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COMMENTS

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THE AT&T ANTITRUST CONSENT DECREE: SHOULD CONGRESS CHANGE THE RULES?

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I. INTRODUCTION

The telecommunications industry in this country was long dominated by AT&T, a fully integrated provider of telecommunications services. Western Electric manufactured equipment; the Bell Operating Companies ("BOCs") provided local exchange service; AT&T provided interexchange (long distance) service that linked the local exchanges into

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a national and international system; and Bell Laboratories researched future industry developments. The antitrust history of the industry has been played out not only in the courts, regulatory agencies, and related settlements, but also in Congress. The most significant single event was the entry in 1982 of a consent decree that separated AT&T, Bell Labs and Western Electric from the BOCs, which were in turn restructured into independently owned and operated Regional Bell Operation Companies ("RBOCs"). The RBOCs were to provide local exchange services and were allowed to sell customer premises equipment, but were restrained from providing interexchange service, manufacturing telephone equipment, providing information services, and, except with court approval, engaging in other unregulated non-telecommunications businesses. The RBOCs are restive under these "line-of-business restrictions," particularly the prohibition against manufacturing telephone equipment. They argue that allowing them to enter this business would make manufacturing more competitive, not less. Having failed to persuade the courts to eliminate the principle line-of-business restrictions,[1] the RBOCs have turned to Congress for relief.[2]

In this Article we consider whether legislation loosening the manufacturing restriction would be sound competition policy.[3] Our inquiry indicates that local exchange service remains a natural monopoly, and that markets for manufacturing telephonic equipment are workably competitive. So long as these two conditions prevail, there would be grave risk of serious competitive harm and little possibility of significant competitive advantage in allowing the RBOCs to enter telecommunications manufacturing markets.[4] We conclude that under the conditions now prevailing in the industry, the case for legislative relief has not been made.

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1. United States v. Western Electric Co., 673 F. Supp. 525 (D.D.C. 1987) [hereinafter AT&T II], *aff'd in relev. part*, United States v. Western Electric, 900 F.2d 283 (D.C. Cir. 1990) [hereinafter Western Electric]. AT&T II reaffirmed the manufacturing and interexchange service restrictions, while lifting or modifying some of the other line-of-business restrictions.

2. Senate Concurrent Resolution 34 proposes that Congress consider allowing the RBOCs "to compete with other companies to provide information services, . . . to conduct research, to design, develop and market software, and to design, develop, manufacture and market customer premises and other telecommunications equipment." 135 CONG. REC. S5047 (daily ed. May 9, 1989); *see also To Permit the Bell Telephone Companies to Conduct Research on, Design, and Manufacture Telecommunications Equipment and for Other Purposes: Hearings on S. 1981 Before the Subcomm. on Communications of the Senate Comm. on Commerce, Science and Transportation*, 101st Cong., 2nd Sess. (1990).

3. We do not address the question whether it would be appropriate or even lawful for Congress to restructure a judicial decree under separation of powers doctrines.

4. The senior author was retained to evaluate the likely competitive effect of a lifting of the manufacturing restriction, and gave essentially this opinion to AT&T in the spring of 1990.

Section II provides a brief overview of the facts and legal history leading up to the 1982 consent decree. Section III examines changes in industry conditions which have occurred since the decree. In Section IV, we present an analysis of (A) the competitive harms likely to flow from lifting the restriction, (B) the potential benefits from RBOC participation in manufacturing, (C) the possible effects on R & D in telecommunications, (D) the existence of less onerous alternatives to the manufacturing restriction which might be used to obtain potential benefits, and (E) the possible effects of lifting the restriction on the United States' balance of trade. Section V reviews our conclusions.

II. THE RELEVANT HISTORY

The 1982 consent decree represented the culmination of more than forty years of executive, judicial and legislative efforts to deal with the formidable anticompetitive harms caused by AT&T's monopoly over all aspects of the telecommunications industry. The details of this history have been thoroughly aired elsewhere,[5] but the technological and social factors leading to the decree, and the theory underlying the decree's structural remedy, can be profitably reviewed here.

Industry observers had long assumed that the entire telecommunications industry would remain a monopoly. Local exchange service and long distance operations were assumed to be natural monopolies while other segments such as equipment manufacturing, though potentially competitive, were thought to function most efficiently when linked to the two monopoly segments within a single firm. Under this reasoning, a single integrated system would assure the most reliable and effective national telecommunications network.[6]

In the 1960s, this assumption was challenged from two directions. The first was technological; with the discovery that microwaves could be substituted for telephone wires in long distance service, AT&T's monopoly in this sector was no longer natural. Without duplicating either the switching system or the enormous network of wires controlled by AT&T, a number of firms could compete in the provision of microwave transmission.

The second challenge was socioeconomic in nature. At mid-century, the United States initiated a major monopoly case against AT&T

5. *See* AT&T II, *supra* note 1, 673 F. Supp. at 529-32 (reviewing consent decree under the terms of the decree's triennial review provision); Western Electric, *supra* note 1; P. TEMIN, THE FALL OF THE BELL SYSTEM: A STUDY IN PRICES AND POLITICS (1987); S. COLL, THE DEAL OF THE CENTURY: THE BREAKUP OF AT&T (1986); *see also* G.W. BROCK, THE TELECOMMUNICATIONS INDUSTRY: THE DYNAMICS OF MARKET STRUCTURE (1981).

6. The Department of Defense expressed opposition to breaking up AT&T on this ground. *See* S. COLL, *supra* note 5, at 186-88.

that was settled with limited relief by a consent decree in January, 1956.[7] However, beginning in the late 1960s, the Federal Communications Commission was deluged by complaints from small central office and user-premise equipment manufacturers claiming to produce efficient, high quality products which AT&T refused to buy, or even to permit end-users to buy.[8] The Commission struggled throughout the 1970s to enact regulations which could monitor AT&T's relationship with these competitors, but by the end of the 1970s it was apparent that its relatively small staff could not keep up with the various technological, accounting and pricing strategies which AT&T could devise to limit competitive incursion by other manufacturers.[9]

In 1974, nearly a quarter of a century after the first suit was brought, and while the first decree was still in effect, the government sued again.[10] It alleged that AT&T had used its lawful monopoly over local exchange services, operated by the BOCs, to also monopolize interexchange (long distance) services and telephone equipment manufacturing by restricting and eliminating competition from other long distance companies and suppliers of telephone equipment. Coinciding as this did with a growing awareness among economists, government policy-makers, and the public at large of the limits to regulation, the groundwork was laid for the deregulatory solution adopted in the 1982 antitrust decree.

After lengthy discovery, the trial began in the District Court for the District of Columbia before Judge Greene. The government's evidence tended to show that AT&T had planned and executed strategies to foreclose market access to telephone equipment and long distance services offered by others, including services and equipment that were as good or better than those AT&T provided. It imposed barriers on other long distance companies seeking to link with the BOCs, caused all the BOCs to buy from Western Electric, and obliged BOC customers to use Western Electric equipment.

Defendants moved to dismiss at the end of the government's case. In denying that motion, Judge Greene summarized the situation as follows:

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7. United States v. Western Electric Co., 1956 Trade Cas. (CCH) ¶ 68,246 (D.N.J. 1956).

8. *See, e.g.*, Matter of Carterfone, 13 F.C.C.2d 420 (1968).

9. The FCC's failure effectively to regulate AT&T was thoroughly examined during the eleven months of trial that completed the government's case in chief and that lead to the 1982 decree. AT&T II, *supra* note 1, 673 F. Supp. at 530-32; *see also* R.G. NOLL & B.M. OWEN, *The Anticompetitive Use of Regulation: United States v. AT&T* in THE ANTITURST REVOLUTION, 290-337 (J.E. Kwoka & L.J. White eds. 1989).

10. This summary of the 1974 suit draws on the material in E. FOX & L. SULLIVAN, ANTITRUST 202-05 (1989).

> The government's evidence has depicted defendants as sole arbiters of what equipment is suitable for use in the Bell System—a role that carried with it a power of subjective judgment that can be and has been used to advance the sale of Western Electric's products at the expense of the general trade. First, AT&T, in conjunction with Bell Labs and Western Electric, sets the technical standards under which the telephone network operates and the compatibility specifications which equipment must meet. Second, Western Electric and Bell Labs ... serve as counselors to the Operating Companies in their procurement decisions, ostensibly helping them to purchase equipment that meets network standards. Third, Western also produces equipment for sale to the Operating Companies in competition with general trade manufacturers.
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> The upshot of this "wearing of three hats" is, according to the government's evidence, a rather obviously anticompetitive situation. By setting technical or compatibility standards and by either not communicating these standards to the general trade or changing them in mid-stream, AT&T has the capacity to remove, and has in fact removed, general trade products from serious consideration by the Operating Companies on "network integrity" grounds. By either refusing to evaluate general trade products for the Operating Companies or producing biased or speculative evaluations, AT&T has been able to influence the Operating Companies, which lack independent means to evaluate general trade products, to buy Western. And the in-house production and sale of Western equipment provides AT&T with a powerful incentive to exercise its "approval" power to discriminate against Western's competitors.[11]

Judge Greene further concluded that the essential facility doctrine mandated that AT&T give competitive long distance companies reasonable, non-discriminatory access to BOCs.[12] Under that doctrine, as he viewed it, BOCs would have a duty to release technical information and compatibility specifications to all would-be suppliers.

The defendants responded that antitrust liability cannot be based on failure to release trade information to the general public, citing *Berkey Photo, Inc. v. Eastman Kodak, Co.*[13] Berkey Photo alleged that Kodak had attempted to monopolize the market for processing film by introducing, without advance notice, a new film which could be processed only with equipment procured from Kodak, and by refusing to disclose the

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11. United States v. AT&T, 524 F. Supp. 1336, 1372 (D.D.C. 1981).

12. United States v. Terminal R.R. Ass'n, 224 U.S. 383 (1912); Otter Tail Power Co. v. United States, 410 U.S. 366 (1973). The essential facility cases teach that a vertically integrated firm with a lawful monopoly at one vertical level arising from ownership of a unique and essential resource that cannot be duplicated is guilty of monopolization if it exploits that resource to its own advantage at the next level by denying any access to the monopolized facility or by granting it only on terms that put its competitors at an arbitrary or invidious disadvantage. *See* L. SULLIVAN, ANTITRUST 131 (1977).

13. 603 F.2d 263 (2d Cir. 1979), *cert. denied*, 444 U.S. 1093 (1980).

chemicals used in the new photo finishing process. The Court of Appeals for the Second Circuit held that a decision to withhold information from competitors would constitute an antitrust violation only if it involved abuses of market power rather than aggressive competition on the merits.[14] Convinced that Kodak had done no more than take advantage of its integration across possible market boundaries, the court concluded that Kodak's conduct was merely aggressive, competitive behavior.[15]

AT&T's behavior, by contrast, looked to Judge Greene much more like market power abuse than competition on the basis of a new, improved product. Kodak's conduct had increased Berkey's costs, but Berkey had still been able to process the new film despite Kodak's non-disclosure. By contrast, AT&T's non-disclosure was far more harmful:

> No piece of equipment can be interconnected with the country-wide public switching network unless it conforms to the compatibility standards set by Bell. An inability to obtain Bell technical information/compatibility standards thus constitutes an insuperable barrier to entry to the market (and the record does not show a reasonable basis for defendants' having withheld this type of information).[16]

During the pendency of the government's suit, William Baxter had become Assistant Attorney General in charge of the Justice Department's Antitrust Division. Viewing antitrust through the lens of neo-classical microeconomic theory, Baxter was convinced that AT&T had an incentive to cause regulated BOCs to pay Western Electric hidden premiums on its equipment, to get monopoly profits where it faced little competition, and to subsidize markets where there was political pressure to keep prices low.[17] Although earlier settlement negotiations had focused on possible conduct remedies, Baxter supported a plan to break up AT&T.

As viewed by Baxter, the 1982 decree was necessary because AT&T's control over the natural monopoly segment of the industry, local exchange service, had placed it in the position to leverage its power into other industry segments which depended on the local exchange network. For example, AT&T could leverage power by denying local service access to competitors, or discriminating in the quality of such access. AT&T's 1960s and 1970s behavior in long distance service and manufacturing utilized this strategy to some degree. Other leveraging devices, possibly used against manufacturing competition, included: (1) foreclosing

14. *Id.*
15. *Id.*
16. United States v. AT&T, 524 F. Supp. at 1375.
17. For discussions of the economic analysis that lay behind the consent decree, see R. G. NOLL & B.M. OWEN, *supra* note 9, and Brennan, *Why Regulated Firms Should Be Kept Out of Unregulated Markets: Understanding Divestiture in United States v. AT&T*, 32 ANTITRUST BULL. 741 (1987).

opportunities of competitors either through direct self-dealing or through the more subtle means of product differentiation, price discrimination, delayed notification of changes in design, etc.; and (2) cross-subsidizing its competitive products and services by shifting costs incurred in competitive activities to its regulated local exchange monopoly, thereby breaking the link between price and cost in both the competitive and regulated markets. As regulatory oversight had failed to control these practices adequately, Baxter believed that the decree's structural solution was required. The relevant opinions make clear that the district and reviewing courts accepted essentially this conception of the decree.[18] Even AT&T saw the wisdom of Baxter's approach after Judge Greene denied AT&T's motion to dismiss. The expense and risk of litigation made a consent decree more attractive for AT&T. Some eight years after litigation began, a settlement was reached and the consent decree entered.

The decree relied on the theory that separation of local exchange service from industry segments vertically linked to the local exchange network was essential.[19] This separation resulted, on the one hand, in an AT&T divested of its power over the local exchange market, and, on the other, in seven RBOCs,[20] forbidden from entering manufacturing, long-distance, and other related markets. As Judge Greene took pains to demonstrate in considering the RBOCs' 1987 motion to modify the line-of-business restrictions, these restrictions were not ancillary to the deregulatory solution adopted in 1982, but went to the very "root [of] the problem of claimed monopolistic conduct in telecommunications."[21]

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18. United States v. AT&T, 552 F. Supp. 131 (D.D.C. 1982), *aff'd sub nom.* Maryland v. United States, 460 U.S. 1001 (1983) [hereinafter AT&T I]; AT&T II, *supra* note 1; Western Electric, *supra* note 1. Cross-subsidization is perhaps the least obvious of the possible leveraging devices. Here is a hypothetical example: suppose personnel from Western Electric and AT&T BOCs worked together to plan new switching equipment. The BOC was a lawful, regulated monopolist; it could recover all its costs plus a reasonable return from local rate payers. Western Electric sought to sell switching equipment not only to AT&T BOCs but to others also, and faced competition from foreign manufacturers. If planning and development costs that should be assigned to Western Electric could be successfully assigned to the BOC, these costs would be covered by the regulated returns from the monopolized segment. Western Electric, appearing to have lower costs than it actually experienced, could price down to its apparent costs when encountering foreign competition without appearing to have engaged in predatory, below-cost pricing. *See infra* note 36.

