-based approach taken here helps explain the operation of the current patent system and also suggests some modest reforms. The patent system is shown to have a stronger effect on the incentive to develop inventions as opposed to the incentive to invent. Yet it is also shown that the prospect of a patent does have an important minor influence on decisions to try to invent. Some features of current nonobviousness doctrine are shown to be justified by the incentive role of the nonobviousness standard. For instance, the exclusion of firm-developed information from the prior art is readily explainable in the context of an uncertainty-based view of nonobviousness. The

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5. Studies consistently show that society often gains a very large share of the total value generated by an invention. *See* Jeffrey I. Bernstein, *The Structure of Canadian Inter-Industry R&D Spillovers, and the Rates of Return to R&D*, 37 J. INDUS. ECON. 315 (1989) (social rates of return at least twice private rates for industries studied); Timothy F. Bresnahan, *Measuring the Spillovers from Technical Advance: Mainframe Computers in Financial Services*, 76 AM. ECON. REV. 742, 753 (1986) (very large social gain from mainframe computers, 1.5 to 2.0 orders of magnitude above cost of inventing them); Robert E. Evenson & Yoav Kislev, *Research and Productivity in Wheat and Maize*, 81 J. POL. ECON. 1309 (1973); Zvi Griliches, *Research Expenditures, Education and the Aggregate Agricultural Production Function*, 44 AM. ECON. REV. 961 (1964); Edwin Mansfield et al., *Social and Private Rates of Return from Industrial Innovations*, 91 Q.J. ECON. 221 (1977) (concluding that median social rate of return on 17 major products was more than twice the private rate of return). The problem with this argument is that the social rate of return from non-technical innovations may be just as high. Also, all of the inventions studied were commercialized; thus the studies also support the notion that innovations are what really count.

6. Edmund W. Kitch, Graham v. John Deere: *New Standards for Patents*, 1966 SUP. CT. REV. 293, 301 (stating that "a patent should not be granted for an innovation unless the innovation would have been unlikely to have been developed absent the protection of a patent"); *see also infra* note 53 and accompanying text.

uncertainty-based model also suggests a moderate lowering of patentability standards for very high-cost research.

Part II describes the doctrinal contours of the nonobviousness standard, after a brief consideration of a threshold issue: whether patents matter. Part III presents a simple two-step R&D decisionmaking model. The model assumes that inventors initially decide whether or not to conduct a preliminary experiment, and that the decision to develop a technology is made only after the results of this initial experiment are known. This formalizes the notion that patents augment perceived payoffs from experimentation, hence helping to overcome a rational decision-maker's resistance to high uncertainty research projects. It also reveals that patents offer only a limited incentive to perform research, but may add a significant incentive to *develop* technology—a position held by a small number of commentators. Part III then offers a restatement of the general nonobviousness standard, as well as doctrines touching on serendipitous research results and the treatment of private, firm-specific information, in light of the proposed emphasis on uncertainty. The model is then used to justify a slight lowering of the nonobviousness standard where initial experimentation is very costly. The analysis is then applied to a group of cases involving methodical and costly screening procedures.

Part IV sketches a brief formal model of high-cost research in a multi-firm industry. This model illustrates the need for enhanced appropriability[7] (via a lower patent standard for high-cost research) to achieve socially optimal levels of R&D. Part V reveals the relationship between the economic function of the nonobviousness standard and theories of the patent system. The conclusion sounds a mercifully brief refrain on the themes of uncertainty and the economic function of the patent standard.

II. THE LEGAL STANDARD

A. Threshold Issues

1. *DO PATENTS MATTER?*

This section title might seem a question with a straightforward answer: of course patents matter, firms would not apply for them in such large numbers and litigate them with such tenacity if they were irrelevant. I touch on the subject here only because a medium-sized (but growing) literature puts this straightforward answer in doubt.

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7. Appropriability can be briefly defined here as means for capturing the value created by R&D expenditures.

While there have always been some critics who questioned the need for patents,[8] the recent critique carries extra weight because it is both current and based on substantial empirical research. These researchers find that patents are regarded by firms in only a very few industries as important means of capturing returns from research.[9] The most recent and complete study along these lines shows that in most industries head start advantages, including establishment of production and distribution facilities, and rapid progress down a learning curve, were judged significantly more effective than patents in enabling a firm to reap returns from innovation.[10]

Of course these studies and earlier sources contain some counter-indications. There certainly are inventors who swear by the patent system,[11] and a historian recently proclaimed the positive effects of the patent system on technical advance during the "first" industrial revolution in Britain.[12] Likewise, some recent empirical work finds that in

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8. *See, e.g.*, KEVIN BROWN, INVENTORS AT WORK 44, 189, 325 (1988) (quoting from interviews with inventors describing the importance of technical challenges and the unimportance of monetary gains to their pursuit of inventions); FRANK W. TAUSSIG, INVENTORS AND MONEY-MAKERS 17-54 (1915) (discussing what he calls "the instinct of contrivance" in all inventors, an instinct they would probably follow even without monetary gain); *cf.* S.C. GILFILLAN, THE SOCIOLOGY OF INVENTION (1935); Jack Hirshleifer, *The Private and Social Value of Information and the Reward to Inventive Activity*, 61 AM. ECON. REV. 561, 571-72 (1971) (since inventors have "inside information" about their inventions, they can reap gains by investing in assets that their inventions will make more valuable and selling short assets that their inventions will make less valuable; because of this, inventors might be overcompensated for their inventions if they are given special rewards such as patents).

9. *See* C.T. TAYLOR & Z.A. SILBERSTON, THE ECONOMIC IMPACT OF THE PATENT SYSTEM (1973); Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173, 176 (1986) (patents found not essential to protecting innovations in many industries); *cf.* ERIC VON HIPPEL, THE SOURCES OF INNOVATION 46-53 (1988) (patent licensing does not permit firms to reap rents from inventions).

10. Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 1987 BROOKINGS PAPERS ON ECON. ACTIVITY 783 (reporting results of extensive empirical survey of research and development personnel at U.S. corporations).

11. *E.g.*, Richard Halstead, *Silence Golden for SF-Based Dolby*, S.F. BUS. J., June 23, 1986, at 1 (interview with Ray Dolby, inventor of audio engineering devices: " 'I have a general principle that I follow,' Dolby says. 'I don't go into any area that I can't get a patent on.' If you don't stick to that approach, 'you quickly find yourself manufacturing commodities.' ").

12. HAROLD I. DUTTON, THE PATENT SYSTEM AND INVENTIVE ACTIVITY DURING THE INDUSTRIAL REVOLUTION 1750-1852 (1984) (arguing that patents were instrumental in the introduction of all the major technical improvements of the industrial revolution). Dutton also notes that the patent system's inefficiencies actually made it close to an ideal system, since it encouraged invention but did not protect new technology too much from those who would try to improve it. *Id.* at 204-05; *cf.* Joel Mokyr, *The Industrial Revolution and the New Economic History*, *in* THE ECONOMICS OF THE INDUSTRIAL REVOLUTION 1 (Joel Mokyr ed., 1989).

> Property rights in new techniques were protected, albeit imperfectly by British patent law. Some inventors who failed to capture any of the social benefits of their work were rewarded directly by society. . . . The cumulative

a handful of industries patents are essential.[13] But it is safe to say there is a consensus among economists that in the aggregate patents offer only a very limited incentive to invent.[14]

This recent scholarship does not contend that firms seeking patents are irrational. Those writing in this vein ascribe the continued vitality of the patent system to a number of motivations. For the most part these are negative; they center around using the patent system defensively, to insure that one is not excluded from a profitable product line.[15] This literature views patents as bargaining chips used to counter those of competitors as ulterior instruments in a broader game of competitive intrigue. These commentators imply that no firm would obtain patents if its competitors did not. A variant of this scholarship stresses how cheap patents are, and implies that the occasional defensive benefit is worth the relatively low cost of patenting.[16]

A similar but less critical view concedes that most patents are not worth the cost. It stresses the *exceptional* case of a highly lucrative invention covered by a strong patent. The idea here is that no one knows

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> effect of small improvements made by mostly anonymous workers and technicians was often more important than most of the great inventions.

Id. at 28 (footnote omitted).

13. *See, e.g.*, DAVID SCHWARTZMANN, INNOVATION IN THE PHARMACEUTICAL INDUSTRY (1976).

14. A nice summary of the consensus has been given by the economist Paul Stoneman: "[D]espite a long-standing concern over the nature and impact of the patent system, the importance of the system, in practical terms, may not be particularly great." PAUL STONEMAN, THE ECONOMIC ANALYSIS OF TECHNOLOGY POLICY 115 (1987).

15. *See* VON HIPPEL, *supra* note 9, at 51-53; Edwin Mansfield, *Intellectual Property, Technology and Economic Growth, in* INTELLECTUAL PROPERTY RIGHTS IN SCIENCE, TECHNOLOGY AND ECONOMIC PERFORMANCE 26 (Francis W. Rushing & Carole G. Brown eds., 1990) (patents taken out in some industries because "the prospective benefits of patent protection, including (besides royalties) whatever delay is caused prospective imitators and the use of patents as bargaining chips, are judged to exceed costs").

16. *See, e.g.*, VON HIPPEL, *supra* note 9, at 51-53. A completely different perspective on the continuing use of patents is given in GEORGE BASALLA, THE EVOLUTION OF TECHNOLOGY 124 (1988) (arguing that patents serve largely to perpetuate the culture of invention):

> The significance of patents is not that they offer strong and indisputable incentives for invention. . . . In fact, the effectiveness of the patent system is less important than the fact that every industrialized country in the West has made patenting a national institution, complete with supporting bureaucracy, legislation, and state funding. When combined with the zealous pursuit of patents by industry, the existence of professional careers in patent law practice, the transformation of the patent in Communist countries, the popular enthusiasm for the idea of the patent, and the economist's and historian's interest in probing the meaning of patents, the result is an obsession with technological novelty that is without precedent. No other cultures have been as preoccupied with the cultivation, production, diffusion, and legal control of new machines, tools, devices, and processes as Western culture has been since the eighteenth century.

at the time the patent must be filed whether an invention is exceptional. Because of the relatively low cost, it makes sense to file. The few exceptional inventions—estimated by one observer to be no more than one thousand per year—justify the many worthless patents, as well as the social cost they carry with them.[17]

Yet another critique of patents starts from the premise that they were originally quite successful in promoting innovation—the actual introduction of inventions into commerce—but have become almost useless in furthering this goal under current conditions.[18] This critique is

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17. F.M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 440 (2d ed. 1980) ("[I]n any given year there are likely to be a thousand or so moderately to extremely important inventions patented."); *see also* JOEL MOKYR, THE LEVER OF RICHES: TECHNOLOGICAL CREATIVITY AND ECONOMIC PROGRESS 252 (1990) (patent system justified by high-value, low probability innovations—when "a crackpot hits the jackpot"). For an interesting and valuable proposal to extend special patent-like protection to these rare "revolutionary" inventions, see A. Samuel Oddi, *Beyond Obviousness: Invention Protection in the Twenty-First Century*, 38 AM. U. L. REV. 1097 (1989).

18. *See* DIRECT PROTECTION OF INNOVATION 1-34 (William Kingston ed., 1987). (proposing a system of property rights to come into effect only when a new product is actually introduced on the market). These proposals contain some useful suggestions, as indicated by the commentators assembled to critique them. *See* Gordon Tullock, *Intellectual Property*, *in* DIRECT PROTECTION OF INNOVATION, *supra*, at 171; Brian D. Wright, *On the Design of a System to Improve the Production of Innovations*, *in* DIRECT PROTECTION OF INNOVATION, *supra*, at 227. This premise was well stated in the concurrence of Judge Frank in Picard v. United Aircraft Corp., 128 F.2d 632, 642-43 (2d Cir.), *cert. denied*, 317 U.S. 651 (1942).

> But if we never needed, or do not now need, patents as bait for inventors, we may still need them, in some instances, as a lure to investors. It is sometimes said that there is no need thus to coax investors, because our giant corporations, with their research laboratories, will, without such bait, do the needful. The answer perhaps is that industrial history discloses that those corporations, at times and to some extent, have been prodded into undertaking such research and into developing improvements because of the threat of competition from occasional "outsiders," armed with patent monopolies, and supplied with funds by a few private enterprisers. Thus, paradoxically, monopoly may evoke competition: The threat from patent monopolies in the hands of such "outsiders" may create a sort of competition—a David versus Goliath competition—which reduces the inertia of some huge industrial aggregations that might otherwise be sluggish.

Id. (footnotes omitted); *see also* SUBCOMM. ON PATENTS, TRADEMARKS & COPYRIGHTS OF THE SENATE COMM. ON THE JUDICIARY, 85TH CONG., 2D SESS., AN ECONOMIC REVIEW OF THE PATENT SYSTEM (Comm. Print 1958) (written by the economist Fritz Machlup).

> And it is after all the "difficulty" of inventing which determines the relative scarcity of invention and, consequently, provides the rationale for the policy of creating an extra stimulus for inventive effort. This presupposes, however, as do most other problems under discussion, that it is invention rather than enterprising innovation which the patent system is supposed to encourage. If society aims at stimulating innovation and at attracting venture capital into pioneering investment, then the controversies about the nature of "inventions" are beside the point. After all, the innovators' risks are not proportional to the costs and results of the inventive efforts.

merely a prelude to the proposal to protect innovations directly, rather than indirectly through the protection of inventions.[19]

Taking all these critiques together, two arguments may be made in defense of the patent system: first, that the criticisms are not true; and second, that they are irrelevant, even if true. I believe the latter. But I will run through both arguments.

The main problem with the data on which the criticisms are based is that it may be out of date. It predates an important discontinuity in the patent system: the creation of the Court of Appeals for the Federal Circuit in 1982.[20] It appears that the Federal Circuit has strengthened patents considerably since 1982.[21] A student recently found a marked increase in published patent damage awards after 1982, compared to the 1970-1981 period.[22] All this indicates that the value of a patent may have increased in recent years. If so, the criticisms of a patent's worth may be out of date.

The second, and more powerful, retort is that the critics' arguments are irrelevant. Even if the *average* patent is not particularly valuable, this does not mean that the lure of patents will not act as a powerful stimulus to invention, at least in some cases. In fact, there are several good reasons to believe it will. The first is the well-known optimism of inventors—the "socially wholesome illusion" championed by the economist Fritz Machlup.[23] Many inventions that turn out to be average are backed by inventors who believe they are special; the power of patents in special cases thus induces inventors to perfect many an average invention.[24]

Id. at 9 (footnotes omitted).

19. *See, e.g.*, DIRECT PROTECTION OF INNOVATION, *supra* note 18, at 59 (discussing notion of an "innovation warrant" to protect the first commercialized embodiment of a new invention or idea).

20. *See* Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (codified at scattered sections of 28 U.S.C.).

21. Between 1982 and 1985, the Federal Circuit found that only 46% of the patents it adjudicated were invalid, a marked contrast to the old invalidity rate of approximately 66%. This 1982-1985 figure is derived from data presented in Donald R. Dunner, *The Court of Appeals for the Federal Circuit—The First Three Years: Introduction*, 13 AM. INTELL. PROP. L. ASS'N Q.J. 185, 187-88 (1985) (Tables 1-3). The data cover cases decided through October 1985. The older data are presented in Lawrence Baum, *The Federal Courts and Patent Validity: An Analysis of the Record*, 56 J. PAT. OFF. SOC'Y 758, 760 (1974). Baum found that in some circuits, patents were practically never upheld. *See id.* at 762 (between 1961 and 1973, the Eighth Circuit invalidated 89% of adjudicated patents). There is some evidence that the *unpublished* opinions of the Federal Circuit are even less likely to find a patent invalid. *See* Erica U. Bodwell, *Published and Unpublished Federal Circuit Patent Decisions: A Comparison*, 29 IDEA 233 (1989).

22. *See* SEREBOFF, A STUDY OF AWARDS IN PATENT SUITS AND SETTLEMENTS FOR THE PERIOD 1970 TO 1989 (1990).

23. *See* MACHLUP, *supra* note 1, at 166-67.

24. Do not read "worthless" for average here. Most technical progress is made up of small, incremental improvements to existing products and processes. *See, e.g.*, SAMUEL HOLLANDER, THE SOURCES OF INCREASED EFFICIENCY: A STUDY OF DUPONT RAYON PLANTS

Another way of stating this argument is that the patent system should *only* be concerned with the marginal inventor, the one who without the patent system is equally likely to pursue an invention as not. To this hypothetical inventor in equipoise, patents may be the deciding factor. If so, the fact that many other inventors and inventive entities consider patents inconsequential is unimportant. It is this "inventor at the margin" we are concerned with, at least from the incentive point of view.[25]

The approach taken in this article builds on this assumption. It assumes that inventors who consider patents insignificant will invent regardless of the patent system. These inventors thus make no difference to a defender of the patent system. Society will obtain useful devices from these inventors whether or not they get patents; it is the other, perhaps smaller, group of "patent-dependent" inventors whose behavior society is trying to influence with the patent system. As long as there are some inventors to whom patents make a difference, it is worth having a patent system and it is worth trying to influence their behavior. Thus the critique of the patent system built around the average inventor is irrelevant to the incentive side of the ledger.[26] From an economic policy standpoint it is interesting to note that small firms may be more likely to be marginal inventors.[27] Patents thus may be particularly important to

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(1965) (detailed study of major and minor process improvements at various DuPont rayon plants); *cf.* ALFRED MARSHALL, PRINCIPLES OF ECONOMICS 281 n.1 (8th ed. 1948) ("In many businesses only a small percentage of improvements are patented. They consist of many smaller steps, which it would not be worthwhile to patent one at a time.").

25. Of course, if many inventions that are patented would have been made if patents did not exist, it can be argued that there is a net loss: we may have encouraged some inventors—the "marginal" ones referred to above—to invent, but at the cost of awarding costly monopoly rights to all those inventors who would have invented anyway. While it is not a complete answer to this objection, I would point out that this is another justification for the nonobviousness requirement. Although society may wind up granting monopoly rights over inventions that would have been made even in the absence of a patent system, at least it will not do so where the inventions are completely trivial. That is, a somewhat stringent "gatekeeper" will cut down on the number of patents issued to all inventors, including those for whom patents are an easy way to restrict competition, rather than a major incentive in producing their inventions.

26. Of course, this assumes that the availability of a patent system won't act as a *disincentive* to those who are otherwise indifferent to patents. I have yet to see a persuasive argument why this might be so; certainly such inventors are not disparately affected by the availability of patents to those who care about them. On the myriad non-economic motives to invent, see TERESA M. AMABILE, THE SOCIAL PSYCHOLOGY OF CREATIVITY (1983); S. Colum Gilfillan, *Fundamental Inventions—Nobody's Baby, in* JOINT ECON. COMM., 88TH CONG., 2D SESS., INVENTION AND THE PATENT SYSTEM (Comm. Print 1964); Ron Westrum, Motives for Inventing (paper presented at the Society for the History of Technology Annual Meeting, Cleveland, Ohio, Oct. 1990) (on file with author).

27. *See, e.g., Biotechnology Patent Backlog: Hearings Before the Subcomm. on Regulation and Business Opportunities of the House Comm. on Small Business,* 100th Cong., 2d Sess. 25 (1988)

the firms which are reputedly superior innovators and job-creators.[28]

Of course, opponents of the patent system would point out that motivating the marginal inventor might still result in a net social loss, depending on the social costs that result from her patent monopoly. Yet surely this critique would be better directed at the standard of patentability or some other feature of the patent system, rather than at the existence of the system in toto. In at least some cases, patents contribute to social welfare. Perhaps it can be shown that patent standards are too low, or patent scopes are too wide, or the seventeen year term is too long; but there is no reason to suppose that the whole system is wrong. As long as every inventor who receives a patent is required to contribute something of value to society, the potential for welfare loss attending the patent monopoly must be weighed against this contribution. Indeed, as long as patent doctrines require such a contribution and as long as there is competition in the markets where inventions are introduced, the burden would seem to be on those who would show that the current balance is too favorable to inventors.

2. *DOES THE PATENT STANDARD INFLUENCE THE AMOUNT OF RESEARCH?*

The discussion above shows why there is good reason to believe that patents are important. There is also good reason to believe that the criteria for granting patents (the patent standard) are important. The analysis used in this article presumes that today's decisions regarding the patentability of one firm's research influences the amount and direction of other firms' research. The standard of patentability is assumed to have behavioral effects and thus merits careful review. Firms will say, "Look, Firm A got a patent for doing that risky research; let's do some risky research ourselves." There are several reasons to believe the patent standard has such effects. Detailed case studies show that almost every firm at least tries to evaluate the cost effectiveness of proposed research

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(statement of Robert P. Merges) (reciting instances of small business reliance on individual patents).

28. *Cf.* Zoltan J. Achs & David B. Audretsch, *Innovation in Large and Small Firms: An Empirical Analysis*, 78 AM. ECON. REV. 678 (1989) (small firms were 43% more innovative than their larger counterparts for the entire sample of manufacturing industries); DOUGLAS K. SMITH & ROBERT C. ALEXANDER, FUMBLING THE FUTURE: HOW XEROX INVENTED, THEN IGNORED, THE FIRST PERSONAL COMPUTER 119 (1988) (after Federal Trade Commission investigation suggesting that compulsory licensing of Xerox's basic document copying patents to competitors might be part of antitrust remedy, Xerox officials stated that patents were no longer as important as they had been when the company was small). *But cf. American Patent System: Hearings on S. Res. 92 Before the House Subcomm. on Patents, Trademarks, and Copyrights of the House Comm. on the Judiciary*, 84th Cong., 1st Sess. 221 (1956) (statement of Walton Hamilton) ("A strong patent in weak hands is not worth anything.").

and development projects.[29] R&D managers also consider "patentability" or "patent strength" prior to investing in R&D projects.[30] Thus the prospect of getting a patent may enter into the *initial* project investment or selection choice.[31] If so, the standard of patentability enters at this stage.[32] Even for firms whose research proceeds further before making a

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29. *See* Edwin Mansfield & Samuel Wagner, *Organizational and Strategic Factors Associated with Probabilities of Success in Industrial R&D*, 48 J. BUS. 179, 190 (1975); NUALA SWORDS-ISHERWOOD, PROCESS OF INNOVATION 93, 103, 107, 110, 121, 131, 134, 142 (1984) (project evaluation by firms in the paper, oil, medical imaging, and semiconductor industries); *but see id.* at 103 (company that "no longer attempts to quantify returns from R&D investment," but still monitors progress); NEIL H. WASSERMAN, FROM INVENTION TO INNOVATION 120, 121 (1985) (importance of economics in the development of almost every phase of telephone cable technology, for example, decision whether to pursue line-loading technology, where "uncertainty as to benefits and costs and the large anticipated outlays for the development of the invention made it imperative to construct a detailed, accurate theory of the economics of the innovation"). For an interesting case study on the way R&D project decisions, decisions regarding individual experiments, and the prospect of patent protection interact, see Akzo, N.V. v. E.I. du Pont de Nemours, Inc., 810 F.2d 1148, 1149-50 (Fed. Cir. 1987) (description of parallel research efforts to produce Kevlar, a synthetic fiber).

30. Jackson, *Decision Methods for Evaluating R&D Projects*, RES. MGMT., July-Aug. 1983, at 16, 17 (illustrating a "scoring model" decision technique where one of seven factors to consider is "Patent and License Situation"); William E. Souder, *A System for Using R&D Project Evaluation Methods*, 21 RES. MGMT. 29, 32 (1978) (using patentability as one of five criteria on which projects are ranked in a side-by-side comparison); EDWARD B. ROBERTS, GENERATING TECHNOLOGICAL INNOVATION, 170, 175 (1987) (noting that a chemical company studied by author uses patentability as a criteria when assessing research project viability, and that two firms—Fetterlof and Merck—said they "would not touch unpatentable products"); J.J. Hutter, *The Development of Fluorescent Lamps at Philips up to 1940*, *in* PHYSICS IN THE MAKING 273, 288 (A. Sarlemijn & M.J. Sparnaay eds., 1989) (describing how Philips's patent position influenced the development of the fluorescent lamp); *cf.* Karl Heinrich Oppenländer, *Patentschutz und Wettbewerb im Innovationsprozeß*, *in* PATENTWESEN, TECHNISCHER FORTSCHRITT UND WETTBEWERB 47, 60-62 (Karl Heinrich Oppenländer ed., 1984) (No. 113 in the series Schriftenreihe des Ifo-Institutes für Wirtschaftsforschung) [hereinafter PATENTWESEN] (a survey of West German firms by the Ifo-Institut showed that without patent protection an average of 21% of all the inventions surveyed would not have been made; for large companies, this figure was 39%); L. Uhlman, *The Innovation Process in Industrialized Countries*, *in* INNOVATION, ECONOMIC CHANGE AND TECHNOLOGY POLICIES 21, 32 (Karl A. Stroetman ed., 1977) (study of 218 innovations from 126 companies finding that "[l]aws relating to competition, taxation, patents, etc." influenced the decision to commercialize inventions in 13% of the cases studied); WASSERMAN, *supra* note 29, at 91 (Alexander Graham Bell's patents on the telephone were crucial to getting financiers to back him).

31. *See, e.g.*, Halstead, *supra* note 11; BROWN, *supra* note 8, at 115 (quoting Bob Gundlach of Xerox: "[T]he patent umbrella was crucial [in development of xerography]. The fact that Xerox could invest in new processes with some assurance that it could get a return on that investment later was essential when it came to developing xerography."). *See generally* Westrum, *supra* note 26, at 13 ("The monopoly granted by a patent may very much increase the expected returns from commercialization of an invention, and for this reason it may be a powerful motivation to bring the invention to fruition or actually to put products derived from it on the market.").

32. Firms also look to the potential that their research will infringe other firms' patents; in this sense, patents enter into research selection as a negative influence as well. *See, e.g.*, Michael E. Gorman & W. Bernard Carlson, *Interpreting Invention as a Cognitive Process: The*

detailed cost/benefit analysis, patentability might enter in the very rough (and sometimes implicit) economic feasibility decisions made by the R&D department at the outset of the research project.

The discussion here is not meant to imply that patentability is the sole or even a major influence on firm R&D decisions. Yet as the literature reviewed above suggests, patents do have an effect on firms' R&D investment decisions. This is not surprising; as long as patents are worth something—and the volume of patent applications and litigation suggest they are—they will have some effect at the margin. A firm whose decisionmakers are closely divided as between pursuing an R&D project and investing elsewhere can be expected to be influenced by the enhanced returns a patent may bring. And so long as the prospect of patents has any influence on R&D decisions, it is worthwhile examining the standard of patentability.[33] Indeed, because the standard will influence these decisions, courts charged with interpreting the nonobviousness standard ought to be cognizant of its impact on the behavior of firms, and ought to modify it where necessary to carry out the underlying goals of the patent system.

B. Doctrine

The patent code says an invention must be "novel," "useful," and "nonobvious" to be patentable.[34] These criteria applied together determines the patentability of inventions. A novel invention is one whose combination of features is not found in any single preexisting invention, technical article, or other piece of "prior art." The logic behind this is fairly straightforward; surely it would be improper to permit someone to claim property rights in something that has been well-known

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Case of Alexander Graham Bell, Thomas Edison, and the Telephone, 15 SCI. TECH. & HUM. VALUES 131, 145 (1990) ("[T]he leaders of Western Union decided that there was no need to buy Bell's patent because the telephone could be easily duplicated and improved by inventors already associated with the company."). For a suggestion about the magnitude of the costs of "inventing around," see Edwin Mansfield et al., *Imitation Costs and Patents: An Empirical Study*, 91 ECON. J. 907, 913 (1981) (survey of R&D personnel in random sample of companies produced result that patents caused a "median estimated increase in [the cost of imitation] of 11%").

33. As a fallback, I would argue that even assuming the patent standard has little or no effect on firm behavior, there are reasons we would desire a non-trivial standard of patentability. Regardless of the motives firms have in pursuing research, the grant of a patent can involve fairly significant social costs. Thus we would want to make sure society does not incur such costs without receiving some benefit. This is a more conventional "static tradeoff" view of the matter than the prospective, behavioral impact view taken in the text. *See, e.g.*, WILLIAM D. NORDHAUS, INVENTION, GROWTH AND WELFARE 86-88 (1969).

34. 35 U.S.C. § 103 (1988). This is in addition to the other requirements in 35 U.S.C. §§ 101 (utility) and 102 (novelty). Novelty means "literal newness"; nothing exactly like the invention sought to be patented has been invented previously.

for a long time—say, in the practice of cutting cheese by using a cutting board and knife. This information is already in the public domain when the "inventor" seeks to patent it; society has no need to grant a patent to get this information. It is not novel, either in the everyday sense or the patent law sense.

Now imagine an inventor who seeks to patent a method of cutting cheese using a knife as a cutting tool and a sheet of *titanium steel as a cutting board*. Our inventor searches diligently and finds no evidence of prior patents or periodical articles describing her method; there also seems to be no record of people actually using her method. Because the *prior art contains no mention of it, it is novel, in the patent sense.*

The invention must still satisfy § 103 of the patent code. This bars the granting of a patent, although the test of novelty has been passed, when the invention is obvious. Nonobviousness, it has been said, is "the ultimate condition of patentability."[35] In our example, the invention would be found obvious. It merely combines two well-known components—a knife and a sheet of hard material—to achieve a well-known objective, cutting things. Thus in our example, the Patent Office would likely reject the titanium steel cutting board patent application. Alternatively, because accused infringers normally raise the invalidity of the patent as a defense, a court might well invalidate the patent for obviousness if it were somehow granted in the first place.[36]

The rationale for obviousness is evident from the cutting board example. Without it, anything differing only slightly from the prior art would be patentable. Even if the award of a patent to this particular patentee did not reduce social welfare much, surely such a patent would

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35. NONOBVIOUSNESS—THE ULTIMATE CONDITION OF PATENTABILITY (John F. Witherspoon ed., 1980). Thomas Jefferson, who oversaw the first American patent act, recognized early on that the patent system must concern itself with the difficult task "of drawing a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not." 13 WRITINGS OF THOMAS JEFFERSON 335 (memorial ed. 1904).

36. Thus nonobviousness must in effect be established twice by the patentee, at least if she ever litigates her patent. However, an issued patent which is litigated comes with a presumption of validity under the patent code which makes it less likely—though by no means impossible—that a court will declare the patent invalid. *See* 35 U.S.C. § 282 (1988) (presumption of validity); *see also* Dunner, *supra* note 21, at 187-88 (Table 1) (data show that for cases decided under § 103 by the Court of Appeals for the Federal Circuit—the unified, national court of appeals for all patent cases—the court affirmed 86% of district court decisions finding patents nonobvious and therefore valid, and 60% of district court decisions finding patents invalid for obviousness). It is interesting to contrast this figure with older data; between 1921 and 1973 the circuit courts found nearly two-thirds of adjudicated patents invalid. Baum, *supra*, note 21. In some circuits, patent validity was practically never upheld. *See id.* at 762 (between 1961 and 1973, the Eighth Circuit invalidated 89% of adjudicated patents). Note that certain evidence not normally available to the Patent Office may assist the patentee in establishing the nonobviousness of her invention; some forms of this "objective" evidence of nonobviousness have been criticized. *See* Merges, *supra* note 2.

deplete the stock of publicly-available resources available to the next inventor.[37] From this perspective, nonobviousness is designed to maintain a penumbra around the stock of known devices, techniques, etc., insuring that trivial extensions from what is known will not be granted property rights.

The legal standard of nonobviousness is built on this rationale. As it is often stated, the test of nonobviousness views the inventor's situation just prior to making the invention and asks how "nonobvious" it was that the invention would work.

At the outset, notice that there is something of a temporal paradox built into the standard. *Given* that the invention does work—there will be no patent application if it doesn't—how uncertain was it that it would work just prior to the time it was invented?

The cases hold that no patent will issue if, just prior to the invention, there was a "reasonable probability of success"[38] that the invention would work, as judged by someone "skilled in the art." If there was *no* reasonable probability of success, the resulting invention deserves a patent.[39] That is, an invention must be downright improbable for it to be patentable.[40]

The probability of the invention is viewed from the perspective of an ordinary skilled artisan,[41] *not* from the perspective of the actual inventor. There are good reasons why an objective standard is favored here. A subjective standard would be quite difficult to apply, and applicants would have an incentive to downplay their technical knowledge. Also, the objective standard guarantees that an inventor will contribute truly valuable information to the technical community.

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37. *See, e.g.*, Jessica Litman, *The Public Domain*, 39 EMORY L.J. 965 (1990).

38. *See, e.g., In re* Merck & Co., 800 F.2d 1091, 1097 (Fed. Cir. 1986) (the standard for obviousness is not "absolute predictability, [but] only a reasonable expectation that the beneficial result will be achieved"); Loctite Corp. v. Ultraseal, 781 F.2d 861, 874 (Fed. Cir. 1985) (obviousness is an objective standard, and it is only material what a person of ordinary skill would have thought); *In re* Longi, 759 F.2d 887, 897 (Fed. Cir. 1985); *In re* Lamberti, 545 F.2d 747, 751 (C.C.P.A. 1976).

39. *See, e.g.*, W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1520 (Fed. Cir. 1983) (upholding nonobviousness of invention, since "there was no testimony and no finding that one skilled in the art would transfer conventional thermoplastic processes to those for unsintered PTFE [polytetrafluoroethylene, i.e., "Gore-tex"], *or would have been able to predict what would happen if they did*") (emphasis added); *Ex parte* Old, 229 U.S.P.Q. (BNA) 196, 200 (Bd. Pat. App. & Int. 1985) (reversing final rejection by patent examiner for obviousness, because "he himself does not urge that the character of [the invention] ... could be predicted").

40. *See, e.g.*, Continental Oil Co. v. Witco Chem. Corp., 484 F.2d 777, 784 (7th Cir. 1973) (invalidating patent for invention that was "[a]t most ... somewhat doubtful until after an experiment had been made").

41. Under the statute, a "person having ordinary skill in the art," 35 U.S.C. § 103 (1988)—thus the acronym "PHOSITA." *See* John O. Tresansky, *PHOSITA—The Ubiquitous and Enigmatic Person in Patent Law*, 73 J. PAT. & TRADEMARK OFF. SOC'Y 37 (1991).

Finally, since the objective standard judges the obviousness of the invention on the basis of publicly-available information,[42] it does not punish inventors who produce "private" information not available to the ordinary skilled artisan.[43] Thus the standard indirectly encourages inventors to generate valuable private information, secure in the knowledge this will not be held against them when they apply for a patent.[44]

Again, what is important is not the chance of success measured with the aid of hindsight, but what someone skilled in the art would have predicted that chance of success to be before the invention was made.[45] For purposes of applying this test, it is useful to imagine not one omniscient skilled artisan, but rather a "roomful of engineers." The relevant probability of success is the *consensus* probability these engineers would estimate with all relevant knowledge in mind just prior to the actual key experiment.

C. The Patent Standard and Races to Invent

We have seen that the patent standard insures that each invention will contribute a minimal quantum of information to the technical arts. Implicit in this view is the notion that inventors must be kept from patenting *too soon;* that technological advance should be rewarded when it is "ripe." An important rationale behind requiring a minimal contribution of information is to distinguish patent races from so-called "common pool" situations such as overfishing.

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42. The hypothetical "skilled artisan" is endowed with all relevant knowledge in the prior art. *See In re* Winslow, 365 F.2d 1017 (C.C.P.A. 1966). But the skilled artisan may also be misled by all this prior art; a long line of cases hold that if the prior art "teaches away" from the solution found by a patent applicant, this is strong evidence of the nonobviousness of that solution. *See, e.g., In re* Diminski, 796 F.2d 436 (Fed. Cir. 1986); *In re* Gordon, 733 F.2d 900 (Fed. Cir. 1984); Robert W. Harris, *Apparent Federal Circuit Standards for Weighing Nonobviousness Argument that Prior Art Reference Teaches Away from Present Invention*, 70 J. PAT. & TRADEMARK OFF. SOC'Y 79 (1988).

43. That is, even if an inventor's own research shows that the critical experiment is quite likely to succeed, this will not render the invention obvious. Only publicly available information, for the most part, is used to determine whether the invention is likely to succeed, and therefore obvious. Consequently, an inventor's own private information will not render her invention obvious, despite the fact that, had the "reasonably skilled artisan" known this information, this artisan would have predicted success for the critical experiment.

44. I argue later that even if an inventor *in fact* knew for certain that a particular experiment would work, because she invested time and effort in a series of experiments leading up to the critical successful experiment, the patent should be granted if a person of ordinary skill in the art would have predicted that there was no reasonable chance of success for that experiment. This arguments turns on the non-availability of "private prior art" in the general prior art from which obviousness is judged; the argument explains a feature of nonobviousness that has been of interest in recent years.

45. *See In re* Adams, 356 F.2d 998, 1002 (C.C.P.A. 1966).

Using economic modeling, many analysts have concluded that multi-firm R&D races indeed resemble common pool situations such as overfishing.[46] Most of these models utilize game theory techniques where firms make investment decisions sequentially, using varying amounts of information about their rivals' moves and responses. The basic assumption is that inventions can be planned and rationally pursued; the primary variable is the *speed* at which a firm pursues a particular invention. Under the basic form of these models,[47] the incentives (which often include a patent) to "win" the race cause firms to invest in R&D "too fast" (and sometimes "too much") compared to the socially optimal rate.[48] In this way these race models resemble the basic common pool model for assets such as fish.[49] Under the common pool model, multiple fishermen inefficiently rush to exploit a commonly-owned (i.e., public) resource. The fish are available to the fisherman who first appropriates them. Similarly, patent rights are available to the firm which first does

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46. *See, e.g.*, Partha Dasgupta & Joseph Stiglitz, *Uncertainty, Industrial Structure and the Speed of R&D*, 11 BELL J. ECON. 1 (1980); Glenn C. Loury, *Market Structure and Innovation: A Reformulation*, 94 Q.J. ECON. 395 (1979); F.M. Scherer, *Research and Development Resource Allocation Under Rivalry*, 81 Q.J. ECON. 359 (1967). For recent treatments of the topic, see Steven A. Lippman & Kevin F. McCardle, *Dropout Behavior in R&D Races with Learning*, 18 RAND J. ECON. 287 (1987).

47. Other attempts to model interfirm R&D competition include refinements such as the possibility that information generated by one firm's research may benefit competitors (the so-called "spillover" effect). *See, e.g.*, Benjamin Bental & Dennis Fixler, *Firm Behavior and the Externalities of Technological Leadership*, 32 EUR. ECON. REV. 1731, 1744 (1988) (externality created by ability of trailing firm to learn from leading firm's technology makes it a viable strategy to "lag behind" in some circumstances, thus changing the dynamic of the "race"); *cf.* Richard C. Levin & Peter C. Reiss, *Cost-reducing and Demand-creating R&D with Spillovers*, 19 RAND J. ECON. 538 (1988) (summarizing empirical data on industries where each firm's research has industry-wide benefits). For other refinements and extensions, see JEAN TIROLE, THE THEORY OF INDUSTRIAL ORGANIZATION 396-99 (1990) (describing embellishments on basic race models); Partha Dasgupta, *Patents, Priority and Imitation, or the Economics of Races and Waiting Games*, 98 ECON. J. 66 (1988) (exploring conditions that make waiting more profitable than entry in races to invent); Michael L. Katz & Carl Shapiro, *R&D Rivalry with Licensing or Imitation*, 77 AM. ECON. REV. 402 (1987) (exploring effects of post-invention dissemination, i.e., licensing or imitation, on two-firm strategic race to invent).

48. For an explanation, see Pankaj Tandon, *Rivalry and the Excessive Allocation of Resources to Research*, 14 BELL J. ECON. 152 (1983) (excessive duplication of research results when competitors race for "common" result that will be covered by a strong property right). *See also* Partha Dasgupta & Paul Stoneman, *The Economic Theory of Technology Policy: An Introduction*, *in* ECONOMIC POLICY AND TECHNOLOGICAL PERFORMANCE 18-21 (Partha Dasgupta & Paul Stoneman eds., 1987) ("[T]he winner-takes-all form of compensation to research units . . . encourages excessive R&D investment and excessive risk-taking on the part of R&D units competing for the prize.").

49. *See generally* Brian D. Wright, *The Resource Allocation Problem in R&D*, *in* THE ECONOMICS OF R&D POLICY 41, 49-56 (George S. Tolley ed., 1985) (describing the relationship between the general common pool model and "race" models: "The dissipation of the benefits of research . . . before the socially optimal time . . . is a dynamic intertemporal version of the same type of market failure [described in the common pool models].").

the necessary research. The problem in both situations is that too much is spent too quickly on the "capture" of valuable assets.

A significant criticism of the common pool models as applied to R&D is that new technology, unlike things such as fish, is *not* "already out there." It must be invented—i.e., conceptualized, synthesized, constructed—and so differs fundamentally from fixed assets like fish, which need only be found and harvested. With technology, unlike fish, there is independent value in the "search" for the asset. Consequently, the question of what search costs are optimal is more difficult for technology; expenditures on search can, in effect, make new fish, or even (sometimes) entirely new beasts altogether.

Implicit in this critique of common pool models as applied to R&D is the notion that patentable technology is not "already out there." It must be made, not found. And this suggests a further defense of the nonobviousness standard of patentability. For it is this standard which guarantees that the search for a patentable invention will not be like the search for fish—it will be for something not only new, but beyond the penumbra of the already-known. In short, having a standard of patentability is what makes the search for patentable technology different from the search for a fixed asset that is already out there.

The gatekeeping function of the patent standard makes a great deal of sense from this point of view. Without it, firms would be making patentable inventions all the time. If every one were patented, a great deal of technology would be locked up. In fact, because it was so predictable—so "easy to find," to extend the fishing metaphor—patentable technology would closely resemble the fixed assets that are the subject of the common pool models. Under these circumstances, with no viable patent standard to prevent firms from taking out numerous patents, the predictions of the pool models might well be borne out: overfishing (i.e., too much patenting) compared to the socially optimal level would ensue. Thus there is another justification for the patent standard—to prevent wasteful expenditure on the capture of trivial pieces of technology.[50]

D. Relationship Between Patent Standards and Patent Scope

As shown above, the nonobviousness standard is clearly a *threshold* standard. It determines which inventions deserve the reward of a patent.

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50. Note that this point corresponds to one part of Mark Grady's thesis that the patent system is designed to minimize rent dissipation. *See* Mark F. Grady & Jay I. Alexander, *Patent Law and Rent Dissipation*, 78 VA. L. REV. 305 (1991). On that thesis in general, see Robert P. Merges, *Rent Control in the Patent District: A Comment on the Grady-Alexander Thesis*, 78 VA. L. REV. 359 (1991).

Yet this standard of patentability is incomplete without a legal definition of the breadth of the invention.

Nonobviousness is determined with reference to the claimed invention. That is, the Patent Office or court asks whether the invention *as claimed* is obvious or not.[51] Thus inventors often amend or modify their patent applications by reducing the scope of their claims, to overcome a nonobviousness rejection from the Patent Office. For example, consider an inventor who perfects a chemical process that uses a certain chemical compound in concentrations ranging from 15% to 80%. In her patent application, she claims the process using that compound in the full range of concentrations she has found effective—from 15% to 80%. Next, assume the patent examiner turns up a prior art reference (a scientific article, for instance) that describes the use of a similar compound in a similar process in concentrations from 1% to 20%. The examiner may assert that this reference makes the applicant's invention obvious, at least in the lower ranges of compound concentration. In response, the applicant may modify her claims to include the process using the compound only in some higher range, say from 40% to 80%. This modified claim, the examiner may rule, meets the test of § 103 (i.e., is not obvious), and hence is patentable.

Yet the conclusion on nonobviousness does not determine another issue of importance to the applicant—the upper boundary of her claim. Perhaps she wishes to extend the upper boundary to 100%, so she would be claiming a process using all concentrations of the compound from 40% to 100%. Clearly if an 80% concentration is nonobvious, so is a 100% concentration. Thus the nonobviousness test cannot be used to determine if this new, expanded claim, is patentable.

In this situation the enablement test set forth in § 112 applies. In general, enablement seeks to determine whether the inventor's claims adequately reflect her research—whether, in effect, she is claiming more than she taught her fellow artisans. If she has claimed more than she has taught, the legal conclusion is that she has not adequately "enabled" one skilled in the art to make or use all embodiments of her invention. Those claims that are not enabled are rejected by the Patent Office or invalidated by a court.

From an economic point of view, the purpose of enablement doctrine is to insure that the property right granted to an applicant is of an appropriate scope, in light of the contribution her research makes to the relevant field. Enablement insures that the scope of the right accurately reflects the value of the invention. Contrast this to the function of nonobviousness as previously discussed. Nonobviousness insures that

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51. *See, e.g.*, Windsurfing Int'l, Inc. v. AMF, Inc., 782 F.2d 995 (Fed. Cir.), *cert. denied sub nom.* BIC Leisure Products, Inc. v. Windsurfing Int'l, Inc., 477 U.S. 905 (1986).

the information inherent in the invention claimed has some minimum threshold quantum of value. As long as the claimed invention had a low enough probability of success before it was made, it is deemed to be valuable enough, and is therefore patentable. But beyond this, nonobviousness does not seek to determine exactly how large the inventor's contribution is to the art, and hence how expansively she may define her invention in her claims.[52] This is the domain of enablement, and the other doctrines that collectively determine patent scope.

E. The Proposed Patent Standard

The conventional ideal standard of patentability is that patents should only be awarded to those inventions that would not have been made without the availability of the patent.[53] That is, patents should only be given out when they make a difference. They should never be "icing on the cake" for an otherwise motivated inventor.

It would be impossible in most cases to apply this standard. If asked, firms would always say they need patents. Also, as the preceding discussion indicates, very few patents would be granted today under this standard, since so few industries consider patents essential.

The *patentability* standard I propose aims to influence the marginal firms and marginal inventors referred to above. It should influence at least these marginal inventors to pursue riskier research than they otherwise would. My preferred standard rewards one who successfully invents when *the uncertainty facing her prior to the invention makes it more likely than not that the invention won't succeed.* Uncertainty under this

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52. Even so, certain aspects of the enablement doctrine have a probabilistic twist, viz.: did the patentee make it probable that someone skilled in the art could produce the subject matter she claims in her patent? This is especially true in relatively empirical arts such as biotechnology, where there are limits to the guidance a patentee can provide in her specification. *See, e.g., In re* Wands, 858 F.2d 731 (Fed. Cir. 1988); Patrick Kelly, *Patenting EPO Analogs: Screening vs. Predictability*, BIO/TECHNOLOGY, Feb. 1990, at 112; *see also* Pierserafino Marsico, *The Chemical-Pharmaceutical Product Patent: Absolute Protection, General Formulas and Sufficiency of Description*, 11 EUR. INTELL. PROP. REV. 397, 405 (1990) (citing decision of Rome Tribunal, stating that a "patent must be held invalid where the description does not completely indicate a given solution for the implementation of the invention, but imposes on the technician all the experimentation and randomness of success that characterise the studies and research of the patentee"). This same concept is reflected in the "undue experimentation" doctrine in U.S. law. For a description of this and other scope-related concepts, see Merges & Nelson, *supra* note 2.

53. *See* S.C. Gilfillan, *The Root of Patents, or Squaring Patents by their Roots*, 31 J. PAT. OFF. SOC'Y 611, 611 (1949) ("A patent is helpful and proper when it rewards sufficiently useful creative work which *might not have been done without* that prospective reward.... This principle has always been the basis for granting patents for inventions won by genius or luck, and denying them for inventions that could have been made by anyone skilled in the art, or inventions that follow logically from already known principles."); Kitch, *supra* note 6.

standard is measured from the perspective of the average skilled inventor in the field.

One possible objection to this approach is that it might work too well; under this standard firms might undertake more high-risk research than is otherwise warranted because the results of high-risk research are more readily patentable. This is bound to be true to a certain extent; assuming the amount of potential R&D investment is fixed, when patents are introduced there will be some displacement from the low-risk research that would have been pursued absent patents. On the other hand, if the social rate of return from the higher-risk projects is greater—and there is reason to believe it will be—this displacement is warranted. Again, the evidence is empirical; I refer to the studies of returns from major technological advances discussed previously.[54] Many of these advances were achieved in the face of significant uncertainty, suggesting a correlation between this uncertainty and the eventual rate of return.

Yet the risk of a very serious degree of displacement appears low. At some point even for the marginal inventor the risk of failure will be so high that the admitted lure of a patent will not induce her to attempt the invention. There is no real danger, in other words, that a standard based on technical uncertainty will shift all research toward the high-risk category.

III. MODELING THE STANDARD: PATENTS AS INCENTIVES TO INVENT

The incentive theory of patents is the most widely accepted theory; references to it are everywhere. As with any incentive, patents are thought of as a "sweetener" to influence a particular decision. The decision in the case of patents is usually taken to be the decision to invent. The disclosure theory of patents is also important in understanding our patent system. An attempt to integrate these two theories appears in Part V below. But for present purposes, it is best to focus on the incentive theory.

A. A Formal Model of the Invention Process

There is a model of the invention process, and of the patent system's role in this process, implicit in the incentive theory as it is usually presented in the patent literature. This model is of the inventor deciding whether to attempt an invention. The decision can be thought of as an investment decision like any other. The inventor faces the choice of attempting to invent, or of investing her money elsewhere. In this

54. *See* sources cited *supra* note 5.

conception, patents are held out as a potential reward to induce the inventor to decide to proceed with research.

This section explores the incentive theory by presenting a simple formal model of this decision process. The first stage of the model consists of an inventor facing the choice of whether to attempt preliminary experimentation on the invention.[55] The next stage of the model presents another decision: whether to develop the nascent invention. By separating the invention process into two steps, the model tries to "unpack" some features of the conventional (implicit) model of invention, and thus capture more of the complexity of the invention process.

In this two-step decision model, the inventor makes an *initial* estimate of the potential returns from the inventive process, prior to beginning any experimentation.[56] This is equivalent to the common

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55. This corresponds roughly to a common stage in research and development (R&D) projects: the preliminary screening of candidate technologies, or preliminary investigation of a technology for a suspected or hoped for quality. *See, e.g.*, Steven N. Wiggins, *The Pharmaceutical Research and Development Decision Process*, *in* DRUGS AND HEALTH 55, 58 (Robert B. Helms ed., 1981) ("The screening procedure is a low-cost method of separating compounds that warrant more careful testing from toxic substances and from substances that have no observable pharmacological action."). On the use of formal decision-making techniques in research and development management, see WILLIAM E. SOUDER, PROJECT SELECTION AND ECONOMIC APPRAISAL (1984); Uhlman, *supra* note 30, at 32 (study of 218 innovations from 126 companies finding that, at least at the stage of deciding whether to develop an invention, "[t]he formal procedure adopted in [this] decisionmaking process has, therefore, to a considerable extent been standardized in industrial enterprises"); *cf.* Edwin Mansfield, *How Economists See R&D*, HARV. BUS. REV., Nov.-Dec. 1981, at 98 (reporting results of empirical research indicating that although economic evaluations based on quantitative techniques increase a project's chances of commercial success, some managers are reluctant to adopt project selection methods).

> The precise extent to which quantitative models of this sort are being used in the United States is unknown. Some surveys indicate that many of the laboratories—particularly the bigger laboratories—in the chemical, drug, and electronics industries have used them. But the surveys cannot tell how significant these techniques really are in the decision-making process. In some laboratories, they are taken quite seriously indeed; in others, they are little more than window dressing for professional hunches and intracompany politics.

Id. at 102.

56. Aficionados of the literature on uncertainty may note that a discussion of rational investment decisions in a paper ostensibly concerned with uncertainty requires some explanation. This is so because, ever since Frank Knight's pioneering work in 1921, this literature has recognized a fundamental distinction between risk and uncertainty. Risk is generally defined as an assessment of likelihood based on repeated instances of an event. *See* FRANK H. KNIGHT, RISK, UNCERTAINTY AND PROFIT 19-20, 233 (1921). Uncertainty, by contrast, usually describes a unique situation not susceptible to measurement by repeat instances over time. *Id.* at 20, 233. Decisions regarding invention are clearly attended by uncertainty, not risk, as Knight himself recognizes. *See id.* at 318 ("The most fundamentally and irretrievably uncertain phases or factors of progress are those which amount essentially to an increase of knowledge as such. This description evidently holds for the improvement of technological processes and the forms of business organization

situation of the R&D manager deciding whether it is even worthwhile to begin to explore a research area.[57] If she decides the preliminary experimentation is worthwhile, she is faced with a second choice when that experimentation is successfully completed: to develop the invention, or to abandon it.[58] Figure 1 shows a simple "decision tree" describing the

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and for the discovery of new natural resources."). Yet this does not mean that inventors facing an investment decision cannot make probability judgments about the chances of success, nor does it imply that such judgments are meaningless. Knight recognizes that

> [t]hough we cannot describe a new invention in advance without making it . . . yet it is possible in a large degree to offset ignorance with knowledge and behave intelligently with regard to the future. These changes [i.e., advances] are in large part the result of deliberate application of resources to bring them about, and in the large if not in a particular instance, the results of such activity can be so far foreseen that it is even possible to hire men and borrow capital at fixed remunerations for the purpose of carrying it on.

Id. at 318. This is simply a particular instance of Knight's general observation about decisions made under uncertainty: "that a judgment of probability is actually made in such cases." *Id.* at 226. Note in this connection Kenneth Arrow's treatment of research as overcoming uncertainty: "The outcome of any research project is necessarily uncertain, and the most important results are likely to come from projects whose degree of uncertainty to begin with was greatest." Kenneth J. Arrow, *Insurance, Risk, and Resource Allocation, in* ESSAYS IN THE THEORY OF RISK-BEARING 135, 138 (1974); *see also* JON ELSTER, RATIONAL CHOICE 19 (1986) (describing uncertainty as a situation where the decisionmaker does not know the value of gathering more information, and so must make *"some* decision"). Knight identifies such judgments as "subjective," KNIGHT, *supra*, at 233, which is in full keeping with the model that follows, in the sense that the "Bayesian" features I use are often characterized as reflecting a subjective outlook. *See, e.g.*, THEODORE M. PORTER, THE RISE OF STATISTICAL THINKING 78-80 (1986) (describing eighteenth century reactions to Bayes' Theorem which charged that it was "illusory" and "arbitrary"); COLIN HOWSON & PETER URBACH, SCIENTIFIC REASONING: THE BAYESIAN APPROACH (1989) (responding to charge that Bayesian approach is too subjective). Note, however, that the test for nonobviousness is an *objective* test in that is asks whether "one skilled in the art"—a "reasonable person"-like construct that is essentially objective—would have predicted success for the key experiment faced by the inventor. As a consequence, the nonobviousness test as I see it employs an interesting duality: it measures the *subjective* judgment of the *objective* "skilled artisan" to assess likelihood of experimental success, and hence patentability.

57. *See, e.g.*, Wiggins, *supra* note 55, at 63 ("[A]t some point the [researcher] who has the [research] idea goes to the head of his or her research unit and suggests that the idea be pursued in a formal project. This is the *primary* source of all new research projects undertaken by pharmaceutical companies.").

58. The use of project "hurdles" or decision points in the pharmaceutical industry is described in Wiggins, *supra* note 55, at 70. One researcher finds that for a majority of inventors, patents act primarily as an incentive to commercialize, rather than invent. *See* Giorgio Sirilli, *Patents and Inventors: An Empirical Study*, 16 RES. POL'Y 157, 164 (1987). But unless this is true of all inventors, it does not undercut the model in the text, since, again, the patent standard is designed to influence only those marginal inventors whose initial decisions to invent *are* affected by profitability and patentability. For case studies where patents have primarily influenced the decision to commercialize, see SCOTT LANDIS, THE WORKBENCH BOOK 210-20 (1987) (inventor of collapsible workbench would not have commercialized invention without promise of a patent because it was so easy to copy) and Westrum, *supra* note 26, at 15 (describing Pilkington Company's decision to commercialize "float glass" glass production technology only with patent protection).

two-step investment process. In the figure, squares represent decisions which must be made and circles represent chance events over which the decisionmaker has no control.

An important feature of this model is that the researcher does not know at the time of the initial experiment whether it will be a success. She may have some idea, or even a strong belief; but until the experiment is actually performed, there is no way of definitely knowing whether it will work. This matters because of a key assumption in the model: that a patent is much more valuable if it covers a product which is successful in the marketplace.[59] This is equivalent to assuming that a patent has little or no value in and of itself; its value stems solely from its ability to prevent competitors from appropriating the intrinsic benefits of the invention which the patent protects.

As a result of this assumption, and in light of some reasonable values for the probabilities of each event in the model, increasing the payoff associated with a patent strengthens the reward to successful innovation, but not as directly as one might think. The researcher knows that neither a promising experimental result nor a commercially successful product based on the invention[60] are certain at the outset. Thus the added financial return that accompanies a patent has only a *contingent* value; it is not certain.

This may seem obvious. But when some realistic numbers are plugged into the basic model, it quickly becomes apparent just how limited the incentive effect of a patent is. To take a reasonable case, suppose the probability[61] of obtaining a promising experimental result is

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59. Or, what amounts to the same thing, if it covers some *aspect* of a product which is successful in the marketplace. Note here that I have previously described my misgivings about a standard of patentability that relies on evidence of "commercial success" to *prove* that an invention ought to be patented. *See* Merges, *supra* note 2.

60. I.e., a successful innovation.

61. Throughout this article, I use probability in the *subjective* sense: a person's best estimate, based on past experience, of the likelihood of some event occurring. This must be contrasted with "objective" probabilities, such as those involving dice and coin flips.

> There are two fundamentally different ways of arriving at [a] probability judgment .... The first method is by *a priori* calculation, and is applicable to and used in games of chance.... It must be strongly contrasted with the very different type of problem in which calculation is impossible and the result is reached by the empirical method of applying statistics to actual instances.... [T]he first, mathematical or *a priori*, type of probability is practically never met with in business, while the second is extremely common.

See KNIGHT, *supra* note 56, at 214-15. Knight goes on to explain a third type of probability judgment, with no empirical backing, made in a unique situation, which he terms an *estimate*. *Id.* at 225. He says that these estimates or judgments under uncertainty form the real basis of profit in a capitalist economy, since the other types of risk can be planned for and thus minimized. *Id.* at 232, 310-11. From the passage quoted, it is fairly clear that Knight would see invention as a highly uncertain activity, and thus one that is not capable of "statistical" characterization. Nevertheless, he recognizes the need to form judgments,

50%, and the probability of a commercially successful project is 40%. Suppose further that past experience indicates that for projects that are ultimately successful, the initial experiment produces promising results 70% of the time. Assume that the chance of obtaining a patent for a product that is a commercial success is 50%.[62] Finally, assume that the award of a patent increases the financial payoff of a successful invention by 20%; we can say that without a patent, the payoff for a successful invention is $1000, but with a patent it would be $1200.[63] (There is a net return of zero if the initial experiment does not produce promising results, or if the experiment is promising but turns out to yield a commercially unsuccessful product.[64])

With these numbers, the extra incentive offered by a patent can be analyzed. If we allow the decisionmaker to decide whether to continue with the project after the initial experiment,[65] the incentive effect of a

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albeit subjective, about the likelihood of uncertain events. *See, e.g., id.* at 282 ("The judgment [under uncertainty] . . . is a judgment of the probability of a certain outcome, of the proportion of successes that would be achieved if the venture could be repeated a large number of times."). Thus the probabilities discussed in this article can be seen in Knightian terms as either empirical-statistical probabilities or probability estimates under uncertainty. The only catch is that the standard of patentability asks whether an invention would have been obvious to one skilled in the art to which it pertains. 35 U.S.C. § 103 (1988). Since this implies an "objective" standard—the "reasonably skilled inventor"—it might be seen as incompatible with Knight's classification of uncertainty estimates as inherently subjective. The standard may, however, be stated in a way that squares with Knight's category of true uncertainty: it might be thought of as a consensus of the actual judgments of actual artisans of reasonable skill in the field. This is in effect what is done, because the prior art that is consulted to determine patentability is written by actual practitioners in the field.

62. Others have modeled the issuance of a patent as a random variable. *See, e.g.*, Ben-Zion, *The R&D and Investment Decision and Its Relationship to the Firm's Market Value: Some Preliminary Results, in* R&D, PATENTS AND PRODUCTIVITY 209, 302 (Zvi Griliches ed., 1984).

63. This is a conservative estimate of the average value of a patent to the average patentee, since it has been found that the average patent increases the imitation cost only modestly. *See supra* note 32.

64. This is a plausible assumption under either of two scenarios. First, an unpromising experimental result eliminates the chance of a successful project. This would make the probability of a successful project zero. Alternatively, there might be a small chance that the unpromising experimental result could still lead to a successful project. Even so, the high probability of an unsuccessful project, together with a plausible estimate of the net loss that would attend such a project, could produce a zero or negative *net* expected value after an promising experiment. Note, however, that if the probability of a successful project after an unpromising experiment is some number greater than zero, the probability of a successful project after a promising experiment would have to be reduced accordingly; the sum of both these must equal the overall probability of a successful project. This would simply lower somewhat the expected value of a project undertaken after a promising experiment.

65. This corresponds with how R&D decisions are actually made in many instances. *See* Mansfield & Wagner, *supra* note 29 (reporting survey of R&D decisionmaking in 20 large corporations, where three identifiable stages are common: technical completion, commercialization, and evaluation or profitability). Mansfield and Wagner add that "[i]n

patent becomes clear. Given the figures discussed above, the inventor will be facing one of two situations after the initial experiment. If the experiment produced promising results, the inventor will increase her estimate of the chances of commercial success because of the additional information that the experiment was successful. Her initial estimate was that the chance of a successful project was 40%; she will *raise* this estimate in light of the promising experimental results. Specifically, as shown in Figure 2, the probability of a successful project increases to 56%—up from the original estimate of 40% before the experimental results were known.[66] Likewise, if the experiment had produced *unpromising* results, the probability of a successful project would drop to 24%.

In such a two-step decision model, the expected value of a project, as viewed before the experiment, with a patent that increases the payoff of a successful project by 20% (to $1200) is $308 (see Figure 3), and the expected value without the possibility of a patent is $280 (see Figure 4). By contrast, when estimated at the time of a decision to develop, the expected value of the project is $560 without patents (see Figure 3) and is $616 with patents (see Figure 4). The marginal effect of the patent on the incentive to develop is thus twice as large as on the incentive to experiment.

In any event the main point is the same: under plausible assumptions the incentive effect of a patent is relatively modest. The availability of a patent would only change the behavior of a rational decisionmaker in cases where the expected value of the project without the possibility of a patent is slightly below the cost of undertaking the project. While this of course depends on the magnitude of the patent's contribution to expected payoff, under plausible assumptions of this magnitude the incentive effect will be quite small. This finding conforms to the views of some research and development managers, who consider

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recent years, there has been a tendency for firms to utilize formal, quantitative project selection techniques based on estimated rates of return, payment periods, and other such criteria." *Id.* at 190.

66. Although it is intuitive that the chance of success would increase given a promising result, a precise figure for the increase can be arrived at using Bayes' Theorem. This allows us to calculate the probability of commercial success given a promising experiment, when we have available the data stated in the text. Specifically, the probability of success given a promising experiment (written $P(\text{Suc} \mid \text{Prom})$) is calculated by the following formula, where $P(\text{Suc})$ is the probability of success, $P(\text{Prom})$ is the probability of a promising result, and $P(\text{Prom} \mid \text{Suc})$ is the probability that a successful project will begin with a promising experiment.

$$P(\text{Suc} \mid \text{Prom}) = P(\text{Prom} \mid \text{Suc}) \cdot P(\text{Suc})/P(\text{Prom})$$

In the example in the text, this produces the following result: $(0.7 \cdot 0.4)/0.5 = 0.56$.

See generally HOWARD RAIFFA, DECISION ANALYSIS: INTRODUCTORY LECTURES ON CHOICES UNDER UNCERTAINTY 14-20 (1968).

patentability as a factor—albeit only one of many—in selecting research projects.[67]

Of course, while the extra payoff from a patent does not translate directly into an identical extra incentive, it still has some effect. Presumably, the difference might matter in some cases. Consider for example the case where the expected cost of the research project is $300. Then the extra incentive of the patent would add the extra stimulus needed to lead the researcher to do the project. (Recall that without the possibility of a patent, the expected value of the project is $280, which the rational decision maker would not pursue it because of the expected net loss; with the patent, however, there would be an expected net gain of $8.)

But what if public policy demanded an increase in the expected value of the research project? Assuming for the moment that the only policy instrument for affecting this decision is the payoff from a patent, how much would we have to increase this payoff to cause, say, a 50% rise in the decisionmaker's initial expected value?

For the sake of simplicity, and to mirror real world practice, let's stay with the two-step decision model. That is, the inventor can do an initial experiment, and then decide whether to develop the experimental result or not. Under this scenario, the increase in the patent payoff needed to raise the initial expected value 50% (to $462) would be a whopping $2300, or a 130% increase over the non-patent payoff! Although patents may have this effect in some industries, especially pharmaceuticals, the analysis strongly suggests that in most cases where a *major* incentive is needed patents will not be the most effective policy instrument. To encourage basic research with patent incentives, for example, would take the promise of "super-patents" of extremely broad scope or long length. These would presumably carry high social costs. Thus the current system of outright public funding for basic research seems sensible by comparison.

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67. *See supra* notes 29-30. Note that some commentators believe it is anomalous to talk of "rational choices" to invent, since invention, which is suffused with creativity, is primarily the subject of inspiration. *See, e.g.*, ANDREW HARRISON, MAKING AND THINKING: A STUDY OF INTELLIGENT ACTIVITIES 67-68 (1978) (noting the difficulty of a rational account of invention, since it is usually thought of as a creative undertaking). *But see id.* at 70 (noting distinction between invention, where one knows one's goal and is searching for an end, and creativity, where neither is really known). Suffice it to say that I believe there is at least some rational component to invention. And note that, as argued elsewhere, the patent standard is irrelevant as an inducement where an inventor would attempt her invention regardless of the magnitude of potential reward. *See supra* notes 25-28 and accompanying text.

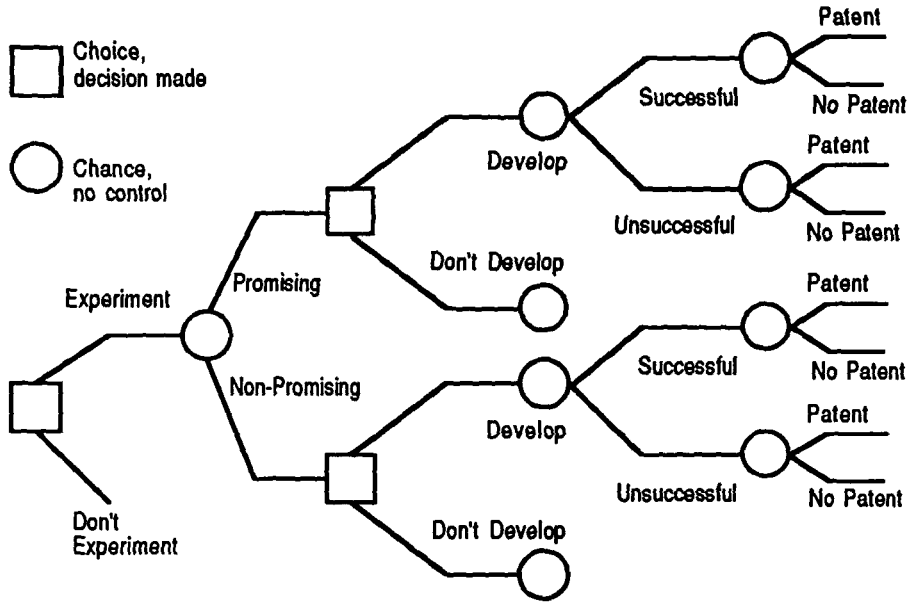

Figure 1

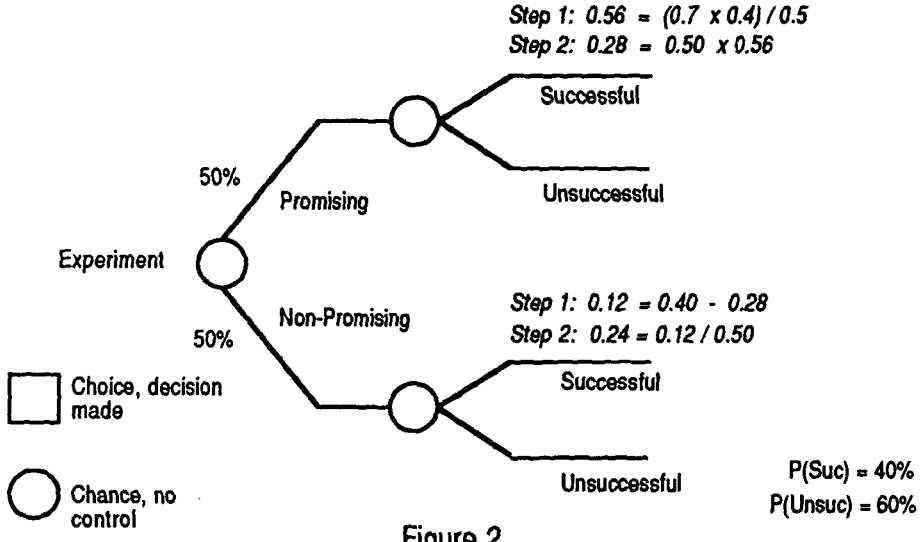

Figure 2

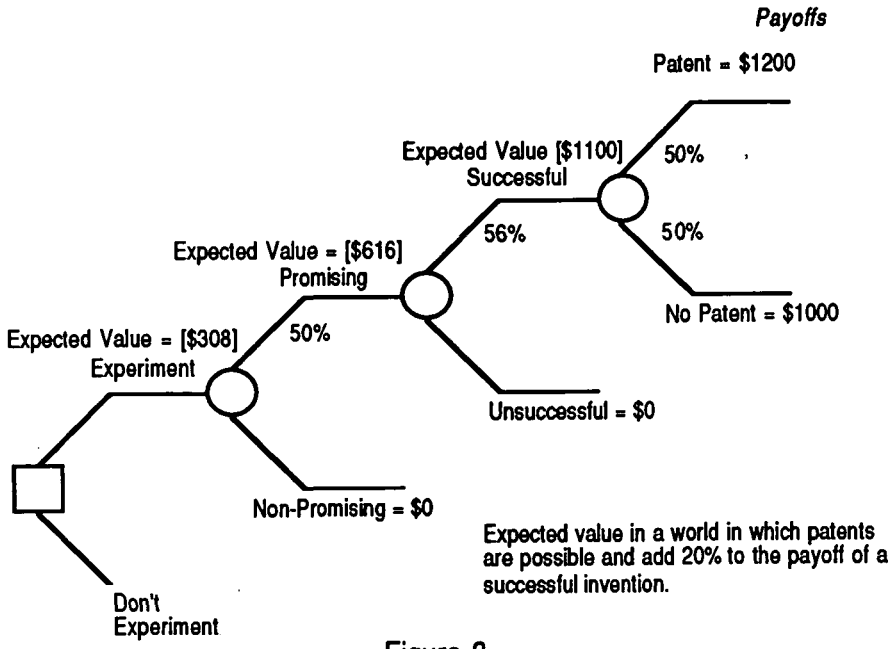

Figure 3

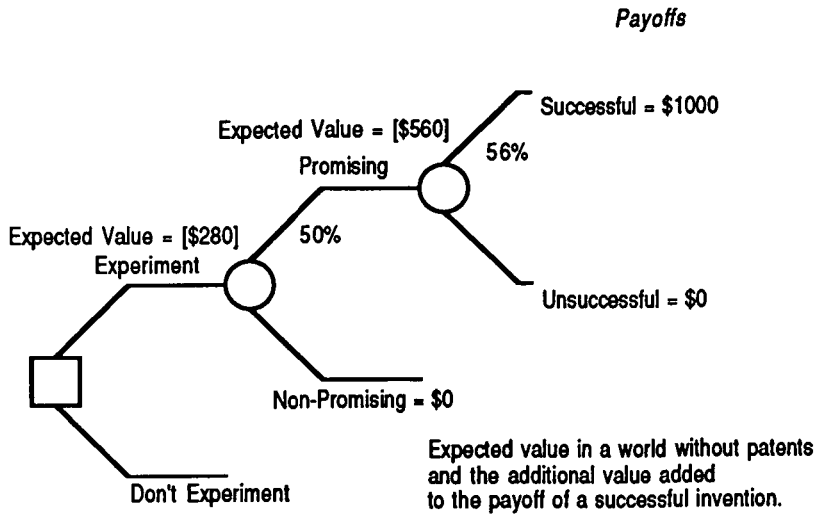

Figure 4

B. Low Uncertainty Research and the Model

The model provides justification for denying patents on research with a high probability of promising results. Where there is both a low payoff and a good chance of initial experimental success, making a patent easier to obtain—increasing *P*(Pat) in the example above—would amount to increasing the payoff from doing a research project whose outcome is quite predictable. This would be tantamount to rewarding success in rather obvious projects. What would be the cost to society of allowing patents on the results of projects with predictable outcomes?

To get an idea, picture the same decision tree without a branch for patents; that is, imagine the payoff from success did not include the possibility of getting a patent. Given a high probability of a promising experimental result, high correlation between commercial success and promising results, and a reasonable payoff from success, the absence of patents would not make much of a difference. The rational inventor might well go ahead with the project anyway.[68]

If she did, society would benefit from the research without the cost of granting the patent. The key point is that, *regardless of the social cost of granting a patent*,[69] it is better for society to have an invention for free. *Any* patent-related cost for an invention that could have been obtained without a patent is too high.

In 1966 Edmund Kitch explained the nonobviousness standard in terms quite consonant with the point just made,[70] although S.C. Gilfillan, a sociologist who wrote on the patent system, said much the same in 1949.[71] These commentators both believed that the standard of patentability should be used, in the words of Kitch, "to sort out those innovations that would not be developed absent a patent system."[72]

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68. Assume for example the same probabilities outlined above, an expected payoff from success of $1000, and project expenses totaling $250. Since the expected value of the project is $280, the rational inventor would go ahead with it since she stands to gain $30 (expected value of $280 minus cost of $250).

69. As long as this cost is not zero. Empirical evidence indicates that whatever the total social cost of a patent, it is not, on average, zero. *See* Merges & Nelson, *supra* note 2, at 908-09 (case studies of the anticompetitive effects of various key patents).

70. Kitch, *supra* note 6, at 301 (stating that "a patent should not be granted for an innovation unless the innovation would have been unlikely to have been developed absent the protection of a patent").

71. Gilfillan, *supra* note 53, at 611 ("A patent is helpful and proper when it rewards sufficiently useful creative work *which might not have been done without* that prospective reward. . . .") (emphasis in original). *See also* SCHERER, *supra* note 17, at 442-43 (patents were granted only to those inventions that the patent system actually induced, society would receive a net benefit); Oddi, *supra* note 17, at 1101 (citing SCHERER, *supra*, note 47, and dubbing as "patent-induced" those inventions produced only because of the patent system).

72. Kitch, *supra* note 6, at 301. From one perspective, the Kitch thesis is uncontroversial, since it merely highlights the "gatekeeping" function of the nonobviousness test. But from another perspective, it presents an interesting logical

In an ideal patent system, the social benefit of the invention would be weighed against the cost of creating it and the social costs accompanying exclusive rights to it.[73] If the "net" was positive, the patent would be granted and the project would be undertaken. But this is nonsense; it is virtually impossible to arrive at reasonable values for these figures *ex ante*, and even *ex post* such valuations will prove difficult. The model's assumptions regarding private firm valuation of expected costs and benefits are unrealistic enough. The social welfare calculations would take it outside the realm of credibility!

Given that these cost/benefit calculations are difficult, there are two possibilities. One choice is to grant patents even though the experiments on which the projects depend are fairly certain to prove promising; the other choice is to deny patents, even though in some cases this will mean that projects that might have been undertaken had patent protection been available will be foregone. Which is preferable?

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problem. If it is taken literally, then each inventor must be questioned about her motives, and if she avers that the promise of a patent is the only reason she pursued her invention, a patent must issue. Even if we take the test less literally, it presents problems. For if we restate it as requiring patents only when the "reasonable inventor" would not have pursued an invention unless it were patentable, we are still left with the difficult question of applying the test to particular cases. *When* would the reasonable inventor need this extra stimulus; what kinds of research projects would be left undone without patents? In the end, questions like these indicate that Kitch's original insight is only a starting point. This article fleshes out the insight by explicitly tying the gatekeeping test to a measure of uncertainty.

73. It might be thought that in such a situation *any* loss in welfare accompanying exclusive rights is worth the cost, since without those rights (in the example I have given) the technology under consideration would never have been invented. In other words, it must be efficient to permit *any* restrictive practice on the part of a patentee who has created something that did not exist before; from society's point of view, it is preferable to have a new thing with restrictions, no matter how onerous, than to not have it at all. This is implicit in much of the "property" view of patents. However, a good deal is missing from this description. For example, it assumes that an invention is a distinct and identifiable thing, and that the patent which covers it protects only that thing. This is not necessarily true; for example, a patent may protect one feature of a larger machine or process. If so, the patentee may use the "leverage" of the patented item to raise prices for the entire machine or process. *See* Louis Kaplow, *Extension of Monopoly Power Through Leverage*, 85 COLUM. L. REV. 515, 525-32 (1985) (there is evidence that market power may in some circumstances permit a licensor to "extend" his monopoly over the tying product into the market for a tied product); *cf.* Louis Kaplow, *The Patent-Antitrust Interface: A Re-assessment*, 97 HARV. L. REV. 1813 (1984). In this case, the effect on the market for the tied product—the overall process or machine—can be seen as an externality generated by the creation of the property right in the tying product. While it is true that the tying product may have some intrinsic value, it is not true that this justifies the level of social cost—the negative externalities—that may be attendant upon the grant of an unrestricted property right in that product.

This comes down to an empirical judgment. Kitch, in a judgment I agree with, says that denying patents is preferable.[74] There are more projects with a high probability of promising results that would still be undertaken without a patent system than there are such projects that need the extra incentive of a patent.

There is support for this view both in my model and in some recent empirical research. In my model the initial decision to undertake a project is much more sensitive to changes in the probability of experimental success than it is to changes in the payoff structure, resulting from changes in the probability of getting a patent.[75] This is simply a function of the fact that the model has several stages, and the payoff from obtaining a patent comes at the end of a series of actions and decisions. The probability of experimental success, on the other hand, has a much more direct impact on the initial decision.

Empirical research bolsters this conclusion. In a recent study of a large number of companies, a team of economists found that in most industries advantages associated with a head start, including establishment of production and distribution facilities, and moving rapidly down a learning curve, were judged significantly more effective than patents in enabling a firm to reap returns from innovation.[76] In another recent study of 100 U.S. manufacturing firms, Edwin Mansfield found that in only 2 of 12 industry groups would firms have decided not to develop products they had in fact developed if no patents had been available.[77] These studies show clearly that a relatively small number of projects depend critically on the availability of patent protection. Since there is no reason to believe that projects with a chance of initial experimental success differ from the average project in this respect, there

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74. Kitch puts it in terms of cost, saying that "it is the implied judgment of the [nonobviousness] test that the cost of innovation of [a low] . . . order of difficulty can probably be recouped in a competitive situation while the costs of innovations of a greater difficulty cannot." Kitch, *supra* note 6, at 302.

75. That is, in the decision model outlined above, the initial decision of whether to invest in the experiment and thus begin the project depends more heavily on the probability of a promising result than the payoff if the project is a success. An increase in the payoff for a successful project is an easy way to model an increase in the probability of receiving a patent, since the payoff for a successful project is the probability of getting a patent times the payoff with a patent plus the probability of not getting a patent times the payoff of a successful project without a patent.

76. Levin et al., *supra* note 10; *see also* NANCY S. DORFMAN, INNOVATION AND MARKET STRUCTURE: LESSONS FROM THE COMPUTER AND SEMICONDUCTOR INDUSTRIES (1986) ("first-mover" advantages are the main reason firms innovate in these industries, with patents a secondary consideration).

77. Mansfield, *supra* note 9, at 175 (Table I). The two industry groups where patents have a significant impact are pharmaceuticals, where firms that were surveyed said 65% of recent innovations would not have been developed in the absence of patents, and chemicals, where the figure was 38%. *Id.* The average of the other 10 industry groups was 6.7%. *Id.*

is no reason to believe that patents are necessary to induce very many of these projects. Consequently, society should not be concerned if the standard of patentability denies protection for high-probability-of-success projects: they are likely to be pursued anyway.[78]

To be sure, there may be cases where the expected value of a project is below zero, given a certain cost and without the added payoff from a patent. One such case might be where there is a fairly certain experiment, leading to a product likely to succeed in the market, but involving very high experimentation costs and/or costs of commercial failure. Should patents be granted in these cases? Although the conventional doctrine says no, section F below presents an argument for granting patents in such circumstances.

C. Incentives to Develop

The model provides an interesting insight into the patent incentive structure. Despite the fact that one of the most common rationales for the patent system is the incentive theory, the truth is that on average patents provide only a modest incentive at the outset of the research process.[79] And another point emerges as well: we should not try to tamper with

78. There will be cases where the expected payoff is too low without proprietary rights for firms to pursue high-probability-of-success projects. In most of these cases, it will be worth the cost of the forgone projects to have a patent system that does not protect inventions which are clearly achievable *ex ante*. Yet there may be some cases where the loss is great. An example might be so-called "orphan drugs," drugs for diseases with so few sufferers that pharmaceutical firms do not foresee enough of a market to make drug development worthwhile. Certainly this is one rational account of why Congress passed the Orphan Drug Act in 1982. Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1982) (codified as amended at 21 U.S.C. §§ 360aa-ee). This Act provides "market exclusivity"—patent-like protection—for orphan drugs, many of which fall short of the requirements for patentable inventions. *See* 21 U.S.C. § 360cc(a) (1988). For a case indicating that a chemical firm would have preferred patent protection, but settled for a first-mover advantage, see Continental Oil Co. v. Witco Chem. Corp., 484 F.2d 777, 782 n.14 (7th Cir. 1973) (internal memo indicated that firm "has no unique or patentable features" so "the only possible advantage we can hope for is to be first or early in the market").

79. The approach taken here is consistent with that of F.M. Scherer, *Time-Cost Tradeoffs in Uncertain Empirical Research Projects, in* INNOVATION AND GROWTH: SCHUMPETERIAN PERSPECTIVES 67-82 (1984). Scherer models the tradeoff between time and cost by constructing a decision function that allows the researcher to invest in sequential research approaches until the marginal value of taking the next approach equals the expected benefit of the project, minus the cost of all the research approaches. In the version of his model that assumes unequal probabilities of success for the different approaches, he notes that "it will . . . be advantageous to schedule the approach with the highest success probability first, and so on." *Id.* at 74. This model could easily be extended to support the conclusions reached here since as it becomes more and more expensive to pursue low-probability approaches, the extra incentive of a patent might be necessary in some cases to encourage the researcher to try these approaches. Note also that as in my model, assuming that a patent adds only modestly to the payoff of a successful project, this would have only a modest effect; in terms of this model, researchers would try a few more approaches, but not many more.

this, at least in the average case. It would cost too much to significantly augment the potential payoffs from obtaining a patent.

The model also shows that patents may have a greater impact on incentives to *develop* than incentives to invent. Once a promising result is in hand, the heightened payoff from a patent more directly affects the expected value of developing the product. This is because the incentive is much less "diluted." If the researcher knows from past experience that a promising experimental result is more likely to be successful, she can revise her estimate of the chance of success *given* a promising result. Because the researcher's estimate of the probability of receiving the payoff from a successful invention rises after the experiment, her expected value rises as well. *This* is the point at which the patent has the most direct effect: providing an incentive to develop. It is because the experimental results are promising that the researcher revises her estimate of the probability of a successful innovation; hence the enhanced payoff from a patent enters into her expected value assessment with less "dilution" and a higher probability.[80] Note that while this appears also to support the notion of awarding "innovation patents," there are independent reasons to doubt the efficacy of such a policy.[81]

D. Why Not Use Commercial Certainty as the Patentability Standard?

The preceding section argued that patents have only a modest effect on the decision whether to initiate an R&D project. As a consequence, high social costs attend a decision to raise the value of a patent, or the probability of obtaining one, in every case. This section will return to the theme introduced earlier: that in determining when it *is* appropriate to award a patent, the key factor is the level of uncertainty facing the inventor just prior to the crucial experiment leading up to the patent.

As a preliminary matter, recall that in the two-step model presented above, the probability of a promising experiment greatly affects the expected value of the project as a whole. When an experiment is highly unlikely to be promising, ultimate commercial success is quite unlikely indeed. In just these situations, the enhanced payoff that comes with a patent will be welcomed. As noted above, there are scenarios under which high-risk research will not be performed if patents are not available.

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80. Interestingly, this premise was well stated in the celebrated concurrence of Judge Frank in Picard v. United Aircraft Corp., 128 F.2d 632, 642-43 (2d Cir. 1942) ("But if we never needed, or do not now need, patents as bait for inventors, we may still need them, in some instances, as a lure to investors."). *See also* Fritz Machlup, *Patents, in* 2 ENCYCLOPAEDIA OF THE SOCIAL SCIENCES 461, 467 (1968) (stating that one theory of the patent system is that it gives incentives to develop technology).

81. *See supra* note 18 and accompanying text.

But the structure of the model indicates that the probability of commercial success also affects the inventor's prospects. The thought might well occur: why not augment the payoffs where the chance of commercial success is low? Why focus on uncertainty at the initial experimental stage, when uncertainty at the second, or commercialization stage, can also drive expected returns below the break-even point, hence discouraging perhaps useful research?

There are two primary reasons for excluding commercial uncertainty from the patentability standard. First is the intrinsic social value of producing information in the face of highly uncertain technical challenges. As discussed in Part II above, every promising experimental result contributes valuable technical information to the relevant technical community. But unlike technical information, information about what the market desires would seem to produce relatively few positive externalities. Although a few firms may benefit from it, this information is difficult to extrapolate, and it quickly loses its value in any case as market conditions change. Only if the incentive to market a product encourages a reluctant firm to introduce a product that comes to be valued highly by consumers will it have produced much of consequence. Even in this case, the legal system will be asked to assess commercial or market uncertainty. This would seem to be even more difficult than assessing technical uncertainty, as in the current patent system.

The second reason for excluding commercial uncertainty from the patentability standard is that in the model outlined above, a promising experiment produces valuable information *even if it never leads to a viable commercial product*. Contrast this with the prospect of encouraging an entrepreneur to market a product in the face of high commercial or market uncertainty: the only immediate payback for the incentive given is the availability of the new product on the market. If the product is ultimately unsuccessful, the incentive will not have achieved much. In the current system, humbling commercial failure does not deprive a patent of all social value. But in a system of rewards for overcoming commercial uncertainty, failure would be total.

E. Nonobviousness Doctrine and the Uncertainty-Based Model

So we see that patents provide only a modest incentive to undertake research. And we have addressed the reasons why patents are not granted for the results of all research projects. In addition we have touched on the rationale for a standard of patentability, namely the need to sort out those inventions that would probably have been forthcoming without patents. Now we will explore the precise mechanism by which this sorting out takes place under current doctrine.

As implied above, the ideal patent system would weight the benefit to the inventor of the prospect of a patent against the cost to society of issuing that patent. If the resulting figure were a net positive, the patent would issue; otherwise, no patent would be granted.

How does the current system compare to this ideal? In general, not too badly. Specifically, the current system has the following features:

- It uses technical difficulty as a proxy for the likelihood that an invention would have been made without the promise of a patent; and
- It presumes that there is a high social cost to granting patents that cover inventions that could have been made by any researcher with ordinary skill.

The wisdom of this approach lies in its use of technical difficulty as a measure of social value. The more difficult an invention is to make, the more likely a patent will issue. Conversely, the easier an invention is to make, the greater the social cost involved in granting a patent to cover it.

And the current system is administratively tractable. One major flaw in the ideal patent system mentioned earlier is the high cost of administering it. Difficult estimates would have to be made for elusive quantities: social benefit, social cost, etc. Even if it were possible to make these estimates, it would be expensive.

The test of nonobviousness in patent law attempts to make the analysis more tractable by focusing on technical difficulty. While at first blush it might seem just as troublesome to estimate technical difficulty as "social cost," the patent system has developed a procedure that make this estimation possible, albeit never easy.

The first part of this approach is a set of clearly defined rules that help define the relevant universe of technical expertise. Detailed provisions of the patent code define precisely what material falls within the "prior art."[82] It is this prior art which serves as the backdrop for the nonobviousness analysis; it is this information which helps the Patent Office and the courts ask, "nonobvious compared to *what*?" The second part is a less clear cut, but still useful, set of guidelines for determining the knowledge, skills and characteristics of the person "skilled in the art," the mythical "reasonable" inventor against whom the efforts of the actual inventor are measured.[83] The patent code requires the courts to presume

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82. The precise content of the prior art is defined by 35 U.S.C. § 102. *See* 35 U.S.C. §§ 102(a), 102(c) (1988); 2 DONALD S. CHISUM, PATENTS § 5.03[1][a] (1986). Although these provisions setting forth prior art appear in the section of the patent code defining the novelty requirement, they also apply to the nonobviousness inquiry. *See In re* Bass, 474 F.2d 1276, 1289 (C.C.P.A. 1973); Paul M. Janicke, *What is "Prior Art" Under Section 103? The Need For Policy Thought, in* NONOBVIOUSNESS—THE ULTIMATE CONDITION OF PATENTABILITY 5:101-5:111 (John F. Witherspoon ed., 1980).

83. Cases have held that the "skilled person in the art" means those responsible for most of the technical advances in an industry. *See, e.g.*, Orthopedic Equip. Co. v. United States, 702 F.2d 1005 (Fed. Cir. 1983); Jacobsen Bros. v. United States, 512 F.2d 1065 (Ct. Cl.

that this reasonably skilled inventor knows *everything* in the prior art. This has been criticized as unrealistic.[84] But like so much in this area of patent law, it is defensible on the grounds of administrative feasibility. In other words, a test based on "reasonably accessible" prior art or the like would require difficult decisions, while the current practice of assuming knowledge of all prior art, no matter how obscure, is easy to administer.

The third part of this approach incorporates the case law which has grown up around the test of nonobviousness, and contains a set of loosely-applied rules of thumb that help determine whether a patent should be issued. One such rule, examine below, restates the test of obviousness by asking whether the skilled inventor would have estimated that there was a "reasonable chance of success" for the experiment that led to the invention. If so, no patent is issued; if not, the result is deemed nonobvious.

The case law has long recognized the importance of certain "objective" factors in determining nonobviousness: the commercial success of the invention (which I have criticized),[85] the failure of competitors to make the invention (which I have suggested ought to be *the* major objective factor), a long-felt need in the industry for an invention, and recognition in the industry of a notable achievement.[86] A principal advantage of these factors is that, unlike the technical merit of an invention, they are relatively easy to ascertain. Since most finders of fact in patent cases are not technically trained, it has been argued that the use of these factors makes patent law more manageable for the courts and more predictable for the parties.[87]

The basic doctrine thus appears to mesh well with the emphasis on uncertainty presented in the preceding text and model. The uncertainty approach can now be applied to specific doctrinal features.

1975); *see also* Environmental Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 696 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1043 (1984), where the court provided a list of factors relevant to a determination of the level of skill in the art:

(1) educational level of the inventor;

(2) type of problems encountered in the art;

(3) prior art solutions to the problems;

(4) rapidity with which innovations are made;

(5) sophistication of the technology; and

(6) educational level of active workers in the field.

84. *See* Michael Ebert, *Superperson and the Prior Art*, 67 J. PAT. OFF. SOC'Y 657 (1985) (proposing that courts' presumption that skilled artisan knows everything in a field should be restricted by taking account of cognitive limitations of real people).

85. Merges, *supra* note 2.

86. *Id.*

87. *See, e.g.*, Rochelle C. Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1, 25-26 (1989).

1. *INCENTIVES FOR PRIVATE INFORMATION*

An important question that one might ask at this point is how the standard is applied if an inventor knows more than the reasonably skilled person in the art. Does this reduce her chances of obtaining a patent?

Clearly the answer is "no" because all manner of mischief would accompany a system that refused a patent simply because an inventor had been certain of her experiment: it would encourage early experimentation with little background work, it would lead to lying on patent applications, and the like. Instead, patent law measures the chances of success not against the inventor's subjective evaluation, but against the objective standard of the reasonably skilled worker in the field. Because this hypothetical reasonably skilled artisan is endowed with only *publicly* available technical knowledge—the prior art—the proprietary knowledge of the actual inventor is immaterial to the obviousness inquiry. This encourages firms to invest in proprietary knowledge prior to the commencement of a particular invention project.[88] Of course, investment in such information might well affect the inventor's cost calculus. She will need to justify the expense by a reduction in costs or an increase in expected payoff. For example, if the preliminary research indicates that the project will not be a success, the inventor can avoid the expense of a failed project. On the other hand preliminary research might lead to a larger expected payoff, e.g., by focusing the project on a more promising or profitable technology.[89] In either case the

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88. In fact, since private knowledge is not held against the inventor when patentability is determined, the inventor can be expected to invest in such knowledge up to the point where its money value is just equal to the cost of obtaining more of it. *See* George J. Stigler, *The Economics of Information*, 69 J. POL. ECON. 213 (1961). If this were part of the prior art, the implicit cost of obtaining such knowledge would rise and less would be produced. This would naturally affect the firm's decision to invest in such preliminary research. But it would also affect society at large, since much of this preliminary knowledge takes the form of basic research, which is often publicly disclosed, even when undertaken by private firms. The analysis of this problem in terms of incentives to invest in private information is very similar to the argument made by Anthony Kronman regarding the appropriateness of contract rules permitting parties to keep certain information confidential during negotiations. *See* Anthony T. Kronman, *Mistake, Disclosure, Information and the Law of Contracts*, *in* THE ECONOMICS OF CONTRACT LAW 114 (1979).

89. To some extent the simple model above reflects this. In that model, recall that the cost of performing the initial experiment is weighed against the expected value of the project. To be more complete in this respect, however, the model would have to have at least one round of preliminary research *before* the "initial experiment" stage. There would then be a preliminary decision: pursue the pre-experimental research or not? While it is possible to model this in the framework presented earlier, it would detract from the simplicity of the model. For an important treatment of the "focussing" effect such iterative decisionmaking can have on research and development, see Richard R. Nelson, *The Role of Knowledge in R&D Efficiency*, 97 Q.J. ECON. 453, 459 (1982) (constructing a "search" model showing how firms refine their approach to R&D with experience). *See generally* RICHARD R. NELSON & SIDNEY G. WINTER, AN EVOLUTIONARY THEORY OF ECONOMIC

inventor who performs preliminary research has in effect bought information. The patent system should not—and does not—discourage this by including private information in the prior art against which the ultimate invention is judged.[90]

2. *SERENDIPITOUS DISCOVERIES*

One objection to the foregoing might be that many discoveries are accidental; by centering the analysis on a rational decisionmaker, the model presented here omits an important class of inventions—those made unintentionally.[91] The first response to this is to reiterate a point made at the outset: for the purpose of this paper, inventors who will perform research regardless of the incentives facing them are irrelevant. Just as society need not worry about adding to their financial rewards if they are motivated by non-financial considerations, we need not worry about the incentive effects of the patent system on serendipitous inventors.

CHANGE (1982) (making extensive use of models and simulations where firms modify their search for new products and processes over time based on past experience).

90. The notion of private information might help explain a phenomenon long associated with the patent system, the practice of filing a long series of improvement patents to build on a basic invention. Many observers have complained of this as a major flaw in the patent system, since it permits firms to "lock up" entire fields of technology for extended periods of time. *See, e.g.*, DAVID F. NOBLE, AMERICA BY DESIGN: SCIENCE, TECHNOLOGY, AND THE RISE OF CORPORATE CAPITALISM 93 (1977) (outlining techniques for "prolonging monopolies" used by General Electric and AT&T, including extensive acquisition of "auxiliary patents"); United States v. General Elec. Co., 82 F. Supp. 753, 815 (D.N.J. 1949) (accusing General Electric of this practice with regard to the incandescent light bulb). What needs to be recognized in such situations, however, is that it may be easier for the firm that pioneered a technology to compete for improvements because of their informational advantages. If they are rewarded for their achievements as anyone else who made them would be, they have earned them and are acting rationally to invest in them. *See* JACOB RABINOW, INVENTING FOR FUN AND PROFIT 245 (1990) ("After the birth of the idea comes . . . the process of 'inventing around yourself.' If you don't invent a picket fence of systems to compete with your own, some other son of a bitch will. . . . You end up with not one invention but with a dozen. You end up with a portfolio of patents. Your first brilliant idea was just a beginning."); *cf.* HERBERT A. SIMON, *Theories of Bounded Rationality, in* 2 MODELS OF BOUNDED RATIONALITY: BEHAVIORAL ECONOMICS AND BUSINESS ORGANIZATION 408, 410 (1982) (describing class of models of decisions under uncertainty where decisionmaker's task "is to find the alternative [choice of action] that maximizes his expected profit net of search cost"; by extension, these models suggest rationality of searching for improvements on one's own prior inventions, given that search costs for these will be lower than for others because of pre-existing knowledge).

91. *See, e.g.*, ROYSTON M. ROBERT, SERENDIPITY: ACCIDENTAL DISCOVERIES IN SCIENCE (1989); *cf.* JAMES H. AUSTIN, CHASE, CHANCE, AND CREATIVITY: THE LUCKY ART OF NOVELTY (1978).

But it might be argued that granting patents to such inventors is socially wasteful.[92] The ideal test of patentability described earlier holds that a patent should only be granted where it is necessary to call forth an invention. Since accidental discoveries are not motivated by financial incentives, it might be argued that issuing a patent in such cases violates this ideal test.

There are two responses to this. First, while serendipitous research is not *directly* motivated by financial rewards, in many cases a serendipitous discovery is made in the course of a research project aimed at another goal. Without the possibility of a patent covering the *intended* result, perhaps the inventor would never reach the unintended result. An example may be the discovery of drugs to treat very rare diseases; these are often made in the course of research on more widespread diseases.[93]

Second, allowing an exception to the rules on patentability might further complicate and lengthen the process of obtaining a patent or defending it in infringement litigation. If the Patent Office or an accused infringer could argue that an invention did not deserve a patent because it was discovered through serendipity, an extra layer of elaborate fact-finding would be added to the patentability inquiry. It is simpler, and thus more administratively feasible, to apply the same *ex ante* nonobviousness standard as is applied in other cases. Section 103 of the patent code even contains a sentence that reflects this view, although it was inserted into the code for other reasons.[94]

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92. This position is hinted at in Oddi, *supra* note 17, at 1116 (defending proposition that high cost-low benefit inventions are some of the few where patents are truly justified, and arguing that alternative appropriability techniques and lack of self-interest in suppressing inventions make it less necessary to protect low cost-high benefit inventions such as those made serendipitously).

93. "Orphan drugs are discovered more often by accident than by design. A survey of orphan drugs conducted by the Subcommittee on Health and the Environment of the House Energy and Commerce Committee found that about one-fifth of known orphan drugs were discovered solely as a response to an orphan disease, while two-thirds were discovered serendipitously. Chance discovery often occurs during research or clinical testing of drugs for nonorphan diseases." Donna B. Grossman, *The Orphan Drug Act: Adoption or Foster Care*, 39 FOOD, DRUG & COSMETIC L.J. 128, 130 (1984) (citing SUBCOMM. ON HEALTH AND THE ENVIRONMENT OF THE HOUSE COMM. ON ENERGY AND COMMERCE, 97TH CONG., 2D SESS., PRELIMINARY REPORT ON THE SURVEY ON DRUGS FOR RARE DISEASE 9 (Comm. Print 1982)).

94. "Patentability shall not be negatived by the manner in which the invention was made." 35 U.S.C. § 103 (1988). This was made a part of the statutory standard to limit the effect of Supreme Court cases implying that a patentable invention required a "flash of genius." *See* Giles S. Rich, *Congressional Intent—Or, Who Wrote the Patent Act of 1952?, in* NONOBVIOUSNESS—THE ULTIMATE CONDITION OF PATENTABILITY 1:1, 1:7-1:8 (John F. Witherspoon ed., 1980). *See generally* HANNS ULLRICH, STANDARDS OF PATENTABILITY FOR EUROPEAN INVENTIONS 85-86, 89-91 (IIC Studies in Industrial Property and Copyright Law No. 1, 1977).

3. *METHODICAL SCREENING: A SPECIAL CASE OF RISKY RESEARCH*

Since the early 1960's[95] the courts have been ruling consistently that "obvious to try" is not the standard of patentability.[96] One court said:[97]

> [A]pplication of the "obvious to try" test would often deny patent protection to inventions growing out of well-planned research which is, of course, guided into those areas in which success is deemed most likely. These are, perhaps, the obvious areas to try. But resulting inventions are not necessarily obvious. Serendipity is not a prerequisite to patentability. Our view is that "obvious to try" is not a sufficiently discriminatory test.

One group of "obvious to try" cases involves prior art which suggests that a certain area should be investigated, and yet the resulting invention is either not suggested in the prior art, or has unexpected properties.[98] For example, in *Novo Industri A/S v. Travenol Laboratories,*

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95. At one time "obvious to try" was an accepted standard of obviousness, and even a showing by the applicant that unexpected results were reached or success was unlikely would not defeat a finding of lack of invention. Mandel Bros. v. Wallace, 335 U.S. 291, 295 (1948) (patent for an improved anti-perspirant declared invalid due to lack of invention). The Court rejected the patentee's argument that, in the process of trying a number of compounds, he was surprised by the compound which was ultimately successful. A reasonable chemist would have expected it to fail. The Court held, however, that the prior art demonstrated that the solution lay in a limited number of permutations, making the success of any of them obvious: "we think that the state of the prior art was plainly sufficient to demonstrate to any skilled chemist searching for an anticorrosive agent that he should make the simple experiment that was made here. . . . It is not surprising therefore that after experimenting with various standard alkalies in an effort to find a corrosion inhibitor that would not greatly reduce acidic astringency, the patentees promptly turned to urea." *See also In re* Sejournet, 285 F.2d 823, 825 (C.C.P.A. 1961) (claims for patent for method of extruding a composite steel billet was not patentable for lack of invention because the method would have been obvious to try in light of the prior art).

96. *See, e.g., In re* Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988) (claims of application for patent for system for detecting and measuring small quantities of nitrogen compounds held not obvious because none of prior art, alone or in combination suggested the claimed invention—at most they made it obvious to try); *In re* Dow Chemical, 837 F.2d 469, 473 (Fed. Cir. 1988) (patent for impact resistant rubber-based resin having improved resistance to heat distortion held nonobvious). The court ruled that the PTO used the impermissible "obvious to try" standard because the prior art did not provide a reason for selecting the procedure used.

97. *In re* Lindell, 385 F.2d 453, 455 (C.C.P.A. 1967) (patent application for circuit interrupter construction was invalid as obvious; while the lower court used the impermissible "obvious to try" standard in its analysis, a reexamination of the record indicated that the invention was obvious, nonetheless) (citing *In re* Tomlinson, 363 F.2d 928 (C.C.P.A. 1966)).

98. *In re* Goodwin, 576 F.2d 375, 377 (C.C.P.A. 1978) (application relating to an improved mold lubricant used in glass manufacture was not obvious, merely obvious to try, because the results were unexpected); *In re* Mercier, 515 F.2d 1161, 1167 (C.C.P.A. 1975) (claims of patent application for process for splitting acetals and hemi-acetals held not obvious; even though prior art disclosed a known relationship between compounds, this differs from a disclosure of equivalent compounds; a known relationship merely

Inc.,[99] the court upheld the patentability of a species of fungus that produced an enzyme used for making cheese, holding that while it was obvious to examine this species along with others, the results obtained were unexpectedly good. Again, courts do not ask for certainty of success; an invention is held obvious if the resulting invention does not differ significantly from what was suggested in the prior art or if the inventor was reasonably certain that she would succeed.[100]

The law is more complicated when the prior art suggests that the inventor either try a number of choices or vary a number of parameters.[101]

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indicates obviousness to try because many compounds have a known relationship but are not substitutes in different reactions); *In re* Tomlinson, 363 F.2d 928, 931 (C.C.P.A. 1966) (some claims in application for product and process patents relating to stabilized polypropylene held invalid for obviousness, and other found to be valid; the examiner incorrectly based his finding on the fact that it would have been obvious to combine two of the elements); *In re* Eisenhut, 245 F.2d 481, 486 (C.C.P.A. 1957) (patent application for process for manufacture of washable, cloth-like material from cellulose fibers without spinning or weaving rejected for lack of invention because a result which flows naturally from the prior art is not an invention unless an unexpected result is obtained); Merck & Co. v. Danbury Pharmacal, 694 F. Supp. 1, 29, 32 (D. Del. 1988) (patent for cyclobenzaprine held nonobvious, citing *In re* Merck, 800 F.2d 1091 (Fed. Cir. 1986), in holding that the standard is not whether an invention would be obvious to try, but whether such an experiment would have been expected to succeed), *aff'd*, 873 F.2d 1418 (Fed. Cir. 1989); *Ex Parte* Old, 229 U.S.P.Q. (BNA) 196, 200 (Bd. Pat. App. & Int. 1985) (claims in patent for monoclonal antibodies recognizing human renal cell antigenic systems upheld as nonobvious; while the experiment was obvious to try, the results were clearly unpredictable).

99. 677 F.2d 1202, 1208 (7th Cir. 1982) (patent involving the identification of a fungus species which produces a milk-coagulating enzyme needed for the production of cheese held not obvious because, although it was obvious to try the particular fungus species, the results were totally unexpected).

100. *In re* Dow Chemical, 837 F.2d 469 (Fed. Cir. 1988).

101. *See, e.g.*, Uniroyal v. Rudkin-Wiley Corp., 837 F.2d 1044, 1053 (Fed. Cir. 1988) (patent infringement suit concerning an air-deflecting device for reducing wind resistance encountered by tractor-trailer trucks is remanded because district court incorrectly applied obvious standard by using "obvious to try" reasoning; the lower court rejected the patent as obvious even after finding that beyond the prior art, "experimentation [would be needed] to extract the exact parameters that would make the device work," and after holding that "even an expert would be unable to predict the result an aerodynamic device would have on a tractor-trailer vehicle"); *In re* Geiger, 815 F.2d 686, 688 (Fed. Cir. 1987) (holding that prima face case of obviousness was not established in Patent Office rejection of claims in application relating to method of inhibiting scale formation and corrosion of metallic parts in cooling water systems; the prior art merely made it obvious to try various combinations of known corrosion prevention agents); *In re* Yates, 663 F.2d 1054, 1057 (C.C.P.A. 1981) (prima facie case of obviousness was not established by the PTO on patent concerning a process for oxidizing an olefin to an unsaturated aldehyde, since examiner merely suggested a reason why it might have been obvious to try varying a number of parameters); *In re* Antonie, 559 F.2d 618, 620 (C.C.P.A. 1977) (patent application for rotating biological contactor apparatus held not obvious, merely obvious to try, because inventor varied every parameter of a system in order to optimize the effectiveness of the system without guidance from the prior art as to which parameters to vary or how to vary them); Polaroid Corp. v. Eastman Kodak Co., 641 F. Supp. 828, 853 (D. Mass. 1985) (Polaroid's patents for film and camera were held valid because "[t]he fact that one skilled

In *In re O'Farrell*, the court stated that an invention is merely obvious to try when the prior art "gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful."[102] The courts are not clear as to how many parameters need to be varied, or how many permutations are necessary to render an invention nonobvious.[103] One case has held, however, that "routine optimization" is not tantamount to nonobviousness.[104] Instead, the court has focused on the amount of guidance the prior art gives, which steers the inquiry back to the reasonable certainty of success standard.[105] If the worker expects to succeed by working through many permutations, then the invention should be obvious.[106]

In *Merck & Co. v. Biocraft Laboratories*[107] the prior art suggested 1200 combinations, but the invention was found to be obvious because each of the combinations was expected to be effective, thus rendering any of the 1200 obvious.

Based on the recent "obvious to try" cases, it appears that the standard is a subset of the reasonable expectation of success standard. If an inventor is faced with a large number of variables, and the prior art does not provide enough guidance to narrow those down to a manageable level, then an inventive step is needed to proceed. Consequently, the skilled worker could not be reasonably certain of success. On the other hand, if the number of possible permutations has been limited by the prior art, then a mechanic could plod through them one at a time and be reasonably certain of success.[108]

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in the art would consider as possible candidates in an extensive search the mordants disclosed in these references does not meet the standard of obviousness under 35 U.S.C. § 103"), *aff'd*, 789 F.2d 1556 (Fed. Cir.), *cert. denied*, 479 U.S. 850 (1986).

102. 853 F.2d 894, 903 (Fed. Cir. 1988).

103. *See, e.g., id.*

104. *In re* Kulling, 897 F.2d 1147 (Fed. Cir. 1990); *see also Ex parte* Sugimoto, 14 U.S.P.Q.2d (BNA) 1312 (Bd. Pat. App. & Int. 1990) (invention involving routine substitution would have been obvious).

105. Merck & Co. v. Biocraft Lab., 874 F.2d 804, 807 (Fed. Cir.) (patent for pharmaceutical combination of amiloride and hydrochlorothiazide held invalid due to obviousness), *cert. denied*, 493 U.S. 975 (1989). "[A]n invention is 'obvious to try' 'where the prior art [gives] either no indication of which parameters [are] critical or no direction as to which of many possible choices is likely to be successful." *Id.* (quoting *In re* O'Farrell, 853 F.2d 894, 903 (Fed. Cir. 1988)). In this case, the invention was not only obvious to try, but also obvious because although the prior art did not single out the applicant's combination, it did suggest 1200 effective combinations, making all of them obvious. "That the [prior art] discloses a multitude of effective combinations does not render any particular formulation less obvious." *Id.*

106. *Ex parte* Erlish, 3 U.S.P.Q.2d (BNA) 1011 (Bd. Pat. App. & Int. 1987); *Ex parte* Allen, 2 U.S.P.Q.2d (BNA) 1425, 1429 (Bd. Pat. App & Int. 1987), *aff'd in unpublished opinion*, 846 F.2d 77 (Fed. Cir. 1988). *But cf. In re* O'Farrell, 853 F.2d 894 (Fed. Cir. 1988).

107. 874 F.2d 804 (Fed. Cir. 1989).

108. *See infra* note 130 and accompanying text.

F. Risk Aversion and High-Cost Research

In the model presented so far, the focus has been on the "expected monetary value" ("EMV") of the research project. This is calculated simply by using the researcher's best estimate of payoffs, probabilities, and costs. The resulting EMV is the value the "rational" decisionmaker would give to the entire project, viewed prospectively.

But of course there is no single definition of "rational."[109] Some inventors may quite rationally prefer projects with a certain range of probabilities, or they may prefer one type of payoff structure, or they may be especially wary of projects with certain features. While it is very difficult to capture all the precise variations in preferences that might exist, it is possible to model at least one preference that deviates from straight EMV: the case of risk aversion. As will be shown below, positing a risk-averse inventor has interesting implications for the model.

Risk aversion is a simple idea: some people prefer a safer but lower expected payoff to a riskier but higher payoff. Put another way, the risk-averse investor would demand a higher expected return for a project as compensation for an increase in risk.

There are a number of ways to formalize the notion of risk, but one common one, suitable here, is to say that the riskiness of a project increases as the variance in potential outcomes increases. A simple case will demonstrate. Picture a lottery where one has a 50% chance of winning $20 and a 50% chance of losing $10. The EMV for this lottery is $5. Now picture a lottery with a 1% chance of winning $1000, a 1% chance of winning $100, a 1% chance of losing 100, a 1% chance of losing $500, and a 96% chance of neither winning nor losing anything; again the expected value is $5. Many investors, however, would likely prefer the first lottery to the second. The risk-neutral investor, of course, would be indifferent since the expected return is $5 in both cases.

It is possible to use a mathematical measure of this phenomenon—variance—to model risk aversion. The variance in the first lottery would be 225, while that of the second lottery would be 12,675. The standard deviation—a familiar statistical measure, defined as the square root of the variance—is 15 for the first lottery and roughly 113 for the second. Putting the issue in these terms makes it clear why someone might prefer lottery one over lottery two.

We can use the variance-based account of risk aversion to describe how a risk-averse inventor would approach the decision described above. A common way to demonstrate the effects of risk aversion is to find the

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109. *See* NELSON & WINTER, *supra* note 89, at 8-9, 58; ELSTER, *supra* note 56; Henk Bodewitz et al., *Towards a Cognitive Model for Technology-Oriented R&D Processes*, 17 RES. POL'Y 213, 223 (1988) (discussing social as well as economic determinants of R&D decisionmaking on several projects studied).

amount of money a risk-averse person would take in place of the risky decision. This amount is called the "certainty money equivalent," or CME; by comparing the CME to the straight (risk-neutral) expected value of the decision, we get an idea of how much the risk-averse decisionmaker is willing to give up to avoid taking the risk. This is sometimes called the "risk premium," although it might better be termed the "risk avoidance" premium, since it measures how much one is willing to give up in expected value to avoid risk.

To analyze the effect of risk aversion on our decision, we must begin with an assumption about the degree of risk aversion.[110] This will take the form of a mathematical function. The function will take as its argument (or "input") a payoff, i.e., a number representing a straight risk-neutral assessment of the money value of a particular event. In the example above, the payoff for a successful project where no patent was obtained was set at $1000. This function will produce (as "output") the risk-averse decisionmaker's *personal utility* for that payoff. It will, in a sense, map real-world payoffs onto the decisionmaker's personal valuation system, thus taking account of her risk aversion.

The shape of the function must correspond to the intuitive notion that as payoff value increases, so will personal utility; everyone, risk-averse or not, values more money over less. So the function must be sloped upward. But as payoff value increases, the risk-averse decisionmaker's personal utility would be expected to increase less rapidly. That is, the personal utility valuation of the first dollar will be higher than the valuation of the million-and-first dollar. In economic parlance, we would expect "diminishing returns," or a concave function. On the other hand, for the risk-neutral decision maker, we would expect a linear utility function. The relationship between risk-averse and risk-neutral utility functions is captured in Figure 5, where the curved line

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110. In a sense, the entire analysis implicitly makes another assumption: that a firm cannot select a portfolio of R&D projects in a way that diversifies away the risk (or a large portion of the risk) of failing. This is assumed because it is impossible to tell much about a research project before it is complete, and therefore one cannot separate out risk factors that are specific to particular project from those that run through an entire portfolio. It is a simply impossible, or at least very expensive, to discover along what dimensions the projects vary, and therefore to diversify one's portfolio of research projects in a way akin to an investor diversifying away "specific" or "unsystematic" risk in her portfolio of stocks, bonds, and the like. *See, e.g.*, STEPHEN A. ROSS & RANDOLPH W. WESTERFIELD, CORPORATE FINANCE 159-73 (1988) (describing models of diversified investment portfolios). For an interesting model of how firms in the petroleum industry select investments with an eye toward minimizing the overall risk of their project portfolio, see CONSTANCE E. HELFAT, INVESTMENT CHOICES IN INDUSTRY (1988) (using a covariance model to predict optimal risk-adjusted portfolio choices). Note that where the firms Helfat studied made investments in new technologies, "the cost estimates for these projects [were] likely to be understated," suggesting that these were the most difficult projects to accommodate to the firm's overall risk-level goals. *Id.* at 93.

represents the risk-averse utility function and the straight line the risk-neutral utility function.

Using this function, personal utilities can be calculated given payoffs. The first quantity to be determined is the risk-averse decisionmaker's personal valuation of the $1000 payoff, the amount that will accompany a successful project where there is no possibility of obtaining a patent. Using a common concave function,[111] we would get 900.[112] This means that a decisionmaker with the risk aversion described in the function would value the $1000 payoff at only 900 "personal utility units."[113] The personal utility of the alternative payoff, the one accompanying an unsuccessful project, is similarly computed. Since the payoff in this case is by definition zero, the personal utility is also zero. Now, by multiplying both 900 and 0 by their respective probabilities, we can get an *expected* utility figure for the entire decision; using the figures derived earlier, this would be 504.[114]

This number tells us what the decision is worth to the risk-averse decisionmaker. Unfortunately, it gives us the answer in personal utility units. The question of what certainty money equivalent (CME) corresponds to this personal utility valuation still remains; this will give us a sense of the risk avoidance premium—in *dollars*—of this decisionmaker. Now that the value of the decision has been "translated" into terms that have meaning for the individual decisionmaker, this figure must be "translated back" from this figure into dollars. A formula that gives us the appropriate CME for any expected utility valuation by the decisionmaker is needed. The CME of the decisionmaker needs to be evaluated in *dollars*, not utility units.

CME in dollars can be found through the use of a formula which relates expected utility to expected payoff and payoff variance.[115] By

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111. We will use the general form $U = P - (k \cdot P^2)$, where k is some constant which determines exactly how concave the function is over a restricted domain of P. We will use a small value for k—0.0001—and therefore employ a function with only a minor degree of concavity. This corresponds to the assumption that our decisionmaker is not *highly* risk averse.

112. $U = P - (0.0001)(P^2) = 1000 - (0.0001)\,(1000)^2 = 900.$

113. It is important to remember that personal utility is *not* measured in dollars. A dollar is worth a dollar to everyone, but a payoff of $1000, assuming some degree of risk aversion, or diminishing value of money, may be translated into 900 personal utility units. These units can *only* be used to compare one personal valuation to another, not a personal value to a dollar amount.

114. That is, the probability of success given a promising result, times the personal utility valuation of a successful project, plus the probability of no success times the personal utility valuation of an unsuccessful project, or (0.56)(900) + (0.24)(0), which equals 504.

115. The formula is as follows:

$$E(U) = E(P) - k(E^2(P) + V)$$

where $E(U)$ equals expected utility, $E(P)$ equals expected payoff, k equals some constant (0.0001 in our example above) and V equals the population variance of the range of

plugging in the appropriate expected utility value, we can solve for a straight, risk-free expected value figure that represents how much in dollars the risky decision is worth to the decisionmaker. In doing so, we will set the variance term in this formula equal to zero, since this corresponds to a risk-free CME for a given expected utility. Using this formula in the example above, we would get $532.[116] This means that the risk-averse person described by our function would be indifferent as between the project we have described and a cash payment of $532. Compare this with the straight expected value of the research project, $560.[117] Since the risk-neutral decisionmaker would not take anything less than this $560 in place of the opportunity to pursue the project, this means that the risk-averse decisionmaker values the project some 5% less than the risk-neutral decisionmaker.