19. *See Competitive Impact Statement on Settlement with AT&T,* 1052 ANTITRUST & TRADE REG. REP. (BNA) 401 (1982).

20. The initially twenty-two (local) Bell Operating Companies were reorganized into seven Regional Holding Companies in 1983. United States v. Western Electric Co., 569 F. Supp. 1057, 1062 (D.D.C. 1983), *aff'd sub nom.* California v. United States, 464 U.S. 1013 (1983).

21. AT&T II, 673 F. Supp. at 600.

III. POST-DECREE INDUSTRY DEVELOPMENTS

Since the decree, a number of technological and business developments have occurred, some as a direct result of divestiture, others not. While many of these changes have enhanced competition in segments such as manufacturing and interexchange service, none of them alters the basic division of the industry into a natural monopoly in the provision of local service and competitive markets in other industry segments.

The natural monopoly in local exchange services remains intact. While it would be perilous to predict long-range industry developments, industry analysts agree that it will remain impossible to organize competitively the core of that monopoly—the millions of wires providing the initial link between a residence or business and the first switch joining this user to the local network—at least until as yet unforeseen technological changes[22] and accommodating regulatory responses[23] have become realities. A few large, high-volume users have invested in the equipment needed to bypass the local exchange through multi-site private networks or by connecting with an interexchange carrier directly. There has also been a gradual growth of competition within some Local Access Transport Areas ("LATAs") for the carrying of calls from the first

22. One must be cautious in predicting future technological developments, or the lack thereof. It is conceivable that cellular phone technology will reach the point where users could connect though cellular devices to alternative, competitive microwave switching centers, thus ending the natural monopoly status of local exchange service. Knowledgeable observers, not foreseeing any such development in the near future, expect the natural monopoly to continue for some time. Separate reports by the Department of Justice and its independent consultant, Peter Huber, were submitted to the court in connection with AT&T II and concurred in this conclusion. *See* DEPARTMENT OF JUSTICE, REPORT AND RECOMMENDATIONS CONCERNING THE LINE OF BUSINESS RESTRICTIONS IMPOSED ON THE BELL OPERATING COMPANIES BY MODIFICATION OF FINAL JUDGMENT 97-98 (1987) [hereinafter DEPARTMENT OF JUSTICE REPORT] (cited in AT&T II, 673 F. Supp. at 538); P. HUBER, THE GEODESIC NETWORK: 1987 REPORT ON COMPETITION IN THE TELEPHONE INDUSTRY 3.44-3.46 [hereinafter HUBER REPORT]. Of course, if local service did at some future date cease to be a natural monopoly, and competitive options became generally available, there would no longer be a rationale for the line of business restrictions.

23. There is a massive literature on the character and effects of traditional regulation. *See, e.g.*, TELECOMMUNICATIONS POLICY FOR THE 1990S AND BEYOND (W. Bolter, J. McConnaughey, & F. Kelsey eds. 1984). Thoughtful commentary, such as R.C. HARRIS, A REPORT TO THE CALIFORNIA ECONOMIC DEVELOPMENT CORPORATION (1988), suggests moderate, incremental movement away from traditional regulation toward regulation better adapted to market forces. Such change could lead, in the course of time, to regulatory devices for sharing productivity gains between rate-payers and shareholders, or to other modes of mimicking markets more effectively than does traditional regulation. However, we are aware of no serious commentator who thinks all rate regulation of the local exchange sector of the telephone industry can or should be abandoned, given the current stage of technological development.

switch to other points within the LATA. The potential for this kind of competition arises not because local exchange natural monopolies are eroding, but because some LATAs, serviced by a single RBOC, are large enough in area and dense enough in usage so that different regions within one LATA could support competitive microwave connecters. An example is competitive connections between local exchanges in two cities in separate parts of a LATA. But even this development, which leaves the basic natural monopoly undiluted, is tentative, limited both by scale and scope economies and by regulatory hesitancy.[24] To the extent feasible, intra-LATA competition should be encouraged and regulators discouraged from restricting it.

To the extent that any RBOC's local exchange service natural monopoly is narrower than a LATA serviced by that RBOC, users should have the benefit of available competitive options, just as they do for inter-exchange service. But further development of such intra-LATA competition would not deprive RBOCs of their natural monopolies. In order to pose a genuine threat to the natural monopoly of user-to-switch wiring, it must be technologically possible and economically feasible for large numbers of users to bypass the initial exchange link. A number of factors militate against the large-scale use of bypass.[25] First, with present or foreseeable technologies, there remain substantial economies of scale and scope in local exchange telecommunications, making bypass prohibitively expensive for almost all users.[26] Second, from the point of view of the consumer, bypass only substitutes dependence on the local exchange network for dependence on the interexchange network to which one establishes a link. In order to avoid dependency altogether, a user must establish links with a number of competing services, wastefully duplicating costs.

In other telecommunications segments, by contrast, competition has thrived since the decree. There are now a number of significant interexchange carriers. Competition in the equipment manufacturing

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24. Most LATAs, extended metropolitan areas, are probably adequately configured to serve as markets of appropriate scale for regulated, local exchange service by a single carrier. Some, however, are much larger. While regulators in some states have accommodated some intra-LATA competition, others have not or have moved slowly. After divestiture, the California Public Utilities Commission, for example, decided against intra-LATA competition except for high-speed data services, and is only now exploring the possibility of facilitating other forms of intra-LATA competition that have long been technologically feasible. Keppel, *Local Phone Companies Feeling Heat*, L.A. Times, Jan. 5, 1990, at D1, col. 3.

25. *See supra* note 22. The Court of Appeals reaffirmed the district court's assessment that "only a minute percentage of telephone users can bypass the local exchange carriers for any of their calls." Western Electric, 900 F.2d at 295.

26. *See* AT&T II, 673 F. Supp. at 538; *see also* HUBER REPORT, *supra* note 22, at 2.2.

market is even healthier. Both the customer premise and the transmission equipment segments are occupied by numerous suppliers, small and large.[27] The most concentrated portion, the private branch exchange ("PBX") market, has three major and many smaller suppliers that compete effectively.[28] In central office equipment, the market for many products is vigorously competitive,[29] while in the only segment that remains at all concentrated, central office switches, there is, at worst, a decidedly rivalrous international oligopoly.[30] As could be expected, prices for customer premise equipment have dropped significantly.[31] Innovation in equipment design and service, such as voice-instructed machines, in-coming call display, and call filtering devices, has dramatically improved.[32] It is noteworthy, however, that competition in the manufacturing industry comes largely from foreign firms, often powerfully positioned in their own countries through government subsidy or integration with exchange services, thereby facilitating self-supply at high prices which are passed on to consumers in their own countries.[33]

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27. *See* Kahn, *Deregulation: Looking Backward and Looking Forward*, 7 YALE J. ON REG. 325, 328 (1990); *see also* R.G. NOLL & B.M. OWEN, *United States v. AT&T, An Interim Assessment*, in FUTURE COMPETITION IN TELECOMMUNICATIONS, 172-86 (S. Bradley & J. Hausueon eds. 1989).

28. Western Electric, *supra* note 1, 900 F.2d at 304. A private branch exchange is the equipment used by a telecommunications customer, such as a corporate office or a law firm, to switch incoming calls from the local exchange to individual extensions within the customer's premises.

29. AT&T's share of various transmission equipment and media segments now ranges from 17% to 49%, and RBOCs now make about 40% of their aggregate purchases from firms other than AT&T. HUBER REPORT, *supra* note 22, at 15.4-15.6.

30. Before the decree, AT&T used its vertical integration to supply all of its own needs in this segment until 1980. In that year it approved Northern Telecom as a supplier. Post-decree changes have been profound. As a result of new entry and investment stimulated by the decree, AT&T's share of central office switches fell from over 95% to 50%. HUBER REPORT, *supra* note 22, at 14.9 & Table CO.6 Competition, moreover, has resulted in the price per line of some central office switches falling by as much as 50%. *Federal Telecommunications Policy Act of 1986: Hearings on S. 2565 Before the Senate Comm. on Commerce Science, and Transportation*, 99th Cong., 2d Sess. 94, 96 (1986) (Statement of Douglas H. Ginsburg). One firm, GTE, has withdrawn, but several other firms capable of supplying central office switches (Siemens, Ericsson and Plessey) have already entered in addition to Northern Telecom. Other capable competitors, such as Alcatel-Thomson, CGE-ITT, Italcom/Telettra, Telenoka, NEC, Fujitsu, and Hitachi, are currently probing for opportunities to supply RBOCs.

31. DEPARTMENT OF JUSTICE REPORT, *supra* note 22, at 162-63, 171-73 (cited in AT&T II, *supra* note 1, 673 F. Supp. at 560 n.159).

32. AT&T II, 673 F. Supp. at 601, n.330.

33. A Commerce Department study, released in August of this year, attributes indications that American firms are decreasingly competitive in telecommunications equipment to foreign market barriers faced by American firms and to the lack of a "skilled American work force." Bradsher, *U.S. Lag in Phone Trade Seen*, N.Y. Times, Aug. 17, 1990, at C3, col. 4. To the extent that America's disadvantage as an exporter is attributable to

IV. ANALYSIS OF THE MANUFACTURING RESTRICTION

Deciding whether or not it would be wise to lift the restriction on RBOC participation in telecommunications manufacturing requires a weighing of the risks of anticompetitive injury against any potential benefits from RBOC entry. Separate consideration should be given to the effects of lifting the restriction on R & D in the telecommunications industry as a whole. One must inquire whether less onerous alternatives to the current blanket restriction exist. Finally, one must examine the foreseeable impact of lifting the manufacturing restriction on the United States' balance of trade. In other words, given the history and current conditions of the industry, is the remedy embodied in the 1982 consent decree still appropriate?

A. Competitive Harms Likely from a Lifting of the Manufacturing Restriction

As the review of current industry conditions suggests, despite slightly improved possibilities for bypassing local exchange networks, erosion of the natural monopoly in local exchange operations has been minimal, and the possibility for significant competition in these operations seems quite remote. Given this conclusion, the overwhelming competitive harm of lifting the manufacturing restrictions would be to provide an RBOC with both the capacity and the incentive to leverage its monopoly power into the manufacturing sector. Such power could be used to cross-subsidize its manufacturing operations with returns from its regulated monopoly and to coordinate local exchange services with manufacturing so as to prefer its own equipment and foreclose possibly more efficient competitors from access to the RBOC as a buyer. A variety of undesirable scenarios is imaginable under either the cross-subsidization or foreclosure strategy.

The principal feature facilitating cross-subsidization in the telecommunications industry is the high degree of common or joint costs of operation; that is, costs which cannot be clearly attributed to one industry sector because of the complex interdependence between wiring,

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protectionist policies, these disadvantages may diminish over time, at least in Europe. Despite some American concerns that European integration may be adverse to American economic interests, initiatives aimed at making the EEC market a level playing field for all EEC suppliers of telephone equipment by breaking down member-state policies that favor their own suppliers may also make it easier for non-EEC suppliers to reach EEC markets. Millard & King-Johnson, *Recent Developments in Telecommunications Regulation in the EEC*, CLIFFORD CHANCE EC NEWSLETTER, Aug. 1990, at 1-6. See also *ABA Focuses on Various Issues Presented by European Integration*, 1479 ANTITRUST & TRADE REG. REP. (BNA) 278 (1990), which catalogs possible adverse effects of integration on American business.

servicing, switching and equipment functions.[34] This feature, intensified by the dynamic nature of technological change in many sectors of the industry, allows for costs from manufacturing to be subsumed under the local exchange cost umbrella in ways which are extraordinarily difficult to detect in a timely fashion.

If an RBOC entered manufacturing, cross-subsidization would allow it to market equipment at prices competitive with, or below,[35] those of other firms in the market, while covering some of its own actual manufacturing costs under its regulated local exchange rates.[36] Such cross-subsidization, unless plainly *de minimis*, would distort competition in the manufacturing market in which the RBOC's activities were being subsidized. By insulating the RBOC from the rigors of competition, cross-subsidization would enable it to attract market share from more efficient

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34. Both the district court and the Justice Department noted the problem of common costs at various junctures. *See* AT&T II, 673 F. Supp. at 531 n.15, 568; *id.* at 531 n.16 (citing the Justice Department's memorandum of Aug. 16, 1981, at 46-47, 125, 161-62, 281-82, 285, 372).

35. By enabling an RBOC to price below its actual manufacturing costs but above apparent manufacturing cost as reported to the regulator, cross-subsidization disguises and thereby facilitates a form of predatory pricing which would be extremely difficult to detect under current antitrust tests for predation. Current predatory pricing law focuses almost exclusively on the relationship between price and cost first discussed by Profs. Areeda and Turner in *Predatory Pricing and Related Procedures Under Section 2 of the Sherman Act*, 88 HARV. L. REV. 697 (1975). *See, e.g.*, Matsushita Elecs. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 585 (1986). Profits gained from cross-subsidization could also be used to support other modes of predation, such as excess capacity, and predatory advertising.

36. Traditional rate regulation sets a target rate-of-return on an estimated rate base plus allowed expenses consistent with levels of investment, expenses and service. *See generally* A. KAHN, THE ECONOMICS OF REGULATION, Vol. 2 (1971). Any costs successfully shifted from manufacturing activities to the regulated natural monopoly would be paid for by users of the regulated service. Rationalized regulation, toward which some regulators are moving, would maintain these basic elements, but would attempt to rationalize the rate design process by pricing all services in reference to their own costs and by specifying performance objectives. Eventually, incentive regulation might be attempted by some regulators. If so, greater reliance would be placed on sharing productivity gains between the utility and its customers when the utility found ways to reduce costs. *See* R.C. HARRIS, *supra* note 23, at 34-35.

The possibility for cross-subsidization does not depend on regulators continuing to use traditional rate-of-return regulation. Under rationalized regulation RBOC incentives and opportunities for cross-subsidization and discrimination would be only marginally reduced. Nor would such a system necessarily be better at uncovering leveraging; that would depend more on the density, thoroughness and skill of the regulatory staff than on the regulatory philosophy. Incentive regulation would alter incentives. Costs shifted from a competitive segment to the regulated segment would still be covered by the rate-payers, but if the RBOC removed those costs again and if the regulators characterized the removal as a productivity gain under the incentive system, then the RBOC could still keep rates somewhat higher than its new, lower cost. This, presumably, would not reduce the incentive to shift costs in the first instance, but would perhaps reduce the RBOC's incentive to continue the cost shift over as long a period as it would have under a traditional or rationalized system.

firms, thus distorting the allocation of resources in the manufacturing market. This distortion, which would always be present to some degree, would be significant where the subsidized RBOC had significant market share, and might be acute in markets like central office switches and transmission equipment, where the RBOC would likely be its own primary customer, and thus would be able to raise prices and earn monopoly profits in manufacturing at the expense of local rate payers.[37] Over time, of course, an RBOC could gain power in a market in which it originally had none, not by virtue of efficiency but through cross-subsidization.[38] Alternatively, monopoly returns from cross-subsidization might take the form of excessive payments to management, labor, or other factor suppliers, or potential profits might simply be dissipated through waste which remained sheltered from competitive pressures, thus distorting resource allocation not only in manufacturing but in related input markets as well. Such cross-subsidization would also

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37. *See* 3 P. AREEDA & D. TURNER, ANTITRUST LAW ¶ 726e (1978). The regulatory objective and the skill of the regulatory staff would effect the extent to which distortion would occur. *See supra* note 36.

38. The Court of Appeals recently implied that, under the language of Section VIII (C) of the decree, such distortion is not relevant to the "Triennial Review." *See supra* note 5; Western Electric, *supra* note 1, 900 F.2d at 296-97. Under the Court's view, cross-subsidization would be cognizable under the Section VIII (C) procedure only when an RBOC possessed or threatened to obtain market power in the market it was seeking to enter.

The coverage of Section VIII (C) of the decree is not, however, the only question relevant to whether Congress should lift the manufacturing restraint. Regardless of the construction of the decree, cross-subsidization would do competitive harm whenever it sent distorting market signals in the non-regulated market, and that might well occur even if the RBOC entered with a relatively small market share and relatively little market power. The question of competitive concern is whether power in one market is being used to distort competition in another; if it is, competitive injury is manifest. *See* P. AREEDA & D. TURNER, *supra* note 37, at ¶ 726e. Moreover, distortion of price-cost relationships to the disadvantage of local rate-payers was a factor in structuring the decree. AT&T II, 673 F. Supp. at 556. Consequently, cross-subsidization may well violate the decree irrespective of the way in which Section VIII (C) is construed. Indeed, conventional analysis under Section 2 of the Sherman Act makes clear that leveraging power from a monopolized market to a vertically adjacent market violates Section 2 whenever that practice distorts competition in the adjacent market, and regardless of whether monopoly is obtained or threatened in the second market. Berkey Photo, Inc. v. Kodak Co., 603 F.2d 263 (2d Cir. 1979), *cert. denied*, 444 U.S. 1093 (1980); *see also* Kerasotes Michigan Theatres, Inc. v. Nat'l Amusements, Inc., ___ U.S. ___, 109 S. Ct. 2461 (1989); Sargent-Welch Scientific Co. v. Ventron Corp., 567 F.2d 701, 711-13 (7th Cir. 1977), *cert. denied*, 439 U.S. 822 (1978). Therefore, whatever a court concludes about the limits of the Section VIII (C) procedure, or the coverage of the consent decree, use by a RBOC of its local exchange natural monopoly power to distort competition in another market would independently violate Section 2. Sound competition policy requires that Congress give due consideration to all these factors when considering whether to lift the decree's ban on manufacturing.

"tax" local service rate-payers, and frustrate the regulatory goal of keeping local exchange service rates properly related to costs.

Similarly, were RBOCs to enter manufacturing, they would have a variety of strategies at their disposal for foreclosing the business opportunities of competing manufacturers and self-preferring in purchasing telephone equipment. As under the pre-decree AT&T regime, RBOCs could delay the release of local service design information, thereby handicapping competitors in the timely production of new equipment.[39] Furthermore, RBOCs would now have an incentive to make unnecessary or inefficient changes in local service technology to facilitate self-preference, to the ultimate detriment of the consumer who pays for such needless innovation.

In their 1987 motion to eliminate line-of-business restrictions, the RBOCs argued that none of them, acting alone, could foreclose more than 15% of the national market in equipment and, consequently, that any self-preference in purchasing could have only limited anticompetitive effect.[40] It seems likely, however, that were one RBOC to prefer itself in the manufacturing market, others would follow suit, whether for "corporate image" reasons, as Judge Greene suggests,[41] or simply because they learn how to increase profits from one another's behavior. If RBOCs self-preferred in an interdependent manner, they could achieve, by conservative estimates, an aggregate foreclosure of as much as 70% of the market.[42] The further possibility of explicit or tacit "live and let live" relationships developing between the structurally similar RBOCs cannot be dismissed; after entry into manufacturing, RBOCs might quickly learn that they have much to gain by not competing aggressively among themselves and by jointly pricing significantly above cost.

As Judge Greene points out, the problems posed by the pre-decree AT&T regime were not essentially problems of size; hence, the 1982 division of the single national firm into seven regional firms did not diminish the basic risk of anticompetitive behavior which follows when a regulated monopolistic market and other competitive markets are combined under unitary control.[43] RBOCs can, and from a stockholder's point of view should, decide complicated issues of accounting, design and marketing strategy to their own advantage.[44] One need not assume

39. *See* AT&T II, 673 F. Supp. at 553.

40. HUBER REPORT, *supra* note 22, at 1.15, 14.8, 14.13-14; JUSTICE DEPARTMENT REPORT, *supra* note 22, at 74-75, 169-70 (cited in AT&T II, 673 F. Supp. at 556).

41. AT&T II, 673 F. Supp. at 557.

42. *Id.* at 558.

43. *Id.* at 547; *see also* Western Electric, *supra* note 1, 900 F.2d at 299.

44. The business literature of the last decade is replete with publications that essentially amount to training manuals for management in ways to gain and exploit positions of power by sophisticated strategic moves. *See, e.g.*, M.E. PORTER, COMPETITIVE

dark-heartedness to recognize that leveraging monopoly power from the local exchange sector into manufacturing is far more than a speculative possibility. It is a likely outcome of eliminating the structural separation of local exchange service monopolies from competitive markets embodied in the 1982 decree.[45]

B. Competitive Benefits Possible from a Lifting of the Manufacturing Restriction

But for the line-of-business restriction, RBOCs would be potential entrants into telephonic equipment manufacturing. The principal benefit which could flow from lifting the restriction, then, would be the addition of seven potential entrants to the market. However, given (1) that the customer premise, transmission, and some portions of the central office equipment submarkets are already highly competitive, and (2) that the central office switching market is at worst an increasingly rivalrous international oligopoly, the addition of these potential competitors seems of modest significance.[46]

ADVANTAGE: CREATING AND SUSTAINING SUPERIOR PERFORMANCE (1985); F.E. WEBSTER, INDUSTRIAL MARKETING STRATEGY (1979); Caves & Porter, *From Entry Barriers to Mobility Barriers: Conjectural Decisions and Contrived Deterrence to New Competition*, 91 QUART. J. ECON. 241 (1977).

45. The counter-argument is that an RBOC, dependent as it is on the good will of regulators and political actors, would have a strong incentive to avoid even the appearance of socially harmful, inappropriate conduct. A similar argument might have been made about AT&T prior to the consent decree, but the history of AT&T's pre-decree strategies do not lend the argument much force. A comparable example, perhaps, is the cross-subsidizing by NYNEX recently challenged by the FCC. *See* Order to Show Cause and Notice of Apparent Liability for Forfeitures, F.C.C. Docket No. 90-57, 5 F.C.C. Rcd. 866 (1990). In essence, NYNEX (which owns both New York Telephone and New England Telephone) was charged with self-dealing with unregulated subsidiaries in ways that enabled it to pass on overcharges to local exchange customers through access charges for connections to interexchange operators. *See* Andrews, *Settlement for NYNEX and F.C.C.*, N.Y. Times, Oct. 5, 1990, at C1, col. 3 (reporting that NYNEX agreed to pay a $1.4 million fine and to lower access charges by $35.5 million for one year in order to settle the FCC charge that NYNEX had "bought equipment at inflated prices from an unregulated NYNEX subsidiary"). That charges of leveraging against NYNEX will cost it regulatory and political good will as well as penalites can hardly be doubted. Indeed, New York State's Public Service Commission recently recommended that the agency consider forcing NYNEX to divest itself of its local exchange monopoly in order to preclude leveraging. *See* Verhovek, *State Urged to Consider Removing New York Telephone from NYNEX*, N.Y. Times, Oct. 4, 1990, at A1, col. 5.

46. In reviewing the consent decree, the Court of Appeals takes the fact that the equipment market is already competitive as an argument for, not against, allowing entry; in its view, entry should be denied only when it will distort competition in the market entered, and the existence of competitive conditions may make such distortions less likely. Western Electric, 900 F.2d at 300. However, for reasons similar to those reviewed in subsection (A) above, the court found that distortion was likely if RBOCs were permitted to enter manufacturing, even given existing structural conditions in manufacturing markets

The RBOCs' presence as potential competitors might be helpful to discipline the pricing and strategic behavior of manufacturing firms, but as there are already sufficient firms in the market to assure market discipline, this theoretical benefit is superfluous at present.[47] Even actual entry by RBOCs would lack significance because there are already enough firms in manufacturing to yield effectively competitive results. Furthermore, in manufacturing segments other than central office switching, there are many potential entrants besides the RBOCs,[48] and there may be some in the central office switching segment as well.[49] If the manufacturing markets RBOCs might enter were presently non-competitive rather than already workably competitive, the addition of seven potential entrants would be a counterweight tending to offset the competitive risks that arise from the possibility of leveraging monopoly power from the local exchange service market to the manufacturing market. But given the already competitive condition of the manufacturing markets, there is little benefit to offset the risk of monopoly leveraging that would follow from lifting the manufacturing restriction.

The significance of the RBOCs as potential entrants is further reduced by the likelihood that in central office switching, the only segment where performance might be noticeably improved, RBOC entry would be achieved through vertical joint venture relationships with foreign manufacturers already in the market.[50] Such entry would do

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today. *Id.* at 56-67. Congress, of course, is not bound by the terms of the consent decree. It could give appropriate weight to whether there would be significant competitive benefit from allowing entry into manufacturing, a competitive benefit that might counterbalance the apparent competitive harm. *See supra* note 38.

47. *See* Steiner, *Economic Theories of the Effect of Potential Competition* in ECONOMIC ANALYSIS AND ANTITRUST LAW 342-46 (T. Calvani & J. Siegfred eds., 2d ed. 1988).

48. One might argue that other firms would be less likely to enter the manufacturing market than would RBOCs. However, those features which highly motivate RBOCs to enter are precisely the features which pose risks of competitive harm. *See supra* subsection IV. A.

49. Foreign firms that could enter are mentioned *supra* note 30. In this country, IBM would seem to have the skills and resources needed to enter the central office switching market, and might be motivated to do so if it could earn supra-competitive returns.

50. *See* AT&T II, *supra* note 1, 673 F. Supp. at 556 n.135, 561-62. No RBOC has thus far shown an interest in *de novo* entry into central office switching manufacturing and the Department of Justice, and the Huber Report, imply that entry, if it occured, would be in the form of joint venture relationships. Industry observers generally assume that the technological changes that have been increasing the market share needed to attain efficient scale will continue to reduce the likelihood of *de novo* entry. The Huber Report points to economies of scale in the switching market such that even the largest RBOC buys less than the minimum switching equipment necessary to turn a profit. HUBER REPORT, *supra* note 22, at 14.8-14.16. It also notes that many foreign manufacturers have set themselves specific goals of an approximate 10% share of the U.S. market, making the likelihood of "dancing partner" relationships between the RBOCs and foreign firms even higher. *Id.* at

nothing to deconcentrate the central office switching industry, and might not even yield new capacity. Indeed, its most probable consequence is to harm competition further by encouraging the newly integrated unit to try to foreclose other manufacturers and by stabilizing market shares. In any event, there is a high probability that foreign firms would further displace domestic firms in the manufacture of crucial central office equipment. It is conceivable that a particular RBOC might in the future show an interest in entering the central office switching market *de novo* by investing in new capacity rather than by entering into a joint venture and likely preferred customer relationship with one of the firms already in that market. If this occurred, that RBOC could still seek focused relief from the manufacturing restriction to allow for such entry. The court, at that point, could then evaluate the current state of the central office switching market and weigh any apparent benefit from entry against leveraging risks. Although having the court review the RBOC's investment plans would be awkward, it is certainly preferable to a blanket lifting of the restriction on the strength of the unlikely possibility that *de novo* entry might occur and that, if it did, it would be on balance competitively helpful.

Finally, the possibility of integrative efficiencies in establishing manufacturer-RBOC links must be examined. Such efficiencies could include facilitating information flow between industry sectors, and cooperative planning among local service providers and manufacturers for the future technological and marketing directions of the industry. However, not only are such efficiencies notoriously difficult to measure, but also any effort to attain them gives rise again to the dangers of cross-subsidization and foreclosure discussed above.

C. The Effects of Lifting the Manufacturing Restriction on Telecommunications R & D

The effect of lifting the manufacturing restriction on the locus, direction and volume of R & D is to some extent imponderable. Some distinctly unfavorable effects seem likely, as do some favorable ones. Some effects are not predictable with any confidence, as perhaps is inevitable when considering the dynamic consequences of significant structural change in a complex industry. Nonetheless, certain tendencies and incentives can be identified, and industry history utilized, in an effort to evaluate possible outcomes.

14.16-14.17. It may well be that direct *de novo* entry on a profitable scale in the central switching industry is not currently possible for any RBOC, and that vertical linkage (with foreclosure) is the only conceivable means by which even the largest RBOCs could enter this market.

Before any effort was made to stimulate competition through antitrust or regulatory means, a vertically integrated AT&T was an inaccessible market to other manufacturers, who thus had no incentive to invest in innovation that would improve AT&T's performance. During this period, AT&T, being fully integrated and unencumbered by regulation, had strong incentives for innovation since it could exploit economies of scale and scope, capture the profit from any innovation produced by its research, and exploit interactive relations between segments doing R & D and segments using equipment.

Beginning with *Carterfone*,[51] the structural conditions for R & D took on a second configuration which may well have represented the worst of all worlds for innovation. Manufacturers other than the integrated AT&T, while encouraged to compete with AT&T, could hardly be confident of having consistent access to necessary information in comparison to AT&T's own manufacturing arm. Thus, the R & D incentives of these manufacturers, while improved, were not maximized. At the same time, regulatory efforts to make the playing field level, such as the FCC's highly complex *Computer II* requirements[52] and threats of even more complicated information flow regulations, adversely affected the R & D incentives of AT&T itself, since AT&T could no longer count on being able to appropriate all of the returns from its R & D. Also, because of regulatory constraints, its transaction costs rose, and its potential for information-flow and learn-by-doing efficiencies in product development were reduced.