One realistic feature of this risk-aversion function is that as the difference between the payoff for a successful and unsuccessful project—the variance—increases, the ratio of CME to expected value goes down. As the payoff structure indicates a riskier and riskier project, the risk-averse and risk-neutral valuations of the project diverge more and more. At some point, the divergence is so great that, given reasonable estimates of the cost of experimentation and development, many decisionmakers

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payoffs. Population variance for a range x_1 through x_n equals $((x_1 - m)^2 + (x_2 - m)^2 + \ldots + (x_n - m)^2)/n$, where m is the mean (or average) of the range x_1 through x_n. This formula for $E(U)$ is derived for the formula for U given above in the following manner. The variance V equals

$$\begin{aligned} V &= E((P - E(P))^2) \\ &= E(P^2 - 2E(P)P + E^2(P)) \\ &= E(P^2) - 2E^2(P) + E^2(P) \\ &= E(P^2) - E^2(P). \end{aligned}$$

Also,

$$U = P - kP^2$$

so that

$$\begin{aligned} E(U) &= E(P - kP^2) \\ &= E(P) - kE(P^2) \\ &= E(P) - kE^2(P) + kE^2(P) - kE(P^2) \\ &= E(P) - kE^2(P) - k(E(P^2) - E^2(P)) \\ &= E(P) - kE^2(P) - kV \\ &= E(P) - k(E^2(P) + V), \end{aligned}$$

as desired.

116. From above, $E(U) = E(P) - k(E^2(P) + V)$. In our example, we know $E(U)$, k, and V: the expected utility is 504 personal utility units, see *supra* notes 113-14 and accompanying text; k equals 0.0001, as above; and we will set variance equal to zero because we are looking for a certainty money equivalent. Solving the formula above for $E(P)$ will produce the CME our risk-averse decisionmaker would accept in place of the opportunity to make the decision. Putting the above formula in quadratic form and solving for $E(P)$ yields:

$$E(P) = (1 - (1 - 0.0004E(U))^{1/2})/0.0002$$

With $E(U)$ equal to 504, $E(P)$ equals $532.

117. This is the expected value *given* a promising experimental result.

would opt out of the project, even though it still has a net positive expected value.

For example, compare the CME of two projects. Project one gives an equal chance of earning $2000 and $0, as in our example. The expected payoff ($E(P)$) is therefore $1000; the variance is 1,000,000.[118] Project two gives an equal chance of making $4000 and $0. The expected payoff of project two is $2000, but the variance is higher—4,000,000. The CME for project one is $876; when compared to the expected payoff of $1000, this gives a CME/$E(P)$ ratio of 0.876. The CME for project two is $1394; the CME/$E(P)$ ratio is 0.697. Thus it is easy to see that as the variance increases, the CME/$E(P)$ ratio decreases. According to the risk aversion function, the decisionmaker becomes more risk-averse.

This means that for a high-variance project, inventors trying to decide whether to pursue the project will be more risk-averse. When deciding on these projects the benefits will be heavily "diluted" by the extra risk. Assuming that society values inventions in a risk-neutral way, the result will be fewer such invention projects than the preferred number.

The policy solution is easy to envision: create some extra incentive to offset the inventor's lower perceived utility. This might take a number of forms. For example, the initial experimentation stage of the high-risk project could be subsidized by the government. Government funding of basic research is one instance of this; basic research projects often involve high costs and potentially high but quite uncertain rewards.[119]

In addition, a patent-related policy solution is possible. This could be accomplished by creating an extra-high payoff for those successful projects whose inventors faced a high-variance project. Because perceived payoff is a combination of dollar payoffs and probabilities, this could be achieved by either augmenting the potential profit from a patent or by increasing the probability of obtaining one. Naturally, this paper focuses on the latter alternative. Although as mentioned above, the effects of any patent-related incentive on initial decisions to invent are quite limited, some marginal inventors might be swayed by the extra reward. Thus it is at least worth attempting.

One practical way to assess whether a project involved a high degree of risk is to look at the cost.[120] If the project was very costly

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118. Recall that population variance for a range x_1 through x_n equals $((x_1 - m)^2 + (x_2 - m)^2 + \ldots + (x_n - m)^2)/n$, where m is the mean (or average) of the range. Here this yields $((2000 - 1000)^2 + (0 - 1000)^2)/2$ or 1,000,000.

119. *See* Richard R. Nelson, *The Simple Economics of Basic Scientific Research*, 67 J. POL. ECON. 297 (1959).

120. The relationship between cost and variance can be seen from a simple qualitative example. Assume a game of chance where you are asked to pick balls from an urn; each pick costs some money. Even if the number of winning balls is fixed, i.e., does not vary with the number of picks, the possible loss from playing the game increases as you pick

relative to others in the industry, it is a good candidate for the extra "risk bonus" discussed here.[121] As previously discussed, the cases seem to indicate that patents on high-cost inventions do meet with extra success in the courts.[122] The discussion here confirms the wisdom of this practice. Moreover, I have attempted to furnish another rationale for the practice. Once again, I would merely add that it would be better for inventors if the courts made this practice explicit in the patentability jurisprudence.[123]

I am not suggesting that Congress should change the statutory standard.[124] I am suggesting an *interpretation* of the current standard that would recognize the central place of uncertainty. I see nonobviousness as a test of whether an invention entailed a high degree of technical uncertainty at its outset. In the case of an inexpensive or moderately

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more balls. Because your possible loss increases with more picks, more picks entails greater variance.

121. This bears a close relationship to a point made by the economist F.M. Scherer: patents are especially defensible where they award inventions whose costs are high relative to their benefits. *See* SCHERER, *supra* note 17, at 448 (innovations with low potential benefits relative to costs need promise of a patent to hasten development). The proposal outlined here merely stresses that what is important is *perceived* costs—which may be a function of risk aversion when variance is high—as compared to benefits. Note also that this is in line with Kitch's analysis of nonobviousness. *See* Kitch, *supra* note 6, at 302.

122. Panduit Corp. v. Dennison Mfg., 774 F.2d 1082, 1099 (Fed. Cir. 1985) (fact that patent holder took seven years and spent millions of dollars is evidence that prior art did not render invention obvious), *vacated on other grounds*, 475 U.S. 809 (1986); Hardinge Bros. v. Marr Oil Heat Mach. Corp., 27 F.2d 779, 781 (7th Cir. 1928) (fact that patentee and infringer both made long and expensive experiments in an effort to make an oil burner with a cover on it is evidence that invention was not obvious); Bethlehem Steel Co. v. Nelies-Bement-Pond Co., 166 F. 880, 896 (C.C.D.N.J. 1909) (patentee showed that he spent between $50,000 and $125,000 "perfecting" his invention; the court, in invalidating the patent, found that the actual experimentation was extremely limited, the large amounts of money were spent after the invention was made, and were merely to fine tune it; decision implies that had the money been expended for the original research, it would have been relevant); Edoco Technical Products, Inc. v. Peter Kiewit Sons' Co., 313 F. Supp. 1081, 1086 (C.D. Cal. 1970) (the fact that a long and expensive period of experimentation was required to solve the problem was important evidence of nonobviousness), *aff'd*, 177 U.S.P.Q. (BNA) 481 (9th Cir. 1973); *cf.* Eli Lilly & Co. v. Generix Drug Sales, 460 F.2d 1096, 1103 (5th Cir. 1972) (inventor who undertook costly and painstaking research in developing propoxyphene hydrochloride should be rewarded with a product patent; a use or process patent would be insufficient incentive and would discourage the inspiration process); United States v. Ciba-Geigy Corp., 508 F. Supp. 1157, 1168 (D.N.J. 1981) (for patent relating to hydrochlorothiazide, the costly research undertaken should be rewarded with a product patent).

123. *Cf.* Oddi, *supra* note 17, at 1127 (suggesting that courts ought to consider "qualitative and quantitative investment in research and development" as an additional objective factor in determining nonobviousness).

124. I will note, however, that from an economic point of view the statute's concern with "pure obviousness" is besides the point. As suggested here, the inquiry should be "how obvious *given a reasonable budget constraint*"? However, for purposes of this paper at least, I concede the administrative difficulty of evaluating technical uncertainty in light of industry and firm R&D *in every case*. Thus the emphasis on a discrete and more easily identifiable class of cases—*very* high cost projects.

expensive research project, the inquiry need go no further than technical uncertainty.[125] But for a high-cost research project, one whose cost is much higher than the average project in the industry, we must also take account of the fact that a reduction in *perceived payoffs* makes the project look less attractive to the reasonably skilled inventor.

The notion of including cost as a component of technical uncertainty may be disquieting. After all, it might be thought that if the end result of a certain experiment is obvious, it is no less obvious simply because it may be very expensive to verify. The high cost, it will be argued, does not make the result any less likely. But a little reflection reveals that there is a relationship between predictability and cost, especially when cost is very high. The reason, once again, involves risk aversion.

As previously shown, the greater the divergence between potential outcomes, the more a risk-averse person's preference for choice diverges from expected value. So far this has been modeled as a reduction in the perceived payoffs from the risky activity. It would be easy, however, to treat the payoff as constant and say instead that the risk aversion lowers the anticipated *probability* of the positive payoff.

For example, using our risk aversion function, we calculated earlier that a risk-averse person would be indifferent as between a project with expected value of $560 and a cash payment of $532.[126] The risk-averse person implicitly discounts the expected value of the risky project. The same general conclusion is reached by keeping the payoff constant and changing the probability. With a payoff of $1000, the risk-averse person *in effect* assesses the probability of a successful project at only 0.532, since 0.532 times $1000 equals $532. From this perspective, the risk-averse person implicitly subtracts 0.028 (0.56 – 0.532) from the probability of successfully completing the project.[127]

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125. The cases for the most part agree with this. *See, e.g., In re* Farrenkopf, 713 F.2d 714, 718 (Fed. Cir. 1983); Orthopedic Equip. Co. v. United States, 702 F.2d 1005, 1013 (Fed. Cir. 1983). At least one case, however, seems to question whether technical achievement is required, by implying that *commercial* uncertainty might satisfy the nonobviousness requirement. *See* Leinoff v. Louis Milona & Sons, 726 F.2d 734, 740 (Fed. Cir. 1984), *overruled by* A.C. Auckerman Co. v. Chaides, 960 F.2d 1020 (Fed. Cir. 1992) (upholding patent for inserting leather strips between strips of fur to make pelts, even though prior art made clear this technique was possible; court held, in face of defendant's objection that patentee had merely "discovered" market demand for furs made with this technique, that an invention "may create a new want and be nonobvious"). Except in the case of very high-cost research projects, commercial uncertainty ought not to support a claim of nonobviousness, for the reasons stated above in the discussion of disclosure theory.

126. That is, (0.56)($1000) + (0.24)($0). *See supra* notes 116-17 and accompanying text.

127. The example in the text uses probabilities and payoffs of success *given* promising experimental results. This is irrelevant to a discussion of patent standards, of course, since it is the probability of experimental success—technical uncertainty—that is at the heart of the patentability test. The analysis yields the same general conclusion, however, when applied to implicit reductions in the probability of a promising experiment caused by

Assuming once again that high project costs are a good proxy for high variance, and thus risk, one result is that the cost of doing research does in effect impact prospective assessments of technical uncertainty. Thus it is entirely defensible to take these costs into account in assessing the perceived *ex ante* probability of project success.

Yet it is feasible to do so only under when the invention whose patentability is at issue came as part of a very high cost research project. Although the foregoing might suggest the desirability of taking cost into account in all cases, it would not have much of an impact in low to moderate cost research projects, which by assumption involve only low to intermediate levels of variance. Moreover, cost data adds a layer of complexity to patentability decisions that would not often be worth the gains.

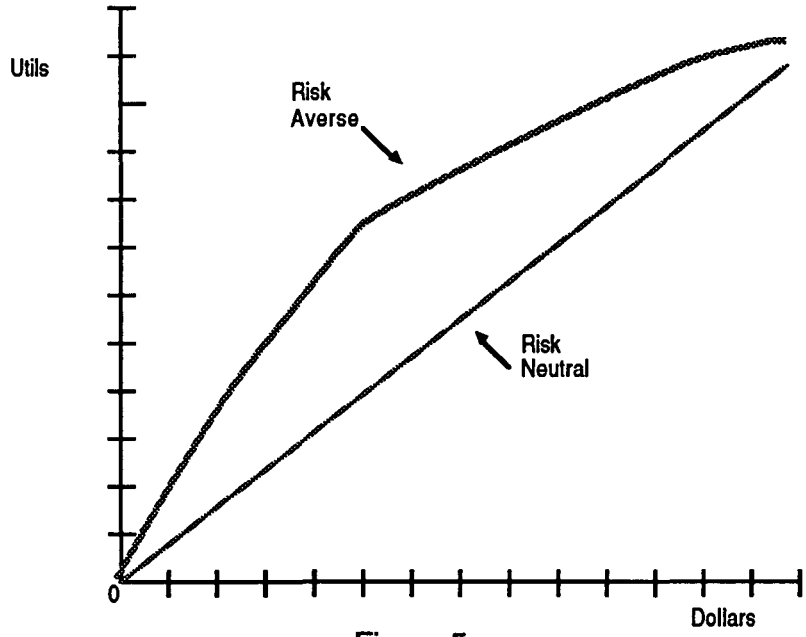

Figure 5

1. *BUT AREN'T INVENTORS RISK-SEEKERS?*

A plausible objection to my treatment of risk aversion begins from the premise that inventors are not risk-averse, they are risk-takers.[128] My

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devaluation of high-risk payoffs. I simply choose to use the same numbers as in earlier examples.

128. Many people seem to believe this. Support can be found in FRANK W. TAUSSIG, INVENTORS AND MONEY-MAKERS (1915) (describing the psychological differences between

response is that while in the main this may be true,[129] for the subclass of inventions we are concerned with here—high cost projects with a roughly even chance of success—this objection is irrelevant. My argument turns on two points: (1) a precise characterization of the kind of research that would be affected by a "risk adjustment" to the standard of patentability; and (2) empirical research elucidating the differences between R&D in large and small firms.

Allowing high research costs as a "plus factor" in determining patentability would affect a small number of cases. First, of course, only those patents sought in connection with high-cost projects would be affected. To keep this number small, "high-cost" should be defined as 50% or more above the average research project in the *industry* (not the

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inventors and financiers, including attitudes toward money and risk); and JOSEPH A. SCHUMPETER, CAPITALISM, SOCIALISM, AND DEMOCRACY 73-74 (1950):

> Spectacular prizes much greater than would have been necessary to call forth the particular effort are thrown to a small minority of winners, thus propelling much more efficaciously than a more equal and more 'just' distribution would, the activity of that large majority of businessmen who receive in return very modest compensation or nothing or less than nothing, and yet do their utmost because they have the big prizes before their eyes and overrate their chances of doing equally well.

Id. See also BROWN, *supra* note 8, at 44, 189, 325 (quoting from interviews with inventors describing the importance of challenges and the unimportance of monetary gains to their pursuit of inventions).

129. And society should be glad if risk-seeking inventors pursue ambitious research, whether it succeeds or not. There are many social benefits when an inventor *overestimates* a project's chances of success, or the efficacy of patent protection, or even the chances of patentability. MACHLUP, *supra* note 1, at 166-67:

> It will be best from the point of view of society if innovators optimistically overestimate th[e] lag [between innovation and imitation]. If they expect the lag to be longer than it actually is, innovation will be enhanced and imitation will not be delayed. That it may create this socially wholesome illusion on the part of innovators is the strongest justification for a well-designed patent system.

Id. Assuming the project is not successful but the patent is granted, society will benefit from the knowledge of a technology that works but cannot be successfully developed—i.e., a path that others should *not* try. There are even some benefits without public disclosure, since there is a market for "negative know-how," or knowledge of what will not work. *See, e.g.*, Metallurgical Indus. v. Fourtek, Inc., 790 F.2d 1195, 1203 (5th Cir. 1986) (characterizing the value of negative know-how as integral to improvement, and thus in most cases the equivalent of "positive knowledge"); Continental Group, Inc. v. Kinsley, 422 F. Supp. 838, 845 (D. Conn. 1976); Gillette Co. v. Williams, 360 F. Supp. 1171, 1173 (D. Conn. 1973). But see dictum to the contrary in Materials Dev. Corp. v. Atlantic Advanced Metals, Inc., 172 U.S.P.Q. (BNA) 595, 606, 610 (Mass. Super. Ct. 1973). *Cf.* Mansfield, *supra* note 55, at 98:

> Many . . . [formal project selection] models fail to recognize that R&D is essentially a process of buying information, that *unsuccessful projects can provide valuable information*, and as a result that the real task is to facilitate sequential decision making under conditions of uncertainty.

Id. (emphasis added).

firm). Moreover, the patentee should have the burden of establishing these high costs. Second, although the risk adjustment would be available for all high-cost projects resulting in patents, in many of these it would make no practical difference. If the pre-adjustment probability of success were low, a patent would issue even without the risk adjustment. If the pre-adjustment probability of success were high, the minor "plus factor" would not be enough to overcome the nonobviousness test. Risk adjustment would matter only in those high-cost cases where the probability of success was close to the line of patentability; in these cases, it would give a helping hand to the inventor.

Now that I have made clear which research projects would be affected by the risk adjustment mechanism I have described, it remains to be shown that risk aversion is a real concern for these projects. To begin with, many high-cost research projects are done by large firms,[130] whose R&D managers are presumably at least somewhat risk-averse.[131] While

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130. *See* Keith Pavitt, *R&D, Patenting and Innovative Activities*, 11 RES. POL'Y 33, 38 (1982). Pavitt, in an attempt to refute the hypotheses that large firms do more non-patentable R&D, or that they are less inefficient than small firms, states:

> I correlated the proportion of individuals [i.e., small inventors not associated with a company] in total patenting in each [industry] sector (a measure of ease of patenting) . . . against average plant sales in the sector (a measure of level of resources required). . . . [T]he correlation was -0.49 and significant at the 2% level: scale of resources required may influence to some extent the degree to which individuals contribute to sectoral patenting activity. This suggests [an] explanation of the inverse relationship between size of firm and R&D intensity, on the one hand, and the patent to R&D ratio on the other. *Smaller firms gravitate to sectors, and within sectors to products, where the costs of making innovations are somewhat lower than those of big firms.*

Id. (emphasis added). *See also* CHRISTOPHER FREEMAN, THE ECONOMICS OF INDUSTRIAL INNOVATION 137 (2d ed. 1980) (reviewing data which seems to show that smaller firms are more efficient R&D spenders, based on the fact they obtain more patents per dollar of R&D than large firms).

> [T]here are significant differences between *industries* in the relative performance of small and large firms. In the *chemical* industry, where both research and development work are often very expensive, large firms predominate in both invention and innovation. In the mechanical engineering industry, inexpensive ingenuity can play a greater part and small firms or private inventors make a larger contribution.

Id. For a review of the data on large vs. small firm "research efficiency"—largely a matter of number of patents per R&D dollar—see F.M. Scherer, *Corporate Size, Diversification and Innovative Activity*, *in* INNOVATION AND GROWTH: SCHUMPETERIAN PERSPECTIVES 222, 228-29 (1984) ("The patents of larger [lines of businesses] tend more frequently to cover more complex systems and subsystems entailing high R&D outlays per invention. [But] [t]he relationship is a weak one."). *See also* MORTON I. KAMIEN & NANCY L. SCHWARTZ, MARKET STRUCTURE AND INNOVATION 67 (1982) (review of research tending to show that inventive efficiency increases with size up to a point, then begins to decrease).

131. Most large firm executives are risk averse. *See* KENNETH R. MACCRIMMON & DONALD A. WEHRUNG, TAKING RISKS: THE MANAGEMENT OF UNCERTAINTY 260 (1986) (study of 500 senior business executives which found that "managers in large firms were more averse to risk than other managers"). There is no reason to believe that R&D managers would have different "risk profiles" than the cross-section of executives surveyed for this

small risk-neutral or risk-seeking firms also undertake a good number of high-cost research projects,[132] these projects often involve higher technical risk on average than those undertaken by large firms.[133] Since the chance

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study. For example, the study found that senior executives from the chemical, pharmaceutical and manufacturing industries—which traditionally rely heavily on research—had risk preferences which did not diverge from the from the average. *Id.* at 262. One study of investments in oil industry projects—including several that involved the development of new technology—showed that managers behaved in a risk-averse fashion; specifically, they chose projects as if they were diversifying the "portfolio" of firm projects with respect to risk. HELFAT, *supra* note 110, at 5, 127; *see also* Mansfield & Wagner, *supra* note 29, at 181 (reporting results of interviews with R&D personnel from 16 large corporations; average probability of technical completion of attempted projects was 0.57); *cf.* ROBERTS, *supra* note 30, at 157 (Texas Instruments tries to overcome risk aversion of R&D decisionmakers by supporting three internal funding sources, which encourages R&D managers to take more risks). *But cf.* Dasgupta & Stoneman, *supra* note 48, at 18-21 (theoretical model of race for a patent shows that competition among firms may actually cause too much high-risk research); Tor Klette & David de Meza, *Is the Market Biased Against Risky R&D?*, 17 RAND J. ECON. 133 (1986) (same).

132. Biotechnology, an industry where small firms predominate, is a good example. *See, e.g., Biotechnology Financing: Stocks Face Mixed Outlook*, BIOTECHNOLOGY NEWSWATCH, Oct. 2, 1989, at 1 (reporting on presentation by accountant stating that "[o]n average, smaller [biotechnology] firms are spending $100,000 a month on R&D, the larger ones $7 million to $8 million"; and reporting estimate by venture capitalist that since 1976, $5 billion has been raised to fund biotechnology companies); *Biotechnology's New Strain of R&D Cash*, BUS. WK., Apr. 18, 1983, at 104 ("Developing a new therapeutic drug can cost a company from $3 million to $100 million, and rigorous Food & Drug Administration tests can take more than five years. . . . For genetic-engineering companies, many with no marketable products to generate cash flow, the investment burden is tough to bear."); Ann Hagedorn, *Suits Sprout Over Rights to Seeds*, WALL ST. J., Mar. 5, 1990, at B1 (describing suit over genetically advanced celery variety: "With companies spending millions of dollars yearly on biotechnology to create novel seed varieties, the costs of losing the seeds to competitors are greater than ever."). *But see* SCHWARTZMANN, *supra* note 13, at 85 (noting that small firms in the pharmaceutical industry usually perform relatively inexpensive, low-cost research such as finding new dosage forms for old, well-known drugs). *See generally* KEITH PAVITT & S. WALD, THE CONDITIONS FOR SUCCESS IN TECHNOLOGICAL INNOVATION 34-52 (1971) (describing interaction between large and small firms in R&D).

133. For example, Edwin Mansfield studied the research and development projects of primarily large firms in the chemical and petroleum industries in the 1960's. He found that his "findings seem to support the hypothesis . . . that the bulk of the research and development carried out by large corporations . . . is relatively safe from a technical viewpoint." MANSFIELD ET AL., *supra* note 69, at 20; *see also id.* at 25 ("With regard to the median estimated probability of technical success . . . the regressions suggest that [it] is higher (not lower) . . . in the largest [chemical] firm in the sample than in a firm that is one-half its size.") (footnote omitted); J.Y. Kamin, I. Bijaoui & R. Horesh, *Some Determinants of Cost Distributions in the Process of Technical Innovations*, 11 RES. POL'Y 83, 89 (1982) (in study of 33 innovations in Israeli chemical and electronics industries, authors "found that the small firms [i.e., under 500 employees] undertake a significantly higher proportion of complex [technological innovation] processes than are undertaken by the larger firms"); D. Hamberg, *Invention in the Industrial Research Laboratory*, 71 J. POL. ECON. 95, 99-103 (1963) (summarizing empirical research from the 1950's tending to show that large firms pursued relatively safe research; discusses why medium to small firms might pursue riskier projects). *But cf.* MANSFIELD ET AL., *supra*, at 25 (noting the limitations of the data and some counter-indications). It also appears that firms which spend a higher

of obtaining patent coverage increases with the degree of technical uncertainty at the outset of the project, many projects undertaken by these small firms are likely to result in patentable inventions anyway (assuming the projects are successful). The added incentive of a higher probability of obtaining a patent in high-cost cases will simply not matter where small firms conduct high-cost research; the plus factor will not change the outcome in most cases. As a consequence, the fact that small firms are often risk-neutral or risk-seeking does not weaken the case for an upward adjustment in the standard of patentability for high-risk research.[134]

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percentage of their revenue on R&D use a formal decision-making process more often than other firms. *See* Uhlman, *supra* note 30, at 30-31 (study of 218 innovations from 126 companies finding that "[t]he higher the share of [revenue] spent on research and development . . ., the more frequently a detailed target is set for the time, funds and solution possibilities . . . available for solving a specific problem"). Assuming firms that spend more on R&D undertake more high-cost projects, and further assuming that a formalized process leads to more risk-aversion, this might indicate another rationale for the plus factor. For a spirited argument that small inventors contribute most of the major breakthroughs in many industries, see JOHN JEWKES ET AL., THE SOURCES OF INVENTION (2d ed. 1969), especially at 205-09. *See also* Robert E. Berney & Ed Owens, *Small Business Policy: Subsidization, Neutrality, or Discrimination*, 22 J. SMALL BUS. MGMT. 49 (1984):

> The tendency for small business to develop a larger number of important advances in technology is often attributed to less separation of ownership and management. In large firms, managers tend to have shorter time horizons than owners. Consequently, managers tend to push projects with short-term payoffs even when other projects have higher present value to the stockholders. However, both small and large businesses innovate to secure monopoly profits from innovation.

Id. at 54.

134. It might be argued that the growing emphasis on large firm-small firm joint ventures may mitigate the differences between the two types of firms' R&D efforts. *See, e.g.*, John Case, *Sources of Innovation*, INC. MAGAZINE, June 1989, at 29 ("Big companies frequently enable a small company's inventions to become marketable innovations. Pharmaceutical and chemical giants . . . have helped create the biotech industry—by distributing grants to university researchers, by investing in fledgling companies, by contracting to do production or marketing for small firms. . . . Today . . . there's more and more of this joint venturing."). Note, however, that the transaction costs associated with such arrangements are considerable, making them less than an ideal solution. Note too that many of the transaction costs involved have yet to occur for the joint ventures being formed today. Perhaps when disputes over ownership and control of joint venture technology increase, firms will realize they are less than a panacea. And in the meantime, large firms continue to be accused of harboring more risk aversion than is good for the economy. *See, e.g.*, NATIONAL ADVISORY COMM. ON SEMICONDUCTORS, A STRATEGIC INDUSTRY AT RISK: A REPORT TO THE PRESIDENT AND THE CONGRESS 25 (1989) (calling for pools of "risk-tolerant" capital to encourage more high-risk research); Susan Dentzer, *The Maypo Culture*, BUS. MONTH, Nov. 1989, at 26, 29 (low rate of investment by U.S. corporations in part attributable to unwillingness to take risks); Robert H. Hayes & William J. Abernathy, *Managing Our Way to Decline*, HARV. BUS. REV., July-Aug. 1980, at 67, 68-69 (accusing U.S. companies of losing their taste for the high-risk investment needed to keep innovations flowing).

Lowering the standard of patentability in high-cost research projects will likely affect only those firms that need the extra incentive. For the most part the perverse effects associated with a risk adjustment "plus factor" will therefore be small. And even in those few cases where risk adjustment tips the scale and a patent is granted to a small, non-risk-averse firm, the public will at least have the benefit of the disclosure of valuable (because costly to obtain) information.[135]

2. *CASES ON HIGH-COST RESEARCH*

Although the cost of research has never been part of the formal analysis of nonobviousness, some decisions have noted that the expenditure of a large amount of money tends to show that an invention is not obvious.[136] For example, in *Edoco Technical Products, Inc. v. Peter Kiewet Sons' Co.*,[137] the district court upheld a patent on a device used in pouring concrete. In rejecting the infringer's objection that the invention was obvious, the court noted that "a long and expensive period of experimentation was required by the patentees to solve the problem."[138] But expensive research, in and of itself, has never been seen as an important indicator of patentability. It is proposed here that courts do so in a limited class of cases.

G. Administrative Feasibility and Perverse Incentives

Proving relatively high research cost will not be difficult or burdensome. Patent applicants and patentees collect this information anyway for a variety of reasons, including: (1) tax benefits (e.g., the R&D tax credit), (2) internal cost accounting, (3) use in project evaluation, (4) use in licensing negotiations and the like. Patentees appear to have no trouble showing research expenditures at the damages stage of a patent infringement suit, and as noted above such information has been introduced in some cases to show the nonobviousness of the invention involved. Simply adding one more reason to collect data on the cost of a research project does not appear to pose a major problem.

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135. Although the disclosure function of patents is secondary to the incentive function, firms do rely on patents as one source of technical information. *See, e.g.*, SCHWARTZMANN, *supra* note 13, at 306 ("Scientists in the research laboratories of pharmaceutical companies follow the patents filed by other manufacturers in order to keep abreast of critical developments."). *But see* Michael J. Meurer, *The Settlement of Patent Litigation*, 20 RAND J. ECON. 77, 80-81 (1989) ("Asymmetric information about innovations persists despite the disclosure requirement in 35 U.S.C. § 112 . . . because 'the disclosure regulations of the patent system are often evaded. . .' Even when disclosure is complete, it might not provide crucial information about the content of prior art . . . ." (quoting NORDHAUS, *supra* note 33)).

136. *See supra* note 122.

137. 313 F. Supp. 1081 (C.D. Cal. 1970), *aff'd*, 177 U.S.P.Q. (BNA) 481 (9th Cir. 1973).

138. *Id.* at 1086.

Likewise, the fact that one would need *comparative* data to qualify for the boost in patentability would not pose too great a problem. Currently, evidence of the research approaches and results of industry competitors—including third party competitors not involved in a patent infringement suit—is introduced to show such nonobviousness factors as long felt need in the industry and failure of others to invent. Comparative data is also sometimes used to establish "reasonable royalty" rates in determining a patentee's damages from infringement. It is a short step to determine competitors' research costs. The burden of applying the new test will lessen once enough data is collected to establish basic comparative criteria. This is especially true of the test as it will be applied in the Patent Office, given the volume of patent applications and the specialization of examiners. For instance, after a short time, examiners in the chemical sections of the Office will have some experience applying the test and will therefore have some rules of thumb regarding the normal range of research expenditures for their areas of specialization.

Another objection to the proposed "risk adjustment" for high-cost projects is that it might skew investment decisions. That is, an inventor might decide at the margin to spend extra money on a project to insure that it falls into the high-cost category and therefore qualifies for the beneficial patent standard proposed above. To some extent, this would not be bad; after all, the basic idea behind the patent system is to encourage investment in research and development. And some of this extra research might prove very useful, despite the motivation for undertaking it. As discussed above, however, the patent system is equally concerned not to over-reward routine (low uncertainty) research. Thus the skewing of investment is a real worry.

But not too great a worry. For one thing, the extra incentive of a patent, and therefore *a fortiori* of the extra boost of easier patents for high-cost projects, is modest. A firm would be foolish to lavishly spend its way to a modest benefit. Another reason not to worry too much about skewing is that the qualifying test to receive the extra boost to patentability is quite high. It would be difficult, not to mention unprofitable in many cases, to artificially inflate a research project budget so as to bring it to a level 50% higher than that of the average project in the industry. And finally, of course, where the Patent Office or a litigation opponent discovers the applicant's cost-padding strategy, the doctrine of inequitable conduct can be invoked to render the patent completely unenforceable.

IV. ADJUSTING THE STANDARD FOR EXPENSIVE RESEARCH: A MULTI-FIRM MODEL

This section uses the example of multi-firm competitive research to bolster the argument that patents ought to be slightly easier to obtain for the results of high-cost research projects. Here the single-firm "decision theory" model introduced above is modified to include the presence of other firms.

When more than one firm is capable of undertaking a research project, the decision to invest in the project is more complicated than in the preceding models. The reason is that the decisions of other firms whether to undertake the project affects the possible payoff from the project. This is based on a simple premise: the more firms researching a problem, the more likely that at least one firm will solve it, i.e., come up with the invention. Thus for any particular firm, the number of other firms who have chosen to research a project will affect its decision whether to enter the project "sweepstakes." Of course, if an individual firm always had the right to use the results of its own research, this would not be true. In this case, the simple decision theory model presented in the preceding section would completely describe the choice faced by the firm. But what this model omits, and what the model in the following section tries to capture, is the impact of the patent system's basic rule that even independent discovery is not a defense to patent infringement. Put in terms of the single firm's decision in the multi-firm context, there is some chance that even a success will be a failure—i.e., that even if *this firm's* research project is successful, a successful outcome for another firm which leads to a patent will block this firm's ability to use the research results. This is *not* to say that the activity (or inactivity) of the other firms affects a particular firm's probability of successfully completing the project; only that these other firms, in the aggregate, affect the probability of obtaining the sole patent to cover that success. In this way, the number of competing firms affects a firm's expected payoff.

The other factor affecting a firm's decision to enter the research sweepstakes is the cost of pursuing the research project. If entry were free, every firm that had the capacity would enter, since expected value would always be positive. (There is always some chance that an individual firm would be both successful and first, and therefore obtain the patent; and with zero cost, it would always pay to try.) But once research costs something, this is no longer true. For then a firm will have to balance its expected value—again, determined in light of the number of other competitors—against the cost of the project. Only if entry were cost-effective, i.e., expected benefit minus cost were positive or at least zero, would a firm in fact enter.

This analysis clearly indicates that a rise in the cost of the project will reduce the number of firms that would decide to enter. Viewed from the perspective of a single firm's decision, a rise in cost lowers the expected value of the project. Herein lies the intuitive point developed in the model below. Higher research cost will lead in some cases to a below-optimal number of entrants.

For any given project, a limited number of firms will compete to reach the goal (success) first. Since the rewards are generally larger for the first to complete a patented invention, the model assumes that only the first firm to succeed gets the patent, and thus all the rewards.

As a consequence, each firm views the problem of deciding whether or not to play the research game as one where the expected benefits of winning do not have to be divided among several winners; only *one* winner "takes all."[139] The probability of winning is related to the probability that *at least one* firm will get the research result; but firms do not look at the possibility of dividing the prize among multiple winners. Again, only one will take the prize. Thus the probability term takes into account that more than one firm might play and win: it is calculated as:

Probability of at least 1 success = 1 – (Prob. no one succeeds).

On the other hand, since the cost of research for each firm, i.e., the "price" of entering the research competition, is not divided, there is no need to divide expected benefits by the number of firms playing—no expected value times number of firms or "$E(v)/n$" type of calculation.

This analysis of cost will demonstrate that there is an interesting relationship between the cost of research and some of the other variables interest. Thus, the cost of doing research, c, must be considered.

Assume that the cost c of doing a research project is the same for all firms that decide to pursue the research. Furthermore, assume—perhaps unrealistically—that as the number of firms competing for the research result increases, cost stays the same.

Recall that the probability of success, P, is the same for all firms. Then the probability that no one succeeds will be equal to $(1 - P)^n$, where P = the probability of success and n = the number of firms trying to perform the research.[140] For example, where only one firm is researching, and the probability of success is 0.4, the probability that "no one" (i.e.,

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139. This is consistent with much of the economic literature on races to invent, which uses game theory to model the optimal commitment of resources to inventions pursued by a group of competitors. *See, e.g.*, Jennifer F. Reinganum, *A Dynamic Game of R and D: Patent Protection and Competitive Behavior*, 50 ECONOMETRICA 671 (1982).

140. In a sense, this step is not technically correct since the outcomes of research at each firms are not truly independent. True independence would require an *ex ante* estimate of P so good that information about the success or failure of other firms would not affect it. This is not the case here since such information would affect an *ex ante* estimate of the tractability of the research problem thereby affecting P.

this firm) does succeed is (1 – 0.4) or 0.6. Likewise when two firms are doing the research, the chance that neither will succeed is $(1 - P)^2 = (0.6)^2 = 0.36$, and so on.

This should establish that $(1 - P)^n$ is the proper measure of the probability that no one succeeds. But what is the probability that at least one firm will succeed? It is $1 - (1 - P)^n$. To verify, consider the example of one firm, i.e., where $n = 1$. Then the chance of success will be $(1 - (1 - P))$; if $P = 0.4$, this will be 0.4, which certainly makes sense. What about when $n = 2$? For $P = 0.4$, the probability that at least one of the firms succeeds will be $1 - (1 - 0.4)^2$, or 1 – 0.36 or 0.64. This makes intuitive sense, since two firms with a 40% chance of success should have, one would think, a better than even chance of succeeding.

Anyhow, from society's point of view, the expected value of a research project should equal its anticipated monetary benefits multiplied by its probability of success; that is:

$$\text{Expected benefit} = (\text{Benefit}) \cdot (\text{Probability}) \qquad (1)$$

As discussed above the probability should be equal to $1 - (1 - P)^n$. Thus, (1) should be written:

$$\text{Expected Benefit} = \text{Benefit} \cdot (1 - (1 - P)^n) \qquad (2)$$

Just for convenience, set the benefit of a given project equal to 1. Now this term can be disregarded for purposes of the model. But keep in mind that the real value this term takes on will be some number much higher than $1.00. (If it helps, think of it as "one research payoff unit," and set it equal to $1 million or $10 million in your mind.)

We have discussed two elements of the research problem so far, the expected benefit (benefit times probability of success) and the number of firms researching the problem. It is reasonable to ask at this point, "How are they related?" The answer lies in Figure 6.

This tells us that as the number of firms rises, the expected benefit increases, but at a decreasing rate. (The curve is "concave.") This makes some sense—at some point, there will be so many firms that an additional one does not increase the probability of success much, and thus it adds little to expected benefit.

What about the cost of research? That would seem to be important too. Recalling our assumption above that cost is a constant multiple of the number of firms undertaking research projects, we can add a cost curve to Figure 6; this has been done in Figure 7.

Since cost is constant, total cost will always be the straight line described by the equation c times n.

Now we can begin to analyze the situation from society's point of view. What is the optimal number of firms, n, we would want

conducting this research project? The answer is that number that maximizes the *net* social benefit of the research—that is, the number of firms where the difference between benefits and cost is the greatest. In terms of our model, then, the problem is to maximize the difference between $1 - (1 - P)^n$ and $c \cdot n$.

The maximum difference will be where the slope of the $c \cdot n$ line is equal to the slope of our concave benefit function, $1 - (1 - P)^n$. This is indicated by "n^*" on Figure 8.

So from an optimal social planner's point of view, the best this society can do to efficiently pursue this research project is to put n^* firms to work on it. But even if the firm that was successful, or that was both successful and first, if more than one were successful, could appropriate all the social benefits of the research, the outcome would be different. Even if the potential researching firms knew how many other firms had decided to pursue the project, they would run though the calculations themselves and decide to pursue the project so long as their own investment was likely to pay off—that is, in terms of the model, so long as the number of firms was such that the addition of this firm would not cause the $1 - (1 - P)^n$ curve to cross the $c \cdot n$ line. That is, in terms of Figure 8, so long as the number of firms, n, would still be less than or equal to n_o.

But is it reasonable to assume that the successful firm with its patent gets all the social benefits? Quite clearly, the answer is no. Empirical research has mounted in the last few years, showing that firms do not capture all or even a large part of the social benefits their research generates. This is known in the literature as the appropriability problem.[141]

Thus another variable must be introduced into the model to signify that a firm can only hope to capture a fraction of the social benefits its research generates. This variable is fraction A, the appropriability factor. In terms of our graph, A is a constant; the degree of appropriability does not change with the number of firms pursuing the research. Thus, since A is some fraction of the total social benefits, which we have defined as 1, a curve drawn to signify a *firm's* view of the expected benefits of research will look like the A curve in Figure 9.

Focusing on the A curve for a moment, let's consider how it affects the number of firms that would engage in the research project. Recall that what a firm cares about are the benefits of the project, the probability that it will be successfully concluded by at least one firm, and its cost. The middle concern is important here. It means that firms deciding whether to enter the research competition will keep an eye on their competitors. Any one firm will decide to invest so long as its contribution to the probability of success increases the expected benefit more than the

141. *See, e.g.*, Levin et al., *supra* note 10.

contribution costs. If a large number of firms have already decided to work on the project, a firm will not want to invest in research, since its investment will add less to the expected payoff than it costs.

One way to see this is to view participation in the project, i.e., a decision by a single firm to try the research project itself, as the purchase of a lottery ticket. The question the firm asks is, is it worth it to play? The answer will be determined by comparing the expected benefits of playing against the cost of doing so. The benefits, of course, depend on how many other firms have decided to play; this is because in the model expected benefit equals probability of success times payoff, with payoff fixed at 1. Thus expected benefit depends on the probability of success, which is evaluated according to the formula $1 - (1 - P)^n$. As n rises, the value of this formula falls. Thus a firm trying to decide whether to enter will look at how many other firms have entered the research project or "game."

When will it decide to play? When the benefits are greater than or, at the very least, equal to the cost of playing. When will this be? This happens when c is equal to the firm's expected benefit. What is the firm's expected benefit in relationship to the number of participating firms? Recall that the probability of winning is defined as the probability *that at least one* firm will succeed. This means that, from the entering firm's point of view, it is the total number of participating firms that counts. In other words, it is unconcerned with its *marginal* contribution to expected benefits. So long as the total number of firms, after it joins, is expected to produce benefits that outweigh total cost, it makes sense to join.[142] In other words, so long as after joining the average benefit (expected benefit divided by the number of firms) is greater than or equal to the average cost, the firm will join.[143] On the graph, this is shown as the point where the $A(1 - (1 - P)^n)$ curve intersects the $c \cdot n$ line, shown as n_e in Figure 10.

This is the equilibrium entry point in our model—the point that represents how many firms would elect to attempt the research for a given probability (P) and level of appropriability (A).

One interesting result from this is that for given (and probably realistic) levels of appropriability, the equilibrium number of firms (n_e) will be less than the socially optimal number (n^*). Society is losing at these values of n_e—fewer than the optimal number of firms will try the research project. On the other hand for some levels of appropriability,

142. *See* Wright, *supra* note 49, at 49-56.

143. In terms of the model, we would set $A(1 - (1 - p)^2)/n$, average benefit, equal to average cost, which is $c \cdot n/n$ or c. Thus, after multiplying though by n, we would have: keep investing until $A(1 - (1 - p)^2) = c \cdot n$. Remember that the model assumes that each firm has an equal chance of successfully completing the research and obtaining the patent, thus the division by n.

i.e., values of A, n_e will be greater than n^*—and we will get too many firms trying their hand at the project.

Next we shall examine the optimal level of appropriability, A. Recall that A is a constant which, when multiplied by each value on the Benefit Curve $1 - (1 - P)^n$, produces what we have called the A curve. There is an optimal level of appropriability, A^*—some value of the appropriability factor—that makes the A curve cross the cost curve ($c \cdot n$) at the value of n^*. This is the socially optimal level of appropriation—the level that makes firms join the research until the total number of firms equals n^*. This is shown in Figure 11.

Now we will analyze the effects of a rise in the cost of doing research, c. Consider the rise from c_1 to c_2 in Figure 12. Note that such a rise in cost changes n^*, since higher c increases the slope of the $c \cdot n$ curve and hence changes the point at which the distance between the cost and benefit curves is greatest—n^*. Note further that a new n^* requires a re-calculation of A^*, the optimal appropriability factor, so as to arrive at a new A curve to cross the $c \cdot n$ curve at the new n^*. This is shown in Figure 12.

The important point to note about this diagram is that the rise in cost, leading to a rise in the $c \cdot n$ line, forced a rise in A^*, to bring the A curve up high enough to cross the new $c \cdot n$ at the new n^*, n^*_2.

This is the point of the whole exercise: a rise in cost, especially a steep one, will of necessity require a rise in appropriability, A, to keep the optimal number of firms in the research project. We have previously noted that A has two components—the probability of receiving the benefit of success times the magnitude of the benefit. Assuming the magnitude of the benefit is fixed, we must raise the probability of receiving it. Since this is the factor we have modeled as the probability of getting a patent, the implication is clear: the probability of getting a patent must be raised in order to offset the higher cost of research. This translates quite simply into a straightforward policy recommendation: *lower* the standard of patentability—i.e., increase the probability of getting a patent—when the cost of performing research is high.

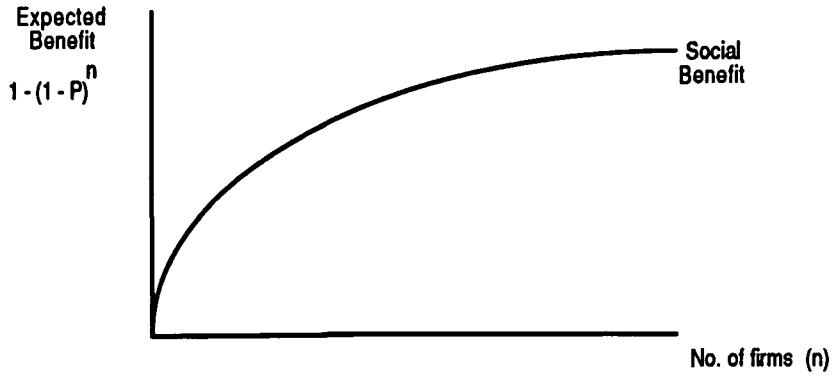
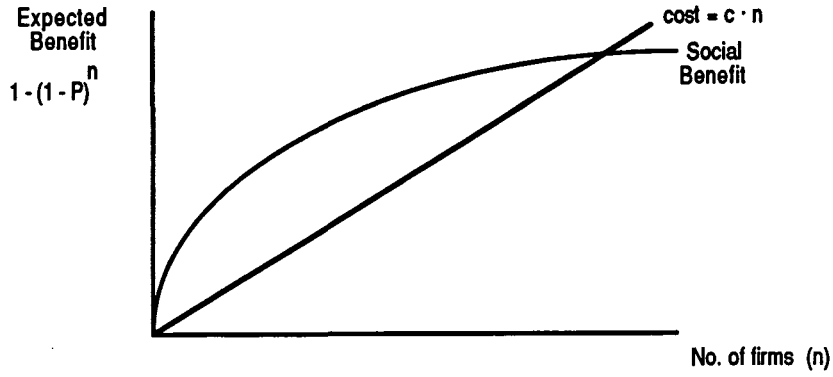


Figure 6



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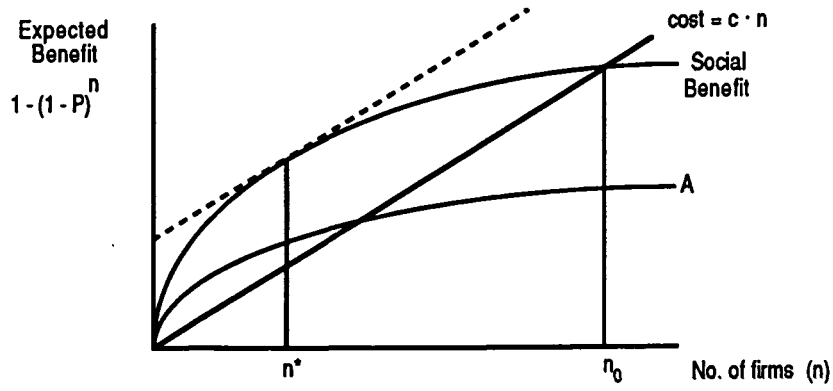

Figure 8

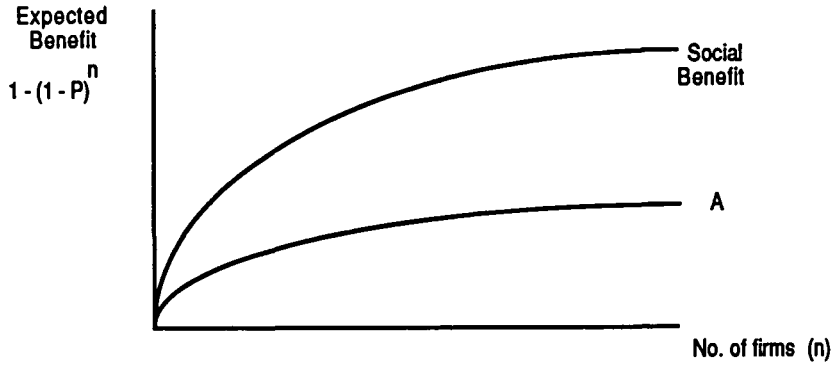

Figure 9

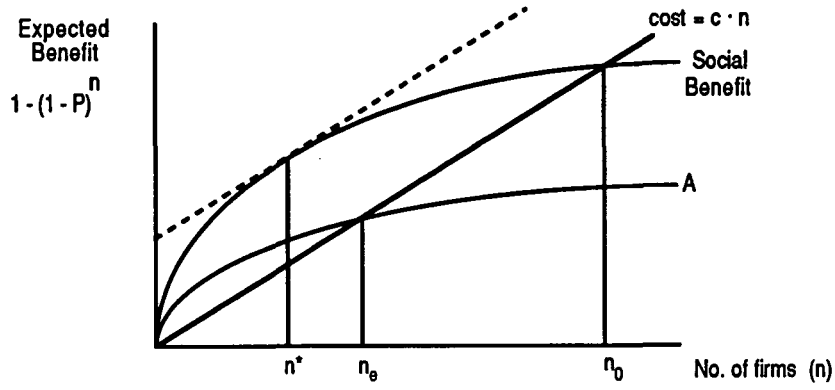

Figure 10

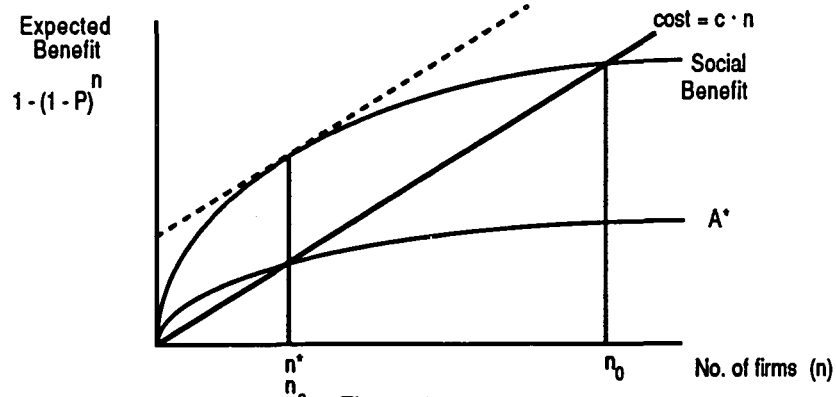

Figure 11

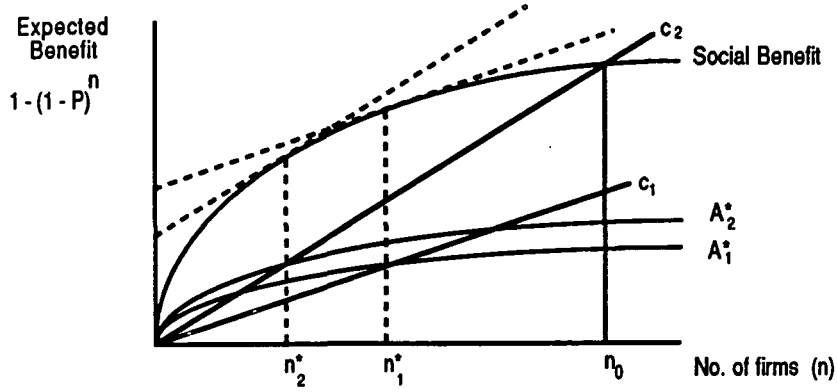

Figure 12

V. THE STANDARD OF PATENTABILITY AND THEORIES OF THE PATENT SYSTEM

Earlier we saw that there are several competing theories of the patent system, and that two—the incentive theory and the disclosure theory—are most prominent. While these two are not inconsistent, they do emphasize different benefits from patents. For the incentive theory, the important function of the patent system is to encourage those who would otherwise not invent to put the effort into an invention. Under this theory the public benefits two ways: by having the inventor's product or process enter into the economy, and by having access to the information the inventor produced, in the form of the patent specification.

This latter benefit is really at the heart of the disclosure-for-monopoly theory. Under this view the chief benefit of a patent is that it adds to the stock of public technical information. The incentive theory, then, tends to emphasize the economic importance of the patentee's invention, with the informational content of the patent a second-order benefit. Disclosure-for-monopoly theory emphasizes the information embodied in the invention as the inventor's primary contribution to economic activity.

Fortunately for purposes of this discussion, a choice between them need not be made. For whether patents encourage the introduction of new devices or simply the disclosure of new information, the nonobviousness test serves a vital gatekeeping function.[144] It may be to

144. One view, moreover, would eliminate the distinction between "product" and "information" altogether. *See* HAROLD DEMSETZ, *The Theory of the Firm Revisited, in* OWNERSHIP, CONTROL AND THE FIRM 144, 159-60 (1988):

> Because it is uneconomical to educate persons in one industry in the detailed knowledge used in another, recourse is had to developing or encapsulating

deny rewards to truly insignificant devices. It may be to weed out truly unimportant information. Either way, its function is to distinguish the patentable from the unpatentable, and hence insure that whatever is patented serves some minimally useful function—either invention as useful device, or invention as information.

Even so, the disclosure theory provides a perhaps more convincing rationale for the nonobviousness standard. For the most part, a patent application is filed long before the invention it describes goes into use. While most patent applications take an average of two years to reach a final decision in the Patent Office, they are still likely to be issued before the invention is used. However, as soon as the patent issues, it is available to the public. Thus even if the invention never goes into widespread use, the information in the patent specification is in the public domain, ready to serve as a source of information to anyone in the relevant technical community who is interested.

Because every patent is available for its information content regardless of whether it is ever embodied in a commercial product, a better defense of the patent system is to emphasize this informational role. This way, the system is not solely justified on the basis of the relatively small number of patented inventions that achieve widespread success, and hence directly contribute to economic activity. Although the informational value of the average patent may be quite modest compared to the commercial significance of this handful of important patents, every patent can at least claim to contribute something to the economy via its information content.

Importantly, patents result in the production of *public* (as opposed to secret or private) information. When a patent is issued, it is published; it becomes available to anyone interested in the relevant technology. The disclosure theory emphasizes the importance of technical information to technical advance, and is consistent with empirical and anecdotal evidence highlighting the importance of patents as a source of technical information.[145] Moreover, disclosure theory recognizes that inventors

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> this knowledge into products or services that can be transferred between firms cheaply because the instructions needed to use them do not require in-depth knowledge about how they are produced .... Roughly speaking ... the vertical boundaries of a firm are determined by the economics of conservation of expenditures on knowledge.

145. Although the value of technical information in patents is often questioned, *see, e.g.*, Susan Scotchmer & Jerry Green, *Novelty and Disclosure in Patent Law*, 21 RAND J. ECON. 131 (1990), actual researchers, at least in some fields, do appear to refer to patents as a source of useful information. *See, e.g.*, Gerald M. Murphy, Jr. & Leonard R. Svensson, *What Patents Teach*, 20 CHEMTECH 146 (1990); J.B. van Benthem, Book Review, 16 INT'L REV. INDUS. PROP. & COPYRIGHT L. 123, 124 (1985) (emphasizing "the significance of comprehensive patent documentation as a source of technical knowledge, which is of value at all stages of the innovative process, and particularly in avoiding ill-advised

have the option of keeping their information secret. Although for many industries, trade secrecy has certain disadvantages compared to obtaining patents, even in these industries it is often a second-best form of intellectual property protection. Disclosure theory recognizes this, and underscores the fact that inventors must be enticed to make their knowledge public. And finally, disclosure theory is in keeping with a general trend in economic theory to appreciate the importance of information in organizing economic activity.[146]

Certainly an emphasis on information content is consistent with the compensation-for-disclosure theory. Stressing the technical information in a patent, moreover, is specifically useful in the context of a discussion of the standard of patentability. This is primarily because, at least during the prosecution of the patent application, the ultimate commercial value of the invention is rarely known with any degree of certainty. Thus it makes sense to view the Patent Office's job not as an assessment of the possible value of the invention in action, but instead as an evaluation of

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investment when research and development projects are being prepared") (citing Erich Häußer, *Mehr Innovation durch Bessere Information, in* PATENTWESEN, *supra* note 30, at 133); *Gleaning Corporate "Secrets" from Patents*, 8 CHEMTECH 532 (1978); Harry M. Allcock & John W. Lotz, *Patent Intelligence and Technology—Gleaning Pseudoproprietary Information from Publicly Available Data*, 18 J. CHEM. INF. & COMPUTER SCI. 65 (1978); *cf.* Lothar Scholz & Heinz Schmalholz, *Patentschutz und Innovation, in* PATENTWESEN, *supra* note 30, at 204 (stating that 10% of project innovators surveyed stated that the immediate impetus for a particular research project had come from information in patent specifications). Second, some scholars studying the interdependencies between technological fields, and the basic research-commercial product linkage, present data showing that patents are often cited in scientific articles—an indication that they contain technically useful information. *See, e.g.*, Mark P. Carpenter et al., *Citation Rates to Technologically Important Patents*, 3 WORLD PAT. INFO. 160 (1981); Mark P. Carpenter et al., *Linkage Between Basic Research Literature and Patents*, RES. MGMT., Mar. 1980, at 30. (For a good review article on the whole field of "patent bibliometrics," see Bjørn L. Basberg, *Patents and the Measurement of Technological Change: A Survey of the Literature*, 16 RES. POL'Y 131 (1987).) Third, detailed case studies of particular industries demonstrate that patents played an important disclosure role in the development of many technologies. *See, e.g.*, Michael E.D. Koenig, *A Bibliometric Analysis of Pharmaceutical Research*, 12 RES. POL'Y 15, 28-29 (1983). And finally, some commentators have even suggested that the line between science and technology is becomingly increasingly blurred. One of the arguments made in support of this thesis is the cross-citation betweeen patents and scientific articles. F. Narin & E. Noma, *Is Technology Becoming Science?*, 7 SCIENTOMETRICS 369 (1985).

146. *See* KENNETH ARROW, THE LIMITS OF ORGANIZATION (1974) (the firm is a rational response to the limited information-processing capabilities of individuals); 2 HERBERT A. SIMON, MODELS OF BOUNDED RATIONALITY: BEHAVIORAL ECONOMICS AND BUSINESS ORGANIZATION 71-73 (1982) (introduction to series of papers on "The Economics of Information Processing"); OLIVER E. WILLIAMSON, THE ECONOMIC INSTITUTIONS OF CAPITALISM 51, 82-83 (1985) (discussion of importance of "informational asymmetry," where one party to a contract has more information than another; this is a key feature of transaction-cost economics); *see also* ALFRED D. CHANDLER, STRATEGY AND STRUCTURE (1962) and ALFRED D. CHANDLER, SCALE AND SCOPE (1990) (detailed historical/empirical evidence for the proposition that the organization of a firm is a rational response to the physical and informational demands of its particular business).

the significance of the inventor's contribution to technical knowledge.[147] And, importantly, those familiar with patents have long cited the disclosure theory as the fundamental rationale of the system.[148]

Under disclosure theory, the role of the Patent Office is to police the "contract" between society and the inventor. In fact, older cases often referred to patents as contracts in this sense.[149] Recall that the terms of this contract are that the inventor gains a monopoly good against society, in exchange for disclosure of the inventor's information. The Patent Office is then in a sense acting to insure the adequacy of the inventor's contribution—guaranteeing that the inventor is providing sufficient

147. The disclosure requirement in § 112 of the patent code can be seen in this connection as a requirement that the patentee submit information in a form that is transferable to other experts in the relevant field. *See infra* part VI. It should be noted, however, that empirical studies show that the value of pure technical information, unembodied in particular products or (especially) people, is lower than many economists once assumed. This is evident from a series of studies of the market for licensed technology, where returns to the licensor are usually quite low. The explanation is that the transfer of pure information—what the authors sometimes call the "blueprint" view of technology—is subject to a variety of problems, including difficulties of transmission and possibilities of intentional obfuscation and misleading disclosure. *See, e.g.*, DAVID J. TEECE, THE MULTINATIONAL CORPORATION AND THE RESOURCE COST OF INTERNATIONAL TECHNOLOGY TRANSFER 44 (1976) (transfer costs constituted 19% of total project costs in international projects studied); FAROK J. CONTRACTOR, INTERNATIONAL TECHNOLOGY LICENSING: COMPENSATION, COSTS, AND NEGOTIATION 105 (1981) (transaction costs averaged over $100,000 for licensing deals studied); FRANCIS BIDAULT, TECHNOLOGY PRICING: FROM PRINCIPLES TO STRATEGY 126, 127 (Brian Page & Peter Sherwood trans., 1989) (possibility of opportunism); David J. Teece, *Profiting from Technological Innovation: Implications for Integration, Collaboration, Licensing and Public Policy*, 15 RES. POL'Y 285, 294 (1986) (transaction costs affect ability to license efficiently); *see also* Robert P. Merges, Patents and Transaction Costs (Sept. 1992) (unpublished draft, on file with author).

148. *See, e.g.*, 11 WILLIAM HOLDSWORTH, A HISTORY OF ENGLISH LAW 424, 427 (1938) ("Under the old practice [before the eighteenth century] the consideration for the [patent] grant was the introduction into, and working of, a manufacture which was new to Great Britain. Under the new practice the new consideration is the written disclosure of the invention contained in the specification."); 1 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 41, at 61 (Boston, Little, Brown & Co. 1890) (stating that one of the "fundamental grounds" on which the patent grant rests is "[t]hat the inventor, having made such an invention as is entitled to the patent privilege, must communicate it to the public by publishing an accurate description of its character and uses"); 1 *id.* § 43, at 66 (speaking of the inventor's "reward for his disclosure" as the patent monopoly). Although the jury instructions by Lord Mansfield in *Liardet v. Johnson* (K.B. July 18, 1778), which stipulated that a patentee must file a full and detailed specification to qualify for a patent, are often said to have enshrined the disclosure theory in patent doctrine, recent scholarship suggests that the growing reliance on specifications reflected the need to distinguish one patent from another. *See* CHRISTINE MACLEOD, INVENTING THE INDUSTRIAL REVOLUTION: THE ENGLISH PATENT SYSTEM, 1660-1800, at 49-53 (1988); John N. Adams & Gwen Averley, *The Patent Specification: The Role of* Liardet v. Johnson, 7 J. LEG. HIST. 156 (1986).

149. *See, e.g.*, Century Elec. Co. v. Westinghouse, 191 F. 350 (8th Cir. 1911). *See also* 1 ROBINSON, *supra* note 148, § 40, at 58-59 ("[A patent] is a true contract, to the stipulations in which each party is bound with the same strictness as in any other contract, and which is to be interpreted in the same manner as other legal obligations." (footnote omitted)).

consideration for the contract. The Patent Office thus acts as society's agent in negotiating a disclosure agreement with an inventor. And nonobviousness is the standard society has given the Patent Office in evaluating which "deals" it considers worth making.[150]

Ultimately, then, the nonobviousness test determines the quantum of information an inventor must supply. To state the test in the terms developed above, it assures society that the information produced by the patentee is sufficient to overcome a good deal of uncertainty in some technical area. Stating the test this way directly links two important concepts in my analysis: the value of the information and the degree to which it clears up uncertainty. And it is consistent with contemporary thinking about information, which many economists have defined as that which overcomes uncertainty.[151]

VI. CONCLUSION

This article has explained the economic function of the nonobviousness standard of patentability: to encourage research that is highly uncertain. Various doctrinal features—including the "obvious-to-try" (non)standard, the irrelevance of in-house research to the obviousness of a firm's inventions, and the rationale for protecting both methodical and serendipitous inventions—have been organized and explained under the rubric of uncertainty. And a modest lowering of the standard has been proposed for research which is very expensive in the early stages.

This article has also highlighted several underappreciated facets of the patent system, which are made clear by an emphasis on the nonobviousness standard. First is the importance of the technological information contained in each patent specification, a feature which most clearly manifests the disclosure theory of the patent system. Second is the fact that patents may spur development more than invention per se.

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150. This way of examining the problem bears some resemblance to Vic Goldberg's reconceptualization of regulatory agencies. *See* Victor P. Goldberg, *Regulation and Administered Contracts*, 7 BELL J. ECON. 426 (1976); *cf.* Seymour v. Osborne, 78 U.S. (11 Wall.) 516, 533 (1871) (referring to patent as a governmentally-granted "franchise").

151. *See, e.g.*, MACHLUP, *supra* note 1, at 25-26 ("Economic decisionmakers as a rule seek more knowledge when they think that the cost of acquiring it will be less than the disadvantages due to their ignorance and uncertainty."); Stigler, *supra* note 88, at 224; J. Hirshleifer & John G. Riley, *The Analytics of Uncertainty and Information—An Expository Survey*, 17 J. ECON. LIT. 1377 (1979). There is a well-developed literature on jobseekers' investments in information to reduce uncertainty about possible openings and wages; see MACHLUP, *supra* note 1, at 78-99; J.J. McCall, *Economics of Information and Job Search*, 84 Q.J. ECON. 113 (1970).

Interestingly, this may in fact be such an important function that it more than outweighs the contribution patents make to incentives to invent.[152]

Throughout, the article has assumed that firms care what the standard of patentability is, and that minor changes in the standard can exert subtle marginal influences on the rate and direction of firm-level R&D. As the literature on the economics of particular patent doctrines expands, it is hoped the analysis presented here and in related works can serve as a rudimentary model for considering the economic consequences of specific patent rules.

152. The incentive-to-develop concept may show other benefits of the patent system, especially vis-à-vis alternative mechanisms for rewarding research such as the R&D tax credit. One advantage of patents over the R&D tax credit is that the latter benefit accrues as soon as research is begun, and therefore cannot be used to selectively reward more promising R&D. Patents are different. Especially when viewed as incentives to develop technology, patents have the advantage of not rewarding all research indiscriminately; they only reward potentially promising research (thanks to the nonobviousness standard). It is interesting to note in this connection that firms try to characterize as many expenses as possible as R&D-related for purposes of the R&D tax credit, and that the regulations on this matter are complex and difficult to administer. *See* J. CORDES, *A Survey of Research Findings on the R&D Tax Credit, in* THE R&D TAX CREDIT: ISSUES IN TAX POLICY AND INDUSTRIAL INNOVATION 5, 11 (1984). The nonobviousness standard in patent law eliminates the need to justify R&D expenses—the input to R&D—by measuring the technical merits of inventions—the output of R&D. While it is not irrational to advocate an indiscriminate tool such as the R&D tax credit, the details of this instrument, as well as the debate on it merits, might be enhanced by recognizing the complementary and in some ways superior features of patents.

ARTICLE

THE SEMICONDUCTOR CHIP PROTECTION ACT: PAST, PRESENT, AND FUTURE

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I. INTRODUCTION

Throughout its legislative history, the Semiconductor Chip Protection Act of 1984 ("SCPA" or "Chip Act") generated considerable interest among businessmen and lawyers. Substantial litigation was anticipated following its enactment in November 1984; however, eight years later, only one published case, *Brooktree v. Advanced Micro Devices, Inc.*, has been decided and the initial excitement has given way to largely academic interest.[1]

This result should astonish lawmakers who in 1979 heard testimony that piracy of chip designs was a widespread problem. Where have all the pirates gone? Have they been driven from the industry by the certainty that design protection exists? Perhaps some U.S. industry leaders, apprehensive of an untried and ambiguous law, have decided to pursue other defenses in their ongoing battle with domestic and foreign competition. While these factors would arguably reduce incidents of piracy or the filing of infringement claims, they cannot explain, without more, the dearth of litigation under the Chip Act.

This Article scrutinizes the SCPA and its legislative history. An examination of the law's interaction with semiconductor technology reveals good reason for the Chip Act's lack of use. The Article also looks to the future and speculates on where the SCPA is going. The discussion begins with an overview of the elements of an infringement claim under the Act and the reverse engineering defense. Part III considers the forces that drove the domestic industry to seek protection for its designs, and reviews early chip protection bills and the SCPA legislative hearings. Part IV sets forth background material for evaluating the SCPA by focusing on semiconductor design and fabrication technology and the mechanical reverse engineering process. Part V examines semiconductor technology against the backdrop of the SCPA and its legislative history. In so doing, it exposes the suspect foundation upon which the SCPA rests—the piracy model and its supporting examples. The Article concludes that:

(1) One of the central examples of chip piracy presented at the 1979 congressional hearing actually represented bona fide non-infringing reverse engineering rather than piracy.

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1. The SCPA is codified at 17 U.S.C. §§ 901-914 (1988). The only published case under the Act arose between plaintiff Brooktree Corporation and defendant Advanced Micro Devices, Inc. (AMD). In that case, a jury awarded Brooktree $26 million as damages for AMD's infringement under the SCPA and several patents. Greg Johnson, *Jury Awards Brooktree $26 Million in Damages*, L.A. TIMES, Sept. 29, 1990, at B2. The litigation resulted in the following published decisions: Brooktree Corp. v. Advanced Micro Devices, Inc., 705 F. Supp. 491 (S.D. Cal. 1988) (denying Brooktree's motion for a preliminary injunction); Brooktree Corp. v. Advanced Micro Devices, Inc., 757 F. Supp. 1088 (S.D. Cal. 1990) (denying AMD's motion for judgment notwithstanding the verdict (JNOV) and motion for new trial), *aff'd*, 977 F.2d 1555 (Fed. Cir. 1992).

(2) Semiconductor designs which existed at the time the SCPA was initially proposed, and upon which the SCPA qualitative piracy model is apparently based, were susceptible to slavish copying.[2]

(3) Advances in semiconductor technology since 1979 now make slavish copying largely impossible. At one time, copyists who appropriated layout designs via mechanical reverse engineering[3] could reproduce a functioning equivalent with minimal forward engineering effort.[4] However, with contemporary semiconductor processes, the copyist must expend substantial resources analyzing an appropriated mask work in order to successfully reproduce it.

(4) Early apprehension over the efficacy of the SCPA may now be dispelled in view of the successful application of the Act in *Brooktree* and the award of $26 million in damages.

(5) Even though the slavish copying problem has been halted, the inherent burdens in forward engineering a contemporary design mean that one who engages in "barren copying" and appropriates a competitor's layout but only invests enough forward engineering to produce a functioning chip, may receive the protection of the Chip Act's reverse engineering defense. This Article questions the fairness of barren copying, but notes that proper application of the Act's infringement test could still provide a remedy in certain cases.

(6) With advances in semiconductor hardware and software design tools, the SCPA will likely find application combating a newly emerging form of slavish copying. Ironically, it appears that technological advances, responsible for ending the slavish copying problem, may once again provide "unskilled" copyists with the capability to slavishly copy a semiconductor layout design.

(7) Finally, several issues must be resolved before the SCPA can find broader application. The most significant of these is administrabilty of the Act's "substantial identicality" infringement test. The author contends that "substantial identicality" was not intended as a shorthand for "no infringement" but is an acknowledgment by Congress of the striking visual similarities inherent between semiconductor designs having the same form, fit, and function.

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2. Slavish copying is the ability to create a functioning chip from the photographic copying of mask works without additional engineering. *See infra* part V.B.

3. Mechanical reverse engineering is the process of starting with a known product and working backward to deduce the process which aided in its development or manufacture. *See infra* part V.B.

4. Forward engineering is the orderly process of conceiving and designing a semiconductor design. It progresses from the system level (market study) through function block, logic schematic, circuit schematic, and layout stages. *See infra* part IV.A.

II. OVERVIEW OF THE SEMICONDUCTOR CHIP PROTECTION ACT

A. Elements of an SCPA claim

The SCPA provides intellectual property protection for the costly and time-consuming process of designing the circuitry embodied in semiconductor integrated circuits ("chips"). Under the Act, protection is extended to "a mask work fixed in a semiconductor chip product."[5] Mask works[6] are used in semiconductor fabrication much like stencils to create different layers of structure which collectively comprise a chip's electronic circuitry.[7]

The SCPA extends protection only to original mask works. Designs that are commonplace in the semiconductor industry, or variations of such designs that—taken as a whole—are not original are ineligible for protection.[8]

Under the Act, a mask work owner has the exclusive rights—or may grant another the rights—to reproduce the mask work and import or distribute a semiconductor chip which embodies the mask work.[9] Protection, lasting for ten years, attaches when the mask work is either registered with the Copyright Office or commercially exploited, whichever occurs first.[10]

B. The Reverse Engineering Defense

The SCPA reverse engineering defense, codified at 17 U.S.C. § 906,[11] is the principal limitation on a mask work owner's exclusive right to prevent others from reproducing, importing, or distributing the original mask work. Under § 906(a)(1), a competitor may reproduce a mask work for the purpose of analyzing it.[12] This section is analogous to copyright's

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5. 17 U.S.C. § 902(a)(1) (1988).
6. A mask work is defined under the Act as:
   a series of related images, however fixed or encoded—
   (A) having or representing the predetermined, three dimensional pattern of metallic, insulating, or semiconductor material present or removed from the layers of a semiconductor chip product; and
   (B) in which series the relation of the images to one another is that each image has the pattern of the surface of one form of the semiconductor chip product.

Id. § 901(a)(2).

7. *See generally infra* part IV (discussing semiconductor design and fabrication).
8. 17 U.S.C. § 902(b) (1988).
9. *Id.* § 905.
10. *Id.* § 904(a)-(b).
11. *Id.* § 906.
12. Notwithstanding the provisions of § 905, it is not an infringement of the exclusive rights of the owner of a mask work for—
    (1) a person to reproduce the mask work solely for the purpose of teaching, analyzing, or evaluating the concepts or techniques embodied in the mask

fair use doctrine[13] in that it allows a competitor to reproduce a protected work for research or educational purposes. However, the SCPA enables competitors to go beyond merely studying protected works. Section 906(a)(2) permits competitors to incorporate the results of their reverse engineering analysis into subsequent *original* mask works.[14]

Section 906(a)(2) reverse engineering "carves out" a substantial limitation to a mask work owner's exclusive rights. So long as a competitor incorporates § 906(a)(1) reverse engineering analysis into an *"original"* mask work, it is free to reproduce elements of a protected mask work in a new design without fear of infringing under the Act.

1. *DEFINING A § 906(A)(2) "ORIGINAL" MASK WORK*

Since a mask owner's rights under the Chip Act are limited by a competitor's right to reverse engineer, exactly what constitutes "reverse engineering" is critical to an SCPA claim. Although a lawful reverse engineering defense does *not* immunize a defendant from liability, it clearly can present a formidable obstacle to successfully proving infringement under the Act.

Giving content to "reverse engineering protection" depends on the interpretation of "original mask work" in § 906(a)(2). Unfortunately, the statute supplies no guidance in this area. However, the Act's legislative history contains two sources of information that clarify its meaning: the House Report accompanying H.R. 5525,[15] the bill from which the SCPA

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work or the circuitry, logic flow, or organization of components used in the mask work . . . .

Id. § 906(a).

13. Notwithstanding the provisions of section 106, the fair use of a copyrighted work, including such use by reproduction in copies or phonorecords or by any other means specified by that section, for purposes such as criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research, is not an infringement of copyright. In determining whether the use made of a work in any particular case is a fair use the factors to be considered shall include—

(1) the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;

(2) the nature of the copyrighted work;

(3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and

(4) the effect of the use upon the potential market for or value of the copyrighted work.

Id. § 107.

14. "[I]t is not an infringement . . . for . . . a person who performs the analysis or evaluation described in paragraph (1) to incorporate the results of such conduct in an original mask work which is made to be distributed." *Id.* § 906(a).

15. The House Report accompanying the SCPA was taken from the report that accompanied H.R. 5525. That bill was approved by the House Committee on the Judiciary on May 15, 1984, and passed by the full House on June 11, 1984. *See* HOUSE COMM. ON THE JUDICIARY, SEMICONDUCTOR CHIP PROTECTION ACT OF 1984, REPORT TO ACCOMPANY H.R.

was largely derived, and the Senate[16] and House[17] Explanatory Memoranda.

2. *THE HOUSE JUDICIARY COMMITTEE REPORT*

One interpretation of "original mask work" is the literal one conveyed by a plain reading of the text. However, must a mask work be "original" in this dictionary sense?[18] The answer is clearly "no." One commentator has argued against construing the House Report's originality requirement as meaning that "no part of the defendant's work may be copied from that of the plaintiff's, but only that defendant's work must also contain matter which is original to the defendant."[19] This suggests what "original" is not, but stops short of providing an analytic basis for determining what an original mask work is.

However, such an analytical framework exists in the House Report. The Committee framed its discussion of reverse engineering around two "*polar*" types of reverse engineering: "photographic reproduction of the layout of the original chip and direct incorporation thereof into a second chip"; and "making improvements on, or at least alternatives to, an existing chip and incorporating substantial but not identical parts of its design into the second chip."[20] The Committee stated its intent "to permit and encourage the second type of conduct,"[21] thereby implying that it would prohibit the first type of behavior: reproducing an original mask work and directly incorporating it into a second chip.

The notion that the SCPA allows the second type of conduct, the substantial appropriation of and improvement upon an original mask work, receives further support from the Report:

> It is the intent of the Committee to permit, under the reverse engineering limitation, the "unauthorized" creation of a second mask work whose layout, in substantial part, is similar to the layout of the protected mask work—if the second mask work was the product of substantial study and analysis, and not the mere result of plagiarism accomplished without such study or analysis.[22]

5525, H.R. REP. NO. 781, 98th Cong., 2nd Sess. (1984), *reprinted in* 1984 U.S.C.C.A.N. 5750 [hereinafter H.R. 5525 REP.].

16. 130 CONG. REC. 28,959 (1984) (explanatory memorandum to the Mathias-Leahy Amendment to S. 1201). The House and Senate Memoranda are nearly identical.

17. 130 CONG. REC. 30,945 (1984) (explanatory memorandum of the Senate Amendment to H.R. 6163, title III, as considered by the House of Representatives) ("Kastenmeier Explanatory Memorandum").

18. *Webster's Ninth New Collegiate Dictionary* (1983) defines the adjective "original" as "1: of, relating to, or constituting an origin or beginning; 2a: not secondary, derivative, or imitative b: being the first instance or source from which a copy, reproduction, or translation is made; 3: independent and creative in thought or action."

19. 3 MELVILLE B. NIMMER & DAVID NIMMER, NIMMER ON COPYRIGHT § 18.06[D], at 18-32.1 (1992).

20. H.R. 5525 REP., *supra* note 15, at 22.

21. *Id.*

22. *Id.*

This suggests a two-step inquiry. First, if it is determined that a competitor has substantially studied and analyzed a protected mask work to produce its own chip, i.e. valid reverse engineering, that chip does not infringe even if it is substantially similar to the mask owner's. However, if the competitor's design incorporates identical parts of the protected design, infringement may yet be found.

3. *THE CONGRESSIONAL EXPLANATORY MEMORANDA AND THE NEW SUBSTANTIALLY IDENTICAL STANDARD*

House and Senate Explanatory Memoranda, developed after the House Judiciary Report, corroborate this interpretation. They also provide additional guidance for what constitutes infringement:

> The end product of the reverse engineering process is not an infringement, and itself qualifies for protection under the Act, if it is an original mask work, as contrasted with a substantial copy. If the resulting semiconductor chip product is not substantially identical to the original, and its design involved significant toil and investment so that it is not a mere plagiarism, it does not infringe the original chip, even if the layout of the second chip is, in substantial part, similar. As noted in the Senate report, the courts are not likely, as a practical matter, to find it unduly difficult to draw the line between reverse engineering and infringement, because the additional work required to come within the privilege established by § 906(a) will ordinarily leave a "paper trail."
>
> Of course, apart from the foregoing, the amendment, like both bills, incorporates the familiar copyright principle of substantial similarity. Although, as a practical matter, copying of an insubstantial portion of a chip and independent design of the remainder is not likely, copying of a material portion nevertheless constitutes infringement. This concept is particularly important in the semiconductor chip industry, where it may be economical, for example, to copy 75% of a mask work from one chip and combine that with 25% of another mask work, if the copied parts are transferable modules, such as units from a cell library.
>
> As the Senate report notes, no hard and fast percentages govern what constitutes a "substantial" copying because substantial similarity may exist where an important part of a mask work is copied even though the percentage copied may be relatively small. Nonetheless, mask work owners are protected not only from wholesale copying but also against piecemeal copying of substantial or material portions of one or more mask works.[23]

This excerpt from the Explanatory Memoranda introduces the infringement test of "substantial identicality." As described, this test applies only when there has been a case of reverse engineering, i.e., where the defendant produces a *paper trail* that its design involved *substantial toil* and *investment*. In that instance, the copyist's chip, even if

23. 130 CONG. REC. 28,960 (1984).

substantially similar to a protected mask work from which it derives, does not infringe so long as it is not *"substantially identical."*

The memorandum further states that "apart from the foregoing, the amendment . . . incorporates the familiar copyright principle of substantial similarity." In other words, when a copyist cannot prove it reverse engineered, its chip infringes the mask owner's if it is substantially similar. Reverse engineering is an affirmative defense.[24] The defendant bears the burden of persuasion and of presenting evidence that its design required substantial toil and investment.[25]

III. DEVELOPMENTS LEADING TO PASSAGE OF THE SCPA

A. Industry Forces and the Perceived Need for Protection Against Unfair Copying

1. *SEMICONDUCTOR INDUSTRY PRODUCT CYCLES*

Semiconductor industry products share a common life and pricing cycle. First, a pioneer introduces an innovative product which creates a new market. Early chips are handsomely priced so that the manufacturer can recoup its investment as rapidly as possible. Later, as the manufacturer becomes more efficient it cuts prices to expand its market and discourage competition. Nonetheless, second-source products—chips electrically and mechanically compatible with the pioneering product—eventually appear on the market. The arrival of competition precipitates further rounds of price cuts.[26]

2. *THE BENEFITS OF COPYING*

The integrated circuit industry arose largely without the benefit of patent[27] or copyright[28] protection for its designs. Pioneering companies had long believed that many second-source products were the result of unfair copying. However, the need for chip protection took on a sense of urgency in the face of two developments. First, the cost of marketing and designing a state-of-the-art chip design began to skyrocket. By 1983, independent development of a cutting-edge design could cost anywhere

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24. H.R. 5525 REP., *supra* note 15, at 23.

25. Leo J. Raskind, *Reverse Engineering, Unfair Competition, and Fair Use*, 70 MINN. L. REV. 385, 398-99 (1985).

26. This cycle has been dubbed "learning-curve" pricing. *See* Robert W. Kastenmeier & Michael J. Remington, *The Semiconductor Chip Protection Act of 1984: A Swamp or Firm Ground?*, 70 MINN. L. REV. 417, 452-53 (1985).

27. Patent law does not protect semiconductor layouts because the creativity involved ordinarily does not meet the patent requirements of being new, useful, and nonobvious. H.R. 5525 REP., *supra* note 15, at 3.

28. Mask works are utilitarian articles and, therefore, fall outside the scope of copyright protection. *Id.* at 15.

from $40 million[29] to $50 million,[30] but could be copied for $50,000 to $100,000 in three to six months.[31] As a result, pioneering companies facing competition from copycat imitators were forced to cut prices before they could recover their investment and gain learning curve efficiencies. Second, U.S. firms began to perceive that time-saving and cost-saving advantages of unfair copying were the primary explanation for sales and market share losses to foreign competition.[32] As one commentator stated in 1985:

> The domestic industry had pioneered the standard random access memory (RAM) chip, which became a staple product of the industry by serving as the operating basis for a variety of consumer products from personal computers to video cassette recorders. By copying this chip product, the Japanese competitors were able to enter the United States market without incurring the design and marketing costs. Given the superior quality control of the Japanese firms, they were able to offer a better product at a lower price. An increased market share and a higher ranking in the industry statistics followed.[33]

3. *EARLY ATTEMPTS AT LEGAL PROTECTION*

Prior to 1977, the Copyright Office registered integrated circuit designs submitted in the form of layout drawings or masks, but advised copyright applicants that, in its opinion, such registrations did not cover the final chip product.[34] In 1977, Intel Corporation attempted to register

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29. Nadine Cohodas, *Special Report: Technology and the Law—New Technology Puts Strain on Old Laws*, 42 CONG. Q. 135 (1984).

30. *Copyright Protection for Imprinted Design Patterns on Semiconductor Chips: Hearings on H.R. 1007 Before the Subcomm. on Courts, Civil Liberties and the Admin. of Justice of the House Judiciary Comm.*, 96th Cong., 1st Sess. 135 (1979) [hereinafter *H.R. 1007 Hearings*] (statement of Richard H. Stern). If 1983 estimates were correct, then it is likely that development costs for cutting-edge designs today reach or exceed $100 million. *See* H.R. 5525 REP., *supra* note 15, at 2.

31. *The Semiconductor Chip Protection Act of 1983: Hearings on S. 1201 Before the Subcomm. on Patents, Copyrights and Trademarks of the Senate Judiciary Comm.*, 98th Cong., 1st Sess. 66, 75-76 (1983) [hereinafter *S. 1201 Hearings*] (statement of Thomas F. Dunlap, General Counsel, Intel Corp.); *id.* at 78-79 (statement of Dr. Christopher K. Layton, Vice-President, Intersil, Inc.).

32. *See H.R. 1007 Hearings*, *supra* note 30, at 31-33 (statement of Andrew Grove, President, Intel Corp.).

One study showed that in 1978 U.S. firms occupied five of the top ten industry rankings by volume of sales. In that year, the Japanese firms ranked third, seventh, and eighth. By 1984, the Japanese firms had moved into the second, fourth, fifth, and seventh places. Raskind, *supra* note 25, at 413 (citing MICHAEL BORRUS, REVERSING ATTRITION: A STRATEGIC RESPONSE TO THE EROSION OF U.S. LEADERSHIP IN MICROELECTRONICS (1985) (Working Paper, Berkeley Roundtable on the International Economy)).

33. Raskind, *supra* note 25, at 413 (citing *S. 1201 Hearings*, *supra* note 31, at 82 (statement of F. Thomas Dunlap, Jr., General Counsel, Intel Corp.)).

For a further discussion of Japanese dominance of the RAM market, see Kathleen K. Weigner, *Is the Sun Setting on the U.S. Semiconductor Industry?*, FORBES, June 17, 1985, at 111.

34. "The Copyright Office historically has refused, and presently does refuse, to register claims to copyright in the design or layout of . . . and the . . . chips themselves. . . .

several new integrated circuit designs by submitting the designs to the Copyright Office in chip form. The Office refused registration on the ground that the chip's artistic features embodied in the chip were not conceptually separated from their utilitarian aspects.[35] Thus, the designs failed to qualify as copyrightable subject matter in that they did not meet the definition of pictorial, graphic or sculptural works under 17 U.S.C. § 101.[36] Intel filed a mandamus action to compel registration[37] but dismissed the lawsuit without prejudice when H.R. 14,293, a bill extending the Copyright Act to semiconductor designs, was introduced.[38] The bill proposed to protect chip designs by adding photographic mask works to the list of copyrightable subject matter set forth in 17 U.S.C. § 102.[39] H.R. 14,293 contained no reverse engineering provision, but impliedly incorporated the Copyright Act's fair use provision. No action was taken on H.R. 14,293 before the 95th Congress adjourned.

Courts have consistently refused to extend copyright to useful articles as such." *Copyright Protection for Semiconductor Chips: Hearings on H.R. 1028 Before the Subcomm. on Courts, Civil Liberties, and the Admin. of Justice of the House Comm. on the Judiciary*, 98th Cong., 1st Sess. 88 (1983) [hereinafter *H.R. 1028 Hearings*] (statement of Dorothy Schrader, Associate Register of Copyrights for Legal Affairs).

35. H.R. 5525 REP., *supra* note 15, at 15. *See also S. 1201 Hearings, supra* note 31, at 29 (1983) (statement of Dorothy Schrader, Associate Register of Copyrights for Legal Affairs).

36. "Pictorial, graphic and sculptural works" include two-dimensional and three-dimensional works of fine, graphic, and applied art, photographs, prints and art reproductions, maps, globes, charts, diagrams, models, and technical drawings, including architectural plans. Such works shall include works of artistic craftsmanship insofar as their form but not their mechanical or utilitarian aspects are concerned; the design of a useful article, as defined in this section, shall be considered a pictorial, graphic, or sculptural work only if, and only to the extent that, such design incorporates pictorial, graphic, or sculptural features that can be identified separately from, and are capable of existing independently of, the utilitarian aspects of the article.

17 U.S.C. § 101 (1988) ("Definitions").

37. Intel Corp. v. Ringer, No. C77-2848 (N.D. Cal. filed Oct. 10, 1978).

38. 124 CONG. REC. 36,628 (1978). The bill was introduced and the suit was discontinued on October 12, 1987.

39. The subject matter of copyright is listed under 17 U.S.C. § 102(a). That section protects "original works of authorship" which includes the following categories: "(1) literary works; (2) musical works, including any accompanying words; (3) dramatic works, including any accompanying music; (4) pantomimes and choreographic works; (5) pictorial, graphic, and sculptural works; (6) motion pictures and other audiovisual works; and (7) sound recordings."

B. An Overview of the SCPA Legislative History

1. *THE 1979 SAN JOSE HEARING*

a. Dissension

H.R. 1007,[40] identical to H.R. 14,293, was introduced during the next congress. Members of a House Judiciary Subcommittee held a hearing on April 16, 1979, to solicit testimony from industry representatives.[41] Subcommittee members were surprised to find sharply divided industry opinion on whether copyright protection for chip designs was beneficial. Opponents of the bill feared that the legislation would outlaw the industry practice of reverse engineering;[42] they also expressed doubt whether protection would deter foreign copying of U.S. companies' chips and sales of them in other countries.[43] Several industry representatives commented on the short advance notice they had been given to prepare for the hearing.[44] One industry supporter of H.R. 1007 responded to a lawmaker's inquiry into the industry's differing views on chip protection by openly accusing a company opposed to the bill of having pirated its designs in the past.[45] Stymied by the industry infighting, legislative chip protection efforts came to a halt. No meaningful congressional action was taken for the next three and one-half years.[46]

b. The 1979 San Jose Hearing Concept of Piracy and Reverse Engineering[47]

At the San Jose Hearing, protectionist sentiment was voiced concerning the moral bankruptcy[48] of those who engaged in wholesale copying of their competitor's designs. Such pirates, it was explained, would make blowup photographs of a chip's top layer and copy the

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40. *H.R. 1007 Hearings, supra* note 30.

41. *Id.*

42. *Id.* at 57 (statement of James M. Early, Director, Fairchild Camera & Instrument Corp.).

43. *Id.* at 51-52 (statement of John Finch, National Semiconductor Corp.).

44. *Id.* at 62 (statement of Congressman Kastenmeier).

45. Intel Corporation accused one competitor of having pirated its 8K-bit programmable reload memory chip and its 8080 microprocessor. *See id.* at 72.

46. After the H.R. 1007 hearings, chip protection efforts by the 96th Congress ceased. The 97th Congress introduced chip protection bills in the House and Senate. *See* H.R. 7207, 97th Cong., 2d Sess., 128 CONG. REC. 26,129 (1982) (introduced by Rep. Edwards on Sept. 29, 1982); S. 3117, 97th Cong., 2d Sess., 128 CONG. REC. 32,356 (1982) (introduced by Sen. Mathias on Dec. 18, 1982). These bills were referred to each branch's Judiciary Committee and no further action was taken.

47. See *infra* part IV.B.1 for a discussion of the legislative history piracy and reverse engineering models.

48. "[V]arious members of the industry . . . have resorted to copying . . . . [O]ur company . . . has never done it . . . . [Only t]he lesser novelty segment of the industry feels it necessary to resort to it periodically." *H.R. 1007 Hearings, supra* note 30, at 28 (statement of Andrew Grove, President, Intel Corp.).

photo line-by-line.[49] "Line-by-line" copying, however, was distinguished from the acceptable practice of "reverse engineering."[50] Unfortunately, only one H.R. 1007 witness defined reverse engineering for the subcommittee.[51] That definition, consistent with copyright's fair use provision, was highly restrictive; it merely allowed a competitor to study and learn from another's design.[52]

2. *THE 1983 HOUSE AND SENATE HEARINGS*

a. Harmony

In 1983, as in 1979, Intel Corporation led the renewed fight for design protection. By rallying the 57-member Semiconductor Industry Association ("SIA"),[53] S. 1201[54] and H.R. 1028,[55] bills similar to H.R. 1007, were introduced. Both bills sought to protect chip designs by creating a new copyrightable subject matter category for mask works. The House bill contained several provisions drafted exclusively to cover mask works.[56] However, an explicit reverse engineering right was not among them. H.R. 1028 implicitly relied on the Copyright Act's fair use provision to confer such a right. By contrast, the Senate bill explicitly conferred a "right of reverse engineering,"[57] but it limited reverse-engineering to analysis and evaluation of protected mask works.

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49. *Id.* at 26-27 (statement of L.J. Sevin, President, Mostek Corp.).

50. "We have no quarrel with [reverse engineering]. It is fair game." *Id.* at 27 (statement of L.J. Sevin, President, Mostek Corp.).

51. "We certainly reverse engineer, as do all of our competitors, which is defined as looking in great detail at competitive chips and utilizing either in future designs or improved designs, the things we learn from those chips. It is standard industry practice." *Id.* at 69 (statement of John Finch, National Semiconductor Corp.).

52. This concept of reverse engineering is also consistent with the definition advanced in Mostek Corp. v. Inmos Ltd., 203 U.S.P.Q. (BNA) 383, 386 (N.D. Tex. 1978). There, reverse engineering was described as "analyzing a competitor's product to discover its design and fabrication processes."

53. The American Electronics Association supported H.R. 1007. The SIA neither took a stand nor was represented at the 1979 hearing. *See H.R. 1007 Hearings, supra* note 30, at 73.

54. S. 1201, 98th Cong., 1st Sess., 129 CONG. REC. 10,974 (1983).

55. H.R. 1028, 98th Cong., 1st Sess., 129 CONG. REC. 937 (1983).

56. These new provisions included a ten-year term of protection, modified exclusive rights for mask work owners, and a compulsory licensing provision for innocent infringers. *See id.*

57. This explicit right was to be created by adding 17 U.S.C. § 119 as follows:

> (a) In the case of mask works, the exclusive rights provided by section 106 are subject to a right of reverse engineering use under the conditions specified by this section.
>
> (b) It is not an infringement of the rights of the owner of a copyright on a mask work to reproduce the pattern on one or more masks or in a semiconductor chip product solely for the purpose of teaching, analyzing, or evaluating the concepts or techniques embodied in the mask or semiconductor chip product, or the circuit schematic, logic flow, or organization of components utilized therein.

b. The 1983 Hearings' Concept of Piracy and Reverse Engineering

Although SIA spokesmen at the House[58] and Senate[59] hearings testified to the ruinous economic effects of chip piracy, their statements failed to elaborate on the slavish copying piracy model presented in 1979. They did, however, corroborate the need to preserve the industry practice of reverse engineering. Several qualitative reverse engineering models were also presented. One witness testified that competitors should be allowed to reverse engineer chips to extract their circuit schematics, but then be required to forward engineer beyond that point.[60] Another witness stated that valid reverse engineering covered forward engineering design and manufacturing enhancements.[61]

Quantitative cost[62] and record-keeping[63] criteria were suggested as means of delimiting and proving reverse engineering. However, little testimony was given in the way of *technical criteria* for distinguishing forward engineering design and manufacturing improvements. Unfortunately, these qualitative and quantitative reverse engineering models, given by an unopposed and unified SIA, were only superficially probed by the legislators.

c. The *Sui Generis* Issue

Legislative hearings on chip protection concentrated on whether the Copyright Act should be used to protect designs embodied in

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58. *H.R. 1028 Hearings, supra* note 34.

59. *S. 1201 Hearings, supra* note 31.

60. A reverse engineering firm should be allowed to analyze the chip, draw a circuit schematic of the chip, and then layout a different pattern. This pattern could be used to fabricate a version of the semiconductor chip which is functionally equivalent to the original chip but has different visual patterns on it.

H.R. 1028 Hearings, supra note 34, at 27-28 (statement of F. Thomas Dunlap, Jr., General Counsel, Intel Corp.).

"In chip language, that would mean that a fair reverse engineering person has the right to analyze the chip, understand the chip, and come up with the circuit schematic." *S. 1201 Hearings, supra* note 31, at 66 (statement of F. Thomas Dunlap, Jr., General Counsel, Intel Corp.).

"The bare fact of taking the chip and photographing the layer and etching it, and so forth, to draw out this schematic is not prohibited by the bill. . . . But if you take it off, get the schematic, and then make a different picture, that would be reverse engineering." *Id.* at 84.

61. The legitimately reverse engineered chip would be a better performing product or a smaller product and therefore less expensive to manufacture. *S. 1201 Hearings, supra* note 31, at 83 (statement of Dr. Christopher K. Layton, Intersil Inc.).

62. "Now, the difference between reverse engineering and direct copying is that reverse engineering is going to cost about 25 percent of the original design and it's also going to advance the state of the art." *H.R. 1028 Hearings, supra* note 34, at 34 (statement of F. Thomas Dunlap, Jr., General Counsel, Intel Corp.).

63. "When there is a legitimate job of reverse engineering, there is a very big paper trail, there's computer simulations, there's all kind of time records, people who spent an enormous amount of time understanding and figuring out how to make the design." *Id.* at 36.

semiconductor chips. Publishing,[64] data processing,[65] computer manufacturing,[66] and Copyright Office representatives[67] all expressed doubts as to the wisdom of extending the Copyright Act to this end. One witness contended that reverse engineering did not fit within the copyright concept of "fair use" without a wholesale distortion of that doctrine's role and parameters.[68]

It was the testimony of Emory University Law Professor L. Ray Patterson, however, that Congress found persuasive.[69] Conceding from a constitutional standpoint that copyright is an author's right, Patterson observed that the Supreme Court had ruled that copyright's primary purpose is to benefit the public.[70] However, Patterson noted that copyright had historically inured to the benefit of publishers. This conceptual weakness between form and function, he argued, would be further eroded if explicitly utilitarian articles, such as mask works, were to become copyrightable subject matter.[71]

In April 1984, the House substituted H.R. 5525[72] for H.R. 1028. The new bill added a separate, independent, and *sui generis* chapter to 17 U.S.C. exclusively to protect mask work designs. H.R. 5525 included a reverse engineering provision, an optional notice requirement, and mandatory registration within two years of first commercialization. The Senate later yielded on the *sui generis* issue and made extensive incorporations of H.R. 5525 into its bill.[73] Both Houses of Congress added Explanatory Memoranda and passed the legislation unanimously. The President signed the SCPA into law on November 9, 1984.[74]

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64. *S. 1201 Hearings, supra* note 31, at 102-11 (statement of Jon Baumgarten, Counsel for the Association of American Publishers).

65. *Id.* at 101-02 (statement of Ronald Palenski, Association of Data Processing Organizations).

66. *Id.* at 99-101 (statement of A.G.W. Biddel, Computer and Communications Industry).

67. *Id.* at 18-25 (statement of Dorothy Schrader, Associate Register of Copyrights for Legal Affairs).

68. *Id.* at 104 (statement of Jon Baumgarten); *see also H.R. 1007 Hearings, supra* note 30, at 57 (statement of James M. Early, Director, Fairchild Camera & Instrument Corp.) (voicing fear that such an extension would distort traditional copyright principles, lead to interpretation problems, and erode some of the exclusive rights given to owners of conventional copyrights).

69. *See* H.R. 5525 REP., *supra* note 15, at 6.

70. Sony Corp. of Am. v. Universal City Studios, Inc., 464 U.S. 417, 429 (1984).

71. *H.R. 1028 Hearings, supra* note 34, at 51-54.

72. H.R. 5525 REP., *supra* note 15, at 5-7.

73. *See* 130 CONG. REC. 28,966-71 (1984) (Senate floor statements).

74. The Semiconductor Chip Protection Act was contained under title III of H.R. 6163, a five-title bill, and became Pub. L. 98-620, 98 Stat. 3335 (1984).

IV. AN OVERVIEW OF SEMICONDUCTOR DESIGN AND PROCESS TECHNOLOGY

This section provides background on semiconductor design and process engineering that is useful in appreciating the legal arguments drawn in this article.[75]

A. Forward Engineering a Semiconductor Design

1. *SYSTEMS LEVEL DESIGN*

Integrated circuit design has traditionally been a lengthy labor-intensive process which is inherently subject to error.[76] A new chip design commences with a market study of the functions that potential customers will purchase. The functions are then analyzed by a system designer to determine if they can be satisfied by an integrated circuit. When a design is large enough, the designer has an additional degree of freedom of partitioning the functions into a family of chips to lower the total cost of the system.[77]

2. *FUNCTIONAL BLOCK DESIGN*

The specifications of chips, such as a complex microprocessors, are defined through the use of block diagrams.[78] These diagrams depict high level modules or functional blocks such as arithmetic logic units (ALUs)[79] and shift registers.[80]

One of the most important features of the block diagram is its use as a floor plan for the chip. The floor plan expresses the spatial relationship of the high level functional modules to one another. The area on the floor plan allocated to each functional block is determined largely by estimating the number, type, and size of transistors in the block along with their interconnections.[81]

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75. For a general discussion of semiconductor fabrication process see BILL PLETSCH, INTEGRATED CIRCUITS: MAKING THE MIRACLE CHIP (2d ed. 1985).

76. This has been changing, however, as the use of semicustom and custom computer aided engineering ("CAE") systems has been rapidly expanding in recent years.

77. Smaller chips are easier to test and design and produce a greater yield but their use must be balanced against the higher cost of handling, testing, and packaging a larger number of chips. MOS INTEGRATED CIRCUITS 331-33 (William M. Penney & Lillian Lau eds., 1972).

78. *Id.* at 333.

79. An ALU is a section of the central processing unit (CPU) that makes arithmetic and logical comparisons and performs arithmetic functions. BRIAN SPINKS, INTRODUCTION TO INTEGRATED-CIRCUIT LAYOUT 151 (1985).

80. Shift registers displace a binary quantity one or more places to the right or left. With binary expressions it is the equivalent of multiplying or dividing the expression by two to the power of the number of spaces shifted. *Id.* at 167.

81. The number of transistors is estimated in turn from the complexity of the function to be performed by the block.

Some of the major factors that influence a floor plan are the data path,[82] modules that must share a common bus,[83] the number of signal interconnections between functional modules,[84] and the presence of a large memory block[85] of RAM[86] or ROM.[87] The final product must also mechanically[88] and electrically interface[89] with the remainder of the system.

3. *LOGIC DESIGN*

After the block diagrams are completed, the logic, circuit, and layout representation of each functional module is successively engineered. The first step is translation of the high level modules into corresponding collections of logic gates, each of which performs a simple logical operation.[90] Representations of these gates and their connections are graphically entered into a computer database to create a logic

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82. For example, in the central processing unit ("CPU") the floor plan is determined by the natural data path. The CPU is the brain of the computer. It fetches, decodes, and executes program instructions and maintains the status of results. *Id.* at 155.

83. Typical buses include power, ground, and signal buses. Two power busses, commonly named Vss and Vdd, provide all of the power used by an integrated circuit. *Id.* at 169-70. A signal bus consists of a collection of functionally related signals. Topologically, most of the circuitry is fabricated beneath the buses. *Id.* at 112.

84. Space must be allocated in the floor plan for interconnection routing between functional blocks. While interconnects are preferably in metal, space limitations may require use of other types of materials, such as polysilicon. THOMAS M. FREDERIKSEN, INTUITIVE IC CMOS EVOLUTION 79-80 (1984). This is called the Poly/Metal crossover, a conventional technique in the industry. *See* Eric W. Petraske, *Technical Overview, in* THE SEMICONDUCTOR PROTECTION ACT OF 1984, at 3 (Jon A. Baumgarten ed., 1984).

85. Memory blocks often dominate a floor plan and cannot be shrunk further. Unless speed is a critical factor, there may be little incentive to engineer decreases in the size of other modules if overall chip size will not be substantially reduced. SPINKS, *supra* note 79, at 122.

86. RAM (Random Access Memory) is:

> a static or dynamic memory device that data can be written into or read from a specific location. The specific RAM location is selected by the address applied via the address bus and control lines. Data are stored in such a manner that each bit of information can be retrieved in the same length of time. This has come to mean, by common usage, read/write memory.

Id. at 166.

87. ROM (Read Only Memory) is memory in which information is permanently stored at the time of manufacture. The information is available at any time, but cannot be modified during normal system operation. Fixed instructions are often embedded in ROM. *Id.* at 163-66.

88. "Second sourcing," whereby a semiconductor manufacturer designs a chip to be fungible with a commercially successful design, is common in the industry. The second source chip must be physically compatible with the original chip. SABURO MUROGA, VLSI SYSTEM DESIGN 41 (1982).

89. The second source chip must also operate the same equipment and perform the same functions as the original chip. For example, a timing clock, often used in dynamic logic networks, presents problems of both physical and electrical compatibility. It requires significant power and floor plan area and must have minimal unnecessary interconnect. SPINKS, *supra* note 79, at 48-49.

90. Logic gates such as AND, OR, and NOT in combination can create any Boolean mathematical operation. *Id.* at 39.

diagram or logic schematic. The logic diagram is then translated into a "netlist"[91] which contains the complete description and interconnection of all the logic gates in the schematic.[92]

a. Logic Simulation/Timing Verification

Computer simulations are then performed on the netlist to verify that the logic diagram is correct and that the circuits are "timed" properly. Timing verification is performed to detect portions of the design that could produce logic "race" conditions.[93] With increasing complexity of designs, timing verification has become much more difficult.[94]

b. Circuit Testing/Test Pattern Generation

A chip must be tested before being sold.[95] Test programs must be generated and evaluated to ensure adequate verification of the chip design as well as detection of chips with manufacturing defects.[96] The effort required to create these programs depends on the complexity of the chip and the ease of visibility of the chip's inner workings from its external connections.[97] To provide increased visibility, designers now routinely add dedicated on-chip self-testing circuitry to facilitate fault grading and testing of the final product.

For Very Large Scale Integration (VLSI),[98] correct circuit design must be verified by using complex circuit simulation software.[99] In a process known as fault grading, testing programs can evaluate the coverage of simulation test patterns by determining the percentage of faults which would be uncovered by a given set of patterns.[100] Fault simulation engines employing multiple high-speed microprocessors are

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91. FREDERIKSEN, *supra* note 84, at 142.

92. *Id.* at 142.

93. Race conditions occur when a circuit's output changes too quickly to be stored by another circuit. MOS INTEGRATED CIRCUITS, *supra* note 77, at 260.

94. Logic simulation programs are available which input discrete Boolean values of 1 or 0 at chip inputs and generate the resulting values at outputs. Michael Feuer, *VLSI Design Automation: An Introduction*, PROC. IEEE, Jan. 1983, at 6.

95. *Id.*

96. FREDERIKSEN, *supra* note 84, at 142.

97. Internal access to chip circuitry can be made by microprobe (using fine metal needles under a microscope to contact metal interconnect); however, increasingly fine geometries make this a difficult process. MOS INTEGRATED CIRCUITS, *supra* note 77, at 365.

98. Very Large Scale Integration began with the appearance of chips bearing 200,000 transistors and 4-micron feature sizes in roughly 1980. SPINKS, *supra* note 79, at 2-3.

99. MOS INTEGRATED CIRCUITS, *supra* note 79, at 365-67.

100. Feuer, *supra* note 94, at 6. These programs sequentially force all internal circuit nodes at a binary 1 or 0 value. The programs then determine if the intended sequence of tests will detect these simulated faults. The percentage of the faults that are detected by the testing program is the numerical fault grade. A grade of 85% faults detected is considered acceptable. FREDERIKSEN, *supra* note 84, at 142.

available to reduce the long testing process.[101] Designers can also evaluate the circuit structure, classify likely faults, and select additional complementary test patterns. However, even with advances in diagnostic tools, circuit testing poses difficult problems, especially as chip complexity continues to escalate.

4. *CIRCUIT DESIGN*

Upon completion of the logic design, a circuit schematic designer translates each logic gate into discrete circuit components, such as transistors and interconnect.[102] A fabrication process, however, must be selected before the circuit schematic can be commenced. The fabrication process determines the layout design rules and which circuits are available to the circuit schematic designer. These fabrication design rules constrain the circuit schematics produced and their implementation by the layout designer.[103]

5. *LAYOUT DESIGN*

The layout designer translates the circuit schematic elements into corresponding types of material on the chip, where each type of material is represented by a two-dimensional set of polygons.[104] The designer graphically inputs and edits ("digitizes") the chip layout on a computer database, similar to that used for schematic entry.[105] The polygons collectively describe the mask data which is used to pattern materials during the chip fabrication process.[106]

The layout design engineer must also work within the design rules of the chip fabrication process.[107] These rules dictate, among other things, the minimum acceptable feature sizes and minimum intralayer and interlayer distances between features.[108] Since there are upwards of 100

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101. These simulation engines can perform over 100,000 circuit emulations per second with circuits containing as many as 1,000,000 logic gates. *See* Loys Gindraux & Gary Catlin, *CAE Station's Simulators Tackle 1 Million Gates*, ELECTRONIC DESIGN, Nov. 10, 1983, at 127.

102. SPINKS, *supra* note 79, at 39-60.

103. *See infra* note 109 for a discussion of typical layout design rules.

104. H.R. 5525 REP., *supra* note 15, at 12.

105. DEWITT G. ONG, MODERN MOS TECHNOLOGY 323-24 (1984).

106. Feuer, *supra* note 94, at 1.

107. As changes are made, he or she must also work with other engineers to ensure the design is logically correct, timed properly, and does not consume too much power. MOS INTEGRATED CIRCUITS, *supra* note 77, at 400-14.

108. Layouts are governed by design rules that dictate size and dimensional relationships between layers. These rules reflect the capability of the particular process. The major design rules prescribe: (1) the minimum widths that can be routinely and reliably patterned without notching or necking (causing a break) in the line; (2) the minimum space that similar features can be routinely and reliably etched separated with no bridging, (3) minimum pitch, which equals the sum of the minimum width and the minimum space and is the true measure of the photolithography and etching capability of a process; (4) overlap required between adjacent layers, for example, in a contact diffusion where the aperture will be enlarged during etching and shrunk during the diffusion stage,

layout design rules for a Metal Oxide Semiconductor (MOS) process, layout design is a complex and intricate task requiring considerable expertise.[109]

Upon completion of initial layout, the graphical layout is printed at high magnification to permit manual checking of timing, power, and additional design rules.[110] After any necessary revisions, the corrected layout data is transferred to a magnetic pattern generation (PG) tape. A mask making pattern generator then produces a magnified reticle from the PG tape data.[111] After more checking, the reticle is mounted in a photorepeat camera which optically reduces the reticle and exposes it on a photosensitive mask plate.[112] After each exposure, the mask plate is translated a discrete distance, aligned by a laser interferometer, and exposed again until the mask plate is filled with rows of identical reticle imprints.[113]

The mask work for each chip layer represents the culmination of the function block, logic, circuit, and layout design efforts. The masks are used as stencils during the manufacturing process to either deposit or remove layers of metal, semiconductor, or insulating material on to or from a silicon substrate.

B. Semiconductor Fabrication

Integrated circuit technology is physically possible because the electrical properties of silicon vary widely in the presence of negatively

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so that the metal will short to the substrate layer if the diffusion does not overlap the contact by a sufficient amount; and (5) minimum distances which must separate dissimilar features because of shrinkage and enlargement during processing. Minimum space and minimum width can be played off against each other. For example, a very narrow line could be obtained by extreme over-etching but it could not be placed close to a similarly narrow line. ONG, *supra* note 106, at 319-21. An important process design parameter that influences layout design rules is mask misalignment tolerance in conjunction with the process mask work sequence. SPINKS, *supra* note 79, at 94.

109. Layout designers were described in the 1979 House hearings as "[c]reative persons and not just draftsmen .... Layout design is a skill that has successfully resisted ... attempts at computerization. It requires a level of human ingenuity that will not be computerized ...." *H.R. 1007 Hearings, supra* note 30, at 26 (statement of L.J. Sevin, President, Mostek Corp.). Twelve years later, however, companies such as Synopsis Inc. of Mountain View, California, have become successful at writing design software for the layout process. *See* Don Clark, *Chip Design—A Crucial Technology*, S.F. CHRON., June 17, 1991, at B1.

110. Design rule checking is typically done by computer program, supplemented by manual checks.

111. The pattern generator writes on the reticle with a beam of light that flashes on and off at a very high rate. The reticle is then magnified between 20 and 200 times to generate transparent films called "blowbacks." The blowbacks are returned to the layout designers for a final check. ONG, *supra* note 106, at 326-28.

112. MUROGA, *supra* note 88, at 34.

113. Working copies are made from the master mask plate for actual use in the wafer processing area. *Id.*

charged[114] or positively charged[115] materials, commonly called "dopants." Positively doped silicon conducts holes; negatively doped silicon conducts electrons.[116] Different circuit elements are created on a silicon substrate by varying the type and concentration of dopant in neighboring regions of a chip.[117] Because of the minute dimensions involved and high purities required, fabrication of semiconductor chips is a lengthy process that requires meticulous quality control.[118]

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114. For example, phosphorus, antimony, and arsenic.

115. For example, boron and gallium.

116. PLETSCH, *supra* note 75, at 38.

117. For example, an npn junction transistor consists of a layer of positive-type silicon between two layers of negative-type silicon. The inner layer is called the base; the outer layers, the emitter and the collector. Applying a positive voltage to the base and a higher positive voltage to the collector (and wiring the emitter to ground) establishes current flow. The positive holes of the base are repelled by the positive voltage of the collector into the negatively charged emitter. Electrons, attracted to the positive voltages of the base and the collector, rush out of the emitter, through the base, and into the collector. The total number of electrons is increased by the extra electrons in the doped emitter and collector. By completing the journey from emitter to collector, the current applied to the base is greatly amplified. PAUL E. GRAY & CAMPBELL L. SEARLE, ELECTRONIC PRINCIPLES: PHYSICS, MODELS, AND CIRCUITS 245-250 (1969).

118. The manufacturing process begins with the growing of a cylindrical ingot of pure silicon. After the ingot is grown a flat edge is cut along its length to serve as a reference point during the fabrication process. Next, the ingot is sliced into .025"-thick wafers which are ground smooth and polished on one side to remove scratches and contamination. An oxygen-ported oven is used to grow a thin surface oxide layer on the wafer. The oxide layer allows materials to be selectively diffused into isolated sections of the wafer.

To create the first layer's circuitry, a liquid photoresist is applied and baked onto the wafer. A mask plate is positioned into a jig and a wafer is placed beneath the mask plate and aligned with it. Ultraviolet light passes through the transparent regions of the mask plate and hardens the exposed photoresist. The wafer is then washed with an organic solvent to remove the non-exposed photoresist. What remains is a mask pattern laid out in hardened photoresist on the wafer's surface. The oxide layer that is not covered by photoresist is next removed by an acid solution. The surviving hardened photoresist is subsequently removed with a chemical bath. This process allows dopants to be diffused into the silicon where the openings in the oxide layer have been selectively made.

A dopant that will appropriately regulate the electrical conductivity of the silicon is selected and deposited across the whole surface of the wafer; the wafer is then again washed with acid to remove the dopant-blocking oxide.

Next, the wafer is placed inside an oxygen-ported oven and a silicon dioxide layer is grown over the areas covered by dopant. The wafer is then removed from the oven and placed inside a furnace where the dopant is driven into the silicon by controlled diffusion. This process of oxide growth, deposition, and diffusion is repeated in a series of up to dozens of masking steps. The chips become multiple layers of pure silicon, silicon dioxide, polycrystalline silicon and dopants. Again, it is subtle differences of dopant type and concentration between neighboring regions that impart circuit characteristics to the regions.

The circuits are interconnected by a metallization layer of an aluminum alloy containing silicon and copper. The alloy is vaporized in a vacuum chamber and deposited across the wafer. At the conclusion of the fabrication process a thin coating of oxide is placed over the wafer to form a protective or "passivation" coating. Each individual chip or "die" is then electrically tested for its ability to perform the operations for which it was designed. Any die that fails the test is marked with an ink blot and later discarded. Data generated from the electrical test is analyzed to improve the yield of future chip batches. The wafers are scribed and cut into individual dies, handled with vacuum tipped wands,

C. The Mechanical Reverse Engineering Process

To successfully enter a integrated circuit market segment with a new product, the new entry must usually be compatible with established products.[119] However, the information needed to achieve compatibility is often not publicly available.[120] Thus, aspiring competitors must gather this information another way. However, they must do so without infringing mask work rights under the SCPA. In defining acceptable reverse engineering under 17 U.S.C. § 906, lawmakers attempted to balance the need for protecting investments in mask designs with procompetition sentiment. However, reverse engineering is not a unitary concept. It consists of two clear steps. In the first step, an engineer works *mechanically* backward to understand the chip's design. In the second step, this understanding is applied to *forward engineer* a new product.

Mechanical reverse engineering generally begins with a known product and works backward through deduction and inference to reconstruct the product's design and manufacturing content.[121] In the semiconductor industry, this method of working backward can involve looking at a chip under a microscope[122] and may involve etching away and successively exposing a chips constituent layers to determine the full layout of the design.[123]

However, the method used to work backward is not important. What does matter is the *depth* to which a competitor mechanically reverse engineers. By studying the mask work layers, a competitor may reverse engineer the chip's polygons or layout geometries. From the layout it may ascertain the electronic circuits represented by the layout polygons and the sequence in which the circuits are connected. It may thus recreate the chip's circuit schematic. From that schematic it may work backwards even further and recreate the chip's logic drawings. Ironically, the deeper the reverse engineering, the greater the forward engineering burdens. Every prior stage that a copyist mechanically reverse engineers (i.e., from layout to circuit schematic to logic to function block stages) represents an additional step to traverse in the forward engineering process. However, the greater the depth of reverse engineering, the greater the potential to

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and packaged. For an excellent discussion of semiconductor fabrication, see PLETSCH, *supra* note 75, at 45.