Divestiture under the consent decree set the current stage in motion. There is no doubt that divestiture has had positive effects on the level of telecommunications innovation in the short run, and these effects are apparently continuing. Virtually all segments of manufacturing have

51. Matter of Carterfone, 13 F.C.C.2d 420 (1968). Prior to *Carterfone*, telephone companies provided customers with access to the local exchange through a cable link and with the telephone that made the use of the link possible. Though there might be extra charges for special phones (touch tone, colors, etc.) or for other end-line equipment (amplifying devices, etc.), basic telephone rates covered the connection and the phone. *Carterphone* was the primer case in which FCC regulations sought to break this bundling and open the end-line equipment market to competitors. Although the issue was hard fought by AT&T, as cases after *Carterphone* were decided it became increasingly clear that AT&T could no longer successfully leverage its local service monopoly by tying end-line equipment to service provision. *See* Litton Sys., Inc. v. Southwestern Bell Tel. Co., 539 F.2d 418 (5th Cir. 1976); North Carolina Util. Comm. v. FCC, 537 F.2d 787 (4th Cir. 1976). For commentary on these developments as they were occurring, see generally, the symposium, *Antitrust and Monopoly Policy in the Communications Industry*, 13 ANTITRUST BULL. 871 (1968); Note, *FCC Computer Inquiry: Interfaces of Competitive and Regulated Markets*, 71 MICH. L. REV. 172 (1972).

52. Imposed in Second Computer Inquiry, 77 F.C.C.2d 384 (1980), *recon.*, 84 F.C.C.2d 50 (1981), *further recon.*, 88 F.C.C.2d 512 (1981), *aff'd sub nom.* Computer and Communications Indus. Ass'n v. FCC, 693 F.2d 198 (D.C.C. 1982), *cert. denied*, 461 U.S. 938 (1983).

been broadened to near global dimensions, and this competitive energy has led to new, better and greater varieties of products for user premises, interexchange and local exchange services.[53]

Most importantly, the incentives for all major actors are now free of conflict. RBOCs, so long as they remain out of manufacturing and "captive market" joint ventures with foreign suppliers, have strong incentives to study the equipment offerings of all suppliers, to inform those suppliers about their needs, and to encourage non-restrictive open interface standards and compatibility among alternative suppliers in order to avoid lock-in problems in the future. These ends are advanced by the standard-setting and clearinghouse activities conducted by the RBOCs through Bellcore. AT&T, in turn, has incentives to innovate on interexchange products where integration efficiencies are available. In local exchange products, AT&T's incentives as a potential seller are also clear. Like other suppliers, it must seek to learn about RBOC needs from Bellcore and from individual RBOCs, must innovate to meet those needs, and must keep RBOCs informed about its product development programs. Moreover, its performance is spurred by the presence of other competing manufacturers who now do perceive a level playing field. All competing manufacturers, none of whom needs now worry about an in-house advantage for AT&T,[54] have fresh incentives to innovate for the RBOC market.

If the manufacturing restriction were lifted and RBOCs independently entered manufacturing markets, those RBOCs would gain R & D incentives they do not now have. RBOCs, hoping to meet their own equipment needs and to benefit from the information flow and interactive advantages of their vertical integration, would no doubt engage in product development activities. But these newly gained incentives would likely be offset by the reduction in incentives for all other manufacturers, since existing manufacturers would no longer expect equal access to the integrated RBOCs as buyers. Moreover, the new incentives for RBOCs would not be maximized. The RBOCs' potential for attaining the kind of integration advantages AT&T possessed before regulation would be diluted by the inefficiencies resulting from inevitable and necessary, but imperfect, regulatory attempts to keep the playing field level. Regulatory efforts to assure information flow to competing manufacturers would put manufacturing RBOCs in the same unhappy situation AT&T faced before divestiture but after regulations to stimulate competition were enforced. Inevitably,

53. *See supra* notes 27-33 and accompanying text.

54. AT&T has some remaining advantage, no doubt, since so much of the installed base of RBOCs is AT&T equipment.

RBOCs would be motivated to evade these regulatory requirements, and knowing that, the R & D incentives of competing manufacturers would be weakened. Finally, if the RBOCs entered manufacturing by linking with existing foreign suppliers, incentives might be even more distorted, thereby increasing the likelihood of regulatory evasion and weakened competition.

In most respects, the balance of incentives to integrate would likely be the same as it was shortly before divestiture. One might expect marginally fewer inefficiencies to result from regulation now than from pre-divestiture regulation due to improved regulatory techniques. But in one important respect the situation might be even worse. Under the current regime, RBOCs have an incentive to standardize in ways that facilitate both nationwide system harmony and wide access by competing manufacturers. When AT&T was the single integrated firm, even if it made efforts to hamper competition by design changes, those efforts did not endanger system-wide standardization. But if seven separate RBOCs are each trying to design away from competition, they may also be designing away from the standardization needed for an effective, integrated national telecommunications system.[55]

In sum, though some of the outcomes are speculative or imponderable, there seems little likelihood that aggregate telecommunications innovation could be improved by lifting the restriction and considerable reason to fear the opposite result.

D. Are There Less Onerous Alternatives to the Line-of-Business Restrictions?

There are two conceivable ways to protect against the harms noted in sub-section (A) above: (1) controlling against cross-subsidization and foreclosure by regulation; and (2) relying on market forces, such as the counter-strategies of adversely affected firms, to deter these competitive harms.

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55. An RBOC integrating into manufacturing would have to decide whether to design a proprietary system tending to lock out manufacturing competitors or to use open standards specifying an interface system for all elements that competing manufacturers could meet. Since the consent decree there has been movement toward wider use of open systems. This is due, in part, to the vertical disaggregation achieved by the decree and, in part, to the growing internationalization of telecommunications technology. *See* S. BESEN & G. SALONER, COMPATABILITY STANDARDS AND THE MARKET FOR TELECOMMUNICATIONS SERVICES, (Rand Corp. Paper P-7393, Management in the 1990s, Sloan School of Management, MIT May, 1988). Nonetheless, a firm deciding between proprietary and open standards faces complex tactical and strategic issues for which there are no obvious answers. *Id.; see also* Braunstein & White, *Setting Technical Compatibility Standards: An Economic Analysis*, 30 ANTITRUST BULL. 337 (1985). The movement toward open standards might prove fragile if significant structural change occurs in the industry.

The RBOCs have argued that these dangers can be addressed through regulatory means. It must not be forgotten that the history of the 1982 decree is a history of failure to regulate effectively these delicate intra-enterprise problems. The FCC's failure was extensively documented at the trial leading to the 1982 decree,[56] and was an integral consideration in the design of the decree's structural remedy. A regulatory agency must attempt to penetrate RBOC accounting systems and pricing strategies, to evaluate the utility of new devices, and to try independently to weigh the reasons given for releasing or refusing to release specific information to other segments of the industry. It cannot be expected that a regulatory body, with limited access to the internal planning decisions of the RBOCs, will achieve such objectives in an effective and timely fashion. If this was true at the time of the decree, it seems more likely now when regulatory agency staffing has been cut, and when the target of regulation would no longer be one large integrated company but seven large integrated companies. It may take years for regulators to uncover and prove cross-subsidization or other distorting strategies, making effective remediation for consumers or competitors nearly impossible.[57] The likelihood of a satisfactory regulatory solution is further diminished by the change of regulatory philosophy over the past few years and, perhaps, by a faltering determination by regulators to deter such practices.[58]

The unaided market will similarly fail to provide effective protection against cross-subsidization and self-preference. Because of the additional profits inherent in the RBOCs' control over local monopolies, the only counter-strategy likely to occur to competing manufacturers without a current RBOC link is imitative vertical integration with another RBOC and self-preference. Thus, if one RBOC linked itself with a major foreign equipment manufacturer, foreign equipment manufacturers and AT&T itself would be pressured to seek out links with other RBOCs. But such steps would not be solutions; from the point of view of the public, they would simply exacerbate the problem. As Judge Greene explained, "Regional Company [RBOC] claims of wishing only to participate with others in ... restricted businesses on a level playing field obscure the fact that there is no level playing field when one of the participants holds an unassailable franchise on the goal lines."[59] Moreover, any attempt to

56. *See supra* note 9.

57. A recent example of the delay in regulatory remedies can be seen in the FCC's six-year battle to force NYNEX to stop the cross-subsidizing that came to the agency's attention. *See supra* note 45; *see also* Burgess, *FCC: NYNEX Padded Millions in Profits; Agency Proposes Refunds, $1.4 Million Fine*, The Washington Post, Feb. 9, 1990, at G1, col. 5.

58. *See supra* note 35.

59. AT&T II, *supra* note 1, 673 F. Supp. at 601.

encourage market forces by regulation would most likely require the repartitioning of the accounting, design and marketing functions of the two segments of the vertically integrated RBOC, thereby reducing, if not eliminating altogether, precisely those efficiencies which might be obtained through the RBOC's vertical integration.[60] Unfortunately, no regulatory approach seems adequate to overcome the dangers posed by allowing the monopolistic local service sector of the industry to join forces with the competitive manufacturing sector.

E. Balance of Trade Concerns

Finally, the effect of RBOC entry into manufacturing on America's international trade and balance-of-payments is not sufficient to justify lifting the manufacturing restriction. If RBOCs entered manufacturing on their own, and conducted their manufacturing operations in this country, lifting the manufacturing restrictions would increase America's share of aggregate world production. However if, as is more likely in the central office switching segment, RBOCs entered the market through vertical integration, there would probably be a geographic division of labor, with product-oriented research and development and basic parts manufacturing performed offshore, leaving only assembly to be performed in the United States.[61] The result would be to increase America's technological dependence on foreign countries. On balance, the possibility of benefits for America's balance-of-payments is speculative at best.

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60. New regulatory schemes can always be devised, of course, as is evidenced by the FCC's regulatory efforts in this industry. *See supra* note 52. But as the history of the industry also suggests, when the incentives to cross-subsidize are significant, new regulatory strategies beget new evasive strategies. Particularly now, in this era of deregulation, when regulatory resources and regulatory initiatives are being reduced, it would be risky to suppose that regulatory inventiveness could succeed in staying ahead of evasion strategies.

61. As competitive American markets become increasingly international, all participants, foreign and domestic, are under pressure to operate in ways that take advantage of global labor to minimize cost. Consequently, activities such as the manufacture of small electronic or telephonic equipment and standardized parts for more complex equipment are often performed abroad because labor costs are relatively low. Before competitive entry, AT&T's phone manufacturing was performed in the United States. After competitive entry, AT&T continued manufacturing here until price competition from foreign manufactures made movement offshore necessary. AT&T continues to do R & D and more complex manufacturing functions in this country. Foreign manufacturers linked with RBOCs would presumably have even fewer incentives than American firms to perform manufacturing or management functions in the United States.

V. CONCLUSION

The lessons of ten years of experimentation with deregulation in this industry and others are relatively clear. Significant gains can be achieved by freeing regulated industries from the expensive and cumbersome constraints of regulatory agencies if, and only if, the antitrust laws are subsequently applied with vigor. As experience in the airline industry demonstrates,[62] little is gained when lax antitrust enforcement allows the newly liberated marketplace to be dominated by the anticompetitive strategies of a tight, and perhaps interdependently cooperative, oligopoly. In the telecommunications field, where technological and organizational limits on competition set by the local service natural monopolies are so evident, the case is even stronger for conscientious and assiduous antitrust oversight aimed at maintaining a structure in which competition is the principal protector of the public interest.

At the present time, the risks of competitive harms likely to follow from RBOC entry into manufacturing are manifest and substantial, while the benefits of potential competition are both more speculative and less weighty. If technology and regulatory responses developed to the point where local exchange service itself became workably competitive, then the need for the current constraints would end. But today, there are simply no realistic and effective alternatives to the structural separation of markets embodied in the 1982 consent decree.

62. *See* Kahn, *Deregulatory Schizophrenia*, 75 CALIF. L. REV. 1059 (1987).

ARTICLE

THE HUMAN PREEMBRYO, THE PROGENITORS, AND THE STATE: TOWARD A DYNAMIC THEORY OF STATUS, RIGHTS, AND RESEARCH POLICY

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I. INTRODUCTION

Technology continues to revolutionize our view of human life. In 1965, *Life* magazine featured the first, remarkable photographs of the human embryo and fetus floating within the womb.[1] Now, as the technology of human reproduction has advanced, it has become possible to see the human "preembryo"—fertilized, sustained, and even frozen outside the human body.[2] Adopted in 1986, the term "preembryo" refers to the initial phase of human development,[3] beginning with the first cell division, continuing for some fourteen days after conception, and ending as the embryo appears and major body systems begin to form.[4]

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1. *Drama of Life Before Birth*, LIFE, Apr. 30, 1965, at 62 (photographed by Lennart Nilsson); *see also* M. FURUHJELM, A. INGELMAN-SUNDBERG & C. WIRSEN, A CHILD IS BORN (rev. ed. 1976) (original ed. 1965) (featuring photographs by Lennart Nilsson of the unborn embryo and fetus).

2. *See infra* notes 70-91 and accompanying text.

3. C. GROBSTEIN, SCIENCE AND THE UNBORN 58-62 (1988); Jones & Schrader, *And Just What Is a Pre-embryo?*, 52 FERTILITY & STERILITY 189, 189-90 (1989).

4. *See infra* notes 43-69 and accompanying text. For the sake of consistency, the term "preembryo" will be used to refer to this stage of human development even if a reference which is cited or discussed in the Article refers to an "embryo," "fetus," "product of conception," etc. This usage is not meant to distort the original source, but rather to maintain the clarity of the argument developed herein. Quotations, however, will not be altered by substituting "preembryo" for some other term.

The preembryo has become the subject of observation, manipulation, and controversy through the process of *in vitro* fertilization. With this process, human conception can be effected "in glass" or outside the body,[5] and the resulting preembryo can be transferred into a woman's uterus.[6] If the procedure is successful, the preembryo will implant in the uterine wall and a pregnancy will begin.[7]

As a form of assisted reproduction, *in vitro* fertilization or "IVF" has become more and more important as a treatment for infertility.[8] In 1978, the first infant conceived by means of IVF was born in England.[9] In 1985, the first birth from a frozen or "cryopreserved" preembryo was reported.[10] In 1988, at least 2,133 babies were born as a result of IVF in the United States[11] and transfer cycles following cryopreservation accounted for another 73 deliveries.[12]

The growing importance of IVF can also be measured by controversy. In 1989, Risa Adler-York and Steven York filed a lawsuit in federal court to obtain their frozen preembryo from an IVF program in Virginia and transport the preembryo to a program in California.[13] The parties assumed that the preembryo was the Yorks' property, but disputed the extent of their property interest.[14] The court also assumed that the preembryo was personal property and upheld the Yorks' right to sue under traditional property doctrines.[15]

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5. *See* C. GROBSTEIN, *supra* note 3, at 59.

6. *See infra* notes 70-79 and accompanying text.

7. *See infra* notes 80-81 and accompanying text.

8. Medical Research International and the Society for Assisted Reproductive Technology, The American Fertility Society, *In Vitro Fertilization-Embryo Transfer in the United States: 1988 Results from the IVF-ET Registry*, 53 FERTILITY & STERILITY 13, 13 (1990) [hereinafter *1988 Results*]; *see also* HOUSE COMM. ON GOVERNMENT OPERATIONS, INFERTILITY IN AMERICA: WHY IS THE FEDERAL GOVERNMENT IGNORING A MAJOR HEALTH PROBLEM?, H.R. REP. NO. 389, 101st Cong., 1st Sess. 3, 7, 9-10 (1989) [hereinafter INFERTILITY IN AMERICA]; Seibel, *A New Era In Reproductive Technology In Vitro Fertilization, Gamete Intrafallopian Transfer, and Donated Gametes and Embryos*, 318 NEW ENG. J. MED. 828, 828 (1988).

Infertility commonly is defined as "the failure of a couple to conceive after one year of intercourse without using contraception." INFERTILITY IN AMERICA, *supra*, at 3. The number of infertile couples in America who want to have children has been estimated at 2.4 million, *id.*, and 2.8 million. Seibel, *supra*, at 828.

9. Seibel, *supra* note 8, at 828.

10. Fugger, *Clinical Status of Human Embryo Cryopreservation in the United States of America*, 52 FERTILITY & STERILITY 986, 986 (1989).

11. *1988 Results*, *supra* note 8, at 14 (deliveries include 356 twin deliveries, 55 triplet, 8 quadruplet, and 2 quintuplet deliveries).

12. *1988 Results*, *supra* note 8, at 18 (deliveries include 7 twin deliveries and 1 set of triplets).

13. York v. Jones (No. 89-373-N E.D. Va.) (verified complaint filed on May 10, 1989).

14. *Id.*

15. *See* York v. Jones, 717 F. Supp. 421 (E.D. Va. 1989) (denying defendants' motion to dismiss, under FED. R. CIV. P. 12(b)(6), for failure to state a claim upon which relief could be granted). The suit was settled out of court, and the Virginia center agreed to release the

Another couple, Mary Sue and Junior Davis, filed a divorce action in 1989[16] and went to trial to determine the disposition of seven frozen preembryos they had created during their marriage. Mary Sue Davis wanted to become pregnant and bring the preembryos to term, if possible, but Junior Davis objected.[17] Concluding that the preembryos were human beings[18] and "children, *in vitro*"[19] whose best interest was served by the opportunity to be brought to term, the Tennessee trial court gave "temporary custody ... for the purpose of implantation"[20] to Mary Sue Davis.[21]

Junior Davis appealed and the Tennessee Court of Appeal reversed the trial court.[22] Emphasizing the fact that a pregnancy had not yet occurred, the appellate court determined that Junior Davis had a "constitutionally protected right not to beget a child where no pregnancy has taken place";[23] that it would be "repugnant and offensive to constitutional principles to order Mary Sue to implant"[24] the preembryos; and "equally repugnant to order Junior to bear the psychological ... consequences of paternity."[25] Hence, the Court of Appeal concluded that Mary Sue Davis and Junior Davis should have "joint control of the fertilized ova ... with equal voice over their disposition."[26]

Further, controversy has simmered for some time with respect to IVF research and research with the preembryo. The controversy is linked to the abortion debate and to the political (if not the legal) issue of when life begins.[27] As a result, federal policy regarding IVF research and research with the preembryo has become a policy of avoidance—

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preembryo. Board of Trustees Report, *Frozen Pre-embryos*, 263 J. A.M.A. 2484, 2484 (1990) [hereinafter J.A.M.A. Report].

16. Davis v. Davis, 15 Fam. L. Rep. (BNA) 2097, 2099 (Tenn. Cir. Ct. Sept. 21, 1989).

17. *Id.* at 2104.

18. *Id.* at 2097, 2103.

19. *Id.* at 2097, 2104.

20. *Id.* at 2097.

21. *Id.*

22. Davis v. Davis, No. 180 (Tenn. Ct. App. Sept. 13, 1990) (LEXIS, States library, Tenn. file) (An application for hearing before the Tennessee Supreme Court was pending when the present Article was prepared for publication. Telephone interview with Deputy Clerk, Tenn. Ct. App. (Oct. 24, 1990)). At the time of the appellate court's decision, Mary Sue Davis and Junior Davis had each remarried; neither wanted a child with the other as a parent; and Mary Sue Davis, whose name had changed to Mary Stowe, sought authority not to implant the preembryos, but to donate them to a childless couple. *Davis*, (LEXIS, States library, Tenn. file) at 1, 1-2 n.1.

23. *Id.* at 6.

24. *Id.* at 8.

25. *Id.* at 9

26. *Id.*

27. *See generally* Fletcher & Schulman, *Fetal Research: The State of the Question*, 15 HASTINGS CTR. REP. 6 (Apr. '85) (summarizing history of relevant federal regulations and urging federal action).

guidelines have yet to be formulated and there is no forum for productive debate.[28] State laws form a political patchwork, generally designed to prevent nontherapeutic research but uncertain in scope and application.[29]

Therefore, at this point, our legal institutions must respond to the challenge of IVF technology. The legal status of the preembryo must be defined. Is the preembryo property, as the *York* court assumed; a human being, as the Tennessee trial court concluded; or neither, as the Tennessee appellate court seemed to believe? Likewise, the relationship between the preembryo, its progenitors,[30] and the state must be analyzed. What rights do the progenitors have relative to the preembryo, the state, and each other? What principles should guide research policies?

This Article will examine these issues.[31] In Part II, the preembryonic stage of development and IVF technology will be described.[32] In Part III, the legal status of the preembryo will be analyzed and the argument will be made that the preembryo should not be defined as either property or a person.[33] Instead, the preembryo should be given a *sui generis* status which entitles it to profound respect.[34] This approach is essentially heuristic in nature. It embodies the value which we attach to the preembryo and supplies a frame of reference for further analysis, but frees our analysis from categories and assumptions which do not seem appropriate when applied to the preembryo.[35]

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28. *See infra* notes 257-270 and accompanying text.

29. *See infra* notes 275-308 and accompanying text.

30. As used in this Article, the term "progenitors" refers to the "gamete providers," those individuals who provide the egg or sperm cells from which the preembryo is created. Both terms are fairly common. *Compare* York v. Jones, 717 F. Supp. 421 (E.D. Va. 1989) (using "progenitors") *and* Andrews, *The Legal Status of the Embryo*, 32 LOYOLA L. REV. 357 (1986) (same) *with* Robertson, *In the Beginning: The Legal Status of Early Embryos*, 76 VA. L. REV. 437 (1990) (using "gamete providers").

31. Other issues involving the preembryo can be illustrated by the following example: In 1983, two California residents, Elsa and Mario Rios, were killed in a plane crash, leaving two preembryos frozen in Australia. The preembryos had been created in 1981, using IVF techniques, with Mrs. Rios' eggs and the sperm of an anonymous donor. The couple left an estate of $8 million, but no instructions as to how the preembryos should be disposed of upon their death. As of October 1989, the preembryos remained frozen. Lieber, *The Case of the Frozen Embryos*, SATURDAY EVENING POST, Oct. 1989, at 50.

A number of questions arise from these facts. For example: How should the preembryos be disposed of? Who should decide and by what standards? If the preembryos ultimately are born alive, who should be defined as their legal parents—the deceased Mr. and Mrs. Rios, the woman to whom they were transferred for gestation and birth, the individuals who might adopt them, some combination of the above, or none at all? Such questions are fascinating but are beyond the scope of this Article.

32. *See infra* notes 42-91 and accompanying text.

33. *See infra* notes 92-159 and accompanying text.

34. *See infra* notes 160-174 and accompanying text.

35. *See infra* notes 94 & 174 and accompanying text.

In Part IV, the progenitors' rights will be analyzed in terms of the constitutional principles which protect and define our reproductive freedom vis-a-vis the state.[36] Based on these vital principles, an argument will be made supporting the progenitors' right to make procreative decisions regarding the preembryo, including decisions which will determine whether a preembryo is transferred with the hope that the progenitors will become parents, donated to other prospective parents, used in research, or disposed of and allowed to die.[37] Further, like the *Davis* appellate court, the Article will conclude that a state cannot resolve a dispute between the progenitors by imposing the choice of one progenitor on the other.[38] However, the implications of this position must be confronted. If each progenitor has an "equal voice" regarding the preembryos' disposition, the progenitors cannot agree to the manner of disposition, and the state cannot intervene in support of one progenitor over another, then the deadlock can only be resolved by allowing the preembryos to deteriorate and die.[39]

Finally, moving outside the area of reproductive rights, Part V will review the state of the law regarding IVF research and research with the preembryo.[40] Also, it will develop an argument supporting such research and propose a set of research guidelines.[41]

Before proceeding further, a caveat is in order. The issues examined in this Article can be emotional and controversial. To make matters even more difficult, the issues require us to confront ambiguity, change, and the subjective meaning of competing values. "Respect," for example, is a subjective, value laden concept, and we may "respect" the preembryo but not always act to preserve its life. Further, we may "respect" the preembryo but treat the preembryo differently than we would treat the newborn, viable fetus, or even the developing embryo. It may be difficult and unsettling to make these distinctions, but we cannot ignore the phenomena of change and human development.

Therefore, as we approach some of the legal issues surrounding the preembryo, we must be ready to look beyond the "bright lines" which are so familiar in legal analysis. We must look beyond our traditional concepts of "property" and "person." We must interpret rights in terms of their human meaning and context, without looking for "winners" and "losers." Further, we must endeavor to define policies which may enrich our common humanity.

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36. *See infra* notes 175-224 and accompanying text.
37. *See infra* notes 225-237 and accompanying text.
38. *See infra* notes 240-248 and accompanying text.
39. *See infra* note 249 and accompanying text.
40. *See infra* notes 257-308 and accompanying text.
41. *See infra* notes 309-357 and accompanying text.

II. THE PREEMBRYO AND *IN VITRO* FERTILIZATION: A BRIEF JOURNEY THROUGH BIOLOGY AND REPRODUCTIVE TECHNOLOGY

A. The Preembryo[42]

Reproduction begins with fertilization. Over a period of at least twenty-four hours, the sperm penetrates the egg[43] and "two cells fuse to become one."[44] The resulting one-cell "zygote" has a unique genetic identity or "genome" derived from the genetic material of egg and sperm.[45]

From this point, the zygote begins to develop as a preembryo. Undergoing a process of cell division or "cleavage," it becomes a loose cluster of smaller cells or "morula"; then, a more compact cluster or "blastocyst."[46] The blastocyst is comprised of about a hundred cells and two cell populations: an external or peripheral layer and a smaller, inner cell mass.[47] The external cells are referred to as the "trophoblast" or "feeding layer."[48] They will penetrate the uterine wall, as the process of implantation begins, and are essential to the later formation of the placenta.[49] The inner cell mass will develop into the embryo.[50]

As events continue, the inner cell mass forms two cavities which will become the amniotic cavity and yolk sac (both embryonic structures).[51] The embryonic plate lies between the two cavities; it is a flat plate of cells and the precursor of the actual embryo.[52] About fourteen days after fertilization, a linear thickening appears on the embryonic disc.[53] Referred to as the "primitive streak," it is a transient, relatively opaque line which marks the direction of what will become the long or head-to-tail axis of the future embryo.[54] Indeed, shortly after the streak

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42. The present account of preembryonic development relies heavily on C. GROBSTEIN, *supra* note 3. For another excellent and concise account of preembryonic development, *see* Ethics Comm. of Am. Fertility Soc'y, *Ethical Considerations of the New Reproductive Technologies*, 53 FERTILITY & STERILITY 31S, 31S-32S (Supp. 1990).

43. Jones & Schrader, *supra* note 3, at 190.

44. C. GROBSTEIN, *supra* note 3, at 82.

45. *Id.* at 24-25, 82.

46. *Id.* at 59-60, 168.

47. *Id.* at 26-27, 60, 168.

48. *Id.* at 60.

49. *Id.* at 27, 60, 168.

50. *Id.*

51. *Id.* at 169.

52. *Id.*

53. *Id.* at 27, 83, 105.

54. *Id.* at 27, 83.

appears, body parts and organs begin to develop ahead of the streak and then appear to spin out from head to tail.[55]

The appearance of the primitive streak marks the dividing line between the preembryonic and embryonic periods.[56] By scientific definition, an "embryo" refers to "an individual multicellular organism in the process of forming major parts and organs from rudimentary beginnings."[57] Before the primitive streak appears, twinning may occur or two preembryos may fuse into one.[58] However, the appearance of the primitive streak marks the initial organization of a single individual from a developmental point of view.[59]

As indicated above, the embryonic period involves a process of extraordinary growth and differentiation.[60] During this period, the major organs and parts of the body appear, including the heart, spinal cord and brain, liver and pancreas, kidney, reproductive organs, head, face, and limbs.[61] This process of "organogenesis" continues until some eight weeks after fertilization.[62] By this point, the major body systems are still immature, but their basic outline has been established in terms of both form and function.[63] Further, primitive movements can be observed "in the form of weak, almost flickering twitches of the head and neck."[64] Hence, although there is no sharp dividing line, the transition from embryo to fetus has been accepted at the end of eight weeks.[65]

To complete and greatly simplify this thumbnail sketch, the fetal period is characterized by rapid growth and steady maturation in terms of both function and behavior.[66] Fetal movement is an important signal of increasing individuality, for it indicates overt behavior as well as the maturation of the central nervous system that makes movement possible.[67] At the end of twenty-six weeks, the fetus is considered viable or able to survive *ex utero*.[68] At forty weeks, the fetus is term.[69]

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55. *Id.*
56. *Id.* at 27-28, 81-83.
57. *Id.* at 59.
58. *Id.* at 25; Jones & Schrader, *supra* note 3, at 190.
59. C. GROBSTEIN, *supra* note 3, at 27-28, 81-82.
60. *Id.* at 85.
61. *Id.* at 83.
62. *Id.* at 28, 83.
63. *Id.* at 84.
64. *Id.* at 85.
65. *Id.* at 30, 85, 108, 143.
66. *Id.* at 107-08, 143.
67. *Id.* at 143.
68. *Id.*
69. *Id.* at 124.