119. Stephen J. Davidson, *Reverse Engineering and the Development of Compatible and Competitive Products Under United States Law*, 5 SANTA CLARA COMPUTER & HIGH TECH. L.J. 399, 401 (1989).

120. *Id.*

121. Kewanee v. Bicron, 416 U.S. 470, 476 (1974).

122. *See, e.g.*, Brooktree Corp. v. Advanced Micro Devices, Inc., 705 F. Supp. 491, 495 (S.D. Cal. 1988).

123. "Again, you would measure the first layer on your computer; you etch it away, and now you have the second layer exposed. You measure that very carefully and etch it away. You continue to do that until . . . you have the set of complete patterns." *S. 1201 Hearings, supra* note 31, at 65 (statement of F. Thomas Dunlap, Jr., General Counsel, Intel Corp.).

improve, adapt, or augment the design. Conversely, shallow mechanical reverse engineering permits only copycat recreation of a competitor's chip.

V. WEAKNESS IN THE SCPA FOUNDATION: THE SCPA PIRACY MODEL AND PIRACY EXAMPLES

A. Semiconductor Technology and the H.R. 1007 Piracy Examples

To substantiate its piracy claims at the H.R. 1007 hearing, Mostek alleged that a competitor had directly copied its 16K RAM chip. To prove this claim, it pointed to the presence in the copy of useless details[124] mistakenly left in the original which exactly overlaid the original design.[125] While these photos were not published as part of the record,[126] other illustrations of piracy were provided in the Hearing Report.[127]

One of the published examples was a 4K static RAM (SRAM) produced by Intel in mid-1977 and allegedly copied and distributed by Toshiba in early 1979. While access to the full set of mask works is needed to properly compare the chips for similarities, an analysis of the two composite photographs yields some interesting observations. The floor plans of the two chips were obviously identical. However, the organization of the SRAM is dominated by highly repetitive, high density, functionally dictated memory arrays. Therefore, the range of expression for fashioning the floor plan of a 4K SRAM is quite limited.

Moreover, there were apparent differences in the layouts of the two chips. By simple measurement of the two photographs, it appeared that the Toshiba chip was smaller. A reduction in size leads to an improvement in performance.[128] These factors, as testified to during congressional hearings,[129] are indicative of legitimate reverse engineering. Smaller transistor feature sizes can be accomplished by either: (1) using higher resolution photolithography equipment whereby all transistors are

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124. Small rectangular areas on the corner of the chip which served no function at all were apparently copied. *H.R. 1007 Hearings, supra* note 30, at 26-27 (statement of L.J. Sevin, President, Mostek Corp.)

125. A similar copying incident involving Intel and NEC was reported four years later. Dan Morgan, *Battling to Innovate and Emulate: Intel Versus Nippon Electric*, WASH. POST, May 2, 1983, at A1 [hereinafter *Intel Versus Nippon Electric*].

126. The chip's design may not have been published because it was state-of-the-art at the time.

127. *See H.R. 1007 Hearings, supra* note 30, at 34-37 (composite photographs of piracy examples).

128. Scaling down the size of MOS transistors by a constant K reduces the propagation delay between transistors by $1/K$ and reduces power consumption by $1/K^2$. FREDERIKSEN, *supra* note 84, at 60.

129. "[A] reverse engineering firm could then improve the performance of the chip, reduce the size of the chip .... Here we have a true cost reduction or advancement in the state of the art." *H.R. 1028 Hearings, supra* note 34, at 28 (statement of F. Thomas Dunlap, General Counsel, Intel Corp.).

reduced in *all directions* by the same scaling constant *K* (also known as an "optical shrink"); or (2) selectively shrinking features by innovating in the mask work design or processing steps.[130]

Measurement of the memory arrays of the two SRAM chips shows that although the horizontal lengths are equal, the vertical length of the Toshiba chip is significantly less. This difference tends to rule out Toshiba's having simply scaled its chip through the use of an optical shrink. Furthermore, Toshiba's transistor patterns appear to be laid out in vertical columns while Intel's appear to be laid out horizontally. Moreover, the Intel SRAM was fabricated with a single metal process while the Toshiba chip appears to have been made with a more advanced double metal process.[131] Finally, there was a one-and-a-half-year time lag between the initial commercial distribution of the Intel chip and the appearance of the Toshiba chip. According to testimony, this delay was sufficient for Toshiba to have legitimately reverse engineered the design: "It would take maybe 3 years, 3 1/2 years to do the original, and 1 year, maybe 1 1/2 years for the pirate to do it. . . . To do just straightforward copying like this would take 3 to 5 months."[132]

The second published example of infringement in the H.R. 1007 hearing record concerns the Soviet Union's piracy of the Intel 2107b 4K dynamic RAM (DRAM). The two designs are the same size and the Soviet chip appears to be a slavish copy of the Intel device. It is important to note that the Intel DRAM was manufactured in 1974.[133] As will be explained, the relative simplicity of 1974 designs and fabrication processes may have allowed such early integrated circuits to be slavishly copied.[134]

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130. For example, in a DMOS process (not used in the 4K SRAM) the basewidth of transistors is narrowed by making use of differences in diffusion depths. FREDERIKSEN, *supra* note 84, at 59.

131. The preceding comparison was made during a June 1986 conversation with the general manager of a major Silicon Valley company. It should be noted that the comparison was made on the basis of composite photographs and, therefore, is limited.

132. *H.R. 1028 Hearings*, *supra* note 34, at 32 (statement of F. Thomas Dunlap, General Counsel, Intel Corp.).

133. *H.R. 1007 Hearings*, *supra* note 30, at 40 (statement of Andrew S. Grove, President, Intel Corp.).

134. Another notorious example of slavish copying also involved a pre-1979 design. The Intel 8086 microprocessor was first introduced in 1978. In 1980 NEC produced its own version of the 8086, a slavish copy that went so far in mimicing the original as to copy two tiny transistors disconnected and dangling from the chip in a useless bed of silicon. The two unneeded transistors were the result of a small last-minute repair job performed by Intel. *See Intel Versus Nippon Electric*, *supra* note 125, at A1.

B. Semiconductor Technology and the Legislative History Piracy Model

1. *THE LEGISLATIVE HISTORY PIRACY MODEL: THE SLAVISH COPYING OF DESIGNS*

At the 1979 Congressional hearing in San Jose, California, chip piracy was simplistically described as the photographic copying of designs.[135] Pirates, it was explained, would merely make a blowup photograph of a chip, trace the photo line-by-line, and feed the design information into a computer in the same manner[136] in which a layout design engineer's mask work drawings are digitized.

When design protection was revisited at Senate hearings in May 1983, the same simplistic piracy model was presented:

> Again, you would measure the first layer on your computer; you etch it away, and now you have the second layer exposed. You measure that very carefully and etch it away. You continue to do that until . . . you have the set of complete patterns.[137] . . . The problem is, once you take the pattern off, then do you just make mask and put it right back on silicon?[138]

This model implies that those who mechanically *reverse engineer* a design (i.e., by etching and measuring a competitor's design layer by layer), encounter no *forward engineering* obstacles to reconstructing the mask layers into a working chip. However, as industry opposition testimony noted in 1979, process differences[139] and the engineering intricacies[140] of semiconductor technology provides natural forward engineering barriers to slavish copying. Unfortunately, the importance of

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135. *H.R. 1007 Hearings, supra* note 30, at 40 (statement of Andrew S. Grove, President, Intel Corp.).

136. *Id.* at 26-27 (statement of L.J. Sevin, President, Mostek Corp.).

137. *S. 1201 Hearings, supra* note 31, at 65 (statement of F. Thomas Dunlap, General Counsel, Intel Corp.).

138. *Id.* at 84.

139. [W]hen one attempts to copy mask sets, the problem is not quite as simple as merely copying a set of masks and putting the copied product into production using those masks. Rather, one has to have a process compatible with the design rules used in a mask and, so, our perception of the problem may be that the natural burdens in trying to adapt a similar process to use such a mask is in itself a barrier to the problem.

H.R. 1007 Hearings, supra note 30, at 64 (statement of Alan McPherson, Counsel, Fairchild Camera & Instrument Corp.).

"[I]t is not a simple matter of taking a chip or copy of a design and just running that in production. This would imply that processes are exactly the same from company to company. All of us in this business know that is not true." *Id.* at 69-70 (statement of John Finch, National Semiconductor).

140. "[C]ircuit designs are so intricate and complicated . . . that any attempt to make geometrical changes in the layout just for the sake of change will meet with disaster." *Id.* at 27 (statement of L.J. Sevin, President, Mostek Corp.).

these comments went unappreciated in 1979, and the issue was not raised by Congress or by the unified SIA during the 1983 hearings.[141]

2. *RECOGNIZING THE INHERENT BURDENS OF FORWARD ENGINEERING*

Today, and perhaps as long ago as 1979, the increased complexity and density of integrated circuits[142] means that slavishly duplicating a mask work set, without more, is unviable. Even those with a pirate's intent—interested in appropriating as much from the originator as possible and doing minimal forward engineering—can only slavishly copy if they possess the same mask work set, design equipment and fabrication process as the originator. This is unlikely. Producing a copied mask work set on even a slightly different process would likely reveal fatal incompatibilities, such as violation of the design rules for intermask and intramask spacing and line widths.

At a minimum, a second-source must first adjust the originator's layout geometries to conform to the target process' design rules and then verify the result by running design-rule-checking computer simulations. Such adjustments often entail analysis and simulation of timing and

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141. The differing process obstacle to slavish copying is eventually solved, but not before a significant amount of time has passed.

> So really, obviously, the proprietary information is protected from the point of view that we don't let our process information out, but . . . most of the companies in the industry have very similar kind of processes, not exactly the same, but after a chip has been out for a year or two, maybe 6 months even, the processes have caught up to the point where the chip pirates can reproduce the same chip.

Id. at 42 (statement of Roger Borovoy, General Counsel, Intel Corp.).

142. The history of semiconductors has been one of continuous miniaturization. Medium scale integration (MSI) was achieved in 1970 when 2,000 transistors and 10-micron line widths were standard. Twenty thousand transistors and 6-micron line widths were prevalent by 1975 and this came to be known as large scale integration (LSI). Chips bearing as many as 200,000 transistors and line width densities of 4 microns were common in the 1980's, and are referred to by the acronym VLSI (very large scale integration). SPINKS, *supra* note 79, at 2-3. Today's era, with sub-micron feature sizes and transistor integration exceeding 1 million, has been named Ultra Large Scale Integration (ULSI).

Note the following trend since the 1983 SCPA Congressional Hearing Testimony:

Wafer Diameter	4"	5"	6"	8"
Year	1983	1985	1987	1989-91
Device	64K DRAM	256K DRAM	1MB DRAM	4MB DRAM
Process Steps	132	170+	300+	450+
Mask Levels	7	10	15	20
Feature Size (μm)	2.5	1.5	1.0	0.8
Defect Tolerance	0.25	0.15	0.10	0.08
CVD/PVD Steps	7	10	15	15
Surface Contamination Removal Steps	18	24+	35+	45+

Table provided courtesy of Advantage Technologies (on file with author).

power and generation of test patterns to verify the function of the revised layout.[143]

After the design is verified, a second-source still has significant forward engineering *process* burdens. It must now ride the learning curve of the new design's process to achieve product yields that permit competitive product pricing. With contemporary processes calling for sub-micron feature sizes,[144] and over 450 processing and 45 cleaning steps,[145] these learning curves can be long and bumpy.

VI. CONCLUSION

A. The Past

1. *IRONIC TIMING OF CHIP PROTECTION LEGISLATION AND DUBIOUS SUPPORTING TESTIMONY*

By approaching Congress in 1978 for legal protection, the domestic semiconductor industry followed in the protectionist footsteps of the sound recording (1971)[146] and typeface design (1975)[147] industries. Sound recordings[148] and typeface designs[149] have long been susceptible to piracy

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143. As stated *supra* part IV.A.3, timing verification and test pattern generation ordinarily require that the original design first be reverse engineered to its circuit diagram. The diagram is then subject to timing verification analysis before test patterns can be generated, fault graded, and pared down to the appropriate sequence of patterns. Thus, although the necessity of testing would seem to imply that there is an inherently substantial reverse and forward engineering burden to "knocking off a chip," that burden is sometimes removed by specialized reverse engineering companies. These companies have historically practiced reverse engineering on commodity high volume RAM and microprocessor products. "Canned" test programs developed by these companies are commercially available. *See How 'Silicon Spies' Get Away with Copying*, BUS. WK., Aug. 21, 1980, at 187.

144. Today's most advanced chips have circuit features of 0.8 microns and greater than a million transistors. *See* Don Clark, *US May Bounce Back in Key Chip Industry*, S.F. CHRON., May 21, 1991, at C1.

145. *See supra* note 143.

146. *Hearings on S. 646 and H.R. 6927 Before Subcomm. No. 3 of the House Comm. on the Judiciary*, 92d Cong., 1st Sess. (1971) [hereinafter *S. 646 and H.R. 6927 Hearings*].

147. *See Copyright Law Revision: Hearings on H.R. 2223 Before the Subcomm. on Courts, Civil Liberties and the Admin. of Justice of the House Comm. on the Judiciary*, 94th Cong., 1st Sess. (1976) [hereinafter *H.R. 2223 Hearings*].

148. "What has changed since 1965 is . . . the seriousness of the [piracy] problem, which is linked to the growing use of tape cartridges and cassettes. The ease of duplicating methods, their low cost, and the lack of clear statutory sanctions, have encouraged the so-called pirates." *S. 646 and H.R. 6927 Hearings, supra* note 146, at 11 (statement of Barbara A. Ringer, Assistant Register of Copyrights).

> With the development of consumer acceptance of tape, and the development of high speed tape duplicators, the need for protection became greater because it was easier to become a pirate; you bought a tape machine and set up operation in your garage. . . . [S]imilarly, when typeface design became embodied in photographic form, to become a pirate all you needed was a camera, and you copied the photo.

owing to the technical ease of their reproduction. Ironically, when chip protection was first proposed, the semiconductor industry was moving in the opposite direction; smaller feature sizes meant that chips would be technically more difficult to copy into forward-engineered functioning imitations.[150] Several witnesses described these forward engineering obstacles to slavish copying at the 1979 hearing.[151] However, neither congress nor pro-protection witnesses pursued or developed this testimony during the SCPA's five-and-a-half-year legislative history.

Moreover, some of the key SCPA supporting testimony was of dubious value. For example, statements characterizing "reverse engineers" as moral implied that they somehow limit their appropriation in a principled manner. But this defies common sense. With the economic and time-saving incentives of copying, and the lack of legal protection for chip designs, it seems highly probable that—except for those few companies that continually produced new state-of-the-art designs—*everyone* was copying as much and as fast as they could.

2. *THE AMORPHOUS NATURE OF REVERSE ENGINEERING*

The Semiconductor Chip Protection Act was publicly portrayed as the United States vs. Japan,[152] the Reverse Engineers vs. Pirates, and the Moral[153] vs. Immoral. Upon reflection, these characterizations seem far-fetched in that they require an agreed upon definition of reverse engineering. To compare reverse engineering with piracy presupposes that both are permanent and unambiguous concepts. Witnesses who wished to preserve the status quo of reverse engineering implied that copying limitations were easily discernible and understood throughout the semiconductor industry. However, the disparate opinions voiced during the SCPA's history demonstrate otherwise. The legislative process tells a similar story as the initial right to reproduce chips was implicitly recognized but limited by copyright's fair use provision; then it was explicitly recognized but limited to educational and analytical purposes;[154] finally it was explicitly recognized as being applicable to all chip designs and restricted only in cases of "substantial identicality."

H.R. 1007 Hearings, supra note 30, at 11 (statement of Jon Baumgarten, General Counsel, U.S. Copyright Office, Library of Congress).

149. Typeface designs can be easily copied by computerized photographic processes. *See H.R. 2223 Hearings, supra* note 147, at 1018-19 (statement of Joseph Gastel, attorney, International Typeface Corp.).

Typeface designs were subsequently held not to be copyrightable. Eltra Corp. v. Ringer, 579 F.2d 294 (4th Cir. 1978).

150. *See supra* part V.B.

151. *See supra* notes 139-41.

152. *H.R. 1028 Hearings, supra* note 34, at 375-79.

153. "Moral companies enter into cross-licensing agreements as if their designs were copyrightable." *H.R. 1007 Hearings, supra* note 30, at 42 (statement of Andrew Grove, President, Intel Corp.).

154. *See supra* note 57.

3. *CLASSIFYING THE COPYING PROBLEM BY TECHNICAL SKILL*

Although copying another company's designs has an obvious monetary reward, the "need" to copy arises not from money but from the technological superiority of one company's products over its competitors. In 1979, this technological disparity could be overcome by slavish copying, since designs of that era could be pirated. The behavior that developed can best be understood by dividing chip manufacturers according to technical ability. Three groups emerge: pioneers and two groups of second-source copyists.

Pioneers or innovators are best known for introducing revolutionary state-of-the-art products and creating new standards for the industry. The two groups of second-source copyists can also be distinguished by technical ability into skilled and unskilled copyists.

Skilled copyists are able to take what they learn from the reverse and forward engineering process, incorporate it with their existing knowledge, and advance the state of the art. Unskilled copyists either lack the ability to learn from the reverse and forward engineering process or possess insufficient design and process expertise to generate improvements. However, in the early days of minimal forward engineering efforts, the unskilled group could still slavishly copy and produce functioning designs.

The improvements contributed by the technically skilled copyists were neither done as an act of penance for taking another's design or out of an altruistic desire to advance the state of the art. Rather, they were made for economic gain. By upgrading a design, second-sources often increased the yield of their manufacturing process. Conversely, failure of the unskilled copyists to forward engineer improvements evidences both technical and ethical deficiencies.

4. *THE SHIFTING APPROPRIATION LINE*

The technological disparity among these three groups was underscored during the SCPA's legislative proceedings as pioneering and second-source domestic companies fought to influence the legal appropriation standard. Industry pioneer Intel Corp. was the driving force behind the first chip protection bills. The early bills[155] proposed to extend the Copyright Act to cover chip designs and contained no explicit reverse engineering right. Legal reverse engineering would depend upon copyright's generic fair use provision and therefore would have been quite narrow.

When chip legislation was reconsidered four years later, the Senate bill contained an explicit, albeit similarly narrow, reverse engineering right. That proposal[156] would have limited a competitor who reproduced

155. H.R. 14,293 is discussed *supra* note 38 and accompanying text; H.R. 1007 is discussed *supra* note 40 and accompanying text.

156. S. 1201, 98th Cong., 1st Sess. (1984), *discussed supra* text accompanying note 54.

another's chip design to merely studying the design. Over the next year and a half, however, a struggle arose within the industry over how to "strik[e] the appropriate balance between the rights of the creator and the needs of the public."[157] In response, the enacted version of the SCPA shifted the appropriation line toward public consideration by allowing competitors to reproduce a protected mask work and incorporate it into an "original" mask work.

5. *CONGRESS' EXCESSIVE TECHNICAL RELIANCE*

Congress deserves praise for having the courage to tackle semiconductor chip legislation.[158] Nonetheless, once it accepted some form of copying as the industry's competitive norm, it should have developed usable legal criteria for distinguishing fair from unfair copying. At hearings, however, legislators avoided scientific inquiry and left technological complexities to the semiconductor community. Lawmakers, instead, dwelled on resolving the philosophical question of what form of legal protection semiconductor designs should receive. As a result, Congress failed to investigate the inherent forward engineering burdens of copying a chip design. Further, the qualitative piracy and reverse engineering models discussed at SCPA hearings were never clearly developed or assented to during the legislative process. Moreover, the basis for the SCPA—the piracy examples displayed at the 1979 hearing—was never questioned. One of Congress' two published examples of piracy probably illustrates valid reverse engineering, not piracy. The other example appears to be valid since it was based on a 1974 design and, therefore, susceptible to slavish copying.

6. *THE LESSON OF* BROOKTREE

a. The Parties' Contentions

The only published dispute under the SCPA arose between Brooktree Corporation and Advanced Micro Devices, Inc. (AMD).[159] Plaintiff Brooktree owned several original mask works that were registered with the Copyright Office for SCPA protection. The masks were used to fabricate integrated circuit chips that converted digital graphics information to high frequency analog information for very high resolution video screen displays. Approximately 80% of the area of the chips consisted of the core ten-transistor SRAM cell, repeated over six

157. H.R. 5525 REP., *supra* note 15, at 22.
158. *See* Kastenmeier & Remington, *supra* note 26, at 418-20.
159. *See supra* note 1.

thousand times.[160] Brooktree alleged that AMD had misappropriated Brooktree's original mask works in producing its second source chips.[161]

b. The Decisions

Prior to trial, Brooktree sought a preliminary injunction to prevent AMD from manufacturing and distributing the disputed chips. AMD challenged the motion claiming that its chip designs were the product of reverse engineering and therefore noninfringing. In support of its reverse engineering defense, AMD produced a paper trail of evidence showing that it had invested over fifteen months and at least as much money as Brooktree did in developing their chips.[162] Brooktree argued that the paper trail evidence demonstrated only AMD's incompetent efforts and should, therefore, be disregarded.[163]

The court ruled that AMD's paper trail was sufficient to require plaintiff Brooktree to prove that the allegedly pirated chips were "substantially identical" to the Brooktree chips and that, in light of this heightened burden of persuasion, Brooktree had failed to make a showing of a strong likelihood of success on the merits.[164] The court further ruled that Brooktree failed to establish that it was sufficiently harmed by AMD's actions to merit a preliminary injunction[165] and that monetary damages were adequate compensation if infringement was later proven.[166]

Although the court denied Brooktree's motion, it noted that *"serious questions as to the appropriate resolution of the substantive issues in the case have been raised."*[167] While Brooktree's defeat in seeking preliminary relief may have dampened interest in the SCPA, this should change in light of the case's ultimate disposition.

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160. Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1563 (Fed. Cir. 1992).

161. The two mask works were allegedly pirated from chips labeled Bt451 and Bt458. The mask works involved the location and configuration of the active areas in the static RAM (SRAM) cells and the location and path of the polysilicon lines in the SRAM cells. Brooktree maintained that the mask works contained a great deal of originality. Their design provided several important benefits including allowing one of the chips to (1) utilize the high frequency, low power CMOS fabrication technology without needing a special negative voltage supply; (2) change the colors in the color palette for display on a video screen without disrupting the selection of particular colors from the palette; and (3) operate at very high frequencies while simultaneously reading information from and writing information to the RAM without synchronizing the read and write operations. Brooktree Corp. v. Advanced Micro Devices, Inc., 707 F. Supp. 491, 494 (S.D. Cal. 1988).

162. *Id.* at 495-96.

163. *Id.*

164. *Brooktree*, 707 F. Supp. at 496.

165. Arguably, the existence of a substantial dispute as to the true facts of the case furnished a strong reason to deny temporary relief. *See* DAN B. DOBBS, HANDBOOK ON THE LAW OF REMEDIES § 2.10, at 109 (1973).

166. *Brooktree*, 707 F. Supp. at 496-97.

167. *Id.* at 497 (emphasis added).

At trial, Brooktree faced a lower standard of proof than it did in requesting the preliminary injunction.[168] Furthermore, it received the benefit of discovery. After a seven-week jury trial, the verdict awarded Brooktree $26 million in damages for AMD's infringement under the SCPA and several patents.[169] AMD's motions for judgment notwithstanding the verdict (JNOV) and a new trial were denied by the district court and AMD appealed. The presence of patent claims gave the Court of Appeals for the Federal Circuit pendent jurisdiction over the SCPA cause of action.[170]

On appeal, AMD asserted that the SCPA "requires copying of the entire chip," as a matter of law, to establish substantial similarity for the purpose of finding infringement. It was undisputed that at least 20% of the chip was not copied, so the judgment of infringement was in error.[171] The court rejected this argument, citing both general copyright law and the SCPA legislative history, and held that substantial similarity could be found from less than wholesale copying, such as the appropriation of the layout of a core cell.[172]

AMD also argued that its core cell was reverse engineered; the reverse engineering was substantiated by a voluminous paper trail; and thus, as a matter of law, its design did not infringe the Brooktree mask works.[173] The court's analysis focused on the term "original" in the Act's

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168. The degree of harm necessary to grant relief after a full scale trial is not necessarily enough to support temporary relief. *See* DOBBS, *supra* note 164, at 108-09.

169. *See supra* note 1; Brooktree Corp. v. Advanced Micro Devices, Inc., 757 F. Supp. 1088 (S.D. Cal. 1990).

170. Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555 (Fed. Cir. 1992).

171. *Id.* at 1564. In the district court, AMD had moved for a new trial based on erroneous jury instructions. The jury was instructed:

> To establish infringement, Brooktree must show that A.M.D.'s mask works are substantially similar to a material portion of the mask works in Brooktree's chips covered by Brooktree's mask work registration. No hard and fast rule or percentage governs what constitutes a, quote, "substantial similarity." Substantial similarity may exist where an important part of the mask work is copied, even though the percentage of the entire chip which is copied may be relatively small. It is not required the A.M.D. make a copy of the entire mask work embodied in the Brooktree chip.

Id. AMD stated that the disputed instructions wrongly permitted the jury to impose liability by comparing only a portion of the AMD chip for substantial similarity, rather than comparing the entire mask work as a whole. The district court denied the motion, holding that recovery under the Act required only that "AMD misappropriated a material portion of the mask work." *Brooktree*, 757 F. Supp. at 1095 (citing Brooktree Corp. v. Advanced Micro Devices, 705 F. Supp. 491, 494 (S.D. Cal. 1988)).

172. *Brooktree*, 977 F.2d at 1564. In the district court, AMD had filed a motion for judgment notwithstanding the verdict claiming that in view of its "substantial investment in developing [the] second source product (along with an accompanying paper trail), no reasonable jury could find that AMD did not prove its reverse engineering defense." 757 F. Supp. at 1092. The district court held that since "at least two of the elements of the [reverse engineering] defense—whether the AMD analysis of Brooktree's mask work was of the type contemplated by the Chip Act and whether the mask works were 'original'—were strongly contested" with credible evidence by Brooktree, AMD had failed to make out a case. *Id.* at 1093.

173. *Brooktree*, 977 F.2d at 1569.

reverse-engineering statutory defense.[174] The court rejected AMD's argument and ruled that "the paper trail is evidence of independent effort, but it is not conclusive or incontrovertible proof of originality."[175] At trial, the jury was instructed to place "great weight" on AMD's paper trail in determining originality.[176] After acknowledging that credible conflicting testimony had been presented regarding the similarity of the core cells, the pertinence of AMD's paper trail, and whether AMD's chips contained improvements, the court held that "reasonable minds could draw different conclusions" as to the originality of AMD's design.[177] This being the case, the judgment was affirmed.

c. The Legacy of *Brooktree*

The absence of a single additional SCPA case apart from *Brooktree* suggests that the intellectual property bar may have been awaiting its final adjudication before adding SCPA claims to their litigation arsenal. However, since *Brooktree* was tried to a jury, there is no possibility of scrutinizing the decisional process leading to the finding of infringement. Moreover, since the jury instructions went unchallenged on appeal, the Federal Circuit had little opportunity to develop the reverse-engineering doctrine. We know from *Brooktree*, however, that it is not necessary to copy an entire chip to infringe under the Act. Moreover, we know that paper trail evidence alone does not establish the reverse engineering defense.

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174. *Id.*; *see* 17 U.S.C. § 906(a) (1988).

175. *Brooktree*, 977 F.2d at 1570.

176. *Id.* at 1567. The jury was instructed:

> Reverse engineering is permitted and is authorized by the Chip Protection Act. It is not infringement of an owner's exclusive right and protected mask work for another person, through reverse-engineering, to photograph and to study the mask work for the purpose of analyzing its . . . circuitry, logic flow and organization of the components used in the mask work and to incorporate such analysis into an original mask work.
>
> The end product of the reverse-engineering process may be an original mask work, and therefore not an infringing mask work, if the resulting semiconductor chip product is not substantially identical to the protected mask work and its design involved significant toil and investment so that it is not mere plagiarism.
>
> You should place great weight on the existence of [a] reverse paperwork trail in determining whether the defendant's mask work is an original mask from reverse-engineering.
>
> A.M.D. mask work constitutes an original mask work if A.M.D.'s mask work incorporates its own new design elements which offered improvements over or an alternative to Brooktree's mask work.

Id.

177. *Id.* at 1570. Much of AMD's paper trail of time and expense was apparently spent pursuing dead ends. *Id.* at 1569.

B. The Present

The Chip Act's legislative history suggests that the "substantial toil and investment" paper trail requirement was created largely to stop slavish copying. However, as discussed above, it appears that increasing integration and its concomitant forward engineering burdens, not the SCPA,[178] are responsible for closing off this form of piracy.[179]

Thus, given the present state of technology and the "substantial toil and investment" reverse engineering standard, it is reasonable to inquire as to what vitality the SCPA retains today. The answer depends on whether the SCPA was intended to only address the specific problem of slavish copying or was also meant to prohibit a competitor from copying to the extent that semiconductor technology and its accompanying design tools allow. This latter form of copying, known as "barren copying," exists when a copyist appropriates a competitor's layout through the mechanical reverse engineering process and then performs only so much forward engineering as is necessary to produce a functioning chip. The decision in *Brooktree* suggests that barren copying of a cell layout can constitute infringement where there is no compelling paper trail or substantial improvement in the product.

Prior to *Brooktree*, there were concerns that the demands of existing technology, which frequently require that a barren copyist engage in substantial toil and investment to forward engineer a working chip, and the corresponding paper trail would likely satisfy the Explanatory Memoranda criteria for reverse engineering. However, *Brooktree* suggests that the paper trail review should not be done in a vacuum, but should focus on the competency of the defendant's forward engineering efforts.

C. The Future

1. *IS A NEW FORM OF SLAVISH COPYING ON THE HORIZON?*

Notwithstanding the SCPA's sparse application, two technological trends may once again enable slavish copying and therefore revitalize the SCPA as an intellectual property weapon. First, CMOS, which has been the design technology of choice for several years, is becoming mature. With maturity, the process and design secrets distinguishing different companies' CMOS technologies become fewer and less profound. CMOS technology is becoming a commodity. As it does, slavish line-by-line copying becomes possible.

Second, and more importantly, semiconductor design and process secrets are being encoded into software that increasingly permits

178. *See supra* notes 142-45 and accompanying text.

179. However, if the prediction of one chip protection proponent is correct, it is the certainty of protection that dried up 90% of all piracy activity. *See H.R. 1007 Hearings*, *supra* note 30, at 44 (statement of Andrew S. Grove, President, Intel Corp.).

semiconductor designs to be created by computer. In earlier years, engineers designed circuits on paper and tested their work by constructing physical prototypes. Computer workstations which partly automate the layout process first appeared in the late 1970's. That breakthrough was followed by software which permits chips to be designed from predefined logic gates or entire blocks of circuitry rather than individual transistors. Today, a new technology called "logic synthesis" promises to free designers from the time-consuming task of connecting circuits. Starting from a textual description of a chip's functions, the software automatically creates a circuit design that performs these functions.[180] These software and hardware improvements can lessen a copyist's forward engineering burdens. Ultimately, neo-slavish copying may arise in which "unskilled" copyists can once again knock-off a chip design.

A final influence is also at work. For decades, chips have been built from bulk semiconductor materials and technological improvements have been achieved through the use of increasingly smaller transistors. In the not-too-distant future, it appears that the pace of miniaturization must slow as advancing chip technology encounters the physical limits of semiconductor materials. When transistor dimensions fall below 0.2 microns, conventional transistors fail as their behavior becomes dominated by "quantum tunneling" effects. Tunneling, a phenomenon of quantum physics, occurs when electrons penetrate solid matter and electrical barriers that, in bulk materials, are usually impassable.[181] If the quantum tunneling problem slows semiconductor advancements, software and hardware design and process equipment improvements that will continue to progress will reduce a copyist's forward engineering burdens and permit slavish copying.

2. *DON'T FORGET THE INFRINGEMENT TEST*

This Article has focused on the Chip Act's interaction with semiconductor technology. However, of equal or greater concern is the application of an SCPA infringement test. Although this topic is beyond the present discussion, the controversy is largely a philosophical one. Congress provided no indication of what constitutes "substantial identicality" much as it failed to do with copyright law's "substantial similarity" test. Apparently, it preferred to let the courts develop the doctrine. However, there are two ways of viewing "substantial identicality."

Advocates of the first viewpoint assert that Congress intended an owner's rights under the SCPA to be narrow. They would argue that "substantial identicality" was intended as an imposing obstacle to infringement liability, a kind of shorthand for "no infringement." It would then follow that once a defendant proved reverse engineering by a

180. *See* Clark, *supra* note 109, at B1.

181. *See Creating Chips an Atom at a Time*, BUS. WK., July 29, 1991, at 54, 54-55.

paper trail of evidence, infringement could only be found in cases involving obvious and substantial misappropriation.

The second viewpoint, to which the author subscribes, regards "substantial identicality" as an acknowledgment by Congress and the semiconductor industry of the striking visual similarities inherent in designs that perform the same functions. This group would maintain that the SCPA is infringed when a defendant's paper trail is deemed insufficient and "substantial similarity" otherwise exists. By this view, a copyist can only defend against infringement allegations by producing a sufficiently compelling paper trail. The practical importance of the SCPA among intellectual property laws likely depends upon which of these two competing viewpoints prevails.

COMMENT

ISSUES IN THE REGULATION OF BIOENGINEERED FOOD

KAREN GOLDMAN HERMAN †

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I. INTRODUCTION

It has been 17 years since the groundbreaking 1975 meeting at Asilomar where scientists discussed the emerging technology of molecular biology, its vast potential and the possible risks that could result from the ability to transfer DNA from one organism to another.[1] Since then, a number of biotechnology-derived pharmaceutical products have already gone on the market,[2] and the first food and agricultural

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1. Paul Berg et al., *Asilomar Conference on Recombinant DNA Molecules*, 188 SCIENCE 991 (1975).

2. Ann Gibbons, *Biotech Pipeline: Bottleneck Ahead*, 254 SCIENCE 369 (1991).

products have been approved or are close to approval.[3] Many more such products are under development, and there have been no adverse impacts on human health or the environment. Rather, reputable scientific and medical sources stress the potential of biotechnology to improve human health and nutrition, and to ameliorate the adverse impacts of traditional agricultural practices on the environment.[4] Despite the abundance of data indicating the beneficial potential of biotechnology and the absence of harmful incidents, genetic engineering has aroused considerable public suspicion and from some quarters a demand for government oversight out of proportion to the demonstrated risks. The negative perception and resulting regulatory response threatens to adversely affect the development and competitiveness of this fledgling industry, and may also delay or even block the introduction of beneficial products.

This Comment examines issues in the regulatory oversight of the production and consumption of bioengineered food. As an introduction, the Comment first examines the range of products under development and their potential benefits and risks. It next considers the recent controversy over the use of genetically engineered bovine growth hormone, which illustrates many of the issues in this area. The next section presents biotechnology's possible risks and then discusses the advantages of a comparative approach to risk regulation of bioengineered food. Next, the Comment examines the current government regulation of this technology. Since the potential risks involve both the genetically engineered food products and the environmental release of the organisms that produce them, regulation in these areas is analyzed. This regulation has been implemented through the "coordinated framework," an adaptation of existing statutes to the oversight of biotechnology. Although regulation under the coordinated framework has the advantage of not singling out biotechnology for special oversight, the Comment examines some of the criticisms that stem from adapting existing statutes to address biotechnology. The Comment next considers, in light of the benefits of a comparative approach, some recently proposed approaches to regulation. Finally, the Comment contemplates what modifications in government policy and regulation might improve the public perception of biotechnology, strengthen the industry, and foster the generation of products that are not merely profitable, but also truly beneficial to both human health and the environment.

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3. Direct Food Substances Affirmed as Generally Recognized as Safe; Chymosin Enzyme Preparation Derived From *Escherichia coli* K-12, 55 Fed. Reg. 10,932 (FDA 1990) [hereinafter Direct Food Substances Affirmed] (codified at 21 C.F.R. § 184.1685 (1991)); Council on Scientific Affairs, Am. Medical Ass'n, *Biotechnology and the American Agricultural Industry*, 265 JAMA 1429 (1991).

4. Council on Scientific Affairs, Am. Medical Ass'n, *supra* note 3, at 1429-34.

II. BIOTECHNOLOGY USED IN THE PRODUCTION OF FOOD

Biotechnology as applied to the production of food has the potential to greatly benefit the public, as well as to improve agricultural productivity. The Council on Scientific Affairs of the American Medical Association has stated that agricultural biotechnology has the potential to "meet the needs of a rapidly growing population and minimize the toxic influences of traditional farming practices on the environment."[5] However, due to agricultural economics as well as scientific complexity, the function of many of the first genetically engineered food products is to improve agricultural efficiency and productivity.[6] Since the technology for producing foreign proteins in genetically engineered bacteria is more established than the technology for transforming entire plants or animals, some of the first products are proteins that can be inexpensively produced to replace or augment the same naturally occurring protein. Thus, the first genetically engineered food ingredient approved by the Food and Drug Administration (FDA) is chymosin, an enzyme traditionally obtained from the stomach of calves and used in the production of cheese.[7] Since the genetically engineered chymosin is identical to the enzyme obtained from the traditional preparation and contains no ingredients that are not generally recognized as safe (GRAS), the FDA has concluded that this product, like the traditional product, is GRAS.[8] Bovine somatotropin, a hormone used to increase milk production, has been produced in genetically engineered bacteria and is virtually identical to the naturally occurring protein.[9] It is expected to be approved in 1992.[10]

Genetic engineering techniques have also been applied to commercial food crops. The "antisense" tomato, one of the bioengineered products closest to FDA approval, has been modified to retard the softening and subsequent spoilage that accompanies ripening. This modification improves the farmer's ability to machine-pick ripe tomatoes without bruising them, thus producing a tasty but easily harvested tomato.[11] This type of modification improves the efficiency of the

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5. *Id.*

6. *Id.* at 1431.

7. Direct Food Substances Affirmed, *supra* note 3, at 10,932.

8. 21 C.F.R. § 184.1685 (1991).

9. OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, OTA-F-470, U.S. DAIRY INDUSTRY AT A CROSSROAD—BIOTECHNOLOGY AND POLICY CHOICES—SPECIAL REPORT 33-34 (1991) [hereinafter OTA, DAIRY INDUSTRY].

10. *See* Presentation of Milk Inventory Management Program Study Results and Solicitation of Comments, 56 Fed. Reg. 22,514, 22,519 (USDA 1991).

11. This "antisense" tomato was produced by insertion of a gene coding in the antisense orientation for the enzyme, polygalacturonase. Polygalacturonase normally softens the cell walls during ripening. The antisense RNA coded for by that gene binds to the endogenous (sense) polygalacturonase RNA, thereby inhibiting production of the enzyme. International Food Biotechnology Council, *Biotechnologies and Food: Assuring the Safety of Foods Produced by Genetic Modification*, 12 REG. TOXICOLOGY AND PHARMACOLOGY i,

agricultural industry and can result in increased supply and lower food prices for consumers. Genetically-engineered herbicide-resistant plants that survive the application of herbicides during weed eradication may also improve the efficiency of farming.[12] Such plants will be used in conjunction with recently-developed herbicides that are rapidly biodegraded and are of low toxicity.[13] Finally, many crops, including tomato, tobacco, potato, alfalfa, cucumber, corn, and soybeans have been genetically engineered to resist plant viruses that might otherwise devastate these plants.[14] This should improve both crop yield and quality, since harvested plants would have far less viral contamination than is present in unmodified plants.[15]

Perhaps the most dramatic improvements in crops will be those that directly improve nutritional quality or reduce environmentally destructive practices.[16] For example, the rapeseed plant has been modified to produce canola oil containing a higher proportion of unsaturated fatty acids.[17] Technical difficulties, however, have hampered the improvement of nutritional quality in the major cereal crops.[18] Research on improvement of nutritional quality, by manipulation of amino acid content or other components, is in progress on these and other

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S110-11 (1990). A second antisense tomato under development accomplishes the production of firm, easily harvested fruit in a different way, by using antisense RNA to inhibit expression of the enzyme that synthesizes the ripening agent, ethylene. Such fruit can be ripened subsequently by exposure to ethylene gas. Paul W. Oeller et al., *Reversible Inhibition of Tomato Fruit Senescence by Antisense RNA*, 254 SCIENCE 437 (1991).

12. Dilip M. Shah et al., *Engineering Herbicide Tolerance in Transgenic Plants*, 233 SCIENCE 478 (1986).

13. Charles S. Gasser & Robert T. Fraley, *Genetically Engineering Plants for Crop Improvement*, 244 SCIENCE 1293, 1295 (1989). Some commentators contend that the genetically-engineered herbicide-resistant plants will lead to the use of more environmentally acceptable herbicides and an overall reduction in herbicide use. *Id.* But others believe that the use of such plants will lead to an increase in the use of herbicides. *See* Council on Scientific Affairs, Am. Medical Ass'n, *supra* note 3, at 1431.

14. Patricia P. Abel et al., *Delay of Disease Development in Transgenic Plants that Express the Tobacco Mosaic Virus Coat Protein Gene*, 232 SCIENCE 232 (1986); Council on Scientific Affairs, Am. Medical Ass'n, *supra* note 3, at 1431; Gasser & Fraley, *supra* note 13, at 1296.

15. Gasser & Fraley, *supra* note 13, at 1296. Virus resistance is accomplished by introducing the gene for viral coat protein into the genetically engineered plants. This results in the production of the coat protein in uninfected plants, but the concentration is typically only 0.01% to 0.5% of that in infected plants. *Id.*

16. Council on Scientific Affairs, Am. Medical Ass'n, *supra* note 3. Also, genetic engineering of livestock is expected to increase the efficiency of meat production on a given feeding regimen and reduce the fat content of the meat. However, pigs modified to produce excess growth hormone exhibited these traits, but also had substantial side effects—high rates of ulcers, arthritis, cardiomegaly, dermatitis, and renal disease. Thus, improvement of livestock by genetic engineering will require technological advances that eliminate these side effects. Vernon G. Pursel et al., *Genetic Engineering of Livestock*, 244 SCIENCE 1281 (1989).

17. Council on Scientific Affairs, Am. Medical Ass'n, *supra* note 3, at 1431.

18. I. Potrykus, *Gene Transfer to Plants: Assessment of Published Approaches and Results*, 42 ANN. REV. PLANT PHYSIOLOGY & PLANT MOLECULAR BIOLOGY 206 (1991).

crops.[19] Plant geneticists have already produced insect-resistant crops by inserting a gene from the bacterium *Bacillus thuringiensis* (*Bt*) into the plant's DNA. The gene produces a protein that is toxic to certain insect pests, and may lead to a reduction in the use of environmentally destructive pesticides.[20] The *Bt* pesticidal protein, like other proteins, is highly specific in its effects and is inactive against mammals, including humans.[21] Although the *Bt* protein is often referred to as a pesticide incorporated into food, it should be stressed that it is much more species-specific in its action than conventional pesticides, and therefore much safer.[22] Scientists are also investigating other approaches to genetically engineering pest resistant crops.[23] Genetic engineering of pest resistant crops has great potential to reduce the use of synthetic chemical pesticides that may pose problems for human health or the environment.[24]

The state of agricultural biotechnology today is that a variety of items are in development or close to marketing. Those that are farthest along are of the type that will increase agricultural efficiency or productivity, but the current technology has the potential for improving nutritional quality and reducing the use of chemical pesticides. Moreover, there have been no hazardous incidents that should create a fear of this technology and lead to tight regulatory oversight. To the contrary, the Council on Scientific Affairs of the American Medical Association has recommended that physicians play a role in educating the public that "genetic manipulation is not inherently hazardous and that the health and economic benefits of recombinant DNA technology greatly exceed any risk posed to society."[25] Yet public perception of biotechnology is one of suspicion,[26] leading to calls for tighter regulation. The following examination of the recent controversy over bovine somatotropin may illuminate some of these conflicting views on biotechnology.

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19. Council on Scientific Affairs, Am. Medical Ass'n, *supra* note 3, at 1431.

20. Gasser & Fraley, *supra* note 13, at 1295-96. *Bt* is toxic to certain moth and butterfly caterpillars, as well as to certain beetles, flies, and mosquitoes. It has also been reported to be inactive against beneficial insects. *Id.* A potential problem, however, has been discovered recently; some pests have evolved a resistance to *Bt*. Ann Gibbons, *Moths Take the Field Against Biopesticide*, 254 SCIENCE 646 (1991).

21. Gasser & Fraley, *supra* note 13, at 1295-96.

22. Gibbons, *supra* note 20. Farmers have used *Bt* in a spray form since the 1950s; environmentalists have praised it as a safe alternative to chemical pesticides. *Id.* However, not all naturally occurring pesticides produced by plants are benign; many such chemicals (generally not proteins) occurring in commonly eaten foods may be carcinogenic. Such biopesticides are actually present in the diet in far greater amounts than synthetic pesticides. Bruce N. Ames et al., *Dietary Pesticides (99.99% All Natural)*, 87 PROC. NAT'L ACAD. SCI. 7777 (1990). Biopesticides selected for incorporation into food by genetic engineering should be noncarcinogenic and specific in their action; proteins with species-limited activity usually satisfy this test.

23. Gasser & Fraley, *supra* note 13, at 1296.

24. Council on Scientific Affairs, Am. Medical Ass'n, *supra* note 3, at 1429-31.

25. *Id.* at 1434.

26. *See infra* text accompanying notes 43-47.

III. BOVINE SOMATOTROPIN—A MICROCOSM OF THE ISSUES

Bovine somatotropin (bST), also called bovine growth hormone, was the first major product of recombinant DNA technology available for use in agriculture.[27] bST occurs naturally in cows, but when additional bST produced by genetically engineered bacteria is administered to dairy cows, their milk production is expected to increase an average of 12% without a commensurate increase in feed consumed.[28] The use of bST has been heralded as the technological advance that will have the most dramatic effect on the efficiency of milk production in this decade.[29] Moreover, numerous studies have shown that milk produced by bST-dosed cows is safe for human consumption.[30] The use of bST is also expected to lower environmental pollution, because the decreased intake of feed relative to milk output will decrease the production of manure, urine, and methane—a gas with a strong greenhouse effect.[31] Simply put, fewer cows are required to produce the same amount of milk.

Despite these benefits, bST has elicited considerable public outcry. Consumer groups are threatening to boycott the milk from bST-supplemented cows, grocery chains and food processing companies refused the milk that was approved by the FDA for sale during the investigation period,[32] and states have considered or taken action either banning the use of bST or requiring labeling of products derived from its use.[33]

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27. OTA, DAIRY INDUSTRY, *supra* note 9, at 45.

28. *Id.* at 35. To meet the nutritional needs of extra milk production, voluntary intake of feed increases in cows receiving bST. Although nutritional requirements for each unit of milk produced are the same in bST-supplemented and control cows, bST-supplemented cows have an increased efficiency of conversion of feed into milk because a larger proportion of the cow's total nutrient intake is used to make milk. By requiring less feed to maintain the same level of milk production, there should be substantial savings in dairy cattle feed nationally. *Id.* at 37.

29. *Id.* at 45. Modern breeding techniques such as artificial insemination and embryo transfer would take 10-20 years to produce a similar increase in the efficiency of milk production. *Id.*

30. The evidence for safety is based on the following facts: bST is normally produced by cows; it is normally present at very low levels in both milk and meat and its concentration is not appreciably altered by bST supplementation; it is degraded in the human stomach and therefore has no chance to act on people; bST is species-specific in effect and even if injected into humans, is inactive; and its effects on the composition of milk or meat are extremely minor. Judith C. Juskevich & C. Greg Guyer, *Bovine Growth Hormone: Human Food Safety Evaluation*, 249 SCIENCE 875 (1990); William H. Daughaday & David M. Barbano, *Bovine Somatotropin Supplementation of Dairy Cows—Is the Milk Safe?*, 264 JAMA 1003 (1990); *NIH Technology Assessment Conference Statement on Bovine Somatotropin*, 265 JAMA 1423 (1991).

31. OTA, DAIRY INDUSTRY, *supra* note 9, at 43.

32. Ann Gibbons, *FDA Publishes Bovine Growth Hormone Data*, 249 SCIENCE 852 (1990); Edmund L. Andrews, *Human Threat Ruled Out in Drug for Cows*, N.Y. TIMES, May 8, 1991, at A18.

33. OTA, DAIRY INDUSTRY, *supra* note 9, at 3, 44-45; Robin Eisner, *State Legislators Seek to Broaden Regulation of Biotech Products*, SCIENTIST, Feb. 18, 1991, at 6.

Though ten states introduced bills restricting the use of bST and two states actually enacted such laws,[34] only a few individuals generated the original controversy. Samuel Epstein, a professor at the University of Illinois, joined with genetic engineering critic Jeremy Rifkin to attack the use of bST.[35] In an evaluation of other scientific studies, Epstein questioned the safety of bST-produced milk for human consumption; in addition, he concluded that bST adversely affects the health of cows.[36] Rifkin's group, Foundation on Economic Trends (F.E.T.), demanded the release of environmental assessment records relating to bST.[37] F.E.T. also petitioned the FDA for an environmental impact statement prior to field testing bST. The petition asserted that use of bST would "(1) significantly affect agricultural land use in milk-producing regions of the United States; (2) adversely affect the internal environment of cattle injected with [bST]; and (3) have adverse economic and social impacts on the dairy industry."[38]

The final reason may actually be the most important impediment to acceptance of bST. Concern that small-scale farmers might not be able to compete with large operations using bST resulted in the European Community's 18-month ban of bST.[39] Similar concerns are apparently at the heart of Minnesota's ban on the sale and use of bST.[40] However, bST is merely the latest of many changes in dairy practices that have favored the large, factory-like operation over the small farmer.[41] Moreover, such

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34. MINN. STAT. ANN. §§ 151.01, .15, .25 (West 1992); WIS. STAT. ANN. § 97.235 (West 1991); Eisner, *supra* note 33.

35. Gibbons, *supra* note 32.

36. *Id.* at 852-53. Despite Epstein's conclusions, other studies indicate that bST does not overtly affect bovine health; no detectable increases in diseases such as ketosis, fatty liver, and milk fever have occurred, and reduced resistance to infections has not been detected. OTA, DAIRY INDUSTRY, *supra* note 9, at 41-42. An industry spokesman said that some cows given five times the normal dose developed mastitis. Gibbons, *supra* note 32, at 853. However, reports of increased mastitis and other difficulties were based on small-scale studies that have not been widely accepted. Although the effects of prolonged use of bST are not known, it appears to cause no adverse reactions during the agriculturally useful life of the dairy animal. Council on Scientific Affairs, Am. Medical Ass'n, *supra* note 3, at 1433.

37. Stephen P. Mahinka & Kathleen M. Sanzo, *Biotechnology Litigation and Federal Regulation: Status and Implications*, 42 FOOD DRUG COSM. L.J. 500, 511 (1987) (citing Foundation on Economic Trends v. Department of Health and Human Servs., Civ. No. 87-1009 (D.D.C. filed Apr. 10, 1987)).

38. *Id.* The FDA denied the petition due to the agency's requirement of confidentiality during the approval period of new drug applications. *Id.*

39. Steven J. Rothberg, *From Beer to BST: Circumventing the GATT Standards Code's Prohibition on Unnecessary Obstacles to Trade*, 75 MINN. L. REV. 505, 509-10 (1990).

40. *Biotechnology, Minnesota Governor Vetoes Extension of Ban on Usage of Bovine Somatotropin*, BUREAU OF NAT'L AFFAIRS, DAILY REP. FOR EXECUTIVES, May 31, 1991, at A-10. The governor's vetoes were declared invalid by the Ramsey County District Court in Seventy-Seventh Minn. State Senate v. Carlson, No. C3-91-7547 (Minn. Dist. Ct. 1991), so the Minnesota ban on bST was extended until June 1992. MINN. STAT. ANN. §§ 151.01, .15, .25 (West 1992).

41. OTA, DAIRY INDUSTRY, *supra* note 9, at 10-12. If a national policy in support of traditional farms were adopted, it would require changes in dairy price-support policy

economic and social impacts have never formed a basis for regulation by the FDA, which approves new animal drugs on demonstration that they are effective, safe for the animals as well as the humans who consume the animal products, and safe for the environment.[42]

The bST controversy illustrates some of the difficulties that may be encountered during the introduction of bioengineered food products. Since biotechnology products are already suspect in the public eye, they are easily attacked by a vocal minority. Even if they meet the current regulatory standards, they are especially vulnerable to criticisms that they have adverse environmental, economic, or social impacts that may result from modern dairy or agricultural practices as a whole rather than just from biotechnology. State or local agencies may impose additional regulation that could impede the development of the biotechnology industry and delay advances that might actually be environmentally, economically, or socially beneficial. The question, then, is what regulatory balance should be struck between the potential or perceived risks of biotechnology and its unknown but almost certain benefits.

IV. RISKS AND REGULATORY ISSUES CONCERNING BIOENGINEERED FOOD

Although new and unknown technologies are often viewed with suspicion, some features of biotechnology make it particularly susceptible to an exaggerated perception of risk. Public concern may stem from scientists themselves, who initiated a moratorium on some aspects of genetic engineering in 1974.[43] While scientists have since grown comfortable with the technology, the public perception of unreasonable risks lingers on. A recent survey found that 52% of the public "believes that genetically engineered products are at least somewhat likely to represent a serious danger to people or the environment."[44] Biotechnology often suggests the "Frankenstein image." While the current technology generally changes but a single gene, producing a relatively small modification, many people may believe that any interspecies exchange of genetic information results in a dramatic change. Perhaps such views underlie the finding that 24% of a group aware of biotechnology felt that creation of hybrid plants and animals through

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and other areas as well as programs to enhance technology adoption by such small farms. *Id.*

42. Juskevich & Guyer, *supra* note 30.

43. Committee on Recombinant DNA Molecules, Nat'l Research Council, *Potential Biohazards of Recombinant DNA Molecules*, 185 SCIENCE 303 (1974).

44. OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY BACKGROUND PAPER: PUBLIC PERCEPTIONS OF BIOTECHNOLOGY, *excerpted in Federal Oversight of Biotechnology: Hearing Before the Subcomm. on Hazardous Wastes and Toxic Substances of the Senate Comm. on Environment and Public Works*, 100th Cong., 1st Sess. 60, 62 (1987).

genetic engineering is morally wrong.[45] Another aspect of biotechnology that invites public concern is the ability of living things to reproduce; thus any deleterious effects of genetically engineered organisms have the ability to escape human control and self-perpetuate. This leads to a fear that although a deleterious result is unlikely, if it occurs, the outcome could be a problem of substantial magnitude. Such fears of an unlikely but potentially disastrous outcome could greatly hinder the progress of biotechnology. A majority of the public would object to the use of genetically engineered organisms if the risk were unknown.[46]

Food products of biotechnology generate their own specific concerns. Production of bioengineered food usually involves not only a consideration of the safety of the food for human consumption, but also the safety of environmental release of the altered plant. The public's perception of potential danger from food biotechnology is enhanced by its heightened awareness of environmental damage from the introduction of exotic species and of health problems that are manifested only decades after exposure to the causative agent. Yet many similar risks from food stem from traditional agricultural and plant breeding practices that are essential to provide sufficient food to the growing population or to assure the taste, quality, and convenience that consumers and farmers have come to expect. Thus, society accepts environmental risks of pesticide use and dispersal of domesticated plants and animals within certain limits and tolerates low levels of pesticide residues in food. Other risks from food are inherent in the food itself. Food contains many naturally occurring toxicants and carcinogens that are nearly unavoidable in the ordinary diet.[47]

Biotechnology presents few risks beyond those already accepted in traditional foods.[48] As to their environmental risks, "[c]rops modified by molecular and cellular methods should pose risks no different from those modified by classical genetic methods for similar traits."[49] Bioengineered

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45. *Id.* at 63. Note that 26% "of the public who are aware of the classic biological techniques of cross-fertilization and cross breeding also believe that these techniques are morally wrong." *Id.*

46. *Id.*; *see also Review and Outlook: Those Terrifying Cows*, WALL ST. J., Jan. 7, 1991, at A14 ("No modern advance is more vulnerable to damaging public assault today than agricultural biotechnology.").

47. Ames et al., *supra* note 22; International Food Biotechnology Council, *supra* note 11, at S11-78, S20-21.

48. *See* International Food Biotechnology Council, *supra* note 11, at S104-08.

49. National Research Council, *Executive Summary, Field Testing Genetically Modified Organisms: Framework for Decisions*, 12 RECOMBINANT DNA TECH. BULL. 183, 187 (1989). "At this time, the potential for enhanced weediness is the major environmental risk perceived for introductions of genetically modified plants. The likelihood of enhanced weediness is low for genetically modified, highly domesticated crop plants . . . ." *Id.* Generally, genetically engineered foods are thought to pose few environmental risks because toxic organisms are not likely to be used in their production. Ecologists, however, voice concerns about possible environmental disruption from the release of genetically engineered organisms, particularly microorganisms. For a discussion of the differing viewpoints of ecologists and molecular biologists, see Sidney A. Shapiro, *Biotechnology and the Design of Regulation*, 17 ECOLOGY L.Q. 1, 6-12 (1990).

organisms' potential for dispersal and environmental disruption is generally similar to their traditional counterparts.[50] Society has long accepted the fact that traditional plant and animal breeding practices may change the nutrient or toxicant levels in the food or alter an organism's potential for environmental dispersal.[51] Although traditional methods usually enhance the safety of the food, they have occasionally increased the level of a deleterious component.[52] The use of antibiotic resistance marker genes in the production of bioengineered food has raised some questions, but most experts agree that the genes should cause no health or safety problem.[53] Bioengineering, as an extension of traditional breeding practices, should pose no greater concern over the safety of the food consumed; it should actually be safer since the recombinant techniques are more specific and thus less likely to produce unwanted side effects such as increased levels of toxicants or weediness.[54] Indeed, as considered above, bioengineering may lower both the environmental and food consumption risks.

New technologies are particularly difficult to regulate when their risks are unknown, but to reap the benefits of such advances it is important that regulation be based on risk and not succumb to exaggerated perceptions of danger. Peter Huber has argued that regulation of new technologies by federal agencies often involves screening that eliminates small risks at the expense of lost opportunity costs of unknown magnitude. By contrast, old technologies are usually

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50. Proposed USDA Guidelines for Research Involving the Planned Introduction into the Environment of Organisms with Deliberately Modified Hereditary Traits, 56 Fed. Reg. 4134, 4135-36 (1991).

51. *See* International Food Biotechnology Council, *supra* note 11, at S21, S92-93.

52. *Id.* at S21, S27-28.