B. *In Vitro* Fertilization

We will now turn to reproductive technology. IVF alters "natural" reproduction through four basic steps: the induction and timing of ovulation, the retrieval of eggs or "oocytes," fertilization *in vitro*, and the transfer of the preembryo to the uterus.[70] Ovulation is controlled by a regimen of fertility drugs to stimulate the simultaneous maturation of more than one oocyte.[71] Only one oocyte matures during the natural cycle, but the success rate of IVF is increased when more than one preembryo is transferred.[72] Further, the drug regimen will cause ovulation to occur at a specific time which, in turn, allows the retrieval procedure to be scheduled for a specific time.[73]

Oocytes are retrieved by means of a laparoscopy or ultrasound techniques.[74] The former involves a surgical procedure in which a surgeon looks into the abdomen through a laparoscope to collect the oocytes through a needle tip.[75] Ultrasound techniques, which are now more common,[76] are less invasive and allow the internal organs and needle tip to be visualized by placement of an ultrasound transducer on the woman's abdomen.[77]

After the oocytes are retrieved, they are placed in a culture medium and sperm are added.[78] Assuming that fertilization occurs and cleavage begins, the preembryo(s) will be transferred to the uterus, at the two to eight cell stage, by means of a thin catheter.[79] At present, the clinical pregnancy and live delivery rates following the transfer procedure correlate with the number of preembryos transferred. According to one set of data regarding transfers initiated in the United States in 1988, the pregnancy and delivery rates were, respectively, 16% and 12% when less than three preembryos were transferred, and 22% and 16% when four or more preembryos were transferred.[80] Further, as the pregnancy and delivery rates increased with the number of preembryos transferred, the rate of multiple deliveries increased from 2.8% to 4.3%.[81]

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70. Seibel, *supra* note 8, at 829-31.
71. *Id.* at 829.
72. *Id.*
73. *Id.*
74. *Id.* at 829-30.
75. *Id.* at 829.
76. *1988 Results*, *supra* note 8, at 14, 19.
77. Seibel, *supra* note 8, at 829-31.
78. *Id.* at 830.
79. *Id.* at 830-31.
80. *1988 Results*, *supra* note 8, at 13-14.
81. *Id.* at 14-15.

If the retrieval, fertilization, and transfer procedures result in "extra" preembryos, the preembryos can be frozen by special procedures or "cryopreserved" for future use.[82] Cryopreservation has become an accepted therapeutic practice[83] and offers several benefits. It can increase the number of potential transfer cycles, reduce the risk of multiple gestation by allowing a maximum of three preembryos to be transferred per cycle, and reduce the overall cost of IVF by eliminating the need for another retrieval procedure.[84] Further, according to current data, the majority of frozen-thawed preembryo transfers are accomplished without using fertility drugs to stimulate and control the woman's natural cycle.[85]

In the early cryopreservation programs of the mid nineteen eighties, only preembryos of two to six cells were frozen.[86] However, data collected through 1988 regarding cryopreservation programs in the United States, show that IVF centers now have experience in freezing zygotes, preembryos in the two cell to morula stage (cleaved preembryos), and preembryos in the blastocyst stage.[87] The survival rate for each group, based on the number transferred per the number thawed, has been similar, (69.4%, 69.5%, and 74.2% respectively),[88] but the pregnancy rate per transfer has varied as follows: 17.4% for zygotes, 12.5% for cleaved embryos, and only 4.3% for blastocysts.[89] Further, fewer zygotes were transferred per pregnancy than with other groups. The statistics are significant: 11.5 zygotes compared to 16 cleaved embryos and 46 blastocysts for each resulting pregnancy.[90] Hence, at present, cryopreservation appears most successful at the zygote stage of development.[91]

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82. C. GROBSTEIN, *supra* note 3, at 64; *see generally* Fugger, *supra* note 10.
83. Fugger, *supra* note 10, at 986.
84. *Id.* at 987.
85. *Id.* at 988.
86. *Id.* at 989.
87. *Id.*
88. *Id.* at 988-89.
89. *Id.*
90. *Id.*
91. *Id.* at 989. The arguments developed in this Article regarding the preembryo would apply with equal force to the zygote (the one cell fertilized egg). For convenience, however, the analysis will refer only to the preembryo.

III. THE LEGAL STATUS OF THE PREEMBRYO: A NEW VIEW AT THE EDGE OF LIFE

A. Something Is Wrong When the Preembryo Is Seen as Property

Long ago, Shakespeare queried, "What's in a name? that which we call a rose By any other name would smell as sweet ...."[92] In this famous passage from *Romeo and Juliet*, Juliet pondered her star-crossed love for Romeo and observed with some feeling, " 'Tis but thy name that is my enemy; Thou art thyself, though not a Montague."[93] In much the same way, the status of the preembryo requires us to ponder the meaning of a name. Is the preembryo "property," a "person," or something uniquely different and still unnamed?

The legal name given to the preembryo may be analyzed on a number of levels. On one level, the naming process is irrelevant. A rose is a rose, regardless of what it is called. A preembryo is a biological entity developing for some fourteen days after conception, regardless of its legal appellation. Further, a legal definition will not necessarily influence the outcome of particular issues involving the preembryo for, at least to some extent, these issues must be analyzed in terms of whatever competing policies are at stake. Nevertheless, the status given to the preembryo will determine the legal principles which are brought to bear on issues involving the preembryo. Moreover, the process of giving the preembryo some legal definition is part of a dynamic process through which our community will define its assumptions, values, beliefs, and desires. Hence, a preembryo will be a preembryo regardless of its name, but the preembryo's legal definition will say something about our society and also influence the society we are becoming.[94]

The view of the preembryo as property has been developed to advance the rights of the progenitors. Under this line of reasoning, if the

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92. ROMEO AND JULIET, Act 2, Scene 2, Lines 43-44.

93. *Id.* at Act 2, Scene 2, Lines 38-39.

94. *See generally* West, *Communities, Texts, and Law: Reflections on the Law and Literature Movement*, 1 YALE J. L. & HUMANITIES 129, 154-56 (1988) (laws constitute "one form of cultural text" as well as one of the ways through which the members of a community communicate and interact with one another); Tribe, *Technology Assessment and the Fourth Discontinuity: The Limits of Instrumental Rationality*, 46 S. CAL. L. REV. 617, 652-54 (1973) (arguing that our "instrumental rationality" must become a "constitutive rationality" which accommodates an organic relationship between personal and communal identity, actors and actions, reason and desire, means and ends); Tribe, *Ways Not to Think About Plastic Trees: New Foundations for Environmental Law*, 83 YALE L. J. 1315, 1326-27, 1327 n.58 (1974) (developing the same idea).

preembryo is considered property and the progenitors are considered owners, the progenitors' decision making authority over the preembryo will be superior to that of a physician, scientist, fertility center, or other third party.[95]

By definition, the property approach defines the preembryo as a thing subject to ownership. Ownership is a right of dominion: a right to possess, use, or dispose of something according to one's own pleasure.[96] As long established in California,

> [t]here may be ownership of all inanimate things which are capable of appropriation or of manual delivery; of all domestic animals; of all obligations; of such products of labor or skill as the composition of an author, the goodwill of a business, trademarks and signs, and of rights created or granted by statute.[97]

Thus, if the preembryo is considered personal property, it will be subject to the same doctrines as inanimate things, domestic animals, and various intangibles.

Property doctrines were applied to the preembryo in *York v. Jones*, and another word about the case is in order. Before undergoing a fourth IVF attempt at a fertility institute in Virginia, the Yorks signed a consent form which explained that cryopreservation was an option if more than five preembryos were produced during the IVF process, described the freezing procedure, and outlined the Yorks' rights relative to any frozen preembryo.[98] The IVF procedure went forward: six preembryos were produced, five were transferred unsuccessfully, and one was frozen.[99] A year later, the Yorks advised the Virginia institute of their intent to retrieve the preembryo and transport it to a California institute where Mrs. York would undergo another transfer cycle, but the Virginia institute refused to release the preembryo.[100]

Litigation ensued and the federal court upheld the complaint against a motion to dismiss for failure to state a claim upon which relief could be granted.[101] The court construed the consent form as a bailment contract which created a bailor-bailee relationship between the Yorks and the Virginia institute.[102] Under Virginia law, a bailment was created by

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95. *See* Robertson, *supra* note 30, at 454-60; Andrews, *My Body, My Property*, 16 HASTINGS CTR. REP. 28, 28-31, 35-37 (Oct. 1986).

96. *See* CAL. CIV. CODE § 654 (Deering 1971).

97. *Id.* § 655; *see also* Yuba River Power Co. v. Nevada Irrigation Dist., 207 Cal. 521, 523 (1929) (property extends to "'every species of estate, real and personal, and everything which one person can own and transfer to another.'" (quoting 22 R.C.L., p. 43, sec. 10)).

98. York v. Jones, 717 F. Supp. 421, 423-24 (E.D. Va. 1989).

99. *Id.* at 424.

100. *Id.*

101. *Id.* at 427.

102. *Id.* at 425.

the elements of "lawful possession ... and [a] duty to account for the thing as the property of another."[103] The court found these elements to be satisfied on the facts before it. The institute had lawfully possessed the preembryo under the terms of the consent form, and the terms and provisions of the form established that the institute had a duty to account for the preembryo as property of the Yorks.[104] Hence, since the purpose of the bailment had terminated, the institute had an absolute obligation to return the property to the Yorks.[105]

Property law, however, does not appear to provide the most appropriate doctrines by which to govern the status of the preembryo.[106] There is a qualitative difference between the preembryo and other "things" recognized as property, and even the commentators who advocate the property approach seem to avoid equating the preembryo with a fungible object. For example, Professor John Robertson has tried to limit the concepts of ownership and property to a question of decision making authority: "Applying terms such as 'ownership' or 'property' to early embryos risks misunderstanding. Such terms do not signify that embryos may be treated in all respects like other property. Rather, the terms merely designate who has authority to decide whether legally available options with early embryos will occur."[107] Similarly, Lori Andrews has argued in favor of a "quasi-property approach"[108] which would allow individuals to treat their own body parts as property (including excorporeal embryos), but would prevent others from treating them as property.[109] Thus, she argues, this approach would "guard

103. *Id.* at 425 (quoting Crandall v. Woodard, 206 Va. 321, 327, 143 S.E.2d 923, 927 (1965)).

104. *Id.* at 425-27.

105. *Id.* at 424-25, 427. The court's opinion does not expressly state but strongly implies that the purpose of the bailment was terminated when the Yorks decided to transfer their preembryo from the Virginia institute to the California institute. The court also upheld a detinue theory which would require proof of the following elements: a "property interest in the thing sought to be recovered," "the right to immediate possession," "property ... capable of identification," "property ... of some value," and defendants' "possession at some time prior to the institution of the act." *Id.* at 427. Further, the court explained that in the context of a bailment relationship, "an action in detinue accrue[d] upon demand and refusal to return the property or upon a violation of the bailment contract by an act of conversion." *Id.*

106. *Cf.* Moore v. The Regents of the Univ. of California, 51 Cal. 3d. 120, 134-47, 793 P.2d 479, 487-97, 271 Cal. Rptr. 146, 154-64 (1990) (cells removed from body and used in medical research cannot be considered property for purpose of conversion action).

107. Robertson, *supra* note 30, at 454-55. Robertson further explains: "Having a property or ownership interest in early embryos ... should not be thought of as identical to having a property interest in furniture or cars, though there are many similarities. The important question is who has dispositional authority and what limits are there on what they may do." *Id.* at 455 n.48.

108. Andrews, *supra* note 95, at 36; *see also* Andrews, *supra* note 30, at 366 n.47.

109. Andrews, *supra* note 95, at 36, 37.

against the appearance that people are commodities"[110] and prevent people from becoming "objects."[111]

One may wonder whether the property or quasi-property approach can be limited so the preembryo does not become an ordinary thing or object. Ideas are powerful; and, once the preembryo is defined as some kind of property, it will be difficult to avoid the implications of property law.[112] Further, property law is not the only source from which the progenitors' decision making authority can be derived. Constitutional law fully supports the progenitors' decision making autonomy.[113] This point will be developed below, after the preembryo's status is analyzed more fully.

B. Familiar Concepts Do Not Apply When the Preembryo Is Considered a Person

At the other end of the spectrum, the preembryo sometimes has been deemed to be a legal "person" with rights. Under a group of Louisiana statutes, enacted in 1986, the "*in vitro* fertilized human ovum" is defined to be a "juridical person"[114] and "a biological human being."[115] It is entitled to sue and be sued,[116] and a curator may be appointed to protect its rights.[117] If the egg and sperm donors "renounce their parental rights for *in utero* implantation,"[118] then the fertilized ovum must be made available for "adoptive implantation."[119] If it develops over a thirty-six hour period, it is considered "viable"[120] and cannot be "intentionally destroyed."[121] Finally, the responsible physician or medical facility has a duty of "safekeeping"[122] toward the *in vitro* fertilized human ovum, the egg and sperm donors "owe it a high duty of

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110. *Id.* at 36.
111. *Id.*
112. *Cf.* Moore v. The Regents of the Univ. of Cal., 51 Cal. 3d. 120, 149, 793 P.2d 479, 498, 271 Cal. Rptr. 146, 165 (1990) (Arabian, J., concurring) ("The ramifications of recognizing and enforcing a property interest in body tissues are not known, but are greatly feared—the effect on human dignity of a marketplace in human body parts, the impact on research and development of competitive bidding for such materials, and the exposure of researchers to potentially limitless and uncharted tort liability").
113. Professor Robertson favors a property approach but admits that a constitutional argument might be persuasive. *See* Robertson, *supra* note 30, at 460.
114. LA. REV. STAT ANN. § 9:123 (West Supp. 1990).
115. *Id.* § 9:126.
116. *Id.* § 9:124.
117. *Id.* § 9:126.
118. *Id.* § 9:130.
119. *Id.*
120. *Id.* § 9:129.
121. *Id.*
122. *Id.* § 9:127.

care and prudent administration,"[123] and any dispute is to be resolved according to its "best interest."[124]

In the *Davis* case, the trial court concluded that "[h]uman life begins at conception"[125] and that the frozen preembryos were "human beings, *in vitro*."[126] Such "children, *in vitro*"[127] were subject to the state's *parens patriae* protection, so the court's sole duty was to determine their best interest.[128] Therefore, as the court explained, "it is to the manifest best interest of the children, *in vitro*, that they be made available for implantation to assure their opportunity for live birth; implantation is their sole and only hope for survival."[129]

Rejecting this analysis, the Tennessee Court of Appeal never speculated as to when life might begin. Instead, it steadfastly referred to the preembryos as "fertilized ova"[130] and observed that "[t]here are significant scientific distinctions between fertilized ova that have not been implanted and an embryo in the mother's womb."[131] Further, based on the progenitors' constitutional rights, it held that it could not "order[] implantation against the will of either party."[132]

The appellate court's decision in *Davis* is significant, but it has not settled the issue of whether the preembryo can be deemed to be some kind of independent person with independent rights. The Louisiana statutes still stand; other states may try to protect the preembryo as a person within the context of *in vitro* fertilization;[133] and the question of

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123. *Id.* § 9:130.
124. *Id.* § 9:131.
125. 15 FAM. L. REP. at 2097; *see also id.* at 2103.
126. *Id.* at 2097.
127. *Id.* at 2097, 2104.
128. *Id.* at 2104.
129. *Id.*
130. Davis v. Davis, No. 180 (Tenn. Ct. App. Sept. 13, 1990) (LEXIS, States library, Tenn. file) at 2-7.
131. *Id.* at 2.
132. *Id.* at 5.
133. For example, as part of a statutory scheme regulating abortion, the Missouri legislature has found: (1) that "[t]he life of each human being begins at conception," MO. REV. STAT. § 1.205.1(1) (Vernon Supp. 1990), (2) that unborn children have "protectable interests in life, health, and well-being," *id.* § 1.205.1(3) (with unborn children defined to include "offspring ... from the moment of conception until birth," *id.* § 1.205.2(3)), and (3) that Missouri laws are to be "construed to acknowledge on behalf of the unborn child at every stage of development, all the rights, privileges, and immunities available to other persons, citizens, and residents." *Id.* § 1.205.2. These "findings," of course, are broad enough to include the preembryo.

In Webster v. Reproductive Health Servs., ___ U.S. ___, 109 S. Ct. 3040, 3049-50 (1989), the Supreme Court declined to determine whether these statutory provisions were constitutional because they could be read to express a mere value judgment and had not yet been interpreted by the Missouri courts or applied in any concrete way.

when life begins has been debated with respect to IVF policy at the federal level.[134]

Our current jurisprudence cannot support the definition of a preembryo as a person with independent rights. Such a definition cannot be maintained under *Roe v. Wade*.[135] In *Roe*, the Supreme Court held that "the word 'person,' as used in the Fourteenth Amendment, does not include the unborn."[136] Further, the Court declined to endorse any particular theory as to when life begins,[137] although it determined that states had an important interest in "the potentiality of human life"[138] which became compelling when a fetus became viable.[139]

The Court adjudicated the constitutional status of the unborn within the context of the abortion debate. Holding that the right of privacy includes the abortion decision,[140] it determined that the right is fundamental but not absolute.[141] Hence, in order to protect fetal life, states can regulate or even proscribe abortion after viability, except when abortion is necessary to preserve the life or health of the pregnant woman.[142]

Roe has been controversial since it was decided in 1973. In the political arena, the abortion debate has been polarized into "pro-choice" and "pro-life" camps, with little meaningful dialogue between the two sides. Even the Court has become more and more divided, and *Roe* and its progeny now form a body of majority, plurality, concurring, and dissenting opinions in which the Court continues to debate the extent of the state's interest in potential life.[143] Nevertheless, the Court has never

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134. *Compare* INFERTILITY IN AMERICA, *supra* note 8, at 18 (noting religious opposition to IVF and related research and concern regarding destruction of human embryos) *with id.* at 33 (dissenting views) (the view that life begins at conception is based not only on religious beliefs but also on "strong scientific and philosophic reasons" and requires Congress to consider whether "frozen embryos ... have rights which should be protected").

135. 410 U.S. 113 (1973).

136. *Id.* at 158.

137. *Id.* at 159-62.

138. *Id.* at 162, 164.

139. *Id.* at 162-65.

140. *Id.* at 153.

141. *Id.* at 153-54.

142. *Id.* at 164-65. The Court also held that states have an important interest in maternal health which becomes compelling at approximately the end of the first trimester. *Id.* at 162-63. From and after that point, the state can regulate abortion in ways reasonably related to maternal health. *Id.* at 163-64. For example, the state could regulate the qualifications and licensure of the person performing the abortion or the nature and licensure of the facility where the abortion is to be performed. *Id.* at 163.

143. This debate has centered on the designation of viability as the point at which the state's interest becomes compelling. *Compare id.* at 162-65 (state's interest in potential life becomes compelling at viability) *with* City of Akron v. Akron Center for Reproductive Health, Inc., 462 U.S. 416, 427-28 (1983) (same) *and Akron*, 462 U.S. at 459-61 (O'Connor, J., dissenting) (state's interest in potential life is compelling throughout pregnancy) *and*

questioned its holding "that a fetus is not a 'person' within the meaning of the Fourteenth Amendment."[144]

It would be a mistake to abandon the relevant principles of *Roe* and, in either substance or effect, to recognize the preembryo as a person in any kind of constitutional sense. Our rights jurisprudence simply cannot stretch in any meaningful way to include the preembryo.

The principle of autonomy is central to our rights jurisprudence. Deeply rooted in our history, this principle is built on a model of the rational, competent adult, free to exercise his or her rights according to his or her own values.[145] Thus, in often majestic terms, our jurisprudence has been extended to protect an individual's freedom

> to contract, to engage in any of the common occupations of life, to acquire useful knowledge, to marry, establish a home and bring up children, to worship God according to the dictates of his own conscience, and generally to enjoy those privileges long recognized ... as essential to the orderly pursuit of happiness by free men.[146]

Thornburgh v. Am. College of Obstetricians and Gynecologists, 476 U.S. 747, 759 (1986) (reaffirming general principles of *Roe* and *Akron*) *and Thornburgh*, 476 U.S. at 778 (Stevens, J., concurring) (arguing in favor of the viability standard because prenatal development is not "static" and the state's interest "increases progressively and dramatically as the organism's capacity to feel pain, to experience pleasure, to survive, and to react to its surroundings increases day by day") *and Thornburgh*, 476 U.S. at 795 (White, J., dissenting) (if state interest in the fetus is compelling after viability, it is compelling before viability) *and* Webster v. Reproductive Health Servs., ___ U.S. ___, 109 S. Ct. 3040, 3057 (1989) (plurality portion of opinion delivered by Rehnquist, C. J. and joined by White, J. and Kennedy, J.) ("we do not see why the state's interest in protecting potential human life should come into existence only at the point of viability") *and Webster*, 109 S. Ct. at 3075-76 (Brennan, J., dissenting) (arguing in favor of viability standard).

144. *Webster*, 109 S. Ct. at 3083 n.13 (Stevens, J., concurring in part and dissenting in part).

145. John Stuart Mill's famous essay of 1859 defines the autonomous individual in terms which still ring familiar and true:

> [T]he only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant. He cannot rightfully be compelled to do or forbear because it will be better for him to do so, because it will make him happier, because, in the opinions of others, to do so would be wise or even right. These are good reasons for remonstrating with him, or reasoning with him or persuading him, or entreating him, but not for compelling him or visiting him with any evil in case he do otherwise. To justify that, the conduct from which it is desired to deter him must be calculated to produce evil to someone else. The only part of the conduct of anyone for which he is amenable to society is that which concerns others. In the part which merely concerns himself, his independence is, of right, absolute. *Over himself, over his own body and mind, the individual is sovereign.*

J. MILL, ON LIBERTY (1859) (emphasis added), *reprinted in* J. AREEN, P. KING, S. GOLDBERG & A. CAPRON, LAW, SCIENCE, AND MEDICINE 356, 356 (1984) [hereinafter LAW, SCIENCE, AND MEDICINE]; *see generally*, Schneider, *Rights Discourse and Neonatal Euthanasia*, 76 CALIF. L. REV. 151, 157, 164-65 (1988) (paradigm of individual rights vis-a-vis the state generally conceived in terms of Mill's paradigm and the competent adult).

146. Meyer v. Nebraska, 262 U.S. 390, 399 (1923).

To be sure, individual freedom is not absolute and may be tempered to serve the public good.[147] Likewise, rights are not only for the strong and able adult. Children have rights which may be modified to account for their special circumstances;[148] the developmentally disabled have rights;[149] and the permanently unconscious have rights which may be protected and exercised on their behalf.[150] Yet, our model of individual

147. *See, e.g.*, Jacobson v. Massachusetts, 197 U.S. 11 (1905) (law which required vaccination for smallpox did not violate individual liberty because it was necessary to protect the public health and safety).

148. Prince v. Massachusetts, 321 U.S. 158, 169-70 (1944); Bellotti v. Baird, 443 U.S. 622, 633-39 (1979) (plurality opinion delivered by Powell, J.) (constitutional rights of children cannot be equated with those of adults because children are vulnerable, may not be able to make important decisions in a mature manner, and parents have a guiding role in child rearing).

149. *See* Youngberg v. Romeo, 457 U.S. 307 (1982) (adult with mental capacity of an 18 month old child, who was committed involuntarily to a state institution, had substantive liberty interests under the due process clause of the fourteenth amendment which protected his rights to safe conditions of confinement, freedom from bodily restraints, and to minimally adequate or reasonable training to ensure his safety and freedom from undue restraint); Conservatorship of Valerie N., 40 Cal. 3d 143, 160-69, 707 P.2d 760, 771-78, 219 Cal. Rptr. 387, 398-405 (1985) (privacy and liberty interests guaranteed by the fourteenth amendment to the federal constitution and the California constitution encompassed the right of a developmentally disabled woman to undergo a sterilization procedure as a form of contraception if that procedure was necessary to her habilitation and the choice was made by a conservator on her behalf in proceedings with adequate safeguards); Conservatorship of Drabick, 200 Cal. App. 3d 185, 208, 245 Cal. Rptr. 840, 854 (1988), *cert. denied*, ___ U.S. ___, 109 S. Ct. 399 (1988) ("Valerie N. stands for the proposition that incompetence does not cause the loss of a fundamental right from which the incompetent person can still benefit").

150. In Cruzan v. Director, Missouri Dep't of Health, ___ U.S. ___, 110 S. Ct. 2841, 2851-52 (1990), the United States Supreme Court determined that a competent person would have a right to refuse lifesaving medical treatment as a liberty interest under the due process clause of the fourteenth amendment. If a person is incompetent because he or she is sustained in a persistent vegetative state (i.e., "evinces no indications of significant cognitive function," *id.* at 2845), the person's "'right' must be exercised ... by some sort of surrogate." *Id.* at 2852. Depending on the specific standard within a particular state, the surrogate's treatment decision must be guided by what the patient would have wanted or what is in the patient's best interest. *Compare , e.g., id.* at 2852-55 (state of Missouri may require clear and convincing evidence that the withdrawal of nutrition and hydration conforms to the wishes which the patient expressed while competent) *with* Barber v. Superior Court, 147 Cal. App. 3d 1006, 1021, 195 Cal. Rptr. 484, 493 (1983) (if the patient's own desires cannot be determined from the desires and feelings which the patient expressed while competent, then a treatment decision can be based on the patient's best interest which depends on a variety of factors, including the relief from suffering, probable quality and expected duration of the patient's life, and the impact of the decision on the patient's loved ones) *with Drabick*, 200 Cal. App. 3d at 210-12, 218, 245 Cal. Rptr. at 856-57, 861 (prior statements of the patient do not compel particular treatment decisions but should be considered, along with other evidence, to determine what is in the best interest of the incompetent patient). Hence, although the standards of surrogate decision making may vary from state to state and evolve within a particular state, the decision making rights of the incompetent patient may be preserved and protected as a matter of constitutional law. (The problems of surrogate decision making may be avoided if, while

autonomy seems to break down when considered in terms of the preembryo. How can autonomy be defined relative to the preembryo? Developing from an entity of two cells to a barely organized cluster of cells, it lacks any kind of organ systems or neural capacity. Unlike children, the developmentally disabled, or the permanently unconscious, it lacks any present or past experience of self awareness. To be sure, the preembryo has a unique human genome and may develop the capacity for feeling, thought, and self reflection. However, our concept of the autonomous individual, free to exercise his or her rights according to his or her desires, values, or beliefs, simply cannot stretch in any meaningful way to include the preembryo *as a preembryo.*

Turning from the principle of autonomy to the concept of personhood, the same result obtains. Once again, the abortion debate is instructive. For many, the morality—and legality—of abortion depend on what constitutes a "person" and whether a "person" comes into being at conception, implantation, viability, live birth, or perhaps even some later time when the capacities for thought, feeling, and social relationships are further developed.[151] Those who oppose abortion pose criteria which can be satisfied from conception or early in pregnancy, while those who would allow abortion pose criteria which cannot be satisfied until later in pregnancy or even after birth.[152]

Relatively early in the abortion debate, a philosopher by the name of Jane English suggested that "our concept of a person cannot ... bear the weight"[153] of this controversy. Observing that our concept of a person could not be "captured in a straitjacket of necessary and/or sufficient conditions,"[154] English argued that it really involved a "cluster of features"[155] related to an individual's biological and psychological makeup, reasoning ability, social nature, and legal identity.[156] Hence, it was impossible to say whether the fetus is a person.[157] Our concept of a

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competent, the patient provided for an effective, advance directive by executing either a living will or durable power of attorney for health care. *See, e.g.*, CAL. HEALTH & SAFETY CODE §§ 7185-7195 (Deering Supp. 1990) (California Natural Death Act); CAL. CIV. CODE §§ 2430-2444 (Deering 1986 & Supp. 1990) (California provisions regarding durable power of attorney for health care)).

151. *See generally* English, *Abortion and the Concept of a Person*, 5 CANADIAN J. PHIL. (1975), *reprinted in* BIOMEDICAL ETHICS 473, 474 (2d ed. 1986) (describing the different criteria for personhood developed by various scholars); Noonan, *An Almost Absolute Value in History*, THE MORALITY OF ABORTION: LEGAL AND HISTORICAL PERSPECTIVES 1, 51-58 (J. Noonan ed. 1970) (discussing various criteria in more detail).

152. *See* English, *supra* note 151, at 474.

153. *Id.*

154. *Id.*

155. *Id.*

156. *See id.* at 474-75.

157. *Id.* at 475.

person does not hinge on a single criterion and "a fetus lies in the penumbra region where our concept of a person is not so simple."[158]

The same may be said of the preembryo within the context of *in vitro* fertilization and preembryo transfer. The preembryo may have a unique genetic identity but it lacks the more developed "cluster of features" which we associate with persons.