53. *Id.* at S122-23. Antibiotic resistance genes linked to the gene of interest are used to identify cells carrying the latter gene. Only those cells carrying the resistance gene, and consequently the gene of interest, survive when antibiotics are applied to a field of cells. There has been concern that these genes could be transferred from crop plants to pathogenic organisms, but such transfer is considered highly unlikely. Such transfer would be extremely rare compared to the known increase in resistance genes in bacterial populations due to the use and overuse of antibiotics clinically and in animal feed. *Id.* The FDA is evaluating whether food containing enzymes produced by antibiotic resistance marker genes could inactivate clinical antibiotics taken orally, as well as other issues stemming from the use of antibiotic resistance genes. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,988 (FDA 1992) [hereinafter FDA Statement of Policy]. The biotechnology firm Calgene has asked the FDA to approve the use of its kanamycin resistance gene as a marker. Calgene Inc., Request for Advisory Opinion, 56 Fed. Reg. 20,004 (1991). Recently new techniques for removing the marker genes have become available. Anne S. Moffat, *Excess Genetic Baggage Dumped*, 254 SCIENCE 1457 (1991); Emily C. Dale & David W. Ow, *Gene Transfer with Subsequent Removal of the Selection Gene from the Host Genome*, 88 PROC. NAT'L ACAD. SCI. 10,558 (1991). Special molecular methods plus a year or two of plant breeding are required to remove the unwanted gene. It is possible that the FDA could require biotechnology companies to remove the marker genes, or they could independently opt to do so. Moffat, *supra*, at 1457.

54. International Food Biotechnology Council, *supra* note 11, at xvii-xviii, S84-94. An exception to this may be the possible unintended transfer of allergens from an allergenic to a nonallergic species. *See infra* note 158 and accompanying text.

subject to more lenient standard-setting regulations.[55] Thus, regulations often preserve the present level of safety by tacitly accepting risks posed by old technologies while excluding new technologies with potentially large benefits.[56] The assumption behind screening new risks but setting standards to limit old risks is that barring new risks is economically and socially less costly, because both producers and a market for the new products are not yet established.[57] The benefits of the new products are generally not considered in the screening process because their values are speculative.[58]

Thus, to foster technological advance and its resultant benefits, Huber argues that a comparative system of regulation of old and new risks, one that permits new technologies functionally similar to established technologies and of no greater risk, should be implemented.[59] The comparative approach, allowing a new risk, is justified when the old, risky product is one that society accepts either because it is essential or desirable.[60] "[E]xcessively strict regulation of the safer-than-average product[s] will drive consumption toward the more hazardous ones."[61] Comparative regulation, on the other hand, would favor the safer product, particularly because modern technology usually replaces an old outmoded source of risk rather than adding to it.[62]

Huber suggests a four-step process for implementing comparative regulation:

> 1) The agency must define a risk market comprising products that are functional substitutes for each other.
>
> 2) It next must identify typically risky products already allowed to compete in that market.
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> 3) The agency must then compare the risks of the new substitute with those of products not in fixed supply and already in the market. Only the less safe substitutes must be excluded or otherwise regulated.
>
> 4) If a new product offers exceptional price or other advantages over existing, more hazardous products, introduction of the safer product could conceivably increase net risk by increasing total consumption. As a final step in comparative regulation, an agency

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55. Peter Huber, *The Old-New Division in Risk Regulation*, 69 VA. L. REV. 1025, 1029-37, 1058, 1065 (1983).

56. *Id.* at 1037-38, 1062-63, 1073.

57. *Id.* at 1051, 1053-54, 1063-66.

58. *Id.* at 1058-59, 1065.

59. *Id.* at 1073-75.

60. *Id.* at 1093-95. Thus, comparative regulation does not justify, for example, allowing a cigarette substitute that is carcinogenic and addictive, though less so than cigarettes, because cigarettes are not accepted as essential or highly desirable (though cigarette smokers might favor a substitute as their only realistic alternative to cigarettes). Food, on the other hand, is obviously necessary, and many of its risks are unavoidable. *See* International Food Biotechnology Council, *supra* note 11, at S11-78.

61. Huber, *supra* note 55, at 1079.

62. *Id.* at 1073.

must therefore consider whether a candidate for regulation is this type of risk.[63]

The comparative approach is appropriate for the two main regulatory hurdles applicable to biotechnology-derived food products, the oversight of the release of the genetically engineered organism during food development and the evaluation of food safety. In neither case are the risks absolutely quantifiable, but they can be compared to the risks of non-genetically engineered food organisms or products in the same situation. Thus, the risk of release of genetically engineered domesticated plants and animals can be compared to the risk associated with the parental or other comparable strain.[64] Genetically engineered food products can be evaluated by comparison to their unmodified counterparts, and if appropriate, to any food additives that might accomplish the same function as the genetic modification.[65] Food, despite its inherent risks, is of course essential, and society accepts many of the environmental risks from its production because of the desirability of traditional agricultural practices. Bioengineered food is certainly a functional substitute for traditional food, and since people's eating habits are unlikely to change dramatically, introduction of the genetically engineered food should not substantially affect total production and consumption of the product, unless there is an exceptional difference in price.

Another reason for adopting a comparative approach to regulation of biotechnology-derived food products is that biotechnology represents a small man-made risk superimposed on a background of naturally occurring toxins and carcinogens in food.[66] To eliminate small increments of risk above a large natural baseline is inefficient and costly.[67] The comparative approach also has a sound scientific basis because the view that genetic engineering in the production of food is an extension of long-established conventional breeding techniques underlies the concept that when analyzing risk, genetically engineered products should be readily comparable to their traditional counterparts.[68]

The regulatory framework for bioengineered food is in transition from an approach that, by focusing on the process used to produce genetically engineered food, did not always accurately assess the risk of the product. The Bush Administration sought to cure this problem by adopting a policy similar to the comparative regulatory approach

63. *Id* at 1075-76.

64. Principles for Federal Oversight of Biotechnology: Planned Introduction into the Environment of Organisms with Modified Hereditary Traits, 55 Fed. Reg. 31,118, 31,120 (OSTP 1990); Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, 57 Fed. Reg. 6753, 6755-56 (OSTP 1992) [hereinafter Exercise of Federal Oversight].

65. International Food Biotechnology Council, *supra* note 11, at S138-43, S165.

66. Ames et al., *supra* note 22; International Food Biotechnology Council, *supra* note 11, at S21.

67. Huber, *supra* note 55, at 1083-85.

68. International Food Biotechnology Council, *supra* note 11, at xvi-xviii.

discussed above.[69] The federal regulatory agencies are currently implementing this policy. This policy approach has the advantage of removing unjustified oversight of biotechnology, but it may have the disadvantage of underregulating the field, especially because it relies on existing statutory authority not directed at biotechnology. Moreover, this policy approach does not address the non-risk based social and economic concerns that contribute to the public's objections to biotechnology. It may, therefore, fuel the demand for state and local regulation of biotechnology.

V. THE REGULATORY FRAMEWORK

Regulation of bioengineered food falls under the general regulatory scheme that has been established for biotechnology as a whole.[70] The "Coordinated Framework for the Regulation of Biotechnology" (coordinated framework), introduced by the Office of Science and Technology Policy (OSTP) in 1985-86, describes the policies for federal regulation of biotechnology.[71] Under the coordinated framework, regulation of biotechnology relies on existing federal statutes, with each agency maintaining jurisdiction over biotechnology applications within its traditional domain.[72] Oversight of each product is within a single agency, but where more than one agency is involved, one is designated the lead agency.[73] Agencies rely upon existing statutory authority to provide immediate health and safety protection, as well as to eliminate any regulatory delay or uncertainty that might hurt the new biotechnology industry. Underlying this decision was the premise that genetic engineering techniques are basically extensions of the traditional techniques of selective breeding and hybridization, and thus the laws that governed products of those techniques could also apply to biotechnology.[74]

The Biotechnology Science Coordinating Committee (BSCC), established by the OSTP in 1985, had broad authority for promoting cooperation between the agencies and establishing consistent scientific

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69. PRESIDENT'S COUNCIL ON COMPETITIVENESS, REPORT ON NATIONAL BIOTECHNOLOGY POLICY (1991).

70. Coordinated Framework for Regulation of Biotechnology: Establishment of the Biotechnology Science Coordinating Committee, 50 Fed. Reg. 47,174 (OSTP 1985) [hereinafter Coordinated Framework—1985]. This regulatory scheme was established during the Reagan Administration, which established a Cabinet Council Working Group on Biotechnology in 1984. Steven H. McNamara, *FDA Regulation of Food Substances Produced by New Techniques of Biotechnology*, 42 FOOD DRUG COSM. L.J. 50, 53-54 (1987).

71. Coordinated Framework—1985, *supra* note 70; Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (OSTP 1986) [hereinafter Coordinated Framework—1986].

72. Coordinated Framework—1986, *supra* note 71. A comprehensive list of the statutes relevant to regulation of biotechnology is found in Coordinated Framework—1985, *supra* note 70, at 47, 181-95.

73. Coordinated Framework—1986, *supra* note 71, at 23,303-05.

74. *Id.* at 23,302-03.

policy and reviews. It was composed of senior policy officials from the United States Department of Agriculture (USDA), the FDA, the National Institutes of Health (NIH), the Environmental Protection Agency (EPA), and the National Science Foundation (NSF).[75] In late 1990, the BSCC was replaced by the Biotechnology Research Subcommittee (BRS) of the interagency Committee on Health and Life Sciences. The BRS is said to have responsibilities similar to the BSCC.[76] Although the BSCC, in its evaluation of the issues, could "develop generic scientific recommendations that could be applied to similar, recurring applications,"[77] it did not re-evaluate agency decisions and thereby delay that agency's response.[78] Two important facets of BSCC's initial mission were to ensure that its constituent agencies regulate biotechnology using scientific reviews of similar stringency, and to establish consistency as to which genetically engineered organisms were subject to regulatory oversight.[79]

The BSCC recognized that many genetically engineered organisms present risks no greater than those developed by traditional techniques. These organisms, like traditionally developed organisms, would require no regulatory approval prior to use.[80] The BSCC established the policy that both intergeneric organisms (organisms with DNA derived from species in more than one genus[81]) and pathogens should come under review. Pathogens include microorganisms bearing DNA from pathogenic organisms.[82] Each agency, using its own statutory authority, then established its own policies or regulations in line with these guidelines.[83]

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75. Coordinated Framework—1985, *supra* note 70, at 48,174, 48,176.

76. OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, OTA-BA-494, BIOTECHNOLOGY IN A GLOBAL ECONOMY 176 (1991) [hereinafter OTA, BIOTECHNOLOGY IN A GLOBAL ECONOMY]. The Committee on Health and Life Sciences is a committee of the Federal Coordinating Council on Science, Engineering, and Technology, which is headed by the President's Science Advisor. *Id.*

77. Coordinated Framework—1985, *supra* note 70, at 47,176.

78. *Id.*

79. Coordinated Framework—1986, *supra* note 71, at 23,302, 23,303.

80. *Id.* at 23,303.

81. A genus is a group of closely related species; species in different genera are phylogenetically more distantly related than species in a single genus.

82. *Id.* at 23,306-07. Intergeneric or pathogenic organisms that contain only non-coding regulatory regions of DNA (regions not leading to the production of protein) are excluded from this definition. *Id.* at 23,307.

83. Statement of Policy for Regulating Biotechnology Products, 51 Fed. Reg. 23,309 (FDA 1986) [hereinafter FDA Statement]; Statement of Policy—Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, 51 Fed. Reg. 23,313 (EPA 1986); Final Policy Statement for Research and Regulation of Biotechnology Processes and Products, 51 Fed. Reg. 23,336 (USDA 1986); Agency Guidelines on Biotechnology, 51 Fed. Reg. 23,347 (OSHA 1986); Statement of Policy, 51 Fed. Reg. 23,349 (NIH 1986); Proposed Rules, 51 Fed. Reg. 23,352 (USDA 1986); Advance Notice of Proposed USDA Guidelines for Biotechnology Research, 51 Fed. Reg. 23,367 (1986).

Under the coordinated framework, several federal agencies, including the EPA, the USDA, and the FDA, could regulate a single bioengineered food product. For example, a plant genetically engineered to contain a biopesticide could come under the authority of the EPA as a pesticide regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).[84] It could also be considered a plant pest regulated under the jurisdiction of the Animal and Plant Health Inspection Service (APHIS), which implements the Federal Plant Pest Act within the USDA.[85] Finally, the safety of the food product could be judged by the FDA through its authority under the Federal Food, Drug, and Cosmetic Act (FDCA).[86] Thus, food products of biotechnology are subject to extensive regulatory authority.[87] Since many food products are subject to both USDA and FDA jurisdiction, this Comment will consider some of their regulations relevant to biotechnology in more detail.

Under the authority granted by the Federal Plant Pest Act and the Plant Quarantine Act, the USDA proposed regulations that have been used to regulate genetically engineered food crops.[88] Specifically, the APHIS requires a permit for the introduction of an organism (regulated article) that "has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent"[89] belongs to one of the genera or taxa listed in the regulations and is a plant pest.[90] A plant pest is "[a]ny living stage . . . which can directly or indirectly injure or cause disease or damage in or to any plants."[91] At first glance, such regulated articles might not appear to include crop plants. Most genetically engineered crop plants, however, have come under this regulation because the most common vector used to introduce the gene of

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84. Coordinated Framework—1985, *supra* note 70, at 47,180. FIFRA is at 7 U.S.C. §§ 136-136y (1988 & Supp. III 1991).

85. Coordinated Framework—1985, *supra* note 70, at 47,188. The Federal Plant Pest Act is at 7 U.S.C. §§ 150aa-150jj (1988).

86. Coordinated Framework—1985, *supra* note 70, at 47,177. The Food, Drug, and Cosmetic Act is at 21 U.S.C.A. §§ 301-392 (West 1972 & Supp. 1992). According to the FDA's new policy, the "EPA will address under its regulatory jurisdiction the food safety issues associated with the pesticide, including marker genes used to confirm the presence of the pesticidal gene. Any food safety questions beyond those associated with the pesticide . . . are under FDA's jurisdiction . . . ." FDA Statement of Policy, *supra* note 53, at 23,005.

87. OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, OTA-BA-360, NEW DEVELOPMENTS IN BIOTECHNOLOGY 4: U.S. INVESTMENT IN BIOTECHNOLOGY—SPECIAL REPORT 100-01 (1988) [hereinafter OTA, INVESTMENT IN BIOTECHNOLOGY].

88. Final Policy Statement for Research and Regulation of Biotechnology Processes and Products, 51 Fed. Reg. 23,336 (USDA 1986); Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests, 52 Fed. Reg. 22,892 (USDA 1987) (codified at 7 C.F.R. §§ 330, 340); 7 U.S.C. §§ 150, 151 (1988).

89. Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests, 7 C.F.R. § 340.1 (1991).

90. *Id.* §§ 340.0-.3.

91. *Id.* § 340.1.

interest into the genetically engineered crop is the Ti plasmid of *Agrobacterium tumefaciens*, a plant pathogen listed in the regulations.[92]

Before the APHIS can issue a permit for the release of regulated articles, it must comply with the requirements of the National Environmental Policy Act (NEPA) and carry out an environmental assessment.[93] Most genetically engineered crop plants pose no more risk to the environment than the parental strains from which they are derived. If the genetically engineered organisms do pose a risk, they are grown in containment. Thus, these assessments usually indicate no risk to the environment and no environmental impact statement is required.[94] The USDA regulations also have mandatory state notification and review provisions.[95] By mid-1991, more than 150 permits for the release of genetically engineered organisms had been issued by the USDA, with no known adverse environmental effects.[96]

A permit is required during the research phase of the development of a genetically engineered food product, when the environmental effects of the bioengineered crop may be unknown. Permits are not required during the commercial phase, however, because it is impossible to effectively monitor crops grown on a commercial scale. Thus, to enter the commercial phase, data obtained from the field tests must show that the organism is not a plant pest or deleterious to the environment. When that is established, the APHIS can exempt the genetically engineered crop from the regulations requiring a permit, so that commercialization can begin.[97]

The FDA has followed a policy, consistent with that stated in the coordinated framework, that oversight of biotechnology products under its jurisdiction requires no new procedures or requirements.[98] The FDA is responsible for assuring the safety and quality of both plant and animal

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92. *Id.* § 340.2; Gasser & Fraley, *supra* note 13, at 1295; Edward L. Korwek, *Towards Understanding the United States Biotechnology Regulatory Framework, in* BIOTECHNOLOGY: NEW DEVELOPMENTS IN FEDERAL POLICIES AND REGULATIONS 1, 27-28 (Practising Law Inst., 1988). When used as a vector, the pathogenic genes of the Ti plasmid are removed, so the "disarmed" Ti plasmid functions only to insert the gene of interest, and does not produce host disease. Gasser & Fraley, *supra* note 13, at 1294.

93. Coordinated Framework—1986, *supra* note 71, at 23,303-04; International Food Biotechnology Council, *supra* note 11, at S180.

94. *See, e.g.*, Availability of Environmental Assessments and Findings of No Significant Impact Relative to Issuance of Permits to Field Test Genetically Engineered Organisms, 56 Fed. Reg. 24,775, 59,925, 66,616 (USDA 1991).

95. 7 C.F.R. § 340.3 (1991).

96. OTA, BIOTECHNOLOGY IN A GLOBAL ECONOMY, *supra* note 76, at 180, 182. As of mid-1990, the USDA had not denied any application for a permit for a small-scale test. *Review of Current and Proposed Agricultural Biotechnology Regulatory Authority and the Omnibus Biotechnology Act of 1990: Hearing on H.R. 5312 Before the Subcomm. on Dep't Operations, Research, and Foreign Agriculture of the House Comm. on Agriculture*, 101st Cong., 2nd Sess. 156 (1990) [hereinafter *Hearing on H.R. 5312*] (statement of Margaret Mellon, Ph.D., J.D., National Wildlife Federation).

97. *Hearing on H.R. 5312, supra* note 96, at 115 (statement of Dr. James W. Glosser, Administrator, APHIS).

98. FDA Statement, *supra* note 83, at 23,309-10.

bioengineered food products. New animal drugs, including those produced by biotechnology, require premarket approval by the FDA. Moreover, the FDA must approve for human consumption the edible portions of animals that have been administered a new drug.[99] To approve the use, the FDA must confirm the safety of the food product for human consumption; the drug must not accumulate as unsafe residues in the edible portions of the animal.[100] Finally, the efficacy of the drug and its safety for both the animals and the environment must be established.[101] When a new drug produced by genetic engineering is virtually identical to an approved substance produced by conventional technology, the showing for approval is reduced and only a supplemental application to the FDA is necessary.[102]

Regulation of biotechnology-derived foods from plants will depend largely on the use of the food. Generally, regulations differ for "whole foods" such as fruits, vegetables, or grains; for substances unintentionally added to foods; and for food additives.[103] The FDA does not require premarket approval for whole foods, but the burden is on the producer or manufacturer to assure that such foods are safe.[104] However, the FDA can regulate whole foods, including those that are products of biotechnology, under section 402(a)(1) of the FDCA,[105] which sets different safety standards for inherent natural constituents of the food and unintentionally added substances that are poisonous or deleterious.[106] Naturally occurring constituents posing safety problems, such as elevated levels of solanine in a new potato variety or poisons in a toxic mushroom, make the food legally adulterated only "if the quantity of such substance[s] ... ordinarily render[s] it injurious to health."[107] Unintentionally added substances on the other hand, are contaminants and are subject to a more rigorous standard. The contaminants may be chemicals introduced accidentally by human activities (e.g., polychlorobiphenyls (PCBs), mercury, and lead) or they may be naturally occurring contaminants (e.g., aflatoxin). "Added substance[s]" cause a food to be legally adulterated if they "may render it injurious to

99. *Id.* at 23,311-12.

100. *Id.* at 23,311. The drug manufacturer must show that methods exist for detection of such residues. *Id.*

101. *Id.* at 23,311-12; OTA, DAIRY INDUSTRY, *supra* note 9, at 5.

102. FDA Statement, *supra* note 83, at 23,311.

103. *Id.* at 23,310, 23,312-13; International Food Biotechnology Council, *supra* note 11, at S160-61.

104. International Food Biotechnology Council, *supra* note 11, at S161.

105. 21 U.S.C. § 342(a)(1) (1988).

106. FDA Statement, *supra* note 83, at 23,312.

107. 21 U.S.C. § 342(a)(1) (1988); *see also* International Food Biotechnology Council, *supra* note 11, at S161.

health."[108] Adulterated food is subject to an enforcement action if it enters into interstate commerce.[109]

Food additives are subject to premarket clearance by the FDA, unless the additive is generally recognized as safe (GRAS).[110] A substance is GRAS either if its safety is known from common use in foods consumed by a significant number of consumers prior to January 1, 1958, or if its safety is determined by well-controlled scientific studies.[111] A company may market a product, believing it to be GRAS, but it runs the risk that the FDA may decide that it is not GRAS and force it off the market. A company wishing to clarify the matter at the outset may obtain the FDA's opinion on the substance by filing a GRAS affirmation petition.[112] If a substance added to food is not GRAS, it is a food additive and under section 409 of the FDCA a company must submit a food additive petition for FDA approval.[113] Thus, if a bioengineered product is a food additive, it requires submission of scientific data showing that it is safe under the conditions for which it will be used.[114] Moreover, under the requirements of NEPA, the manufacturer must prepare an environmental assessment, or an impact statement if the manufacturing process or the use of the food additive will significantly affect the environment.[115]

Since the FDCA does not directly apply to biotechnology, and the first bioengineered food products have only recently or are now undergoing FDA approval, there has been much speculation as to how the FDA will categorize such foods. The FDA has stated that a substance recognized as GRAS may lose that status if production by genetic engineering alters it or produces contaminants such that experts no longer recognize it to be safe.[116] The question of GRAS status is not trivial to the manufacturer, because FDA approval of direct food additives generally takes between five and seven years.[117] So far, the only bioengineered GRAS substance considered by the FDA, chymosin, has retained that status.[118]

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108. 21 U.S.C. § 342(a)(1) (1988); *see also* Jeffrey N. Gibbs & Jonathan S. Kahan, *Federal Regulation of Food and Food Additive Biotechnology*, 38 ADMIN. L. REV. 1, 12 (1988); International Food Biotechnology Council, *supra* note 11, at S161.

109. International Food Biotechnology Council, *supra* note 11, at S161 (citing 21 U.S.C.A. §§ 332 (injunction), 333 (criminal sanctions), 334 (seizure of adulterated articles) (West 1972 & Supp. 1992)).

110. 21 U.S.C. §§ 321(s), 348(a)-(b) (1988); *see also* Gibbs & Kahan, *supra* note 108, at 7, 9.

111. 21 U.S.C. § 321(s) (1988).

112. Affirmation of GRAS Status, 21 C.F.R. § 170.35 (1991). *See generally* Gibbs & Kahan, *supra* note 108, at 11.

113. 21 U.S.C. § 348(a)-(b) (1988); *see also* FDA Statement, *supra* note 83, at 23,313-14.

114. FDA Statement, *supra* note 83, at 23,313.

115. *Id.*

116. *Id.*

117. Coordinated Framework—1985, *supra* note 70, at 47,177.

118. Direct Food Substances Affirmed as Generally Recognized as Safe; Chymosin Enzyme Preparation Derived From *Escherichia coli* K-12, 55 Fed. Reg. 10,932 (1990) (codified at 21 C.F.R. § 184.1685 (1991)).

Another question that arises is whether the FDA will view a food crop with a genetically engineered gene and a resultant change in food composition as a whole food or as containing a food additive.[119] The FDA will soon be setting a precedent on this issue, since Calgene, an agricultural biotechnology company, has recently petitioned the FDA to issue an advisory opinion as to whether its "antisense" tomato is a whole food that contains no food additives.[120] If the FDA views genetically engineered food as whole food, the question arises whether the FDA will regard the altered gene or the resultant change in food composition as inherent constituents of the food subject to the "may render" standard, or as added substances evaluated under the "ordinarily render" standard of section 402(a)(1) of the FDCA.[121] The answer might determine whether the FDA would prevail if it ever attempted an enforcement action where equivocal evidence indicates that a bioengineered food contains a deleterious substance.[122]

VI. CRITICISM OF REGULATION UNDER THE COORDINATED FRAMEWORK

Not surprisingly, regulation of bioengineered food products, and biotechnology in general, is often viewed as too stringent by biotechnology companies, as too lax by environmentalists, and as lacking a sound scientific basis by academicians. Biotechnology companies often cite regulatory uncertainty as a substantial concern in developing new products.[123] In recent years, the main regulatory hurdle that food biotechnology companies have had to face has involved the release of genetically engineered organisms. The companies acknowledge that APHIS' handling of small field tests has worked well and that many delays have been due to suits or to local restrictions on release.[124] Thus, at

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119. A food additive is defined as:

> any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized . . . to be safe under the conditions of its intended use.

21 U.S.C. § 321(s) (1988).

120. Calgene, Inc., Request for Advisory Opinion, 57 Fed. Reg. 22,772 (FDA 1992); Donna K.H. Walters, *FDA Asked to Review Biotech Tomato; Genetic Engineering: The California Company's Request is the First for an Altered Food Product*, L.A. TIMES, Aug. 13, 1991, at D2.

121. 21 U.S.C. § 342(a)(1) (1988); *see, e.g.*, David L. Jones, *Food Safety Aspects of Gene Transfer in Plants and Animals: Pigs, Potatoes, and Pharmaceuticals*, 43 FOOD DRUG COSM. L.J. 351, 359 (1988); Gibbs & Kahan, *supra* note 108, at 7.

122. Gibbs & Kahan, *supra* note 108, at 12 n.58.

123. OTA, INVESTMENT IN BIOTECHNOLOGY, *supra* note 87, at 100, 210-11.

124. *Hearing on H.R. 5312*, *supra* note 96, at 141-42 (statement of Roger H. Salquist, Chairman and Chief Executive Officer, Calgene, Inc.); *Federal Oversight of Biotechnology: Hearing Before the Senate Subcomm. on Hazardous Wastes and Toxic Substances of the Comm. on Environment and Public Works*, 100th Cong., 1st Sess. 34-35 (1987) [hereinafter *Federal*

the federal level, industry concerns for the future stem from uncertainty over regulation of large scale release of genetically engineered crops during commercialization; the adequacy of coordination between the EPA, the USDA, and the FDA when a single product requires oversight by all three agencies; and over how the FDA will handle food products.[125] Industry may actually welcome a case-by-case analysis of the first bioengineered foods, because FDA approval will give an assurance of safety that will boost public confidence in the products.[126] In the long run, however, industry representatives feel that bioengineered foods should require no more screening than traditionally produced foods.[127] Since under current law this would mean that genetically engineered foods classified as whole foods would require no premarket approval, the International Food Biotechnology Council, an industry association, recommends that the FDA establish a voluntary premarket notification system.[128] However, industry's greatest regulatory concern may not be with federal regulations but with the increasing patchwork of state and local regulations. This concern, which will be considered further below, has led industry to lobby for more explicit federal regulation.[129]

Environmental groups have faulted the coordinated framework for incompletely regulating biotechnology through existing statutes not directed at genetic engineering and for not keeping environmental considerations paramount. Environmentalists have criticized the use of the Federal Plant Pest Act to regulate environmental release of genetically engineered agricultural plants and animals because it covers only plant pests.[130] Although use of the Ti plasmid as a vector has brought most plant genetic engineering under the authority of the regulations, environmentalists are concerned that increased use of other means of introducing foreign DNA will leave many bioengineered plants unregulated.[131] Moreover, environmentalists and university researchers are concerned that USDA's statutory authority is inadequate to cover genetically engineered animals.[132] Finally, environmentalists argue that the EPA, rather than the USDA, should be the lead agency in charge of

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Oversight of Biotechnology Hearing] (statement of Dr. Larry W. Moore, Oregon State University).

125. *Hearing on H.R. 5312, supra* note 96, at 143 (statement of Roger H. Salquist, Chairman and Chief Executive Officer, Calgene, Inc.); Mark Crawford, *Biotech Companies Lobby for Federal Regulation*, 248 SCIENCE 546 (1990).

126. Crawford, *supra* note 125, at 547.

127. International Food Biotechnology Council, *supra* note 11, at xvi.

128. *Id.* at S164.

129. Crawford, *supra* note 125, at 546.

130. *Hearing on H.R. 5312, supra* note 96, at 151-56 (statement of Margaret Mellon, Ph.D., J.D., National Wildlife Federation).

131. *Id.* at 155.

132. *Id.* at 153-54; *see also id.* at 131-36 (statement of Dr. Eric M. Hallerman, Virginia Polytechnic Institute) (current regulation of transgenic fishes is incomplete, fraught with procedural uncertainty and legal loopholes).

environmental release of genetically engineered organisms, since EPA's mandate is to protect the environment as a whole, whereas USDA's interest is to promote agriculture.[133]

University researchers cite the nonuniform, overlapping jurisdiction of the many agencies regulating biotechnology as a particularly onerous burden, perhaps because of the smaller scale and budgets of their operations. They are concerned that regulatory agencies will block commercialization of some of their best scientific advances, such as virus-resistant plants containing a gene for viral protein, because the agencies will be unable to decide whether to regulate the plant as a plant pathogen, chemical pesticide, or food additive.[134] This regulatory confusion results in part from the adaptation of existing laws to cover biotechnology.[135] The same types of criticisms of USDA regulation of biotechnology via the Plant Pest Act can be made of FDA's regulation of bioengineered foods through existing regulations and statutes: bioengineered foods do not readily fit into any existing regulatory category. Moreover, university researchers have criticized the scientific basis for the scope of regulation of genetically engineered organisms under the coordinated framework, because they view the emphasis on intergeneric combinations of genetic material as bearing little relationship to the level of risk.[136]

VII. NEW DIRECTIONS

The President's Council on Competitiveness has responded to some of the criticisms of biotechnology regulation under the coordinated framework in its *Report on National Biotechnology Policy (Report).*[137] The watchword of this document is that biotechnology regulation should be risk-based; genetically engineered organisms or products should not be subject to unnecessary oversight solely because of the method of their production.[138] The *Report* stresses that products of genetic engineering are not necessarily riskier than conventionally produced products, and thus should not be subject to additional oversight.[139] However, the *Report* retains the position that regulation of biotechnology does not require new statutes or regulatory structures.[140] It recognizes the need for "improving agency coordination, streamlining the regulatory agencies' evaluation processes, periodically reevaluating regulations, [and] addressing

133. *Federal Oversight of Biotechnology Hearing, supra* note 124, at 149 (statement of Rebecca J. Goldburg, Environmental Defense Fund).

134. *Hearing on H.R. 5312, supra* note 96, at 126 (statement of Dr. Sue Ann Tolin, Virginia Polytechnic Institute).

135. *Id.*

136. *Id.* at 131-32 (statement of Dr. Eric M. Hallerman, Virginia Polytechnic Institute).

137. PRESIDENT'S COUNCIL ON COMPETITIVENESS, *supra* note 69.

138. *Id.* at 12.

139. *Id.*

140. *Id.* at 14.

problems with state and local laws,"[141] but defers these issues for further study. In sum, the Council's approach is to foster the development of the biotechnology industry by promulgating a policy in which this new technology is subject to no more regulation than "old risks."

Specific policy changes reflecting this philosophy have been proposed both for the regulation of the release of bioengineered food-producing organisms and the assessment of food safety and quality. The new policy concerning the release of food producing organisms mandates equivalent, risk-based regulation of traditional and genetically engineered organisms, and thus should lower industries' burden of federal regulation.[142] The new policy no longer specifies that "intergeneric organisms" or "pathogenic" species require oversight. The policy broadly covers all types of genetic modifications, including those resulting from traditional methods, by stating that "[a] determination to exercise oversight . . . should not turn on the fact that an organism has been modified by a particular process or technique."[143] Rather, all organisms should be regulated according to the risk of introducing them into a particular environment. Federal agencies should not exercise oversight of such introductions unless the risk is unreasonable.[144] However, federal agencies need not choose between imposing or not imposing oversight. Agencies have a range of options, such as "[i]ssuance of suggested industry practices, development of guidelines for certain introductions, and requirements for notification, labeling, prior review or approval of certain introductions."[145] In determining what level of oversight should be applied, the policy adopts a comparative approach similar to Huber's. Thus, "[a]n introduction should be subject to no greater degree of oversight than was a comparable organism or product previously used in past safe introductions in a comparable target environment."[146] In short, this policy suggests a comparative approach to regulation by applying comparable oversight to comparable organisms in similar environments. Such an analysis would apply whether the new organism is, for example, a genetically engineered variety or a newly introduced exotic species.[147]

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141. *Id.* at 15.

142. Exercise of Federal Oversight, *supra* note 64, at 6755-56; *cf.* Principles for Federal Oversight of Biotechnology: Planned Introduction into the Environment of Organisms with Modified Hereditary Traits, 55 Fed. Reg. 31,118 (OSTP 1990) (preliminary statement of a comparative and risk-based policy of oversight of planned introductions, but differing from the current policy in that organisms produced by traditional means were excluded from oversight). The USDA has proposed similar guidelines for adoption. Proposed USDA Guidelines for Research Involving the Planned Introduction into the Environment of Organisms with Deliberately Modified Hereditary Traits, 56 Fed. Reg. 4134 (1991).

143. Exercise of Federal Oversight, *supra* note 64, at 6756.

144. *Id.*

145. *Id.* at 6758.

146. *Id.* at 6757.

147. *Id.* at 6758.

Consistent with the principles set forth in the *Report*, the FDA has stated that bioengineered plant food products require no special regulation simply because they are bioengineered, and reiterated its intention to regulate such products under existing statutory authority.[148] It has also given some guidance as to how existing statutory authority will be applied to bioengineered foods.[149] Since DNA is a component of all living organisms, the FDA does not consider DNA transferred to plants by bioengineering to be a food additive. However, the FDA could classify the intended protein, carbohydrate, or oil expression product of a transferred gene as a food additive if the product is not GRAS. Plant foods containing such intended expression products would require premarket review under section 409 of the FDCA.[150] If bioengineering unintentionally results in a harmful expression product, that harmful product will be regulated as an added substance. Therefore, under section 402(a)(1) of the FDCA, bioengineered plant foods are adulterated if the level of unintentionally introduced harmful substances "may render" the food injurious to health.[151]

To avoid an FDA enforcement action against adulterated food or unapproved food additives, industry must determine whether its products are safe or whether premarket approval is necessary. In its recent policy notice, the FDA outlined the scientific basis for such an assessment by a manufacturer.[152] The assessment scheme focuses primarily on the levels of toxicants, nutrients, and food allergens, and on the type and nutritional value of introduced or modified proteins, carbohydrates, fats, and oils.

One feature of this assessment, in addition to qualitative and analytical evaluation, is a comparative approach. Acceptable and unacceptable levels of certain food constituents are determined by reference to the host plant when that plant has a history of safe use.[153] By following FDA's guidelines, a manufacturer is expected to determine whether the product is safe, requires FDA consultation because of questionable safety, or is unsafe.[154] Thus, the FDA suggests that the level of toxicants in the new variety should be within the range of toxicant

148. FDA Statement of Policy, *supra* note 53, at 22,984-85. This statement of policy does not apply to plants containing "pesticide chemicals," which are regulated by the EPA. *Id.* at 23,005; *see also* David A. Kessler et al., *The Safety of Foods Developed by Biotechnology*, 256 SCIENCE 1747 (1992).

149. FDA Statement of Policy, *supra* note 53, at 22,988-91.

150. *Id.* at 22,990.

151. *Id.*

152. *Id.* at 22,986-87, 22,991-3,004.

153. *Id.* at 22,996. The focus on host and donor plants suggests that the assessment scheme applies only to genetically engineered foods. However, in keeping with its policy of regulating bioengineered products within the same framework as food produced by traditional methods, the FDA states that the assessment scheme applies to the evaluation of "food from new plant varieties derived by traditional methods ... tissue culture methods ... and recombinant DNA methods." *Id.* at 22,991.

154. *Id.* at 22,992.

levels in the host variety,[155] and that "the concentration and bioavailability of important nutrients in the new variety [should be] within the range ordinarily seen in the host species."[156] If toxicant levels present a safety concern, the food is unacceptable; if nutrient levels are outside of the normal range, the manufacturer must consult the FDA to determine its course of action.[157] The primary concern raised by the donor species is the potential transfer of allergens or toxicants to the host. The manufacturer must consult the FDA if it is possible that allergens have been transferred from the donor to the host plant.[158] The assessment of food safety may entail qualitative, as well as quantitative comparisons. Thus, a manufacturer must consult the FDA if the introduced protein, carbohydrate, fat, or oil is likely to be a major component of the diet and is not derived from an edible source, or differs substantially from that in the edible source.[159]

This comparative approach is based on the recognition that unmodified, unprocessed foods pose a natural risk by not only varying substantially in nutritional content but also containing a wide variety of toxicants.[160] The baseline level of risk posed by traditional foods is the standard against which genetically engineered modifications must be

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155. *Id.* at 22,996.

156. *Id.* at 22,995.

157. *Id.*

158. *Id.* at 22,997-98. The FDA requires labeling of foods containing an introduced protein that may cause an allergic reaction, e.g., if a bioengineered tomato expresses a peanut protein. Labeling may also be required where other "safety or usage issue[s] exist," but not merely to note that a food is genetically engineered. *Id.* at 22,991. In contrast, the Environmental Defense Fund favors labeling of all genetically engineered foods as well as statutory changes addressing genetic engineering, to ensure that the FDA subjects such foods to premarket safety testing. Jeffrey L. Fox, *Food Proposals for FDA to Savor*, 9 BIO/TECHNOLOGY 1039 (1991).

159. FDA Statement of Policy, *supra* note 53, at 22,999-3,004.

160. International Food Biotechnology Council, *supra* note 11, at S11-78. The International Food Biotechnology Council (IFBC) has also proposed evaluating bioengineered foods on an essentially comparative basis:

> The IFBC recommends that the initial basis of the safety evaluation of a genetically modified food should begin with consideration of the lineage of all genetic materials present in the final food product. . . . The IFBC recommends that a food product be considered to present no safety concern if analytical studies indicate that the concentration of inherent constituents does not differ significantly from the concentration range typical of the traditional food, and any new constituent(s), if present, is already accepted for use in food under the anticipated conditions of use.

Id. at S138-39.

The IFBC fulfills Huber's first three criteria, *see supra* text accompanying note 63, by defining a risk market including the bioengineered food and the traditional foods for which it is a functional substitute, and by specifying that the bioengineered food be compared to the traditional food from which it is derived. The IFBC then concludes, like Huber, that only the less safe bioengineered foods, those that are significantly different or contain an ingredient not accepted for food use, should be regulated. The IFBC also fulfills Huber's fourth criterion, whether increased consumption would increase net risk, since it recommends that a "food product be considered to present no safety concern if use of the food would not be expected to alter significantly present intake of it or its constituents in comparison with the traditional product." *Id.* at S140.

measured. However, the FDA has applied a comparative analytical approach while relying upon the traditional categories of whole foods, food additives, and GRAS substances to govern its regulation of the product.[161] The use of these rigid categories may hinder comparative evaluation.[162]

Comparison to the corresponding unmodified organism essentially regulates products of biotechnology on a par with organisms produced by traditional methods. This type of comparison equilibrates the new and old risks by removing new risks commensurate with old, unregulated risks from the regulatory process. However, because it requires a judgment by the manufacturer involving risks that may be unknown and unquantifiable, environmentalists and others skeptical of the new technology may feel that it leaves too many products of that technology unregulated or underregulated. Critics may also think that manufacturers using the new technology have too much discretion to unilaterally decide whether their products meet the required standards. Moreover, it is difficult to see how agencies can apply a risk-based policy to certain organisms (e.g., transgenic fish) perceived to be immune to oversight due to gaps in statutory authority. Nor does the policy address ideological deficiencies that result from using existing statutory and regulatory authority. Thus, while the policy may ease regulatory burdens at the federal level, it may create a backlash from the public[163] and from state and local bodies that perceive greater risks from biotechnology and wish to regulate it more stringently.

State regulation of biotechnology has grown despite the current level of federal regulation. Nine states have already adopted laws regulating biotechnology.[164] Three of these, North Carolina, Minnesota, and Florida, require a permit to release genetically engineered plants or other organisms.[165] Most states require submission of the same forms required by federal authorities, and some states require notification of county or city authorities.[166] North Carolina generally requires submission of the federal forms, and reviews the adequacy of federal

161. FDA Statement of Policy, *supra* note 53, at 22,988-91.

162. Huber, *supra* note 55, at 1082. If the FDA regulates under its current statutory authority, some bioengineered foods might be classified as whole foods and escape both screening and standard-setting regulations, appropriate for "old risks." Others, classified as food additives, would be subject to premarket screening, which in many cases might be overly strict regulation.

163. *See, e.g.*, Molly O'Neil, *Geneticists' Latest Discovery: Public Fear of "Frankenfood,"* N.Y. TIMES, June 28, 1992, at A1; *Group of Chefs Plans Boycott of Genetically Engineered Food*, S.F. CHRON., July 29, 1992, at A3; Michael Schrage, *Genetically Engineered Foods May Be Safe, but They Still Should Be Labeled*, WASH. POST, June 5, 1992, at B11.

164. Eisner, *supra* note 33, at 6 (listing Florida, Hawaii, Illinois, Maine, Minnesota, New York, North Carolina, Rhode Island, and Wisconsin).

165. FLA. STAT. ANN. § 581.083 (West 1991); MINN. STAT. ANN. § 116C.94 (West 1991); N.C. GEN. STAT. § 106-772 (1990).

166. *See, e.g.*, ILL. ANN. STAT. ch. 111 1/2, paras. 7603-7604 (Smith-Hurd 1991); WIS. STAT. ANN. § 146.60 (West 1990).

decisions, but preempts regulation by counties and municipalities.[167] Minnesota and Wisconsin enacted a one-year moratorium on the use of bovine somatotropin (bST).[168] State regulation of biotechnology adds at minimum another round of paperwork when the state and federal laws are equivalent, but imposes an additional regulatory burden when they conflict. The Minnesota and Wisconsin bans on bST are examples of laws conflicting with federal regulation that also contravene the principles of comparative regulation.[169]

The lack of a unified approach on the federal level and the prospect of a patchwork of state regulations has caused the biotechnology industry to lobby for more comprehensive federal regulations.[170] Moreover, it has been suggested that state law should be preempted in regard to biotechnology.[171] The current statutes from which regulatory authority over biotechnology has been derived generally do not preempt state law, permitting state laws more stringent than federal law so long as they do not burden interstate commerce.[172] Thus, new statutory authority would be necessary to effect state preemption.

The Omnibus Biotechnology Act of 1990 (House Bill 5312, not enacted) was a response to the need to revise federal regulation of biotechnology that also addressed the role of the states in regulating biotechnology.[173] H.R. 5312 sought to unify federal review and authorization of release of genetically engineered organisms.[174] It required a permit for release of all "genetically modified organism[s],"[175] closing any gaps in regulatory oversight, and it established an application management board to coordinate jurisdiction between the agencies.[176] It recognized that release of some categories of organisms would not

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167. N.C. GEN. STAT. §§ 106-772, -775 (1990).

168. MINN. STAT. ANN. §§ 151.01, .15, .25 (West 1992); WIS. STAT. ANN. § 97.235 (West 1991).

169. Banning bST essentially imposes a greater regulatory burden on bST-derived milk than on its traditional counterpart, milk produced without hormone stimulation. Since the risk of the bST-derived milk apparently is no greater than that of traditionally produced milk, the ban contravenes the principles of comparative regulation.

170. Crawford, *supra* note 125; *cf.* Eisner, *supra* note 33, at 6 (the biotech industry is split over whether a national biotechnology policy is necessary).

171. *See, e.g.*, OTA, INVESTMENT IN BIOTECHNOLOGY, *supra* note 87, at 214. Shortly after the initial controversy over recombinant DNA, proposed legislation preempting state laws on biotechnology was suggested, but none has been enacted. *See* Judith P. Swazey et al., *Risks and Benefits, Rights and Responsibilities: A History of the Recombinant DNA Research Controversy*, 51 S. CAL. L. REV. 1019, 1069 (1978).

172. *Hearing on H.R. 5312*, *supra* note 96, at 163-64 (statement of Margaret Mellon, Ph.D., J.D., National Wildlife Federation).

173. H.R. 5312, 101st Cong., 2d Sess. (1990); *Hearing on H.R. 5312*, *supra* note 96, at 3-41 (text of H.R. 5312). H.R. 5312 was introduced on July 19, 1990. 136 CONG. REC. H5120 (daily ed. July 19, 1990). The bill was not enacted, and the last date of action on it was July 19, 1990. *Bill Tracking Report, 1990 H.R. 5312*, *available in* LEXIS, Legis Library, BLT101 File.

174. *Hearing on H.R. 5312*, *supra* note 96, at 3 (text of H.R. 5312).

175. *Id.* at 9.

176. *Id.* at 34.

require full review, but only notification of the agency.[177] Generally, agencies would issue permits unless the proposed activities constitute an "unreasonable risk to human health or the environment."[178] H.R. 5312 also required that the person or company applying for a permit provide the information regarding the release to the appropriate state agency. Further, H.R. 5312 gave the state the opportunity to submit its comments to the overseeing federal agency.[179] In return for this state involvement, H.R. 5312 provided for federal preemption of state authority to regulate or prohibit releases permitted under research and development permits, and allowed state regulation but not prohibition of releases of organisms which have been approved for either a general permit or for commercial purposes.[180] It also required extensive notification of local authorities.[181]

Environmentalists generally approved of the bill for its broad coverage of genetically engineered organisms and its state and local notification procedures, but faulted it for its federal preemption provisions.[182] Industry representatives were pleased with the latter but were concerned that permits might be required in situations where previous experience had shown no adverse effects, suggesting that notification would suffice.[183] Thus, industry may prefer to rely on the administration's policy, which has the potential to remove many organisms from supervision. In the absence of a comprehensive federal biotechnology regulatory scheme, however, both camps are subject to the vicissitudes of the states. Biotechnologists may find more local regulations passed that block their progress to commercialization. Conversely, should a bioengineered organism immune to federal regulation under the current scheme pose a genuine threat to the environment, state regulation could not provide adequate protection to the nation as a whole.

VIII. PROPOSAL FOR FEDERAL REGULATION OF BIOENGINEERED FOOD

Regulation of the release and consumption of bioengineered food products requires a credible, straightforward regulatory framework that addresses all genetically engineered organisms and products and gives the states and the public confidence that the products of biotechnology

177. *Id.* at 10, 20.
178. *Id.* at 15-16.
179. *Id.* at 35-38.
180. *Id.* at 38-39.
181. *Id.* at 10-11.
182. *Id.* at 161 (statement of Margaret Mellon, Ph.D., J.D., National Wildlife Federation).
183. *Id.* at 181, 187 (comments of David J. Glass, Vice President, Government and Regulatory Affairs, Biotechnics International, Inc.); *id.* at 190-91 (comments of Warren Springer, Manager, Regulatory Affairs, Northrup King Co.); *id.* at 198 (comments of Rod Townsend, Manager, Regulatory Affairs, Plant Breeding Division, Pioneer Hi-Bred International, Inc.).

are appropriately regulated.[184] That new statutory authority could be similar to H.R. 5312 in extending coverage to all genetically engineered organisms, and it could ease regulatory burdens by coordinating the review process through an applications management board. New statutory authority should be based on the premise that not all products of genetic engineering require oversight. The new statutory scheme should not impose additional regulatory burdens based solely on the process of manufacture or on possible unknown risks; rather, regulation should be commensurate with the risks of the product.[185] Thus, new statutory authority governing the release of genetically engineered organisms could mandate that agencies implement a comparative approach to regulation similar to that proposed by the Council on Competitiveness, rather than an undefined standard where permits would be denied only when there is a risk to health or environment.[186] Based on present and future experience, the agencies could develop categories of genetic changes in particular types of organisms that would require only notification, but no review. This would help avoid unnecessary oversight but provide the authority to regulate when needed.

Recognizing the complexity of the biotechnology industry and its regulation, the extensive technical resources available to the federal review process, and the strong national stake in biotechnology, new statutory authority should also preempt state prohibition of release of genetically engineered organisms allowed by the federal government. It should, however, permit state and local regulation of biotechnology. For example, it should allow states to designate certain areas such as nature preserves as inappropriate for such activities. By giving such regulatory authority, these is the risk that a state could effectively prohibit genetically engineered organisms, perhaps by requiring excessive containment of biotechnology activities. This, however, is somewhat consonant with other federal regulatory statutes that allow states to regulate more stringently than federal statutes require.[187] Because

184. *See generally* OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, OTA-F-474, A NEW TECHNOLOGICAL ERA FOR AMERICAN AGRICULTURE (1992).

185. A discussion of the benefits and costs of biotechnology regulations, given that no problems have actually occurred, is found in OTA, BIOTECHNOLOGY IN A GLOBAL ECONOMY, *supra* note 76, at 195-96.

186. Such an approach to comparative regulation should provide that the new and reference organism be compared in the same environment; e.g., a faster growing transgenic fish would probably pose no more threat than a parental strain in a fish hatchery, but if the intent is to transfer the transgenic fish to the wild, it should be compared to indigenous wild fish.

187. *See, e.g.*, Wisconsin Pub. Intervenor v. Mortier, 111 S. Ct. 2476 (1991) (state or local regulation of pesticide use is permitted so long as it does not authorize a sale or use prohibited by FIFRA); Processed Apples Inst., Inc. v. Department of Pub. Health, 522 N.E.2d 965 (Mass. 1988) (state could establish tolerances for pesticides more stringent than federal levels under the FDCA). State or local authorities who are most familiar with the local terrain would probably be best suited to enact laws that, for example, permit oversized transgenic fish in a sport fishing lake but prohibit them in nature preserves.

biotechnology is a rapidly changing area, any new statutory authority should contain a sunset provision to allow change that will accommodate new advances and understanding of risks.[188]

Since the food products of biotechnology are comparable to traditional foods, they could be regulated under existing statutes, but new regulations addressing generic concerns related to biotechnology would be helpful to developers and regulators.[189] This proposal is consistent with the recommendation of the Administrative Conference of the United States that agencies adopt rules that address recurring regulatory issues concerning biotechnology.[190] Although the food additive and GRAS categories may be appropriate for evaluating bioengineered chemicals and enzymes, transgenic food crops should be evaluated on a comparative basis without reference to whether the gene/product might be considered an added substance or food additive. The provisions could still be self-actuating in the event that manufacturers are confident that their foods meet the specifications, but notification should be mandatory during this period when bioengineered foods are still being introduced.[191] The agencies should continue the practice of giving advisory opinions when manufacturers request advice on the status of their product.[192] Federal regulation of biotechnology-derived food products would not preempt state law, since state law protecting health and safety is generally given considerable deference where there are no explicit preemption provisions, as in the FDCA.[193]

In conclusion, a more comprehensive and straightforward federal statutory and regulatory scheme, addressing both the environmental release of bioengineered food organisms and the safety of the products, could foster both the development of biotechnology and protection of

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188. H.R. 5312 had a sunset provision of seven years. *Hearing on H.R. 5312*, *supra* note 96, at 40-41 (text of H.R. 5312).

189. Generic concerns might include decisions on the safety of commonly used antibiotic resistance genes used as markers, commonly used vectors, allergens and biopesticides. This would be no different in principle than the regulations listing GRAS substances. For a discussion of antibiotic resistance genes and vectors, see International Food Biotechnology Council, *supra* note 11, at S122-25.

190. General Provisions, Administrative Conference of the United States, 1 C.F.R. § 305.89-7 (1991).

191. Such a notification procedure could include safety data which could be made public and could give the FDA a basis for minimal oversight. OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, OTA-F-475, A NEW TECHNOLOGICAL ERA FOR AMERICAN AGRICULTURE—SUMMARY 21 (1992).

192. The FDA has indicated that industry should no longer submit requests for advisory opinions. FDA Statement of Policy, *supra* note 53, at 22,985. Moreover, the FDA has no obligation to issue advisory opinions, nor does it routinely publish notices of requests for advisory opinions. Calgene, *supra* note 120, at 22,772.

193. *See, e.g.*, Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132 (1963). However, federal regulation of animal drugs may preempt state regulations in that area, since a comprehensive scheme of drug regulation under the FDCA is linked to meat regulation under the Federal Meat Inspection Act, which has explicit preemption provisions. Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corp., 626 F. Supp. 278, 282-86 (D. Mass. 1986); 21 U.S.C. § 301 (1988) (ch. 9).

human health and the environment. It should not, however, thwart state or local laws that have long been accepted in the area of food regulation.[194] The only remedies, then, to unduly restrictive regulation at the state level lie in the credibility of the federal scheme and, more importantly, in the public perception of the technology itself. That perception will be greatly improved when biotechnology advances to the point that products are available to fulfill its promise of improvement of human health and the environment.

194. Many aspects of the FDCA, such as the manufacture and safety of drugs, involve issues so complex and critical that national standards, preempting state law, might best protect the public safety and welfare. Food products have not reached a similar level of complexity and present more situations in which local safety concerns might genuinely exist. In any case, the application of biotechnology to foods or drugs does not seem to present a situation so special that it merits federal preemption even when the FDCA does not preempt state law regarding most food and drug products.

COMMENT

UNIVERSITY PHYSICIAN-RESEARCHER CONFLICTS OF INTEREST: THE INADEQUACY OF CURRENT CONTROLS AND PROPOSED REFORM

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I. INTRODUCTION

The rapidly advancing biotechnology industry continues to generate many critical legal and ethical issues.[1] One unresolved issue is the troubling increase in conflicts of interest,[2] conflicts of commitment,[3] and scientific misconduct[4] in university research. Conflicts of interest exist when "financial or other personal considerations may compromise, or have the appearance of compromising, an investigator's professional judgment in conducting or reporting research."[5] Universities and policy makers have become particularly concerned about conflicts of interest arising when a researcher, "any of his Family, or any Associated Entity

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1. *See generally* OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, SPECIAL REPORT OTA-BA-360, NEW DEVELOPMENTS IN BIOTECHNOLOGY: U.S. INVESTMENT IN BIOTECHNOLOGY (1988) [hereinafter INVESTMENT IN BIOTECHNOLOGY].

2. *See infra* note 5 and accompanying text (defining conflicts of interest).

3. Conflicts of commitment are "situations in which [faculty] members' external activities, often valuable in themselves, interfere or appear to interfere with their paramount obligations to students, colleagues, and the school." Harvard Univ. Faculty of Pub. Health, Policies on Conflict of Interest and Commitment 1-3 (Jan. 9, 1991) (on file with author). This Comment focuses on conflicts of interest, although it will discuss problems associated with conflicts of commitment and scientific misconduct where examples help illustrate the risks arising from industry-sponsored research.

4. Scientific fraud or misconduct involves the deliberate misrepresentation of research findings. For example, a researcher may falsify results to present more positive findings than she obtained. Similarly, a researcher may suppress negative findings or plagiarize research papers, methodologies, and results. Researchers may deliberately misrepresent experimental methodologies, thereby preventing replication or disproval of the findings by others. Authors may report fictional "results," having never performed the experiments at all. HOUSE COMM. ON GOV'T OPERATIONS, ARE SCIENTIFIC MISCONDUCT AND CONFLICTS OF INTEREST HAZARDOUS TO OUR HEALTH?, H.R. DOC. NO. 688, 101st Cong., 2d Sess. 4 (1990) [hereinafter COMMITTEE ON CONFLICTS OF INTEREST].

Although the prevalence of scientific misconduct is unknown, many scientists believe such incidents are fairly common. One study found that of 245 university scientists polled, 32% had suspected a colleague of falsifying data and 32% had suspected a colleague of plagiarism. More than half of these suspecting scientists chose not to investigate the veracity of their suspicions, however. COMMITTEE ON CONFLICTS OF INTEREST, *supra*, at 5 (discussing *Scientific Fraud and Misconduct and the Federal Response: Hearing Before the House Comm. on Gov't Operations*, 100th Cong., 2d Sess. 101-02 (1988) (testimony of Dr. June Price Tangney)).

5. ASSOCIATION OF AM. MEDICAL COLLEGES, GUIDELINES FOR DEALING WITH FACULTY CONFLICTS OF COMMITMENT AND CONFLICTS OF INTEREST IN RESEARCH 6 (1990) [hereinafter AAMC GUIDELINES]. A conflict of interest may exist "when an individual involved in conducting evaluative tests of new products (e.g. clinical trials) also holds an interest in a company that stands to gain from the results of the study." PRESIDENT'S COUNCIL ON COMPETITIVENESS, REPORT ON NATIONAL BIOTECHNOLOGY POLICY 7 (1991) [hereinafter COUNCIL ON COMPETITIVENESS].

possesses a Financial Interest in any activity which involves his responsibilities as a member" of a university faculty.[6]

University researchers' increased dependence on private industry funding has contributed to part of the rise in conflicts of interest. As the demand for biotechnology research funding has skyrocketed, the federal portion of total funds available for research grants has diminished. Industry has eagerly stepped in to fill the funding gap.[7]

In its search for profitable technologies, private industry continues to forge innovative funding arrangements with university research departments and individual researchers. University research departments and biotechnology companies are establishing major joint research institutes in unprecedented numbers.[8] In today's world of "corporate science," industry frequently graces individual researchers

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6. Harvard Univ. Faculty of Medicine, Policy on Conflicts of Interest and Commitment 2 (Mar. 22, 1990) (on file with author); *see also infra* note 19 (discussing the Pajaro Dunes Conference).

7. According to National Institutes of Health (NIH) data, total funding for United States health research and development increased dramatically from $7.94 billion in 1980 to $20.57 billion in 1989. In that same period, NIH's proportion of total funding dropped from 40% to 33%, while industry's contribution rose from 31% to 45%. Other public funding sources dropped from 25.6% in 1980 to 18% in 1989. Likewise, NIH's awards for new grants decreased from a record high of 6446 in 1987 to only 4600 in 1990. Many of the 1987 NIH new grant awards spanned longer terms than had been customary. As a result, NIH has had less funding available for new grants in recent years. John Carey, *'NIH Is Not the Institution It Was,'* NEWSWEEK, Nov. 5, 1990, at 145, 148. The Office of Science and Technology Policy estimates that total federal investment in biotechnology in fiscal year 1990 was $3.5 billion, of which 80% came from NIH. Industry sources provided approximately $2 billion for biotechnology research and development, most of which was allocated for specific product development. *See* COUNCIL ON COMPETITIVENESS, *supra* note 5, at 6.

8. For example, Harvard University's Massachusetts General Hospital received $70 million from Hoechst A.G., a West German-based chemical company, in 1980. In return, Hoechst received an exclusive option to market any potentially profitable technologies developed by the famous researcher Howard M. Goodman during the ten-year research contract. As early as 1983, E.I. du Pont de Nemours & Company gave Harvard Medical School $6 million earmarked for the department of genetics; the Celanese Corporation gave Yale $1.1 million for enzyme studies; the Bristol-Myers Company gave Yale $3 million for the production of anti-cancer drugs; W.R. Grace & Company gave MIT up to $8.5 million for commercial applications of microbiology research; and Monsanto gave $23.5 million to Washington University for research in medical uses of proteins and peptides and $4 million to Rockefeller University for research in photosynthesis. Katherine Bouton, *Academic Research and Big Business: A Delicate Balance*, N.Y. TIMES, Sept. 11, 1983, § 6 (Magazine), at 62.

In a recent report, the President's Committee on Competitiveness reported that the number of cooperative research and development agreements (CRADAs) under the 1980 Technology Transfer Act increased fourfold during the Bush Administration, rising from approximately 110 in 1988 to more than 400 currently. *See* COUNCIL ON COMPETITIVENESS, *supra* note 5, at 6; *see also* Technology Transfer Act, 15 U.S.C. §§ 3701-3714 (1988 & Supp. II 1990) (legislation that fostered joint research and development projects between industry and federally supported universities and laboratories).

with valuable stock options, consulting agreements, or other financial rewards in exchange for agreements to perform valuable research or provide consulting services.[9] To obtain and retain these financially rewarding arrangements, however, researchers must satisfy their industry sponsors.

Of concern is that industry's commercial objectives are often at odds with patient or scientific interests.[10] For example, when granting a lucrative research arrangement, a company may require a researcher to agree that potentially profitable research findings will remain confidential, unpublished, or significantly delayed in publication.[11] As a result, the scientific community may be deprived of valuable findings that suggest treatment options for patients. In efforts to accommodate

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9. A *New York Times Magazine* article in 1983 reported, "So many academics have been hired as part time consultants that, a year or two ago, an investment company looking for an unaffiliated molecular biologist reportedly approached 20 researchers before it found one without a commercial tie. Today, scientists agree, it would be difficult to find even that one among top researchers, so rapid and comprehensive has the entanglement with industry been." Bouton, *supra* note 8; *see infra* notes 63-64, 72-144 and accompanying text.

10. *See infra* notes 22-65 and accompanying text.

11. However, some universities, such as the University of California, will not "accept funding that imposes unreasonable restrictions on the publication and dissemination of research results." Richard P. Seligman, *Implementing California's Regulations on Conflict of Interest in Research*, RES. MGMT. REV., Fall 1989, at 27, 33. The Yale University *Faculty Handbook* states that

> [t]he University does not sponsor secret or classified research projects. This policy rests on two closely related judgments: that one part of the University's essential purpose, to impart knowledge, is clearly restricted when free discussion and open publication are prohibited; that the other part of the University's purpose, to enlarge humanity's store of knowledge, also depends on free discussion and criticism of results by a scholar's peers and would be inhibited along with the professional growth and standing of the individual if free dissemination were prohibited.

YALE UNIV., FACULTY HANDBOOK 96 (1986) (on file with author).

In 1985, Yale added to its faculty handbook a provision to clarify the university's policy on several issues related to sponsored research including publication of research results. The handbook states that "[t]he University's mission, openly and freely to disseminate knowledge, implies a presumption against any restriction of the right of the faculty to publish or against any requirement of approval prior to publication." *Id.* at 97. In a memo to the Yale faculty, the Committee on Cooperative Research, Patents, and Licensing warned faculty members considering consulting agreements:

> You should at all times remain completely aware that confidentiality is antithetical to the basic values of free and open dissemination of information that are at the core of academic life. To the extent possible, you should attempt to restrict the confidentiality requirements of your outside work to a minimum.

Memorandum from the Committee on Cooperative Research, Patents, and Licensing, to the Faculty of Yale University (May 1986) (on file with author) [hereinafter Yale Consulting Memorandum].

industry, researchers may compromise scientific goals in favor of industry's objectives.[12]

Generally, university-industry collaboration is mutually beneficial. Collaboration allows for rapid technology transfer, thereby facilitating the development of new products.[13] Many of these new products are of great benefit to the public.[14] Industry draws from "the collective intellectual and creative talents of university faculty, and academia benefit[s] from additional sources of research and other funds."[15] Fortunately for universities, as competition for federal funds has intensified, industry has supplemented research funds.[16] But collaborative relationships have created a culture ripe for abuse by enterprising researchers.

The exposure of numerous incidents of inappropriate faculty behavior involving industry sponsors[17] has prompted examination of university policies governing faculty-industry research relationships.[18] The scientific community has only recently begun asking whether certain types of university-industry commingling are advisable.[19] Consequently,

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12. Another related concern is that university scientists may be unprepared to represent university and even personal interests in negotiations with sophisticated industry funding sources, particularly since such lucrative funding arrangements were largely unknown to past generations of scientists. *See* YALE UNIV., *supra* note 11; Yale Consulting Memorandum, *supra* note 11.

13. "[T]he translation of new [scientific] ideas into the marketplace is a laudable national goal.... [S]ociety can often benefit from the commercial application of scientific knowledge." COUNCIL ON COMPETITIVENESS, *supra* note 5, at 6. The Council also recommended that agencies should vigorously implement the provisions of the Technology Transfer Act and "[j]oint efforts among the public, university and private sectors to promote the transfer of scientific knowledge should be encouraged wherever possible." *Id.*

14. For example, biotechnological researchers have developed drugs and drug delivery methods to improve treatment of a wide range of diseases. The Food and Drug Administration has approved preventative agents or treatments for hepatitis B, anemia, diabetes mellitus, acute myocardial infarction, human growth hormone deficiency, AIDS-related Kaposi's sarcoma, hairy cell leukemia, venereal warts, and kidney transplant rejection. Development of many other treatment products and methods is currently underway. Gene therapy, in which researchers insert genetic materials into human cells, is among the most recent experimental treatment modalities. Gene therapies could be used to treat myriad diseases such as cancer, immune system disorders, hemophilia, and sickle cell anemia. *Id.* at 2.

15. AAMC GUIDELINES, *supra* note 5, at 1.

16. *See supra* note 7 and accompanying text; *see also* National Insts. of Health & Alcohol, Drug Abuse & Mental Health Admin., *Request for Comment on Proposed Guidelines for Policies on Conflict of Interest*, NIH GUIDE FOR GRANTS & CONT., Sept. 15, 1989, at 1 [hereinafter *NIH Proposed Guidelines*].

17. *See infra* part II.B.

18. *See infra* notes 19-20.

19. In 1982 the presidents of five universities met with leading scientists and industry executives to discuss the conflict-of-interest and other issues presented by university-industry ties. David Perlman, *Business Boom Sparks Big 'Bio-Ethics' Meeting*, S.F. CHRON., Mar. 19, 1982, at 30. *See generally Pajaro Dunes Conference Draft Statement*, 9 J.C. & U.L. 533

clear policy and guidance for participants in biotechnological research are in their infancy.[20]

The widely publicized *Moore*[21] case exemplifies the type of exploitation of conflicts of interest occurring within the biotechnology research arena, largely at the expense of an unwitting patient. In the context of *Moore* and several other disturbing case examples, this Comment discusses the growing prevalence of conflicts of interest in biogenetic research and problems arising out of such conflicts. The particular focus of this Comment is the often overlooked issue of physician-researcher conflict of interest. Part II investigates the impact of increased private industry involvement in biogenetic research and demonstrates that conflict between industry and university research norms fosters physician-researchers' temptation to behave unethically and, consequently, decreases patient protection. Part III discusses the lack of effective university and government regulation of conflicts of interest. It also discusses the failure of the available legal remedies of informed consent requirements and physician's fiduciary duty to fully protect patients. Finally, Part IV proposes reform mechanisms aimed at minimizing incentives to violate ethical standards.

This Comment concludes that in addition to policing physician-researcher conflicts of interest by providing legal remedies to patients, universities and federal research funding sources must develop and enforce their own guidelines regarding industry involvement in scientific research. This Comment proposes that universities require full disclosure of any activities that could present conflicts of interest and demand thorough, multi-tiered review of research proposals. Moreover, universities must minimize physician-researchers' incentives to engage in unethical or illegal activities, promptly investigate allegations of inappropriate behavior, and discipline faculty members who fail to adhere to institutional policies.

This Comment also proposes that funding organizations formulate policies that provide incentives for university researchers to minimize

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(1982-83). In 1990, the Human Resources and Intergovernmental Relations Subcommittee reported an oversight investigation of scientific misconduct and conflicts of interest. The investigation included hearings in which over 30 members of the scientific community testified. The views described in the report indicate that many scientific organizations are currently evaluating the conflict of interest issue. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4.

20. In a recent study, the Human Resources Subcommittee of the Committee on Governmental Operations found that most universities do not limit the amount of money faculty may accept for research, travel, consulting fees, or gifts from drug companies or from other private sources. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 6.

21. Moore v. Regents of the Univ. of Cal., 793 P.2d 479 (Cal. 1990).

conflicts of interest and uphold high ethical standards. Requiring those institutions managing and funding scientific research to take responsibility for problems resulting from conflicts of interest will increase the likelihood that patients' interests will be protected prior to involvement in research. Such additional preventive measures are preferable to merely compensating injured patients after harm has occurred.

II. THE IMPACT OF INCREASED INDUSTRY INVOLVEMENT IN UNIVERSITY RESEARCH

A. Academic Research Norms[22]

In the past, private industry funded little university research.[23] The federal government provided the majority of research funds through grants used for "basic"[24] scientific research.[25] Individual researchers were unconcerned about the availability of funding, whether federal or private, because fundraising occurred at the institutional level.[26] As a result, academic researchers' norms, values, and rules of conduct evolved relatively untouched by financial concerns.[27]

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22. One noted sociologist describes several standards that historically have guided academic scientists' behavior. ROBERT MERTON, *The Puritan Spur to Science, in* THE SOCIOLOGY OF SCIENCE 228, 228-53 (1973), *discussed in* Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 183 (1987). The norm of "universalism" embodies the notion that valid research findings are valid regardless of the particular scientist or institution performing the research. In other words, that which is true is universally true for the entire scientific community. "Communism" expresses the value that because all scientific inquiry relies on prior scientists' efforts to some degree, scientific advancements should be added to the pool of communal knowledge. "Disinterestedness" conveys the idea that scientists should seek truth objectively, without considering their individual interests. Lastly, "organized skepticism" captures the value that before findings are deemed valid, the scientific community at large should examine their veracity. *Id.*

23. Helen Lescovac, *Ties That Bind: Conflicts of Interest in University-Industry Links*, 17 U.C. DAVIS L. REV. 895, 897-98 (1984).

24. *See infra* note 34 (defining basic research).

25. *See supra* note 7, *infra* note 45.

26. Rebecca S. Eisenberg, *Academic Freedom and Academic Values in Sponsored Research*, 66 TEX. L. REV. 1363, 1364, 1372 (1988).

27. University researchers' norms and values evolved in response to university faculties' assertions of academic freedom. As early as 1915, the American Association of University Professors (AAUP) formulated its definition of academic freedom. Eisenberg, *supra* note 26, at 1364 (discussing American Ass'n of Univ. Professors, Declaration of Principles (1915), *reprinted in* ACADEMIC FREEDOM AND TENURE app. A at 157-76 (Louis Joughin ed., 1969)). It stated that faculty members must possess the freedom to research and publish, to teach, and to speak or write as citizens outside the university. *Id.* at 1366. This and other early definitions of academic freedom reflect a universal concern that

In today's environment, however, individual faculty members pursue federal grants and industry sponsors for research funds on their own, often with minimal involvement by university administrations.[28] Once a faculty member attracts a funding source, the university enters the negotiations to finalize the agreement.[29] At the same time that faculty members are assuming greater responsibility for soliciting funding, reductions in federal and increases in industry funding[30] have changed the motivations and rewards for scientists. These changes are, to a degree, incompatible with traditional research norms and values.[31] Some observers caution that the scientific community, and ultimately the public, will suffer as a result of these new forces.[32]

As beneficiaries of substantial public funds, research universities have historically viewed themselves as quasi-public servants, conducting research for the public benefit and working to maintain the public trust.[33] The pursuit of "basic"[34] scientific research was seen as a public good.

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faculty members' controversial or unpopular statements might be suppressed by the lay administrators who employ them. University faculty members feared that university administrators might easily be co-opted by the interests of those funding the university.

Eisenberg explains that

> academic freedom protects faculty members from trustees and university administrators so that professional scholars will say what they think. In the absence of academic freedom, students and the public at large could not be certain that the views presented by scholars were in fact candid opinions of those experts, undistorted by the less informed views of laypersons on whom the scholars depend for their livelihood.

Id. Eisenberg notes, however, that the AAUP was not "argu[ing] for unqualified professional autonomy for individual faculty members or for an unregulated academic profession. Quite the contrary, they warn that the only way to preserve freedom from lay interference is through a system of accountability to professional peers." *Id.* at 1366-67. Thus, the shared norms and values among university researchers constitute a mechanism for self-regulation. These collective norms function as an honor code to which all members are expected to comply.

28. *Id.* at 1372; *see also* Yale Consulting Memorandum, *supra* note 11.

29. Eisenberg, *supra* note 26, at 1373.

30. *See supra* note 7, *infra* note 45.

31. *See infra* notes 33-65 and accompanying text.

32. *See* COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4; Eisenberg, *supra* note 26; Eisenberg, *supra* note 22.

33. *See infra* text accompanying note 35; *see also* Eisenberg, *supra* note 26, at 1371.

34. "Basic" research refers to "pure" research conducted for the sole purpose of expanding scientific knowledge. Conversely, "applied research" is conducted for the purpose of solving practical problems. Eisenberg, *supra* note 22, at 178 n.1. Eisenberg suggests that while this distinction is frequently made, it is no longer useful in the context of biotechnology where basic and applied research have become intermingled. Answers to many basic research questions have immediate commercially profitable applications.

> For example, cells contain more genetic information than they actually use. Learning what causes cells to "express" certain genes and not others would not only answer major questions in biology, but might suggest ways of

According to one scholar, "[t]he role of the states as funder of basic (non-commodity-oriented) research fostered a powerful ideology—one of scientists working for the public good to improve the health status of Americans."[35] Unlike today, when industry avidly pursues marketable biotechnological advances, industry was largely uninvolved in basic scientific research.[36] As a result, industry goals and desires were of little concern to university scientists.

Historically, the academic community freely and openly shared information, techniques, and samples to ensure that subsequent researchers could replicate results.[37] "It was thought contrary to scientific norms to claim exclusive rights in research discoveries. These norms derive in part from the notion that making new observations available to the scientific community for evaluation and extension in further research facilitates the progress of science."[38] Consequently, researchers rarely sought patent protection for their discoveries.[39]

> facilitating the manufacture of desired proteins or suppressing the expression of disease-causing genes. This knowledge would therefore be valuable to both scientists and industry.

Id. at 195 n.96.

35. Eisenberg, *supra* note 22, at 179 n.6 (quoting MARTIN KENNEY, BIOTECHNOLOGY: THE UNIVERSITY-INDUSTRIAL COMPLEX 32 (1986)).

36. *See supra* note 7.

37. Eisenberg, *supra* note 22, at 197. In order to validate other researchers' findings or to build on their own work, researchers often obtain the actual materials used by the original researcher. These might include bacterial strains or other self-replicating tissues such as cell-lines. Mere publication of findings may not be sufficient to satisfy the research norm of replicability.

38. *Id.* at 182 (discussing *Commercialization of Academic Biomedical Research: Hearings Before the Subcomm. on Investigations and Oversight and the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology*, 97th Cong., 1st Sess. (1981); KENNEY, *supra* note 35; MERTON, *supra* note 22).

39. *See generally id.* at 185-90, 196-97 (discussing recent court decisions involving patentability of biological materials and impediments to patentability of basic research findings). Eisenberg explains that traditional patent law protected only applied technology inventions. Consequently, basic research findings that could not be readily applied to practical use were not patentable. *Id.* at 186. Moreover, prior to the Patent and Trademark Act Amendments of 1980, which allowed universities and other institutions of higher education to retain title to patentable inventions derived from government sponsored research, universities assigned most patentable inventions to the government. *Id.* at 196 (discussing Patent and Trademark Act Amendments of 1980, Pub. L. No. 96-517, 94 Stat. 3019 (codified at 35 U.S.C. §§ 200-212 (1988))). The 1980 Amendments promote universities' retention of patent rights by allowing the sponsoring government agency to retain title if the university does not exercise its rights within a reasonable time. Since the 1980 Amendments force universities to share patent royalties with the inventors, the Amendments motivate faculty researchers, as well as universities, to seek patents for their research. *Id.*

Instead, researchers published findings promptly and sought recognition by colleagues as their reward.[40] Offering recognition and esteem to those who contribute to the shared body of scientific knowledge "insures that scientists' self-interest will coincide with the public good."[41] Most researchers complied with this "professional canon,"[42] since deviation was unusual and generally frowned upon.[43] Thus, even particularly self-interested researchers, unconcerned about contributing to the public domain of scientific knowledge or facilitating future researchers' efforts, were highly motivated to disclose their findings. For without publication, researchers received few rewards.[44]

As private industry funding increases for biomedical research have outpaced those from public sources,[45] however, new relationships

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40. One measure of a scientist's prestige is the frequency of citation of her work. JEROME R. RAVETZ, SCIENTIFIC KNOWLEDGE AND ITS SOCIAL PROBLEMS 247, 255 (1971).

41. Eisenberg, *supra* note 22, at 184 (discussing ROBERT MERTON, *The Normative Structure of Science, in* THE SOCIOLOGY OF SCIENCE 275 (1973)). Some scholars believe that allowing proprietary rights in research findings conflicts with the norm of sharing information freely with other researchers. However, others point out that because patent law requires complete disclosure and dedication to the public, proprietary rights may actually further norms of sharing research information.

42. *Commercialization of Academic Biomedical Research: Hearings Before the Subcomm. on Investigations and Oversight and the Subcomm. on Science, Research and Tech. of the House Comm. on Science and Technology*, 97th Cong., 1st Sess. 62-63 (1981) [hereinafter *Commercialization Hearings*] (statement of Dr. Jonathan King).

43. Regarding violation of the norm of sharing research information, Dr. Jonathan King testified: "I don't mean to say there isn't professional jealously [sic]. We have ambition and we have fame and recognition, but it is considered a departure from the normal and you are embarrassed when it comes out. It is not what you are supposed to be doing." *Id.* at 63.

44. *See* RAVETZ, *supra* note 40.

45. By 1950, the federal government funded more than 83% of the research in natural sciences. Predominantly, government funding has financed the development of research departments, equipped laboratories, paid the salaries of support staff, purchased supplies and materials, and provided for the training of researchers. Lescovac, *supra* note 23, at 897 n.11. According to one estimate, federal funding of university research and development declined from 73.5% in 1966 to 65.1% in 1981, while industry sponsorship increased from 2.4% to 3.8% over those years. Donald R. Fowler, *University-Industry Research Relationships: The Research Agreement*, 9 J.C. & U.L. 515 (1982-83).

> Between 1980 and 1984, industrial funding for research and development at universities and colleges increased 93%, from $237,025,000 in 1980 to $457,227,000 in 1984, while federal funding increased only 31%, from $4,096,029,000 to $5,386,578,000. Adjusted for inflation, the total investment in research and development at universities and colleges rose only 4% between 1980 and 1983. This extremely modest rise reflects cutbacks in federal funding, particularly in the health area.

NATIONAL SCIENCE FOUND., NATIONAL PATTERNS OF SCIENCE AND TECHNOLOGY RESOURCES 12-13, 65 (1986) (tbl. 51); Eisenberg, *supra* note 22, at 178 n.2. Another study found that private industry may be funding up to one quarter of all university biotechnology research and that nearly one half of all biotechnology companies fund some university

between universities and industry have evolved. Some new practices contrast dramatically with previously accepted research norms and can create conflicts of interest.[46] A variety of relationships currently exist, including industry sponsorship of university research, university ownership or interest in biotechnology firms, and commercial joint ventures or research consortia between universities and private industry.[47] Relationships between individual university researchers and private industry are also quite commonplace.[48] For instance, university researchers may own stock in biotechnology companies or enter into research contracts, grants, or consulting agreements.[49] Many researchers become company officers or directors or members of scientific advisory boards for industry.[50]

Researchers involved in private industry face pressures from two often-incompatible value systems.[51] For instance, traditional research norms required that researchers remain disinterested[52] by having no stake in the outcome of their studies,[53] whereas industry promotes the pursuit of profits. Entering into collaboration with industry results in conflicts of interest because a researcher's financial tie to a private company may be directly affected by research outcomes. For example, the value of the researcher's company stock may increase if a discovery is favorable to the company's plans.[54]

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research. David Blumenthal et al., *Industrial Support of University Research in Biotechnology*, 231 SCIENCE 242, 243-44 (1986).

46. *See generally supra* notes 22-32 and accompanying text.

47. *See supra* note 8; *see also* Lescovac, *supra* note 23, at 899 nn.16-17 (additional examples of university-industry collaborative arrangements).

48. *See supra* note 9, *infra* notes 63-64 and accompanying text (commentary and examples of relationships between industry and individual researchers).

49. *See infra* note 64.

50. INVESTMENT IN BIOTECHNOLOGY, *supra* note 1, at 111-27; Patricia A. Martin & Martin L. Lagod, *Biotechnology and the Commercial Use of Human Cells: Toward an Organic View of Life and Technology*, 5 SANTA CLARA COMPUTER & HIGH TECH. L.J. 211, 217 (1989); *see also supra* note 48.

51. One observer posits that sponsored research relationships threaten fundamental academic values in several ways. She asserts that sponsored research promotes secrecy of research results, which is in conflict with the norm of disseminating research results. Likewise, she claims that sponsored research relationships may insidiously distort researchers' viewpoints in favor of their sponsors' interests, or may influence research agendas in favor of projects that sponsors will fund. Eisenberg, *supra* note 26, at 1377-78; *see also* Eisenberg, *supra* note 22.

52. *See* MERTON, *supra* note 22, at 275. According to Merton, disinterestedness means that scientists should seek truth rather than furthering their own personal interests by making false claims.

53. Eisenberg, *supra* note 22, at 183 (discussing MERTON, *supra* note 22, at 267).

54. *See infra* part II.B.2.

Whereas traditional scientific research ideals conflicted with industry's desire to develop marketable technologies, today the research goals of universities and industry overlap. Under traditional norms, objective scientists pursued "basic"[55] research purely for the advancement of science,[56] not because it facilitated the development of the latest widget. In modern biogenetic research, however, the lines between basic and applied research are blurred because many scientific discoveries are directly relevant to commercial applications.[57] As a means of furthering commercial interests, industry now funds a substantial portion of university research.[58] The modern researcher therefore serves two masters—private industry and the public.

Industry-allied researchers encounter pressures to tailor research agendas to either fit their sponsoring company's needs or risk losing their private funding.[59] Because funding from outside sources is badly needed by universities,[60] researchers are rewarded for their ability to attract industry funding and sponsorship. To the extent that adopting industry norms enables researchers to please industry, these norms are valued in academia. Universities may offer substantial rewards to those who pursue applied research and gain industry support,[61] whereas under traditional norms the scientific community deemed applied research non-intellectual, and therefore less valued. Some fear that, as a result, "true academic freedom will be threatened as will the honest interchange of

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55. *See supra* note 34 and accompanying text.

56. *See* Eisenberg, *supra* note 22, at 182 n.17. Eisenberg explains that departures from traditional research norms such as disinterestedness, information sharing, and the pursuit of scientific research for the public benefit occur frequently as scientists jockey to establish their own professional reputations. That overtly self-interested, competitive behavior elicits disapproval within the scientific community, however, demonstrates that traditional norms remain intact.

57. *See supra* note 34.

58. *See supra* notes 7, 45 and accompanying text.

59. Eisenberg, *supra* note 22; *see also* COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4; Lescovac, *supra* note 23, at 900. Other problems include bypassing traditional peer review mechanisms in allocating research funds, with consequent deterioration in the quality of research; altering the research and subsequent employment opportunities available to graduate students; and dividing loyalties of faculty affiliated with industry. *See generally* KENNEY, *supra* note 35; David Blumenthal et al., *University Industry Research Relationships in Biotechnology: Implications for the University*, 232 SCIENCE 1361 (1986); Gerald E. Markle & Stanley S. Robin, *Biotechnology and the Social Reconstruction of Molecular Biology*, 10 SCI. TECH. & HUM. VALUES 70 (1985); David E. Korn, Note, *Patent and Trade Secret Protection in University-Industry Relationships in Biotechnology*, 24 HARV. J. ON LEGIS. 191 (1987).

60. *See supra* notes 7, 45 and accompanying text.

61. *See* Eisenberg, *supra* note 26, at 1373. Eisenberg asserts that because academic scientists capable of obtaining funds are highly desirable to universities, those researchers have gained leverage in their dealings with universities. Consequently, universities may be more inclined to accommodate a researcher's demands in order to attract and or retain skilled fundraisers.

new ideas or the latest research findings. Graduate students and faculty members alike will risk having their efforts more tailored to commercial needs than scholarship or the best interests of society as a whole."[62]

Unlike the objective scientist of the past, many of today's scientists are better described as entrepreneurs,[63] seeking to capitalize on their latest research findings before someone else reaps the profits.[64] These

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62. Albert H. Meyerhoff, *Ties that Bind: Conflicts of Interest in University-Industry Links—An Introduction*, 17 U.C. DAVIS L. REV. 891, 894 (1984).

63. Most faculty earn substantial income above their base salaries from consulting relationships and other ties to private industry. One unpublished faculty compensation study found that 70% of faculty earned additional income totaling 21.5% of their base salaries from industry affiliations. Lescovac, *supra* note 23, at 905 (discussing K. Dillon et al., Faculty Compensation: Total University Earnings at Research Universities 1-3 (1979) (unpublished manuscript on file with author)); *see infra* note 64 (examples of scientist-entrepreneurs who have made fortunes through their research endeavors).

64. The University of California annual summary of disclosure statements filed with the California Fair Political Practices Commission reported 340 "positive" cases of university scientists having financial interests in business entities also sponsoring their university research. The Commission Report provides the following eye-opening examples:

> A UCLA scientist proposed a research project with Cetus Corporation, in which he had an investment of between $10,000 and $100,000, as well as income of $1,000 to $10,000. While the director of the University's Molecular Biology Institute stated that "the contract calls for work . . . at the border of basic research and technology," the project was approved. Cetus received an exclusive, world-wide, royalty-bearing license to any patentable discoveries.
>
> [Another UCLA] scientist was involved with a project with Global Geochemistry, of which he was president, 100% owner, and held an investment of between $10,000 and $100,000. He also received in excess of $10,000 in outside income from Global. Global's contract with the University was eventually not renewed.
>
> Another UC scientist proposed a research contract with Serex International from which he had been promised $10,000 per year consulting income and a 5000-share stock option as a "signing bonus." Serex was to receive exclusive patent rights.

Meyerhoff, *supra* note 62, at 893 (discussing Staff Memorandum of the Fair Political Practices Commission, at 10-14, 20-22 (1983)).

Forbes magazine noted several prominent academic research scientists who have profited tremendously from their biotechnological advances, including:

> David M. Goldenberg: founder, chairman and director of Immunomedics, owns approximately 16 million shares, equivalent to 69% of outstanding stock worth $112 million; University of Medicine and Dentistry of New Jersey adjunct professor.
>
> Herbert W. Boyer: founder, vice president and director Genentech since April, 1976, owns over 2 million shares of stock worth $30 million; professor of biochemistry, University of California at San Francisco since 1976.
>
> William J. Rutter: cofounder and chairman of Chiron Corp., owns 930,000 shares or approximately 8% of outstanding stock worth $14 million; chairman, department of biochemistry and biophysics at UCSF from 1969 to 1982.

new pressures, motivations, and incentives introduced into the academic world by industry involvement in research may be irreconcilable with traditional scientific values. As a result, some scientists have abandoned or deviated from the communal research canons that past generations deemed essential.[65]

Increased physician-researcher conflicts of interest are particularly troubling because of physicians' direct involvement with patients. Conflicts can arise from accepting gratuities or special favors from research sponsors, or undertaking clinical research when the physician or a family member has a financial, managerial, or ownership interest in the sponsoring company or the company developing the technology. In conflict situations, basic science researchers risk compromising university autonomy in choosing research agendas and faculty appointments, or inability to report findings freely. Unlike basic researchers, physicians

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Thomas P. Maniatis: member of Genetics Institute's advisory board, owns 637,000 shares of stock worth $9.5 million; professor of biochemistry and molecular biology at Harvard University since 1981.

Mark S. Ptashne: member of Genetics Institute's scientific advisory board, owns 568,000 shares worth $8.5 million; professor of biochemistry and molecular biology, Harvard University.

Donald A. Glaser: founder and chairman of board of scientific advisors, Cetus Corp., owns 570,000 shares or 2.14% of stock worth $6.2 million; professorships in physics, molecular biology and neuroscience at University of California, Berkeley.

Edward E. Penhoet: cofounder and president, Chiron Corp., owns 237,000 shares, or 2.3% of stock worth $4.1 million; faculty member, University of California, Berkeley for 16 years.

Phillip A. Sharp: chairman of scientific board, Biogen, Inc., owns 322,000 shares worth $2.6 million; director of the Center for Cancer Research and professor of biology at Massachusetts Institute of Technology.

John D. Baxter: founder, director and chief scientific consultant, California Biotechnology, Inc., since 1982, owns 470,000 shares or 4% of stock worth $2.7 million; professor of medicine, biochemistry and biophysics at University of California Medical Center in San Francisco.

Kenneth Murray: vice chairman of scientific board of Biogen Inc., owns 295,000 shares of company stock worth $2.4 million; professor of molecular biology at the University of Edinburgh, Scotland.

Patrick J. Scannon: president and director of science, Xoma Corp., owns 200,000 shares or 1.8% of stock worth $2.5 million; clinical researcher at Letterman Army Institute of Research (1979 to 1981).

Walter Gilbert: member of scientific board, Biogen, Inc., owns 211,000 shares of stock worth $1.7 million; Nobel laureate, Carl M. Loeb University Professor, Harvard University.

Gretchen Morgenson, *In Pecunia Veritas?*, FORBES, Nov. 28, 1988, at 208, 208.

65. *See supra* notes 22, 27, 33-64 and accompanying text; *see also* Eisenberg, *supra* note 26, at 1375-78 (discussing threats to academic freedom resulting from industry sponsored research).

inappropriately influenced by industry involvement risk harming patients who have entrusted them with their care.[66]

A recent congressional committee report found that "[t]he most widely publicized cases of scientific misconduct in recent years have tended to involve physicians conducting biomedical research . . . ."[67] Authors of the report attribute this alarming trend, at least in part, to the fact that physicians are more likely to receive funds from companies.[68] The subcommittee's conclusions indicate that in order to protect patients from potential harm, ties between industry and physicians must be monitored more carefully than in the past.

Current guidelines governing the appropriate scope and nature of relationships between industry and universities or their faculties are minimal.[69] This has already resulted in serious problems for physician-researchers, as well as scientific researchers in general.[70] Such findings may have grave implications for patient welfare. As one expert noted:

> Faculty members who are financially dependent on research sponsors may not be counted on to uphold academic values on their own. In such situations, the protection of academic values may require limiting the autonomy of potentially co-opted faculty members. Moreover, the institution of faculty procured research grants has increased the power of outside funding sources and individual faculty members relative to that of universities. These changed circumstances call for a reassessment of traditional mechanisms for preserving academic values in sponsored research.[71]

Appropriate policy must be formulated quickly to ensure that ethical standards are not violated, research participants are not exploited, and public support for scientific research is not sacrificed.

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66. Human subjects involved in research experiments are protected to some degree by the Human Subjects Law, 45 C.F.R. § 46 (1991). *See infra* note 166. However, the goal of human subjects law is not to protect against researcher conflicts of interest arising out of ties to industry. Like informed consent law, human subjects regulations focus on the subject's autonomy and rights to receive full information about participation in research. *See infra* part II.B (illustrating that physician-researchers involved in conflict of interest situations may risk harm to patients).

67. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 6.

68. *Id.* However, the authors noted that "[i]t is not known whether scientific misconduct is more frequent among physicians, or if biomedical research misconduct is more likely to be reported by individuals and the media because of the implications for public health."

69. *See supra* note 20.

70. *See infra* part II.B.

71. *See* Eisenberg, *supra* note 26, at 1374.

B. Some Illustrations of Conflicts of Interest

1. *MOORE V. REGENTS OF THE UNIVERSITY OF CALIFORNIA*

Moore v. Regents provides a shocking example of the violation of ethical standards that can occur when a physician-researcher becomes influenced by the pursuit of industry profits. The conflict of interest in *Moore* began on October 6, 1976, when John Moore first visited Dr. David W. Golde at the UCLA Medical Center. After examining blood and bodily substances drawn from Moore, Dr. Golde determined that Moore suffered from a rare condition, hairy cell leukemia, and that Moore needed a splenectomy[72] immediately. Several days later, surgeons at UCLA successfully completed the operation.

Prior to the surgery, Dr. Golde provided written instructions to members of his research staff at UCLA informing them that Moore's blood and bodily substances were unusual and "instructing them to study and characterize the nature of his unique cells."[73] When Dr. Golde diagnosed Moore's condition, he found that Moore's cells were likely to be commercially valuable because they "overproduced certain [proteins], thus making the corresponding genetic material easier to identify."[74] Using Moore's genetic materials, Dr. Golde could try to develop a cell-line[75] from which bioengineering companies might produce highly

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72. A splenectomy is the removal of the spleen. STEDMAN'S MEDICAL DICTIONARY (25th ed. 1990).

73. Moore v. Regents of the Univ. of Cal., 249 Cal. Rptr. 494, 499 (Ct. App. 1988), *rev'd*, 793 P.2d 479 (Cal. 1990).

74. Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 482 (Cal. 1990). Lymphokines, produced by T-lymphocytes, are proteins which regulate the immune system. Because some lymphokines are of therapeutic value, researchers are interested in locating the genetic materials responsible for producing certain lymphokines. Through recombinant DNA techniques therapeutic lymphokines can be manufactured from the genetic materials. The genetic code for lymphokines is identical among individuals, but is normally very difficult to locate and identify. Because Moore's cells overproduced certain lymphokines, the desired genetic materials were more easily located. *See generally* OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS 31-46 (1987). According to research conducted by Dr. Golde and Quan, Moore's T-lymphocytes had been infected by a virus which has been shown to result in the overproducing characteristic. Irvin S.Y. Chen et al., *Human T-Cell Leukemia Virus Type II Transforms Normal Human Lymphocytes*, 80 PROC. NAT'L ACAD. SCI. U.S.A. 7006, 7006 (1983).

75. A cell-line is a culture capable of reproducing indefinitely. Because the cells continue to reproduce, attempts at identification of genetic materials can be repeated until they are successful. However, the process of developing a cell-line is exceedingly difficult. Generally, it is unlikely that any particular tissue sample will result in a successful cell-line. *Moore*, 793 P.2d at 481 n.2 (discussing OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, *supra* note 74, at 31-46).

profitable products. In pursuit of the cell-line, Dr. Golde requested that Moore travel from Seattle to the UCLA Medical Center on numerous occasions under the guise of treatment.[76] Dr. Golde never told Moore about the cells' possible commercial value, or about the nature of the research that Dr. Golde and his research assistant, Shirley Quan, had undertaken using his cells. In fact, when Moore inquired as to whether there might be commercial value in the research, Dr. Golde and Quan insisted that there was none.[77]

Sometime before August 1979, Dr. Golde and Quan successfully established a cell-line from Moore's cells. In January 1981, the Regents of the University of California applied for a patent to protect the cell-line which they later received.[78] Subsequently, Dr. Golde negotiated development agreements with two biotechnology companies from which he received a consulting contract, 75,000 shares of common stock, and payments to the Regents and himself totaling $440,000.[79] According to Moore's complaint, the potential market for such lymphokines could reach $3 billion by the year 1990.[80] Although Dr. Golde may not have initially predicted such enormous profitability, he was unquestionably aware that a cell-line developed from Moore's cells would be highly profitable.[81]

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76. Moore was required to travel to UCLA from Seattle many times over the course of seven years. "[B]lood, blood serum, skin, bone marrow aspirate, and sperm" were removed on these visits. *Id.* at 481.

77. *Id.* at 485-86.

78. *Id.* at 481-82.

79. Dr. Golde entered into a contract with Genetics Institute. In exchange for exclusive rights to the materials and research performed on the cell line, Genetics agreed to pay Dr. Golde as a consultant, give Dr. Golde rights to 75,000 shares of common stock, and pay Dr. Golde and the Regents $330,000 over three years including a pro rata share of Dr. Golde's salary and fringe benefits. Sandoz, another biotechnology development company, was added to the contract in June 1982 and agreed to pay Dr. Golde and the Regents an additional $110,000. *Id.* at 482.

80. Moore v. Regents of the Univ. of Cal., 249 Cal. Rptr. 494, 500 (Ct. App. 1988). The complaint alleges that products from Moore's cell line included:

> "(a) Colony-Stimulating Factor (CSF) . . .
> "(b) Erythroid-Potentiating Activity (EPA) . . .
> "(c) Immune Interferon (Type II) . . .
> "(d) Neutrophil Migration-Inhibitory Factor (NIF-T) . . .
> "(e) T-cell Growth Factor (TCFG, Interleukin II) . . .
> "(f) Macrophage-Activating Factor (MAF) . . .
> "(g) Factor-Stimulating Fibroblast Growth . . .
> "(h) Factor-Stimulating Human Pluripoten Hematopoietic Stem Cell . . .
> "(i) Factor-Stimulating Human leukemic Cells in vitro . . . ."

Id. at 501 n.6.

81. *Moore*, 793 P.2d at 481.

After Dr. Golde gave Moore a second consent form asking that he relinquish all rights in his cells, Moore became suspicious.[82] Soon after, he sued Dr. Golde, Quan, the Regents of the University of California, and the biotechnology companies. The complaint stated thirteen causes of action,[83] including failure to provide informed consent, breach of fiduciary duty, and conversion.[84] The superior court considered only the cause of action for conversion and sustained the Regents' demurrer to the entire complaint.[85] But the California Court of Appeal held that Moore had adequately stated a cause of action for conversion and directed the superior court to give Moore leave to amend the allegations against the biotechnology companies and to decide the remaining causes of action.[86]

In its July 1990 decision, the California Supreme Court rejected the conversion theory, but did not leave Moore without a remedy.[87] It held that Moore's complaint stated a cause of action for breach of fiduciary duty and failure to obtain adequate consent,[88] but not for conversion. According to the court, Moore stated a cause of action because Dr. Golde allegedly failed to inform Moore of the extent of the research and of his economic interest in Moore's cells before obtaining Moore's consent to research.[89] This constituted an invasion of Moore's legally protected interest in determining the use of his body.[90] The court concluded that:

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82. *Moore*, 249 Cal. Rptr. at 501.

83. The 13 causes of action were conversion, lack of informed consent, breach of fiduciary duty, fraud and deceit, unjust enrichment, quasi-contract, bad faith breach of the implied covenant of good faith and fair dealing, intentional infliction of emotional distress, negligent misrepresentation, intentional interference with prospective advantageous economic relationships, slander of title, accounting, and declaratory relief. *Moore*, 793 P.2d at 482.

84. *Id.* at 482 n.4.

85. The superior court reasoned that subsequent causes of action were incorporated in the conversion allegation. Because the first allegation was defective, all further allegations were also defective. In a later proceeding, Genetics Institute's and Sandoz's demurrers were sustained without leave to amend because Moore had not stated a cause of action for conversion and the allegations regarding secondary liability were conclusory. *Id.* at 482-83.

86. *Id.*

87. *Id.*

88. *Id.* at 485. Informed consent is the requirement that medical and behavioral practitioners inform patients and human research subjects of the risks and benefits of procedures and obtain the patients' or subjects' agreement to undergo any risks. *See* Alexander M. Capron, *Informed Consent in Catastrophic Disease Research Treatment*, 123 U. PA. L. REV. 340 (1974); Richard Delgado & Helen Leskovac, *Informed Consent in Human Experimentation: Bridging the Gap Between Ethical Thought and Current Practice*, 34 UCLA L. REV. 67 (1986); Robert J. Levine, *Informed Consent in Research and Practice*, 143 ARCHIVES INTERNAL MED. 215 (1983).

89. *Moore*, 793 P.2d at 483.

90. *See id.*

> 1) a physician must disclose personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment; and 2) a physician's failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent or breach of fiduciary duty.[91]

Thus, under the court's ruling, as long as a physician asks the patient for consent to the research and explains anything necessary to the patient's decision, the patient's interests are fully protected.[92]

2. *CHEMICAL DELIVERY SYSTEM*

Several other recently reported instances of physician misconduct and conflict of interest demonstrate the profound impact of industry forces within university research communities. For example, the University of Florida's financial interests "conflict[ed] with such important scientific questions as the safe conduct of research, as well as the fair treatment of faculty."[93] In the Florida case, a graduate research professor in the University of Florida's College of Pharmacy, Dr. Nicholas Bodor, invented and patented a new drug delivery system, CDS (chemical delivery system). In return for the patent license, a private company slated $1 million for university funding, and named Dr. Bodor vice president of a start-up company, Pharmatec, created to develop the drugs. Pharmatec hired several other prominent university faculty members and compensated them with Pharmatec stock.[94]

Subsequently, another university researcher, Dr. Kenneth Sloan, uncovered evidence that CDS was similar to a known neurotoxin and could pose serious risks to those working with CDS.[95] Dr. Sloan's repeated attempts to make his suspicions known were rebuffed by pharmacy department faculty members involved with the Pharmatec project.[96] After the media publicized Dr. Sloan's accusations, he received a negative review resulting in a salary increase substantially smaller than

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91. *Id.*

92. *Id.* at 497.

93. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 19.

94. *Id.* at 16-17. In addition to Dr. Bodor, Pharmtec hired three faculty members. Pharmtec compensated them with 1000 shares of stock worth $5000, plus stock options. Pharmtec also gave the Dean of the College of Pharmacy, as well as several prominent administrators, 1000 shares of stock each. *Id.*

95. *Id.* at 17. Based on several research articles, Dr. Sloan cautioned that CDS may be structurally similar to the neurotoxin MPTP and could cause symptoms similar to those found in Parkinson's disease sufferers. *Id.*

96. *Id.* at 17-18. By the late 1980s, the Associate Dean of Research, Chairman of the Department of Pharmaceutics, and Chairman of the Department of Pharmacodynamics were all associated with Pharmatec as consultants or company officials. *Id.* at 18.

his professional accomplishments warranted.[97] Throughout the controversy, university officials insisted that CDS was safe and refused to conduct toxicity testing suggested by Dr. Sloan.[98] Eventually, Dr. Bodor conducted the requested toxicity tests and, perhaps not surprisingly, reported results affirming the university's earlier statements that CDS was non-toxic.[99]

Dr. Bodor's involvement with Pharmatec presented a conflict of interest which may have impaired his ability to evaluate objectively whether CDS is harmful. The University of Florida's refusal to investigate the matter formally and conduct the toxicity testing suggests that the university itself may have been afraid of jeopardizing its Pharmatec ties. Although it is not known whether CDS actually poses any risk, the failure to fully investigate potentially dangerous technologies due to financial interests could result in serious physical harm to physician-researchers and ultimately to patients. Moreover, scandals such as the Pharmatec incident erode the public trust in university research institutions and discourage university scientists from raising concerns about the appropriateness of sponsored research activities.

3. *TIMI TRIALS*

The case of the Number 5 t-PA Multicenter Trial (TIMI Trials)[100] suggests that physician-researchers who own stock in the companies developing products they are evaluating may be unduly influenced by the rise and fall of the stock market. In the mid-1980s, NIH funded research at medical schools and hospitals throughout the country comparing the clotting effectiveness of two thrombolytic agents, t-PA[101] and streptokinase (SK),[102] typically used to treat heart attacks. The first findings, published in a 1985 article, pronounced the superiority of t-PA over SK in dissolving blood clots.[103] At least five of the authors of the

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97. *Id.* Reports of retaliation against those who raise concerns about possible conflicts of interest is profoundly disturbing. Researchers may conclude that it is more advisable to join the pack than stand up for ethical principles in biomedical research. *Id.*

98. *Id.* at 17-19.

99. *Id.* at 19.

100. *See id.* at 19-28; *see also* David P. Hamilton, *White Coats, Black Deeds*, WASH. MONTHLY, Apr. 1990, at 23, 23-24.

101. t-PA is a drug developed to dissolve clots associated with acute myocardial infarction, or heart attacks. At the time of the TIMI trials, t-PA had not yet been approved by the FDA. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 19.

102. At the time of the TIMI trials SK had been approved by the FDA for intracoronary administration. SK had been approved in 1982. *Id.*

103. *Id.* at 20 (discussing *TIMI Study Group: The Thrombolysis in Myocardial Infarction (TIMI) Trial*, 312 NEW ENG. J. MED. 932 (1985)).

article owned stock in Genentech, the company manufacturing t-PA.[104] Following the article's publication, Genentech stock rose to $28, from a high of $18 a few months earlier.[105] Because the article failed to report results unfavorable to t-PA,[106] some critics argued that the NIH researchers were biased toward t-PA due to their later-revealed equity interests in Genentech.[107]

As the TIMI trials progressed, the pattern of researcher involvement with Genentech and reporting of favorable results for t-PA continued.[108] According to findings of the Committee on Government Operations, stock ownership "could have created a conflict of interest for individuals who received Federal funds to study whether t-PA was safe and effective."[109] Most alarming is that scientists with stock in Genentech

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104. The stock owners included Dr. Harold Dodge, Dr. James Willerson, Dr. James Chesebro, Dr. Carl Apstein, and Dr. Joseph Benotti. Dr. Burton Sobel had also received options for 14,000 shares. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 20 n.98.

105. *Id.* at 20. "It is difficult to pinpoint the impact of the article, since information about its findings was available prior to publication. In addition, it would be important to compare the increased value of Genentech stock to a pharmaceutical index during that period." *Id.* at 20 n.99.

106. *Id.* The article did not report evidence that t-PA and SK patients' left ventricle function was equivalent. Generally, left ventricle function is a more important predictor of mortality than is dissolving of blood clots. This finding was later reported by a non-TIMI researcher. *Id.* In addition, the 1985 article left out findings that t-PA and SK could cause bleeding problems. Those findings remained unpublished until other studies reported findings of bleeding problems. *Id.*

107. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 20.

108. In 1987, at least 13 researchers involved in the NIH-funded research owned Genentech stock or held options to buy the stock at a discount. None of the researchers publicly reported their financial interests in Genentech. The Subcommittee report concluded that "[t]he research literature on t-PA has repeated examples of more positive evaluations of t-PA by scientists with relationships with Genentech, compared to scientists without such relationships." *Id.* at 25. By contrast, results reported by international groups were generally favorable to both t-PA and SK. During the TIMI trials, several other research teams were studying the effectiveness of t-PA and SK. These included extremely large trials conducted by GISSI (*Gruppo Italiano Per Lo Studio Della Streptochinasi Nell'Infarto Miocardio*), an Italian group, the International Study of Infarct Survival (ISIS-2), an international group based at Oxford and funded by one of the manufacturers of SK, and ASSET (Anglo-Scandinavian Study of Early Thrombolysis), funded by a European distributor of t-PA. These researchers' results showed that both t-PA and SK reduced mortality. *Id.* at 22-24.

109. *Id.* at 21-22. The eventual approval of t-PA caused the value of Genentech stock to increase significantly. Since then, studies comparing the efficacy of t-PA and SK have continued to influence Genentech stock prices and analysts' forecasts for Genentech. The *Los Angeles Times* attributed a drop in Genentech stock to a rumor that forthcoming results of a British study showed no difference between t-PA and SK. Victor F. Zonana, *Investors Rush to Sell Genentech Stock*, L.A. TIMES, May 28, 1988, § 4, at 2.

In response to subsequent reports of researchers' finding that t-PA and SK were equally effective, securities analysts as well as physicians defended t-PA as the superior treatment. Following the release of GISSI-2 results, a major study of 20,000 patients from 13 countries reporting that t-PA and SK were equally effective, a University of Michigan

participated in decisions to significantly increase dosages of t-PA given to patients participating in the study.[110] These researchers' decisions, which increased risks associated with t-PA use for the study participants, may have been influenced by their stock ownership. Even if the researchers' recommended increases were medically appropriate, their stock ownership casts doubt upon the motivations underlying their decision to increase dosages.

At the time of the suspect dosage increases, the TIMI Steering Committee and Executive Committee[111] controlled study procedures, including changes in t-PA dosages. The Steering Committee recommended that NIH researchers substantially increase t-PA dosages twice in four months.[112] At one facility, the dosage increases caused severe intracranial bleeding in 5 of 311 patients.[113] As a result, three patients died and 41 suffered major non-cranial bleeding.[114] Subsequent dosage reductions to one half the amount indicate that these dosages were grossly inappropriate.[115] The magnitude and timing of the increases suggest that NIH researchers tried to rush the research process, since FDA approval could be hastened by reports of successful treatment without complications.

Others have alleged that physician-researchers involved in the clinical trials may have violated the patients' right to informed consent in

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cardiologist and paid consultant to Genentech in t-PA testing, Dr. Eric Topol, was quoted in the *Washington Post* as having criticized the research methods, thus casting doubt on the study's findings. Malcolm Gladwell, *Comparison of Heart Drugs Challenged as Misleading*, WASH. POST, Mar. 10, 1990, at A3. At the time, Dr. Topol held options on 6,000 shares of Genentech stock. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 24.

110. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 26.

111. Initially, NIH charged the Safety and Data Monitoring Committee with responsibility for overseeing the safety of the TIMI trials. After several Safety and Data Monitoring Committee members expressed concern about the safety and effectiveness of t-PA, NIH eliminated that committee and relieved all but one committee member of any responsibility in the trials. Thereafter, the TIMI Steering Committee and Executive Committee made decisions regarding dosage increases and study procedures. *Id.* at 20-21.

112. *Id.* at 21. At least three of these TIMI Steering Committee members owned Genentech stock when the Steering Committee decided to increase dosages. Since NIH lacked a policy restricting stock ownership in a company by researchers evaluating the effectiveness of that company's product, NIH was unaware of stock ownership. Other sources reported stock ownership by Steering Committee members and TIMI trial researchers. *Id.* at 24-25. The Committee on Government Operations concluded that it was not possible to determine whether the researchers dosage decisions had been "clouded" by stock ownership. However, the Committee implied that where patients are concerned, those making treatment decisions should remain free of conflicts of interest. *Id.* at 26.

113. *Id.* at 21; *see also* Hamilton, *supra* note 100, at 24.

114. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 21.

115. *Id.*

their zeal to sign up willing participants.[116] The son of one patient who died from cranial bleeding believes that a physician-researcher pressured his mother into participating in the trials without adequately explaining the risks involved.[117] Although patients signed informed consent forms, those forms failed to state that t-PA was an experimental treatment not yet approved by the FDA.[118] The forms also minimized potential risks associated with t-PA treatment, even after several patients died of complications induced by t-PA.[119]

In fact, Wall Street, Genentech, and NIH researchers pushed to get early FDA approval for t-PA.[120] As expected, following approval, the value of Genentech stock increased substantially.[121] Assuming that seriously ill patients trust that their physicians have their best interests in mind, even the suggestion that stock profits may have factored into a physician-researcher's treatment decisions is quite disturbing.

4. *TRETINOIN*

In yet another incident, a Harvard University researcher violated university research rules while reaping the financial benefits of stock price increases which may have been fueled by his initial positive

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116. *Id.* at 26.

117. Jacques Galin, the son of Marion Galin, a woman who died of cerebral hemorrhage suffered after receiving t-PA, testified before a Senate subcommittee about the manner in which a physician-researcher obtained his mother's consent to participate in the TIMI trials. Galin stated that his mother was taking morphine and "could not hold the pen to sign the form." Galin added: "My mother asked the doctor, what would you do. He said I would go with the drug. I thought that was very big of him considering it was his program." *Id.*

118. *Id.* at 26-27.

119. The forms failed to warn patients that t-PA could cause a stroke or death and instead stated that the drug rarely caused bleeding into the brain that could result in permanent damage. *Id.*

120. Prominent research physicians, as well as Wall Street analysts, criticized the May 1987 FDA refusal to approve t-PA for intravenous use. The *Wall Street Journal* denounced the FDA refusal. *Human Sacrifices*, WALL ST. J., June 2, 1987, § 1, at 30 (editorial). Following the refusal, Genentech stock dropped from a high in March of $64.50 to $36.35. The FDA finally gave approval to t-PA for intravenous use the following November, holding a special press conference to announce the approval. By contrast, the approval of SK, which had occurred just days before, was not publicized at all. *See* COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 22-23.

121. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 23. In addition, reports of research results and rumors of research findings continue to influence Genentech stock prices. For example, following rumors that a British study found no difference between t-PA and SK, the stock fell sharply. *See supra* note 109. Researchers can easily predict how their results will influence a stock's value. Through selective release of findings, researchers who own stock can prevent personal losses or increase personal gains. This use of researchers' specialized information for personal gain in the stock market could be likened to insider trading.

research findings.[122] Scheffer C.G. Tseng, a former Harvard researcher now at University of Miami, was conducting research on a condition known as dry eye.[123] Tseng and his clinical supervisor, Kenneth Kenyon, were treating patients with Tretinoin, a vitamin A ointment made by Spectra Pharmaceutical Services, a company formed by Tseng and his colleagues.[124]

During the clinical trials, Tseng was a consultant to Spectra.[125] Tseng owned 530,000 shares of Spectra stock and Kenyon also owned stock.[126] When Spectra went public in 1985, the stock was worth just $2.00 per share. A few months later, after Tseng reported favorable research results for 22 patients, the stock rose to $8.25.[127] Soon after, Tseng began clinical Tretinoin testing on over 200 patients without university authorization and cashed in 200,000 of his Spectra shares.[128] Tseng and his relatives made over $1 million from Spectra stock sales.[129] Tseng has maintained that he merely followed Kenyon's orders.[130]

After Tseng left Harvard in 1986, Harvard began investigating Tseng's research.[131] At the same time, Spectra announced that earlier claims of Tretinoin's effectiveness had been premature; the stock fell from a 1987 high of $6.25 to $0.375 per share.[132] Although Tseng's misbehavior did not result in harm to any of his patients,[133] Tseng's stock interest presented a serious conflict of interest that created the appearance of having motivated his unauthorized research activities.

5. *RETIN-A*

Scientists studying the drug Retin-A have been criticized in a House Report for failing to disclose their financial ties to companies whose product they were evaluating.[134] Contrary to the *Journal of American Medical Association*'s (*JAMA*) policy mandating disclosure, authors of a

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122. *See* Peter G. Gosselin, *Flawed Study Helps Doctors Profit on Drug*, BOSTON GLOBE (city ed.), Oct. 19, 1988, at 1; Hamilton, *supra* note 100, at 24; Morgenson, *supra* note 64, at 210.

123. Gosselin, *supra* note 122, at 1, 16; Morgenson, *supra* note 64, at 210.

124. Gosselin, *supra* note 122, at 1.

125. Morgenson, *supra* note 64, at 210.

126. *Id.*; *see* Hamilton, *supra* note 100, at 24.

127. Morgenson, *supra* note 64, at 210.

128. *Id.*

129. Gosselin, *supra* note 122, at 1.

130. Hamilton, *supra* note 100, at 24.

131. Morgenson, *supra* note 64, at 210.

132. *Id.*

133. *See* Hamilton, *supra* note 100, at 24; Morgenson, *supra* note 64, at 210.

134. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 43-44.

1988 *JAMA* article[135] and editorial[136] about Retin-A failed to disclose their financial ties to Johnson & Johnson, the manufacturer of Retin-A.[137] The article and editorial described Retin-A as a wonder drug that could reverse wrinkles and other damage caused by photo aging.[138] After widespread media coverage announced highly promising results, sales of Retin-A jumped from 217,000 to 1,162,000 tubes in just one year.[139] A subsequent *Money* magazine article exposed the authors' extensive financial ties to Johnson & Johnson and evidence indicating that photographic techniques had been used to exaggerate Retin-A's effectiveness.[140] However, because the initial articles received extensive positive media coverage, many consumers and physicians may be unaware of the conflicts of interest and allegedly exaggerated results.

In addition, subsequent contradictory findings indicate that under industry pressure, the authors of the *JAMA* article and editorial released their positive findings prematurely. At a recent National Institutes of Health (NIH)[141] conference, participants acknowledged that Retin-A's effectiveness had not been established and that Retin-A's effect on the development of ultraviolet-induced carcinomas is in dispute.[142] Unfortunately, because of the initial favorable results, consumers may be applying Retin-A to lessen wrinkles when they may in fact be irreversibly damaging their skin.

The cases discussed above, as well as many others,[143] indicate the desperate need for guidance within the research community regarding

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135. Jonathan S. Weiss et al., *Topical Trentinoin Improves Photoaged Skin: A Double-Blind Vehicle-Controlled Study*, 259 JAMA 527 (1988).

136. Barbara A. Gilchrest, *At Last! A Medical Treatment for Skin Aging*, 259 JAMA 569 (1988).

137. Leslie N. Vreeland, *The Selling of Retin-A*, MONEY, Apr. 1989, at 74.

138. Gilchrest, *supra* note 136, at 569-70; Weiss et al., *supra* note 135, at 531.

139. Johnson & Johnson held a press conference that coincided with the release of the *JAMA* article. All three network newscasts featured the Retin-A results that night. In addition, the article and editorial authors appeared on talk shows and morning news programs to further hype the product's effectiveness in combating wrinkles. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 43 (citing Vreeland, *supra* note 137).

140. Vreeland, *supra* note 137.

141. *See infra* note 167.

142. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 44 (discussing NIH Consensus Conference 1990 (documents available in the Human Resources and Intergovernmental Relations Subcommittee files)).

143. For example, Dr. Herbert Boyer, University of California at San Francisco professor and founder of Genentech, became a millionaire overnight when Genentech stock was first sold on the stock market. The stock rose from its initial $35 per share to $89 per share by mid-afternoon. Lescovac, *supra* note 23, at 900. According to *Forbes* magazine, as of November 1988, Boyer owned $30 million worth of Genentech stock. Morgenson, *supra* note 64, at 209.

In another case, University of California at Davis (UC Davis) Professor Ray Valentine secured a $2.5 million research grant from Allied Chemical Co. to investigate nitrogen

university-industry relationships. In particular, faculties must determine which types of arrangements with industry are compatible with their roles as university researchers and educators and which are not. Critics have challenged the university community to "clean its own house" and put forth policy resolving these critical issues.[144]

III. THE INADEQUACY OF CURRENT REGULATION AND LEGAL REMEDIES AIMED AT PROTECTING AGAINST CONFLICTS OF INTEREST

A. University Policy Governing Conflicts of Interest

Although universities have become increasingly involved with private industry,[145] not all universities have developed policies governing industry-sponsored research.[146] Even those universities that have

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fixation in plants. Shortly thereafter, Allied Chemical Co. purchased 20% of the stock in Valentine's start-up company Calgene. After UC Davis identified this conflict of interest, it presented Professor Valentine with an ultimatum. UC Davis insisted that Valentine either terminate his affiliation with Calgene, remove himself from other agricultural research projects at Davis, or resign from the Allied project. Valentine chose to withdraw from the Allied project. However, Valentine has maintained both his financial ties to Calgene and his university position. Because no one else at Davis was qualified to perform the research, the University lost $1 million of the Allied research grant. Lescovac, *supra* note 23, at 907 n.53 (discussing an interview with Dr. Charles E. Hess, Dean of the College of Agricultural and Environmental Sciences, UC Davis (Mar. 3, 1982)); *see also supra* note 64 (for additional examples of researcher-entrepreneurs).

144. Albert H. Meyerhoff, Staff Attorney for the Natural Resources Defense Council, has suggested that universities set policy regarding whether:

> 1) exclusive patent licenses should be provided to corporate or private sponsors of research when public funds and resources are expended;
>
> 2) "faculty entrepreneurs" should be permitted to engage in business ventures that parallel their university functions and make use of "intellectual property" created at the public expense;
>
> 3) private funds should be provided to university scientists "earmarked" for specific research, thereby potentially leveraging greater amounts of public money for commercial purposes;
>
> 4) scientists should be disqualified from participating in research when they have a direct financial interest in its private sponsor; and
>
> 5) public disclosure should be required by university scientists of financial interests in business firms or other sources of income that foreseeably may benefit from publicly financed research and development efforts.

Meyerhoff, *supra* note 62, at 894.

145. *See supra* notes 7-9, 45-50 and accompanying text.

146. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 6. *But cf.* April Burke, *University Policies on Conflict of Interest and Delay of Publication: Report of the Clearinghouse on University-Industry Relations, Association of American Universities, February, 1985*, 12 J.C. &

implemented policies face several ongoing dilemmas. First, industry continues to propose unique and innovative relationships with universities and individual researchers that may not have been contemplated by an existing policy.[147] Second, the university research community has yet to voice collective normative standards outlining the kinds of relationships that are ethically acceptable and those that are not.[148] Likewise, federal funding sources have not presented fully developed guidelines regarding industry sponsorship of projects that also receive federal funding.[149]

Without common wisdom to guide them, university administrators have used their own instinct and intuition to develop ad hoc policies to meet present needs. The wide range of policies among universities demonstrates that norms outlining the proper way to handle industry ties are still evolving. For example, some universities' policies include mandatory intensive monitoring of industry ties while others have no formal policy at all.[150] Collective discussion of industry sponsored research began only recently, as universities and researchers alike acknowledged that financial inducements and other types of industry arrangements may present significant conflicts of interest.[151] Some members of the scientific community have found the lack of institutional leadership in the area of conflict of interest disturbing.[152] According to

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U.L. 175, 181 (1985) (finding that 46 out of 51 university survey respondents in 1984 had established written policies governing potential conflicts of interest arising from privately sponsored research).

147. For example, when receipt of stock options by top researchers was a rarity, universities probably did not think of placing limitations on the equity interest a faculty member could hold in industry. As those arrangements became more common, and resultant conflicts more problematic, some universities saw a need for limitations. *See infra* note 150.

148. The academic research community has begun to discuss conflicts of interest and various means of handling them. *See supra* note 19; *infra* note 150. But these discussions have not yet produced consensus among the experts.

149. *See infra* notes 169-74 and accompanying text.

150. For example, the Association of American Universities' survey found that of those respondents who had policies in place, 19 required faculty-initiated disclosure where a faculty member herself determines whether her industry relationship may present a conflict, while 26 required university-initiated disclosure, an annual report from each faculty member engaged in industry-sponsored research, or university approval of industry consulting or funding arrangements. Similarly, only 21 universities had policies governing faculty equity interest and managerial involvement in industry, requiring disclosure and university approval. None of the universities prohibited faculty members from holding equity interests in industry ventures. Some did, however, limit the amount of equity interest a faculty member could hold. *See* Burke, *supra* note 146, at 182-83.

151. *See supra* note 143.

152. As part of the Human Resources Subcommittee study, numerous researchers testified regarding concern about conflicts of interest. Hearings were held in April and

some university leaders, conflicts presented by certain types of industry ties are irreconcilable with a researcher's role in the scientific community.[153] In response to this increased concern, several universities and scientific organizations have begun promoting reform.[154]

Following amendments to the state of California's conflict of interest regulations in 1982, the University of California took a leading role in developing conflict of interest policy.[155] The amendments mandated that the University of California, as a state agency, require faculty to disclose financial interests in private, non-government sponsors of their research to the university administration when they apply for or renew projects.[156]

September 1988 and June 1989. Over 25 research experts testified at these combined hearings. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 2-3. The Committee on Government Operations report contained several examples of incidents involving conflict of interest. Undoubtedly some of these were revealed by those who testified. In addition, some of those testifying expressed concern over the lack of sufficient guidelines. For example, in a 1989 article, Dr. Arthur Caplan, Director for the Center for Biomedical Ethics at the University of Minnesota, argued that disclosure of financial interests was not enough and advocated complete divestment of researchers' financial interests. Dr. Caplan testified at the hearings. *Id.* at 57 (citing Arthur Caplan, *A Question of Ethics: Divest Your Stock and Do Your Duty*, ST. PAUL PIONEER PRESS DISPATCH, Oct. 9, 1989 (syndicated nationally by Knight-Ridder Newspapers)).

153. *Id.* at 54-55 (noting "considerable support" for PHS restrictions on financial relationships between researcher and sponsor where the researcher is undertaking clinical trials). *Id.* at 57 (quoting Caplan, *supra* note 152).

154. *See* COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 59; *supra* note 19. Harvard University's Faculty of Medicine, for example, instituted a new policy on conflicts of interest in 1990 that "takes a broader view of conflict and contains far more stringent guidelines than did the earlier Faculty of Medicine policy of 1983," thereby suggesting an increased awareness and concern about the potential dangers accompanying conflicts of interest at Harvard. Harvard Univ. Faculty of Medicine, *supra* note 6, at 7. Likewise, the Office of Cooperative Research at Yale University is currently debating revisions in its policy on conflict of interest and conflict of commitment. Telephone interview with Henry S. Lowendorf, Office of Cooperative Research, Yale University (Apr. 1991).

155. *See* Lescovac, *supra* note 23, at 908. The California Political Reform Act of 1974 established the Fair Political Practices Committee (FPPC) as an agency of state government to administer and implement conflict of interest provisions of the Act. CAL. GOV'T CODE §§ 83100, 83111 (West 1976). In 1982, the FPPC amended conflict of interest guidelines to include some university researchers. The amendment, which applies only to the University of California and California State Universities and Colleges, states:

> (b) Disclosure shall be required under Government Code Section 87301 or any Conflict of Interest Code in connection with a decision made by a person or persons at an institution of higher education with principal responsibility for a research project to undertake such research, if it is to be funded or supported, in whole or in part, by a contract or grant (or other funds earmarked by the donor for a specific research project or for a specific researcher) from a nongovernmental entity . . . .

CAL. CODE REGS. tit. 2, § 18705 (amendment filed June 4, 1982).

156. *Id.*

The amendments do not require researchers to disclose financial interests in private entities that benefit from research ties to other private entities or government-supported research, however.[157] For example, suppose company *A* benefits from company *B*'s success. Further suppose a researcher, Joe, is collaborating with company *B* and owns stock in *A*. Joe would not be required to report financial ties to company *A* even though his work with company *B* may dramatically affect his financial interest in *A*. Similarly, if Joe's government-supported research affected company *A*, he would not be required to report financial ties to *A*. Consequently, in 1982, California's disclosure requirement affected only ten percent of funds supporting research at the University of California.[158] Despite its limited impact, the disclosure requirements imposed on the University of California provide an example of the type of conflict of interest policy a major state university might adopt.

The University of California procedure for review of research proposals and renewals attempts to eliminate conflicts of interest. At each University of California campus, independent substantive review committees (ISRCs)[159] examine research applications to evaluate whether projects are within regulatory guidelines.[160] The ISRC submits its recommendations to the university chancellors who make the final decision regarding project approval. Generally, if a principal researcher has a conflict on a project, the chancellor asks her to eliminate the conflict or replaces her with another principal researcher.[161] In some cases, researchers are allowed to go forward despite the conflict if the ISRC gives its approval.[162]

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157. Lescovac, *supra* note 23, at 911.

158. *Id.*

159. For example at the University of California, Los Angeles (UCLA), the chancellor appoints five faculty members to serve on each ISRC, with the advice and consent of the Academic Senate. Seligman, *supra* note 11, at 31. The ISRC must consider six separate criteria in determining whether to recommend approval of a proposal. To satisfy the review criteria: 1) traditional conflict of interest situations should be avoided; 2) the proposed research must be appropriate for the university; 3) the teaching and research environment must be open; 4) there must be no restriction on the freedom to publish and disseminate research results; 5) licensing agreements must be appropriate; 6) university facilities and resources must be used appropriately. *Id.* at 32-33. According to Richard P. Seligman of the Office of Contract and Grant Administration at UCLA, "the confirmation of the absence of these problems—as well as those identified earlier as 'traditional conflicts'—permits the ISRC to determine that a proposed arrangement would not constitute a conflict of interest." *Id.* at 34.

160. The FPPC regulations also precluded the university from accepting grants, gifts, or contracts in which a principal investigator had a financial interest in the research sponsor unless the arrangement gained approval from an "independent substantive review committee" comprised of faculty members. *Id.* at 28.

161. Lescovac, *supra* note 23, at 912.

162. *Id.*

The chancellor files reports documenting the ISRC's findings with the Fair Political Practices Committee (FPPC), the state agency charged with responsibility for implementing conflicts of interest regulations.[163] Filing with the FPPC provides a permanent record of the review committee process and ensures that campuses implement the policy uniformly. Documentation of review proceedings adds credibility to the process and assures researchers that decisions are not arbitrary or capricious. Consequently, faculty are more likely to support university monitoring of research endeavors and outside relationships.

Although the University of California policy provides some protection against conflicts of interest, increasing university-industry collaboration, with the resulting increase in potential conflicts of interest, warrants more comprehensive and stringent policies. For example, the University of California policy should require disclosure of researchers' interests in companies *affected* by outcomes of research, including government-supported research.[164] Without more complete disclosure, many conflicts of interest will remain undiscovered and therefore, unmonitored.

Similarly, faculty members may resist implementing policies requiring divestment of private interests or severing of certain outside relationships.[165] Because the University of California policy is subject to review and acceptance by faculty committees, the university may be unable to implement policies that effectively minimize conflicts of interest. To achieve more objective monitoring of university-industry relationships, government funding sources, as well as universities, must develop and impose stringent guidelines.

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163. *Id.*

164. *See supra* text accompanying notes 155-58.

165. *See* Lescovac, *supra* note 23, at 908 (stating that Berkeley Senate refused to adopt disclosure policies, finding no need to reform the university's policies regarding consulting); Anne C. Roarl, *UCLA Conflict Rules Will Be Investigated: Panel Orders Full Probe After Disclosure That Data on 23 Professors Was Withheld*, L.A. TIMES, Aug. 3, 1983, at A3 (discussing UCLA faculty's resistance to disclosure policies, on grounds that review committee deliberations would violate professors' academic freedom).

B. Federal Government Regulation

Current federal government regulation of university research in the area of conflict of interest is extremely limited.[166] Although the NIH[167] provides the majority of federal funds for university research,[168] it has not yet presented its views regarding conflict of interest management.

The Public Health Service (PHS),[169] which includes NIH and several other agencies, requires that institutions receiving PHS funds implement policies regarding conflicts of interest.[170] Since institutions that have no conflict of interest guidelines may lose PHS funding, the PHS

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166. The Interstate Commerce Clause provides the basis for federal regulation of research. *See* U.S. CONST. art. I, § 8. For example, human subjects research is regulated by the federal government. Lescovac, *supra* note 23, at 916 n.94; *see infra* text accompanying notes 169-77 (discussing current federal funding sources' regulation of conflicts of interest).

167. NIH is comprised of 13 institutes involved in biomedical research investigating the cause, prevention, and cure of disease. These include the National Cancer Institute; the National Heart, Lung and Blood Institute; the National Eye Institute; the National Institute of Allergy and Infectious Diseases; the National Institute of Arthritis and Musculoskeletal and Skin Diseases; the National Institute of Child Health and Human Development; the National Institute on Aging; the National Institute of Dental Research; the National Institute of Environmental Health Sciences; the National Institute of General Medical Sciences; the National Institute of Neurological and Communicative Disorders and Stroke. In addition, NIH includes the National Center for Nursing Research, the Clinical Center, and the Fogarty International Center. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 2.

168. *See supra* note 7.

169. The Public Health Service is the principal health agency of the Federal Government and is one of five principal operating divisions of the Department of Health and Human Services. PHS, which is under the direction of the Assistant Secretary for Health, is comprised of the Office of the Assistant Secretary for Health (OASH) and eight major agencies: The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA); the Centers for Disease Control (CDC); the Food and Drug Administration (FDA); the Health Resources and Services Administration (HRSA); the Indian Health Service (IHS); the National Institutes of Health (NIH); the Agency for Toxic Substances and Disease Registry (ATSDR); and the Agency for Health Care Policy and Research (AHCPR).

U.S. DEP'T OF HEALTH & HUMAN SERVS., PHS GRANTS POLICY STATEMENT, DHHS PUB. NO. (OASH) 90-50,000, at i (rev. 1991) [hereinafter PHS GRANTS POLICY].

170. PHS requires that

> [r]ecipient organizations . . . establish safeguards to prevent employees, consultants, or members of governing bodies from using their positions for purposes that are, or give the appearance of being motivated by a desire for financial gain for themselves or others such as those with whom they have family, business, or other ties. Therefore, each institution receiving financial support must have written policy guidelines on conflict of interest and the avoidance thereof. These guidelines should reflect State and local laws and must cover financial interest, gifts, gratuities and favors, nepotism, and other areas such as political participation and bribery.

Id. at 8-17.

requirement provides a significant incentive for universities to implement some kind of policy governing conflicts of interest. PHS further requires that university guidelines provide safeguards against even the appearance of financial motivation on the part of researchers.[171] Yet, despite their mandatory nature, the PHS requirements merely express general disapproval of activities that potentially may be financially motivated, without offering any specific standards.[172] For example, current PHS requirements do not disallow any specific industry relationships nor do they place limitations on the dollar amounts researchers may receive as industry consultants.[173] Instead, PHS allows individual universities to develop guidelines, within general parameters, as they see fit.[174]

Through the grant process, federal government funding sources have enormous power to dictate policy to which university researchers must conform.[175] For example, NIH could mandate that receipt of NIH funds be contingent on divestment of private financial interests related to the proposed research project. Presently, however, NIH has chosen not to use its position to mandate specific kinds of conflict of interest policies.[176] Although guidelines for policies on conflict of interest are being formulated,[177] government funding sources have yet to make their views regarding conflict of interest explicit.

In September 1989, NIH and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA)[178] released preliminary proposed research guidelines that caused such controversy that then Secretary of Health and Human Services Louis Sullivan revoked them.[179] The

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171. *Id.*

172. *Id.*

173. *Id.*

174. *Id.*

175. *See id.*

176. *See infra* note 177.

177. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 52-53 (discussing NIH's preliminary proposed guidelines on conflict of interest). The proposed guidelines met such disapproval that Secretary Sullivan withdrew them in December 1989, announcing that NIH would establish revised guidelines. No revised guidelines have been issued to date. *See infra* notes 178-89 and accompanying text.

178. ADAMHA is the Public Health Service agency dedicated to improving mental health and addressing substance abuse problems. The ADAMHA includes the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse. In fiscal year 1990 ADAMHA was expected to spend $763.7 million on scientific research. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 2.

179. Michael Unger, *Funding Rules Dropped After Scientists Protest*, NEWSDAY, Jan. 23, 1990, Business section, at 37 (stating that scientists' protests were a major factor in shelving the federal guidelines); Joyce Price, *NIH Drops Guidelines on Conflict of Interest*, WASH. TIMES, Jan. 1, 1990, at A8 (reporting that HHS will require NIH to develop new guidelines

guidelines included relatively stringent measures such as requiring that NIH participating investigators have no financial interests in organizations or entities that produce drugs, devices, or other interventions studied in a PHS-sponsored controlled clinical trial[180] and that "[r]esearch activities supported by NIH or ADAMHA must be conducted in an objective manner, free from any potential for undue influence arising from the private financial interests of those responsible for the conduct of the research."[181] Moreover, among the guidelines suggested was that universities disallow investigators and their dependents from having "personal equity holdings or options in any company affected by the outcome of the research or that produces a product being evaluated in the research."[182]

Because the relationships that the proposed guidelines restricted or disallowed are commonplace, NIH received many complaints.[183] University administrators complained that disclosure requirements including dependents would be too burdensome.[184] Likewise, venture capitalists claimed that restrictions on private source relations would restrict technology transfer.[185] While these complaints may have some merit, guidelines lacking some additional procedures and some restrictions on current relationships would simply ratify the status quo. Since PHS currently requires universities to file detailed descriptions of research projects and to disclose outside funding sources,[186] requiring

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that impose fewer restrictions on the research process); Kenneth H. Bacon, *NIH Is Interrupted in its Effort to Draft Conflict of Interest Curbs for Scientists*, WALL ST. J., Jan. 2, 1990, § 2, at 2 (noting Secretary Sullivan's concern that regulation could hurt U.S. scientific innovation).

180. *NIH Proposed Guidelines*, *supra* note 16, at 4.

181. *Id.* at 2.

182. *Id.* at 4.

183. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 54.

184. *Id.*

185. *Id.*

186. PHS requires that "[t]he source and amount of costs and/or the value of third party in-kind contributions proposed by the applicant or recipient to meet a matching requirement must be identified in the application." PHS GRANTS POLICY, *supra* note 169, at 6-1. Non-federal sources include "cash or in-kind contributions contributed or donated to the project by either the grantee or by third parties." *Id.*

PHS also requires a detailed cost analysis of every grant application, which includes "the process of obtaining cost breakdowns, verifying cost data, evaluating specific elements of cost, and examining data to determine necessity, reasonableness, and allowability of the cost reflected in the grant budget." Grants Management Officers may require applicants to submit:

1. Grantee administrative directives, organization charts, manuals, etc.

2. Corporate charters and bylaws, financial statements, IRS Tax Exemption Certification, etc.

disclosure of researchers' and their dependents' financial ties would add a minimal burden. Likewise, without monitoring private source relations, PHS cannot ensure that technology development is carried out in an ethical manner.

NIH did, however, find "considerable support for *restrictions* on financial relationships with companies making products that scientists were evaluating, particularly in clinical trials."[187] Support for restrictions related to product evaluations suggests that the scientific community fears that scientific integrity may be placed in jeopardy by conflicts of a direct nature. By contrast, commentators opposed restrictions on financial relationships for scientists whose basic research might eventually have product applications in the future.[188] Such objections indicate that universities value autonomy and research freedom highly. Unless researchers' activities present a direct conflict, universities may resist government intervention. Although NIH is in the process of developing revised guidelines,[189] universities that have not yet implemented policies must not wait to begin formulating their own conflict of interest policies.

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3. Grantee accounting manuals, charts of accounts, procedures, etc.

4. Grantee personnel policies and directives.

5. Grantee travel policies.

6. Grantee procurement procedures and property management instructions.

7. Overall institutional audit reports affecting an individual grant or a number of grants.

8. Information on indirect cost rates, items included in indirect cost pools, etc.

9. Copies of, or references to, awards with special conditions (including awards from other agencies), terminations, and any other useful background information.

PHS GRANTS POLICY, *supra* note 169, at 4-14 to 4-15.

Since PHS already requires applicants to submit detailed information regarding program operation and financing, complaints that submitting information about a researcher's and dependents' ties to non-federal funding sources would add *significantly* to the already burdensome process may be overstated. *See* COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 6 (noting that "NIH grant applications require grantees to list all sources of funding for research projects").

187. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 54.

188. *Id.*

189. *See supra* note 177 and accompanying text.

C. Legal Remedies for Patients Harmed by Conflicts of Interest—Informed Consent and Breach of Fiduciary Duty Theories

Two remedies provided under current legal doctrine, informed consent and breach of fiduciary duty, inadequately protect patients and fail to minimize physician conflict of interest. In *Moore*, the California Supreme Court concluded that the best means to protect future patients was to require researchers to obtain fully informed consent, thereby fulfilling their fiduciary obligations to patients.[190] In reaching its conclusion, the *Moore* Court discussed three basic principles of informed consent theory: 1) a patient's right to self-determination, 2) the requirement that consent be informed, and 3) a physician's fiduciary obligation to disclose all information material to a patient's decision when soliciting consent.[191]

The right of self-determination constitutes the basis for the informed consent requirement.[192] As applied in the medical treatment context, self-determination means that "a person of adult years and in sound mind has the right, in the exercise of control over his own body, to determine whether or not to submit to lawful medical treatment."[193] Over time, courts have determined that in order to give meaning to the right of self-determination, patients' consent must be fully informed.[194] According to one circuit court, physicians must provide patients with information that patients would consider material in deciding whether or not to undergo medical treatment, rather than allowing the physician to determine what is material from her perspective.[195]

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190. Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 485-86, 496-97 (Cal. 1990); *see infra* notes 196-99 and accompanying text.

191. *Moore*, 793 P.2d at 483.

192. JAY KATZ & ALEXANDER M. CAPRON, CATASTROPHIC DISEASES: WHO DECIDES WHAT? 80 (1975).

193. Cobbs v. Grant, 502 P.2d 1, 9 (Cal. 1972); *see also* Schloendorff v. Society of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914), *overruled on other grounds by* Bing v. Thunig, 143 N.E.2d 3 (N.Y. 1957).

194. *Cobbs*, 502 P.2d at 9-10; *see also infra* note 195. *See generally* Alan Meisel, *A "Dignitary Tort" as a Bridge Between the Idea of Informed Consent and the Law of Informed Consent*, 16 LAW MED. & HEALTH CARE 210, 214 (1988) (requiring physician to inform patient about the risks associated with treatment, the nature and purpose of treatment, potential benefits of treatment and alternative treatments, including no treatment).

195. Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972). "The scope of the physician's communications to the patient, then, must be measured by the patient's need, and that need is whatever information is material to the decision." *Cobbs*, 502 P.2d at 11.

Similarly, a physician-researcher's fiduciary duty to her patients militates that she act in the patient's best interest, not in her own.[196] In general, fiduciaries[197] possess particular skills or specialized knowledge of value to those who have placed their trust in the fiduciary.[198] To protect these parties against exploitation by fiduciaries, fiduciaries are held to high standards of moral behavior[199] which include minimizing conflicts of interest.

In addition to conflicts created by investment or other commercial interests, physician-researchers routinely face a variety of other conflicts of interest. For example, "[t]he physician's interest in pursuing a medical breakthrough and thereby enhancing both his or her own reputation and that of the department and university may lead the physician to seek less than informed consent."[200] The scientific community tolerates some level of conflict because motivating researchers to achieve status via new scientific discoveries is also in the interest of science.[201] To balance these potentially conflicting interests, some experts have suggested that physician-researchers should be held to a "strict standard of disclosure," thereby lessening their ability to influence subjects or patients inappropriately.[202] As seen in *Moore*, the California Supreme Court deemed this traditional wisdom adequate to protect patients from the conflicts of interest that accompany increasingly prevalent[203] and lucrative[204] researcher collaboration with industry.[205]

The *Moore* court placed too much faith in traditional concepts of informed consent and fiduciary duty, which cannot adequately protect patients against conflicts of interest arising from university-industry collaboration.

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196. *See, e.g., Canterbury*, 464 F.2d at 782-83 (informed consent is an aspect of a doctor's fiduciary duty of disclosure); Hammonds v. Aetna Casualty & Sur. Co., 237 F. Supp. 96, 102 (N.D. Ohio 1965); *Cobbs*, 502 P.2d at 9-11; Lockett v. Goodil, 430 P.2d 589, 591 (Wash. 1962); *see also* Delgado & Lescovac, *supra* note 88, at 108.

197. *See, e.g.*, BLACK'S LAW DICTIONARY 626 (6th ed. 1990) (describing the fiduciary relationship as "one founded on trust or confidence reposed by one person in the integrity and fidelity of another").

198. *See* Delgado & Lescovac, *supra* note 88, at 108.

199. *See id. See generally id.* at 107 n.173.

200. *Id.* at 91-92 (suggesting that less than informed consent may result from experimenters misrepresenting risks of an experimental treatment, misrepresenting the extent to which a new treatment has been accepted by the medical community, or withholding information about treatment alternatives).

201. AAMC GUIDELINES, *supra* note 5, at 6.

202. Delgado & Lescovac, *supra* note 88, at 92.

203. *See supra* notes 7-12.

204. *See supra* note 8 and accompanying text.

205. *See supra* note 190 and accompanying text.

1. THE INADEQUACY OF INFORMED CONSENT

A non-disclosure action cannot protect the interests of patient-research participants, such as Moore, because under current law, patients are unlikely to recover damages for non-disclosure. Informed consent has been termed "illusory"[206] as a remedy, a mere "medical Miranda-warning," and has frequently been trivialized by the courts.[207] It is no news to wronged patients that "[a] serious and fundamental failing of the law of informed consent is its continued lack of recognition that inadequate disclosure of information to patients by doctors is itself a wrong meriting legal protection."[208] In general, courts have denied recovery for lack of proper consent if the patient suffers no resultant *physical* harm.[209] Much to the dismay of uninformed patients, courts have yet to grant legal recompense solely for the violation of a patient's right to choose.[210]

Second, because plaintiffs must prove that had they been provided all relevant information, they would have declined treatment, most plaintiffs' actions will fail.[211] A desperate patient suffering from a serious illness, such as Moore, would seldom decline proper medical treatment on account of a physician-researcher's research interests. As a result, few patients can successfully bring a non-disclosure action. Moore himself never faced this dilemma since Dr. Golde did not ask him to relinquish any commercial interests in his cells until *after* Dr. Golde had removed his spleen. Moore did, however, allege that if he had known of Dr. Golde's commercial research plans, he would have declined treatment.[212]

Not only must a plaintiff prove that he or she would have declined treatment, the plaintiff must also prove that "no reasonably prudent person would have consented to the proposed treatment if the doctor had disclosed" fully.[213] This requirement presented Moore with a nearly insurmountable burden, since few juries would conclude that a reasonably prudent person, dying of leukemia, would decline medically

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206. Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 519 (Cal. 1990) (Mosk, J., dissenting).

207. Meisel, *supra* note 194, at 210.

208. *Id.* at 211.

209. "An unrevealed risk that should have been made known must materialize, for otherwise the omission, however unpardonable, is legally without consequence." *Id.* at 217 n.10 (discussing Canterbury v. Spence, 464 F.2d 772, 790 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972)).

210. *Id.* at 211.

211. Cobbs v. Grant, 502 P.2d 1, 11 (Cal. 1972).

212. Moore v. Regents of the Univ. of Cal., 249 Cal. Rptr. 494, 500-01 (Ct. App. 1988).

213. Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 520 (Cal. 1990) (Mosk, J., dissenting) (discussing Morgenroth v. Pacific Medical Ctr., Inc., 126 Cal. Rptr. 681, 694 (Ct. App. 1976)).

appropriate treatment because of the possibility of future research.[214] Because a plaintiff's burden is so difficult, most patients seeking relief in actions for non-disclosure will fail.

Moreover, patients greatly in need of sophisticated medical treatment may be incapable of rationally considering whether to participate in medical research.[215] Patients may sense that physician-researchers want them to consent and are most interested in treating patients who also participate in their research.[216] Patients may fear that if they do not participate, their future treatment will be jeopardized.[217] Seriously ill patients are more likely to place complete trust in their physician than those with minor ailments.[218] Due to their strong desire to be cured, very ill patients often do whatever they believe will most please their physician.[219] Although patients may give consent, their choice is hardly an objective one. It has been deeply influenced by physician expectations.[220] Under these circumstances, informed consent alone cannot protect patients from physician-researcher conflicts of interest.

The *Moore* dissent stated that the majority asserted that "the threat of [an informed consent cause of] action will have a prophylactic effect: it will give physician-researchers incentive to disclose any conflicts of interest before treatment, and will thereby protect their patient's right to make an informed decision about what may be done with their body parts."[221] Nonetheless, even if physicians disclose all information "material" to a patient's decision, including disclosure of financial interests, numerous studies demonstrate physicians' inability to

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214. *Id.*

215. *See* KATZ & CAPRON, *supra* note 192, at 95-99. In the context of life threatening disease treatment, the authors describe the transference phenomenon as follows:

> Any illness may undermine a person's normal ego strength; a crippling disease which puts a patient in a sick-bed without prospect of recovery can call forth ultimate dependence, cooperation, and devotion to the all-powerful physician who possesses the magical means of curing him. This combination of infantile regression and projection of parental image onto the physician has often been observed in treatment and research settings, particularly when the patient has sought out the physician as a specialist, especially "*the* outstanding specialist" in his field.

Id. at 96. Patients under these influences may not be capable of rationally weighing alternatives and are likely to simply follow the advice of their physician-expert.

216. *See id.* at 95-99.

217. *See id.*

218. *See id.*

219. *See id.*

220. *Id.*

221. Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 519 (Cal. 1990) (Mosk, J., dissenting).

communicate effectively with patients.[222] Physicians often obscure issues and leave out information they believe patients will not understand.[223] Others insist on explaining consent issues in scientific jargon unintelligible to the layperson.[224] Physicians may also minimize risks or indicate that participation in research is expected while discussing consent.[225] Thus, it appears most unlikely that patients will fully comprehend the implications of consent.

2. *WHY FIDUCIARY DUTY CANNOT BE MAINTAINED VIA INFORMED CONSENT ALONE*

Traditionally, a physician's fiduciary duty to her patient has included complying with informed consent requirements.[226] With the influx of private industry funds to university research, however, conflicts of interest are much more frequent and the financial gains available to researchers are often astounding.[227] Industry ties may create the temptation to pursue self-interest, which may render researchers incapable of acting in the best interest of their patients. As discussed above, when explaining treatment options to patients, researchers may unintentionally obscure or leave out information.[228] In *Moore*, Dr. Golde's desires to become an "entrepreneur of the new biotechnology industry" appear to have overwhelmed his sense of obligation to Moore as a patient.[229] Allegedly, Dr. Golde did not merely obscure information given to Moore; he lied outright about the very purpose of Moore's continued visits to UCLA.[230]

Additionally, researchers may send off subtle cues indicating that they prefer patients to choose the option which also serves their research

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222. *See* Delgado & Lescovac, *supra* note 88, at 118. *See generally id.* at 114-22 (suggesting that in some situations, intermediaries not directly associated with the research project should obtain patients' consent); Shelley E. Taylor, *Hospital Patient Behavior: Reactance, Helplessness or Control?*, 35 J. SOC. ISSUES 156 (1979).

223. *See* Delgado & Lescovac, *supra* note 88, at 76-77, 115; Taylor, *supra* note 222, at 161.

224. *See* Taylor, *supra* note 222, at 160.

225. Delgado & Lescovac, *supra* note 88, at 76-77.

226. Canterbury v. Spence, 464 F.2d 772, 782 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972).

227. *See supra* note 63 and accompanying text.

228. *See supra* notes 222-25 and accompanying text.

229. Martin & Lagod, *supra* note 50, at 231-32 (discussing the conflict of interest present in *Moore* and noting that "[p]rofessional fame is the traditional reward of scientific research and great fortune is the new reward of biotechnology. Both are powerful attractions." (citations omitted)).

230. Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 485 (Cal. 1990). Moore alleged that Dr. Golde "expressly, affirmatively and impliedly represented ... that these withdrawals of his Blood and Bodily Substances were necessary and required for his health and well-being" while denying any potential commercial or financial benefits. *Id.*

interests.[231] Researchers may yield to the temptation to order tests or procedures of marginal benefit to the patient to further research goals.[232] In light of these tendencies, experts have questioned whether physicians are capable of maintaining fiduciary obligations, and they suggest looking for mechanisms beyond informed consent to protect patients against conflicts of interest.[233]

Physicians have a duty to disclose conflicts of interest to their patients, but "disclosure is more helpful when . . . outside organizations assess the information disclosed and provide independent advice."[234] This Comment recommends that clear statements of policy and active monitoring of research collaborations at the institutional level, including universities and government funding sources, can protect patients from physician-researcher biases. Institutions can ensure review of potential conflict situations and enforce sanctions against those who fail to comply. Moreover, institutional policies heighten awareness among researchers of situations which may pose conflicts of interest. Without oversight and enforcement mechanisms, however, disclosure to patients merely serves to allow conflicts of interest and biases to continue affecting researchers with the "consent" of patient-subjects.

IV. PROPOSED REFORM

To ensure that conflicts of interest do not undermine the integrity of university research and place unknowing subjects at risk of harm, universities and government funding sources must voice their positions regarding conflict of interest through the development of internal policy. In accordance with several prominent research organizations,[235] this Comment recommends that primary responsibility for developing detailed policies to identify and manage conflicts of interest remain with individual universities.

Universities are better equipped than external regulators to evaluate university research activities.[236] Universities can most easily access information about conflicts of interest by requiring faculty to document and report any industry-sponsored research activities to department heads or to university administration. On-campus faculty have the

231. Delgado & Leskovac, *supra* note 88, at 76.

232. *Moore*, 793 P.2d at 484.

233. *See infra* note 235. *See generally* Delgado & Lescovac, *supra* note 88.

234. Marc A. Rodwin, *Physicians' Conflicts of Interest: The Limitations of Disclosure*, 321 NEW ENG. J. MED. 1405, 1407 (1989).

235. *See, e.g.*, AAMC GUIDELINES, *supra* note 5, at v; *NIH Proposed Guidelines*, *supra* note 16, at 1; *see also* Seligman, *supra* note 11, at 39 (arguing against external regulation of industry relationships at UCLA).

236. *See supra* note 235.

scientific expertise necessary to fairly evaluate research proposals on a case-by-case basis—expertise that external administrative monitors may lack.[237] Moreover, universities have a direct interest in knowing about activities occurring on their campuses because universities are highly concerned with maintaining their reputations as credible research institutions. Many institutions currently collect information about university-industry collaboration, even if they have not yet developed comprehensive policies regarding potential conflicts of interest arising from industry ties.[238] For these universities, developing a policy specifically addressing conflicts arising from industry ties may simply involve augmenting an existing administrative function.

Universities are also best suited to formulate policies and standards acceptable to both faculty and university administrators. Universities must consider faculty preferences and concerns when developing policies in this area in order to gain faculty respect and support for university policies.[239] Otherwise, faculty may try to circumvent policies or tolerate noncompliance by others. Similarly, since each university is a unique community with distinct types of industry relationships and existing administrative structures, externally imposed policies may not address issues relevant to the particular campus or may not mesh with existing administrative systems. Thus, to operate efficiently and achieve credibility, each university must tailor policies to meet its individual needs.

Some commentators have suggested that state or federal legislation is necessary to monitor conflicts of interest effectively.[240] Yet even if Congress or the states passed laws regulating conflicts of interest, detailed implementation guidelines would most likely be left to universities anyway.[241] The California amendments discussed above[242] demonstrate that despite monitoring by the Fair Political Practices

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237. One concern is that external monitors would develop a rigid list of acceptable and unacceptable arrangements without fully assessing individual proposals. Telephone Interview with Richard P. Seligman, Associate Director, Office of Contract and Grant Administration, UCLA (Feb. 1992). Often conflicts of interest can be minimized or resolved by changing some aspect of the proposal. *See, e.g.*, AAMC GUIDELINES, *supra* note 5, at 12 (discussing potential resolution mechanisms). External monitors may be less willing or able to work out problem situations so that research proposals can go forward. In that case, valuable research may be thwarted needlessly.

238. *See* PHS GRANTS POLICY, *supra* note 169 (requiring universities receiving PHS funds to have a conflict of interest policy in place); Burke, *supra* note 146.

239. *See supra* note 165.

240. *See generally* Lescovac, *supra* note 23, at 921-22 (arguing that federal regulations would protect the public interest in the use of federal funds for research and would promote uniformity in regulation of conflicts of interest among universities).

241. *See infra* notes 242-51 and accompanying text.

242. *See supra* notes 155-65 and accompanying text.

Committee (FPPC), the FPPC requires state-supported universities to develop their own individual, detailed policies in compliance with very general state mandates.[243] Perhaps the State of California recognized that one law cannot adequately account for the varying types of activities occurring on every campus within its jurisdiction.[244]

Monitoring by state agencies, such as the FPPC in California, may lend some credibility to the evaluation process.[245] But universities can achieve credibility in other ways without state or federal agency involvement. Arbitrary decisions can be prevented by requiring tiers of review,[246] filing reports with general university administration and faculty participation in policy development,[247] and education regarding university conflict of interest policies. In fact, university-implemented mechanisms may be more credible than state-imposed monitoring since monitors would be on campus, rather than from an external agency bureaucracy.

The federal government currently regulates some aspects of research[248] under grants of authority to an appropriate governmental agency such as NIH, HHS, or FDA.[249] Undoubtedly, if Congress were to pass federal legislation aimed at managing conflicts of interest, an existing agency or a new bureaucratic arm would be authorized to implement the law. Even these powerful agencies typically leave the details of implementation to the individual research center. For instance, "PHS views its relationship with [grant] recipients as a partnership, with the recipient providing the effort and expertise necessary to carry out approved activities."[250] Likewise, in areas of great public policy concern, such as civil rights, federal laws and subsequent agency administration

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243. *Id.*

244. Since legislative history of the California Administrative Code is not kept, one cannot be certain what factors influenced the passage of the FPPC amendments.

245. *See supra* notes 159-63 and accompanying text.

246. *See infra* text accompanying notes 271-81.

247. *See supra* notes 165, 237 and accompanying text.

248. *See supra* note 166. For example, experimentation with human subjects is federally regulated by HHS. 45 C.F.R. § 46.101-.122 (1991). The regulations require that the human subject be told: (1) the purpose of the research, the procedures to be used, and whether any procedures are considered experimental; (2) the risks and discomforts involved; (3) the benefits the subject or others may receive from the research; (4) alternative treatments if treatment is involved; (5) the extent of the subject's anonymity in records that are kept; (6) compensation offered or treatment available in "research involving more than minimal risk"; (7) the name of someone with whom the subject can discuss the research, and whom the subject could contact in the event of a research-related injury; and (8) the subject's right to terminate participation at any time without losing any other benefits. *Id.* § 46.116(a)(1)-(8).

249. *See supra* notes 242-45 (for examples of regulatory authority to carry out federal legislation residing in governmental agencies).

250. PHS GRANTS POLICY, *supra* note 169, at ii.

require organizations to develop internal policies and provide assurance to the federal government that they are in compliance with general federal guidelines contained in the law.[251]

An efficient means of monitoring would be to require university researchers to submit reports disclosing conflicts of interest along with applications for federal funding of research projects. For administrative and accounting purposes, federal funding sources already require grant applicants to submit detailed reports.[252] Through the grant review process, federal funding sources can keep conflicts of interest in check without resorting to the creation of an entirely new administrative process. Virtually every university and most research projects rely on some federal funding and would therefore be affected by funding requirements.[253] Thus, requiring states or the federal government to develop detailed legislation in this area would add little.

Moreover, governance of university research activities has traditionally been considered within the academic domain.[254] Long-standing policies of academic freedom[255] and institutional autonomy[256] militate against the imposition of detailed government regulation. Outside regulation is generally not tolerated in matters of strictly

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251. PHS provides the following explanation of how compliance with Title VI is managed for grant purposes:

> Title VI of the Civil Rights Act of 1964 provides that no person in the United States shall, on the grounds of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance, whether directly or under a subgrant or contract arrangement. The HHS regulation implementing this requirement is contained in 45 CFR Part 80. Every domestic applicant organization is required to have an Assurance of Compliance (Form HHS-441) on file with the Office For Civil Rights, Office of the Secretary, HHS, before a grant may be made to the organization.

Id. at 4-2.

PHS does not attempt to impose its own detailed guidelines that every recipient organization must follow. Instead, recipient organizations develop policies internally. PHS reviews the Assurance forms to determine whether recipient policies and implementation mechanisms meet PHS requirements for compliance with Title VI.

252. *See supra* note 186.

253. In 1987, total federal funding of biotechnology research and development was approximately $2.72 billion. Industry contributed less than two thirds that amount. INVESTMENT IN BIOTECHNOLOGY, *supra* note 1, at 37, 80; *see infra* note 277.

254. *But see supra* note 166 (discussing federal regulation of human subjects research).

255. *See generally* Lescovac, *supra* note 23, at 914-16 (discussing the historical development of and case law resulting in university privileges).

256. *Id.* at 918 (describing the scope of university autonomy and governmental authority to regulate universities).

university concern.[257] If an important governmental interest is involved, however, the government may have the power to regulate.[258] In the case of conflicts of interest, state and federal governments have general authority to regulate.[259] But state and federal governments may lack to authority by dictate to a university the specific methods it should use to comply with funding requirements.[260] Because more governmental regulation "potentially impinges on the free flow of information vital to informed decisionmaking," government should be cautious when establishing new regulations.[261]

Regardless of other state and federal requirements, university policies should include procedures for disclosure of potential conflicts of interest,[262] review of research proposals,[263] and control mechanisms designed to manage situations that present potential conflicts.[264] As this Comment demonstrates, conflicts of interest arising from industry ties can influence physician-researcher behavior inappropriately. Currently available legal remedies and regulations, however, do not protect patients adequately against potential harms resulting from conflicts of interest. Therefore, universities should develop disclosure and review policies. Disclosure and review enables university officials to identify and evaluate potentially problematic situations involving industry ties. Further, universities must adopt control mechanisms to ensure that conflicts of interest are managed effectively. Lastly, universities and federal funding sources must discourage or prohibit direct financial ties between researchers and private industry because direct ties are most likely to affect physician-researchers' behavior.

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257. For example, the University of California is considered a separate branch of government given authority to govern university affairs. CAL. CONST. art. IX, § 9. University affairs have been held to include: curricula, *e.g.*, Hamilton v. Regents of the Univ. of Cal., 293 U.S. 245 (1934) (authorizing Regents to determine student course requirements); course credit, *e.g.*, *id.*; use of student fees, *e.g.*, Erzinger v. Regents of Univ. of Cal., 187 Cal. Rptr. 164 (Ct. App. 1982) (Regents authorized to decide how tuition funds will be spent); employee salaries, *e.g.*, San Francisco Labor Council v. Regents of Univ. of Cal., 608 P.2d 277, 280 (Cal. 1980) (authorizing university to ignore external wage rates); and faculty selection, *e.g.*, Wall v. Board of Regents, 102 P.2d 533, 534 (Cal. Dist. Ct. App. 1940) (authorizing university to select professors).

258. *See* Lescovac, *supra* note 23, at 917 (discussing constitutional analysis of government regulation of universities).

259. *Id.* (stating that state's interests in minimizing conflicts of interest in research may outweigh the interest in unrestricted scientific research).

260. *Id.* at 917-18.

261. *Id.* at 916-17.

262. *See infra* part IV.A.

263. *See infra* part IV.B.

264. *See infra* part IV.C.

A. Disclosure of Potential Conflicts of Interest

As a part of the approval process for research projects and contracts, universities should require faculty to disclose all relevant personal interests, as well as pertinent interests of immediate family members, to appropriate university officials.[265] Relevant interests may include ownership interests, external professional positions, consulting agreements, gifts, honoraria, or loans involving industry. Complete disclosure is essential to the management of conflicts of interest because without full information, universities remain unaware of the types of arrangements in which faculty are involved. Since university policies must stay abreast of trends in collaborative arrangements, universities should require faculty members to disclose all relevant interests annually, regardless of whether the faculty member has submitted new grant applications, proposals, or project renewals.[266]

Although some universities have claimed that requiring disclosure of all financial interests of researchers and their immediate family members would be overly burdensome,[267] such disclosure is essential to uncovering conflicts of interest. Even a well-intentioned researcher may be subconsciously affected by the fact that a son, daughter, or spouse stands to gain financially from positive research findings. If researchers are not required to disclose their immediate family members' financial ties, less well-intentioned researchers need merely place an investment in another family member's name to avoid scrutiny by university officials. Such circumvention of the review process defeats the purpose of disclosure and review requirements, which is to uncover conflicts of interest. Instead, universities should promote complete openness and honesty throughout the disclosure and review process.

Disclosure is important not only as a means of identifying conflicts of interest but also because it demonstrates a researcher's good faith and integrity.[268] Revealing all potential conflicts and allowing careful review implies that one has nothing to hide and is willing to comply with an objective standard of appropriate faculty-industry collaboration. If universities reinforce norms of honesty and openness about research relationships, inappropriate behavior will more likely be discouraged.

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265. *See* AAMC GUIDELINES, *supra* note 5, at 11; *NIH Proposed Guidelines*, *supra* note 16, at 4; Seligman, *supra* note 11, at 28 (advocating faculty disclosure of any financial or other personal interests in industry research sponsors held by the faculty member, his or her spouse, or dependents).

266. AAMC GUIDELINES, *supra* note 5, at 11; *NIH Proposed Guidelines*, *supra* note 16, at 4. *But see* UCLA Policy on Disclosure of Financial Interest in Private Sponsors of Research (Apr. 1984) (on file with author) (requiring disclosure only before final acceptance of a grant or contract, or when funding is renewed).

267. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 54.

268. AAMC GUIDELINES, *supra* note 5, at 10.

Full disclosure allows researchers to maintain their credibility as principled, unbiased scientists. Since all potential conflicts in a disclosure model are subject to university scrutiny, those evaluating a researcher's findings can be more confident that findings are objective, rather than the outgrowth of bias. Similarly, full disclosure allows others to determine for themselves whether a researcher's personal interests may have influenced his treatment decisions or research findings. Thus, journal publishers or lecture audiences should require researchers to disclose any financial ties when presenting their research findings.[269] For example, had the *JAMA* article and editorial discussing the effectiveness of Retin-A[270] disclosed the authors' significant financial ties to a Retin-A manufacturer, readers would have been on notice that the authors' enthusiasm may have been overzealous. As a result, physician-researchers would have been more likely to look for other more objective research findings or perform independent research in attempts to replicate the authors' findings prior to prescribing Retin-A. Further, failure to disclose conflicts may significantly impact the choices community physicians make in treating their patients. Undoubtedly, many physicians who read the Retin-A article trusted the reported results and began treating patients with Retin-A. That treatment may have been inappropriate. Ultimately, the public suffers from the failure to disclose conflicts of interest.

B. Review of Potential Conflicts of Interest

Following disclosure, designated university personnel should review all privately and federally sponsored research agreements. Each university should adopt a review process appropriate to its own administrative structure. However, proposals should be subject to several levels of review, such as given by department heads, faculty committees, and university officials.[271]

1. *INITIAL REVIEW*

Initial review of new research proposals or contracts could be conducted by department heads.[272] Scientific expertise is essential to proper evaluation of research proposals. Due to their knowledge of a specific research area, department heads are better able to evaluate

269. *See* COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 68 (advocating that scientific journals require that authors sign a sworn statement that they have no conflicts of interest, or disclose any conflicts of interest).

270. *See supra* notes 134-37 and accompanying text.

271. AAMC GUIDELINES, *supra* note 5, at 11-12.

272. *Id.*

situations that could be problematic than non-scientist administrators or scientists knowledgeable in other areas.[273] As a result, department heads would serve most effectively as a first-level screen to identify proposals involving conflicts of interest that university officials should examine more closely.[274] In addition to scientific expertise, department heads would need to become well-versed in university policy and federal, state, and local requirements regarding conflict of interest.[275]

Under pressure from the university to obtain private funds, department heads may be biased toward allowing conflicts of interest to remain. However, the desire to maintain a clean departmental record provides department heads with competing incentives to comply with university policies. In addition, university policies should be sufficiently detailed to minimize room for discretionary decisions. If department heads are given little latitude, bias is less likely to enter the decision-making process.

Universities should develop a standard roster of review questions or criteria to maintain uniformity in the evaluation.[276] As part of the process, reviewers should ask how research proposals compare to institutionally mandated standards.[277] Generally, reviewers should examine proposals to determine whether conflicts of interest are present. Reviewers may also need to contact university legal counsel, research administration, government relations, or other appropriate departments to obtain informed opinions on particular proposals.[278]

Under this type of system, industry involvement in the development of a cell-line, as in the *Moore* case, would have been reviewed by a departmental expert familiar with what such a project entailed.[279] Undoubtedly, under review, Dr. Golde's conflicts of interest would have been identified and would have been subjected to further review. At a minimum, Dr. Golde would have been required to provide a thorough explanation of the research methods and to obtain proper consent, prior to continuing Moore's involvement. At that point, Moore

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273. *Id.*

274. *Id.*

275. *Id.*

276. For example, the University of California campuses employ six criteria in evaluating research proposals. *See supra* note 159; *see also* AAMC GUIDELINES, *supra* note 5, at 13-15 (outlining review questions for use in evaluating research proposals).

277. For example, if the university determines that having stock options in a company sponsoring one's research is absolutely forbidden, the researcher's disclosure statement should be checked to determine whether stock options are part of the package.

278. AAMC GUIDELINES, *supra* note 5, at 11.

279. Dr. Golde's research activities involving Moore began in 1976, six years before UCLA instituted its conflict of interest policy. Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 481 (Cal. 1990). Consequently, UCLA did not subject Dr. Golde's research proposal or industry ties involving Moore to its current conflict of interest review.

would have been free to exercise his choice regarding whether to participate in further research at UCLA. Certainly, informed consent doctrine favors respecting a patient's freedom of choice prior to conducting any medical or research procedure over compensation after harm has occurred.[280]

2. *SECONDARY REVIEW*

Secondary-level review would entail scrutiny by a committee comprised of university officials, such as deans or other top administrators.[281] The committee's role would be to make a final decision about whether a significant conflict of interest exists. If a conflict is found, then the committee would determine whether the proposal is wholly unacceptable, permissible with some modification, or permissible as is. In addition, the committee could be responsible for periodic follow-up reviews in situations where proposals were approved subject to modification. For example, a review committee might approve a proposal on condition that the primary investigator divest certain personal interests related to the project or remove himself from certain aspects of the research. Continued monitoring by the review committee would ensure that these conditions were maintained throughout the course of the project.

C. Mechanisms for Management of Conflicts of Interest

A range of control mechanisms is essential to effective management of conflicts of interest.[282] To minimize conflicts, universities might require that contracts between the university or faculty member and a private entity be negotiated by a neutral party. Project approval could be made contingent on making research results, procedures, and samples fully available to other researchers. Similarly, policies could require methods

280. In cases where proper consent has not been sought, patients may bring a tort action for nondisclosure. *See* Meisel, *supra* note 194 (for a history of the nondisclosure action for failure to obtain informed consent). The function of tort law is to compensate "individuals . . . for losses which they have suffered within the scope of their legally recognized interests generally . . . where the law considers that compensation is required." W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 1 (5th ed. 1984). Thus, by recognizing a tort action for failure to obtain informed consent, the law has stated that lack of consent is compensable. One important role of tort law is the prophylactic role of preventing future harm. Once defendants are held liable, they and others like them have strong incentive to prevent future similar harms. In addition to compensating the victim, one reason for imposing liability is to deliberately provide incentives to avoid the particular harm. Thus, by imposing liability on those who fail to obtain informed consent, tort law has provided legal incentives for maintaining the policy of informed consent. *Id.* § 4.

281. AAMC GUIDELINES, *supra* note 5, at 11.

282. *See id.* at 15.

of eliminating researcher bias, such as peer review of research design and third party selection of research participants. Regardless of which specific control mechanisms universities utilize, they must develop mechanisms that serve to manage or monitor potential conflicts of interest.[283]

Likewise, prompt and effective disciplinary proceedings for those who behave inappropriately are an essential component of any university policy for managing conflict of interest.[284] Disciplining researchers who fail to uphold university policy sends a strong message to other researchers as well as to the public that unethical or inappropriate behavior will not be tolerated. The case examples discussed above suggest that some researchers may have fallen into the trap of believing that if everyone else is doing it, it must be all right. In order to prevent the acceptance of conflicts of interest as part of the modern research environment, cases of inappropriate behavior must be exposed and researchers disciplined accordingly.

The Committee on Government Operations Report criticized several prominent research universities for failing to effectively deal with cases of physician misconduct or inappropriate behavior.[285] Among problems identified were delayed investigation, cover-up or denial of any wrongdoing, and retaliation against whistle blowers.[286] Because universities are at risk of losing grant funding if wrongdoing is found,[287] there is strong incentive to employ tactics such as delay and cover-up, thereby lessening the likelihood that wrongdoing will be found. Universities often further obscure the real problem by labeling questionable faculty behavior as a mistake or a case of overly optimistic reporting of findings.[288] However, scandals arouse suspicion within the scientific community and in the public. Failure to publicly acknowledge and confront the conflict of interest issue further erodes the public trust in

283. The AAMC suggests a number of control mechanisms to facilitate management of conflict of interest, such as negotiation of research affiliations or contracts by a neutral party, subjecting a research plan to independent peer review prior to beginning research, incorporating mechanisms designed to eliminate researcher bias within the research design, requiring that projects be supervised by someone without conflicts of interest, ensuring that means are available to verify results, sharing data and materials openly with other independent researchers, publication of findings, and acknowledgment of any outside sponsorship. *Id.*

284. *See id.* at 10; COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 69 (recommending NIH impose penalties against institutions that fail to thoroughly investigate allegations of scientific misconduct).

285. *See* COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 61-63.

286. *Id.* at 28-38, 47-50, 61-62. *But see id.* at 15-16 (discussing the University of California at San Diego's effective handling of an investigation).

287. *Id.* at 69.

288. *Id.* at 62.

the institution. Furthermore, if misconduct and subsequent cover-up are discovered, government funding sources may withdraw funds not only from the specific project in question, but may fail to renew funding to that department or university as a whole.[289] Given that government funding constitutes a large portion of any institutional research budget,[290] loss of research funding is a high price to pay for covering up a faculty member's misconduct.

Similarly, victimizing the whistle blower shifts the focus of inquiry away from potential wrongdoers and onto the loyalty of the whistle blower. Instead of penalizing those who identify inappropriate faculty behavior, individuals should be encouraged to eliminate wrongdoing by bringing it to the attention of proper university authorities. Outlining specific procedures for disciplining faculty is outside the scope of this Comment. However, with proper procedures in place, those suspicious about possible wrongdoing can be assured that their concerns will be investigated effectively without jeopardizing their own careers.

D. Per Se Prohibitions

Finally, government funding sources, as well as universities, should strongly discourage or prohibit certain kinds of affiliations between faculty and private industry.[291] Government funding sources should not provide funds for projects in which clearly inappropriate relationships exist. Universities or federal funding sources could prohibit university researchers from holding equity interests or options in companies sponsoring their research. Likewise, faculty interests in companies affected by the outcome of research should not be allowed. At a

289. If grantees fail to comply with conditions of the grant, PHS may suspend or terminate the grant or take other available legal remedies. In addition, HHS can disqualify or suspend individuals and institutions from eligibility to receive grants or other forms of financial assistance or contracts under HHS discretionary programs. Following any suspension or termination, all HHS components are informed via the HHS Alert System. Any sanctions imposed on the individual or institution are also reported to the HHS Alert System. PHS GRANTS POLICY, *supra* note 169, at 8-21.

290. In fiscal year 1989, total funding for scientific research was approximately $21 billion; 51% of this amount was government funding. Carey, *supra* note 7, at 148. In 1987, companies contributed an estimated $1.5 billion to $2.0 billion in biotechnological research and development. This amount constituted approximately two thirds of the amount invested by the federal government in 1987. INVESTMENTS IN BIOTECHNOLOGY, *supra* note 1, at 80.

291. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 68 (recommending PHS restrictions on financial ties to industry where researchers are conducting evaluations of a product or treatment produced by the industry sponsor); *NIH Proposed Guidelines*, *supra* note 16, at 4. *But see* COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 71 (noting one scholar's opinion that if funders or universities restricted financial ties, many scientists would leave academic research, and consequently the potential fruits of their efforts would be lost).

minimum, university researchers should not enter into consulting agreements or receive honoraria or other payment from private sources if their university research involves evaluating the effectiveness of a product developed by the private company.

Equity interests, fees, and gratuities enable researchers to benefit financially as a direct result of positive research findings. In many cases, researchers conducting privately sponsored research are already under tremendous pressure to report positive findings because continued research sponsorship may depend on findings beneficial to the sponsoring company. With the added factor of personal financial interests involved, researchers are likely to become quite concerned about losing the value of their investment as well as maintaining their research sponsor.[292] These combined pressures may result in a real inability to evaluate findings objectively or an overwhelming temptation to report findings inaccurately. Of greatest concern is the likelihood that researchers receiving payment from a private source while simultaneously evaluating a product of the source, will be unable to remain objective. Consequently, findings would tend to overstate the product's effectiveness and minimize possible negative side-effects or risks.[293]

As the TIMI trials illustrate,[294] researchers could potentially manipulate the stock market to increase their own rewards through an incomplete or biased release of results. Even the best-intentioned researcher is likely to be affected by the prospect of large financial gains.[295] "The real problem is that if you have money in it, your judgment is warped even if you're honest."[296] More importantly, biased reporting of research results may mislead the medical community about the effectiveness of a certain drug, device, or treatment modality. Had the authors of the TIMI trial reports revealed their equity relationships with Genentech, other scientists and physicians would at least have been alerted that the results might be biased. Better yet, if the TIMI researchers had not had a financial stake in the value of Genentech stock, there would

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292. *See supra* notes 59-61 and accompanying text.

293. *See supra* parts II.B.3, 5 (discussing the TIMI trials and Retina-A examples).

294. *See supra* part II.B.3.

295. Although most commentators on conflict of interest guidelines have been concerned with the impact of large financial gains on researcher objectivity, one study suggests that small gifts or honoraria, such as $100 to take part in a symposium examining a drug's effectiveness, may actually have a greater biasing effect on researchers' attitudes. According to the study, researchers may perceive large financial gains as a bribe, and would therefore be consciously aware of the risk of selling out. Conversely, researchers may view small financial benefits as inconsequential, and therefore not guard against potentially biasing effects. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 66-67.

296. *Id.* at 56 (quoting Dr. Leon Eisenberg in PHYSICIAN'S WEEKLY, May 14, 1990).

have been no incentive to report incomplete and biased results, and therefore no suspicion surrounding their activities.[297] Future patients and the public at large may suffer real harm as a result of inflated positive research findings. To prevent such harm, universities should strive to minimize situations in which flagrant conflicts are most likely to arise. Therefore, universities should seriously consider prohibiting direct equity relationships in industry sponsors.

V. CONCLUSION

Although universities are beginning to critically examine the scope and nature of university and faculty relationships with industry, they also need to clarify which types of relationships are acceptable and which are not. Allegations that universities prefer to deny or cover up suspicions of wrongdoing provide disturbing evidence that unchecked activity may be tolerated. Incidents such as *Moore* and the others described above are undoubtedly occurring in some research institutions.[298] These examples and universities' recent focus on conflicts of interest in industry-sponsored research[299] suggest that some researchers are being unduly influenced by ties to industry and, as a result, patients are being harmed. This Comment argues that individual universities must take responsibility for activities occurring on their own campuses by formulating and implementing comprehensive policies. University policies should include mechanisms for disclosure, review, and management of potential conflicts of interest. Further, by exercising their tremendous power of the purse,[300] federal funding sources can command compliance with conflict of interest policies. By discouraging or prohibiting direct financial relationships between faculty members and private industry, both universities and federal funding sources can greatly reduce the prevalence of physician-researcher conflicts of interest.

> [O]bjectivity and vested financial interest do not make good bedfellows. . . . [One can't] expect the average researcher to be any less immune to the siren song of making a fast fortune. . . . If you can't bring yourself to part with your stock or fat consulting fee, then you shouldn't expect anyone to trust what you have to say about the effectiveness of a drug, device, or medical product. Disclosure is not enough. Complete medical divestiture must be the moral rule governing medical testing.[301]

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297. *See supra* text accompanying notes 100-21.

298. *See supra* part II.B.

299. *See supra* note 19 and accompanying text.

300. *See supra* note 7.

301. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 57 (quoting Caplan, *supra* note 152).