Thus, even though our rights jurisprudence can be a powerful and adaptable tool, the preembryo does seem to elude our common understanding of what it means to be an autonomous person with rights. To be sure, we might continue debating "bright line" criteria, but the debate has been futile within the abortion context and may very well be misguided. Jane English, for example, has argued that whether or not the fetus is defined as a person, there are good reasons to allow abortion early in pregnancy and good reasons to proscribe abortion late in pregnancy (except when necessary to prevent serious injury to the woman or death).[159] Therefore if we avoid the temptation to search for secure, bright line definitions which fit the preembryo, we may avoid the pitfalls of the abortion debate and more seriously consider the merits of a *sui generis* approach.

C. As a Unique Entity, the Preembryo Warrants Our Respect and a Unique Legal Status

Even if the view of the preembryo as a person or property is abandoned, the preembryo may still be given some legal status. The challenge is to determine what status is appropriate, and why. A number of advisory bodies have undertaken the study of *in vitro* fertilization and, in effect, given the preembryo a *sui generis* status. Rejecting familiar categories, they have concluded that the preembryo is neither a form of property subject to ownership nor a person with full moral and legal rights. Instead, the preembryo is unique and should be treated with serious respect.[160]

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158. *Id.*

159. *Id.* at 474, 479.

160. Advisory bodies, within both national governments and professional groups, have reached this conclusion. *See* HEW Support of Human In Vitro Fertilization and Embryo Transfer; Report of the Ethics Advisory Board, 44 Fed. Reg. 35,033, 35,056 (June 18, 1979) [hereinafter HEW Report] ("the human embryo is entitled to profound respect; but this respect does not necessarily encompass the full legal and moral rights attributed to persons"); Dep't of Health and Social Security, United Kingdom, Report of the Committee of Inquiry into Human Fertilisation and Embryology, 1984, Cmnd. No. 9314, § 11.17, at 63 [hereinafter Warnock Report] (British committee chaired by Dame Mary Warnock) ("the embryo of the human species ought to have a special status"), *reprinted in* III Bioethics Reporter, Ethical and Legal Issues in Medicine, Health Care Administration and Human Experimentation, Legislation 1 (1985) [hereinafter III Bioethics Reporter

Likewise, Clifford Grobstein, an embryologist, argues that a preembryo is entitled to a special status but not the same status as a newborn. His argument is based on a number of factors: the preembryo is human in terms of its biological nature and has a unique genetic make-up,[161] the preembryo is alive (measured by scientific criteria such as cell division, the exchange of respiratory gases, and the metabolism of chemicals),[162] and the preembryo has the potential to develop into an infant and adult.[163] Nevertheless, the preembryo's potential has not been realized at the preembryonic stage.[164] In and of itself, the preembryo is a barely organized cluster of cells with only a slim chance of further development.[165] Three out of four zygotes are lost during the process of natural development, and many of these are lost during the preembryonic stage; others are subject to a spontaneous abortion after implantation.[166] Further, when fertilization occurs *in vitro*, the rate of preembryo loss is even higher, measured by the current rates of clinical pregnancy and live birth.[167]

Therefore, Grobstein argues that a preembryo is entitled to "special concern"[168] if it has a chance to realize its highest potential as a full person.[169] Further, even if that potential does not exist, Grobstein maintains that "the value of the preembryo as a member of the human community should still be recognized and conserved."[170] Given its genetic identity, the preembryo has "inherent kinship relationships"[171] and is part of the "hereditary web of the human family."[172]

A *sui generis* approach, based on the preembryo's unique biological nature and giving the preembryo a unique legal status, is endorsed

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(1985)]; Ethics Comm. of Am. Fertility Soc'y, *supra* note 42, at 32S-33S ("The existent preembryo ... must be treated with respect because it is human [like human cells, tissues, and organs], but it must also be treated with concern beyond respect as long as the possibility exists that it may achieve full human status ...."); *id.* at 35S ("[W]e find a widespread consensus that the preembryo is not a person but is to be treated with special respect because it is a genetically unique, living human entity that might become a person. In cases in which transfer to a uterus is possible, special respect is necessary to protect the welfare of potential offspring").

161. C. GROBSTEIN, *supra* note 3, at 65-66.
162. *Id.* at 66.
163. *Id.* at 67.
164. *Id.* at 77.
165. *Id.* at 75-77.
166. *Id.* at 77.
167. *Id.* at 78; *see supra* note 80 and accompanying text.
168. C. GROBSTEIN, *supra* note 3, at 82.
169. *Id.* at 82, 138.
170. *Id.* at 82.
171. *Id.* at 137.
172. *Id.* at 138.

here.[173] The implications of this approach must be developed in terms of specific issues and concrete facts. Nevertheless, a *sui generis* approach is important as an expression of the values and common understandings through which society defines itself and is defined. Further, a *sui generis* approach will serve a dynamic function in legal analysis for it will demand that our policies toward the preembryo be informed by respect, but free our policies from bright line principles which do not seem appropriate at the edge of life.[174]

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173. *Cf.* Moore v. The Regents of the Univ. of Cal., 51 Cal. 3d. 120, 137, 793 P.2d 479, 489, 271 Cal. Rptr. 146, 156 (1990) ("the laws governing such things as human tissues, transplantable organs, blood, fetuses, pituitary glands, corneal tissue, and dead bodies deal with human biological materials as objects sui generis, regulating their disposition to achieve policy goals rather than abandoning them to the general law of personal property") (footnotes omitted); Andrews, *supra* note 30, at 368-95 (comprehensive review of the legal status of the embryo and fetus within the context of criminal law, tort law, inheritance law, welfare law, and tax law, showing that the legal identity of the embryo and fetus depends on the context as well as the policies served by legal protection).

174. Professor Robertson appears to assume that "respect" for the preembryo amounts to respect for a symbol or reminder of the "unique gift of human existence," Robertson, *supra* note 30, at 447, and "our membership in the human community." *Id.* at 448. Further, he observes that such respect is merely constitutive or a value choice which does not carry any particular duties or obligations. *Id.* at 448, 450. Hence, Robertson advocates a property approach because the "abstract concept of respect must eventually confront the concrete situations in which the content of special respect is constituted," *id.* at 448, and these situations will be resolved according to whatever competing policies are at stake. *Id.* at 449-50.

This position may be questioned on two grounds. First, it seems that the preembryo is entitled to respect as something more than a "symbol" or "reminder" of something else. To be sure, the preembryo does serve a symbolic function and symbols are an important part of our cultural life; but, it seems that the preembryo is entitled to respect, in and of itself, because of its own unique nature.

Second, the authors of this Article agree that "respect" is a constitutive concept which must be defined through concrete situations. However, constitutive concepts need not be rejected on that ground, for legal analysis can be seen as a constitutive process. *See supra* note 94 and accompanying text; *see also* Tribe, *The Curvature of Constitutional Space: What Lawyers Can Learn from Modern Physics*, 103 HARV. L. REV. 1, 37, 38 (1989) (argument, based on insights derived from post Newtonian physics, that we must "think of law, and of governmental action, as changing the social landscape and redirecting the 'geometry' of human interactions, instead of regarding government as a physical entity that, through the 'forces' exerted by its component parts, tugs and pulls at people who are 'out there' in a 'state of nature'"; in other words, legal analysis must encompass "the *social meaning* of whatever the state has done") (emphasis in original).

IV. THE PROGENITORS, THE PREEMBRYO, AND THE STATE: THE CHALLENGE TO PROCREATIVE FREEDOM

A. Procreative Freedom Is Protected by a Dynamic, Albeit Turbulent, Jurisprudence

In the previous section, the status of the preembryo was explored in terms of what it means to be an individual within the meaning of our jurisprudence. In this section, the rights of the progenitors will be explored, relative to the preembryo, the state, and each other, focusing on the present legal status of reproductive rights.

In 1928, Justice Brandeis penned these famous words, dissenting in *Olmstead v. United States:*[175]

> The makers of our Constitution undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man's spiritual nature, of his feelings and of his intellect. They knew that only a part of the pain, pleasure and satisfaction of life are to be found in material things. They sought to protect Americans in their beliefs, their thoughts, their emotions and their sensations. They conferred, as against the government, *the right to be let alone*—the most comprehensive of rights and the right most valued by civilized men.

These sentiments lie at the heart of the constitutional right of privacy,[176] and the right of privacy protects reproductive freedom.

The right of privacy began to develop, as an explicit constitutional right, in *Griswold v. Connecticut.*[177] In a sweeping opinion, Justice Douglas recognized that "specific guarantees in the Bill of Rights have penumbras"[178] which "create zones of privacy,"[179] and that marriage, which involves "a right of privacy older than the Bill of Rights,"[180] is protected by "the zone of privacy created by several fundamental constitutional guarantees."[181] Indeed, as the Court struck down a statute which had forbidden the use of contraceptives by married persons, Justice Douglas queried: "Would we allow the police to search the sacred precincts of marital bedrooms for telltale signs of the use of

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175. 277 U.S. 438, 478 (1928) (Brandeis, J., dissenting) (emphasis added).

176. *See* Roe v. Wade, 410 U.S. 113, 152 (1973) (citing *Olmstead*, 277 U.S. at 478); Bowers v. Hardwick, 478 U.S. 186, 199 (1986) (Blackmun, J., dissenting) (quoting *Olmstead*, 277 U.S. at 478 (portions of the last sentence of the passage reproduced above)).

177. 381 U.S. 479 (1965); *see* Carey v. Population Servs. Int'l, 431 U.S. 678, 685 (1977) (right of privacy was first explicitly recognized in *Griswold*).

178. 381 U.S. at 484.

179. *Id.*

180. *Id.* at 486.

181. *Id.* at 485.

contraceptives? The very idea is repulsive to the notions of privacy surrounding the marriage relationship."[182]

In *Eisenstadt v. Baird*,[183] the Court further established the right of privacy as a right to be let alone, invalidating a statutory scheme under which contraceptives could be distributed to a persons to prevent pregnancy, but not to unmarried persons for the same purpose. Writing for the Court, Justice Brennan declared: "If the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."[184]

In *Roe v. Wade*, the Court observed that the right of privacy was not specifically guaranteed by the Constitution, but arose from the "Fourteenth Amendment's concept of personal liberty"[185] and "ha[d] some extension to activities relating to marriage ... procreation ... contraception ... family relationships ... and child rearing and education ...."[186] The Court also held that "the right of personal privacy includes the abortion decision ...."[187]

Thus, as the right of privacy has developed, it has created a zone of private life which "concerns the most intimate of human activities and relationships"[188] and "will be kept largely beyond the reach of government."[189] The right seems to rest on our familiar principle of individual autonomy[190] and has evoked stirring visions of personal freedom.[191] Nevertheless, the members of the Court continue to debate the scope of the privacy right. In the years since *Roe*, the nature of the abortion decision has become an ever more divisive issue[192] and, in

182. *Id.* at 485-86.

183. 405 U.S. 438 (1972).

184. *Id.* at 453 (emphasis omitted).

185. Roe v. Wade, 410 U.S. 113, 153 (1973).

186. *Id.* at 152-53.

187. *Id.* at 154.

188. Carey v. Population Servs. Int'l, 431 U.S. 678, 685 (1977).

189. Thornburgh v. Am. College of Obstetricians and Gynecologists, 476 U.S. 747, 772 (1986).

190. *See supra* notes 145, 175 and accompanying text.

191. *See, e.g., Thornburgh*, 476 U.S. at 771-72 (Blackmun, J., part V of Court's opinion); Webster v. Reproductive Health Servs., ___ U.S. ___, 109 S. Ct. 3040, 3067, 3077-79 (1990) (Blackmun, J., dissenting).

192. *Compare Roe*, 410 U.S. at 153-54 (right of privacy includes the abortion decision) (7-2 decision with Court's opinion delivered by Blackmun, J. and joined by Burger, C. J., Douglas, J., Brennan, J., Stewart, J., Marshall, J., and Powell, J.) *with* City of Akron v. Akron Center for Reproductive Health, Inc., 462 U.S. 416, 419-20 (1983) (reaffirming *Roe*) (6-3 decision with Court's opinion delivered by Powell, J. and joined by Burger, C. J., Brennan, J., Marshall, J., Blackmun, J., and Stevens, J.) *with Akron*, 462 U.S. at 453-59 (O'Connor, J., dissenting) (trimester approach is unworkable because improved technology will move forward toward childbirth the point at which the state can regulate to protect maternal health, and move backward toward conception the point at which the

Bowers v. Hardwick,[193] a closely divided Court held that the right of privacy does not extend to acts of "homosexual sodomy"[194] performed between consenting adults within the privacy of the home.[195]

To some extent, the controversies surrounding the privacy right are inherent in its general nature. The privacy right only includes "personal rights that can be deemed 'fundamental,'"[196] but a right can be deemed fundamental only if it is "'implicit in the concept of ordered liberty.'"[197]

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state can regulate to protect the viable fetus) *with Thornburgh*, 476 U.S. at 759 (reaffirming *Roe* and *Akron*) (5-4 decision with court's opinion delivered by Blackmun, J. and joined by Brennan, J., Marshall, J., Powell, J., and Stevens, J.) *with Thornburgh*, 476 U.S. at 788-94 (White, J., dissenting) (abortion decision is a liberty protected by the due process clause of the fourteenth amendment, but is not a fundamental right) *with Webster*, 109 S. Ct. at 3058 (1989) (plurality opinion delivered by Rehnquist, C. J. and joined by White, J. and Kennedy, J.) (abortion is ordinary liberty interest protected by fourteenth amendment rather than fundamental right) (plurality "would modify and narrow *Roe* and succeeding cases" but found no occasion to do so in the case before it) *with Webster*, 109 S. Ct. at 3064 (Scalia, J., concurring in part and concurring in the judgment) (would overrule *Roe* "explicitly") *with Webster*, 109 S. Ct. at 3067-79 (Blackmun, J., joined by Brennan, J. and Marshall, J., concurring in part and dissenting in part) (sharp critique of plurality opinion and impassioned defense of abortion rights) *with* Hodgson v. Minnesota, ___ U.S. ___, 110 S. Ct. 2926, 2936 (1990) (plurality opinion delivered by Stevens, J. and joined by Brennan, J.) ("[a] woman's decision to beget or to bear a child is a component of her liberty that is protected by the Due Process Clause of the Fourteenth Amendment") *with Hodgson*, 110 S. Ct. at 2951-52 (Marshall, J., joined by Brennan, J. and Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part) (right of privacy includes fundamental right to make abortion decision).

193. 478 U.S. 186 (1986).

194. *Id.* at 190, 191, 196. The Georgia statute which was in issue provides that criminal "sodomy" occurs when one person "performs or submits to any sexual act involving the sex organs of one person and the mouth or anus of another." GA. CODE ANN. § 16-6-2 (1984), *quoted in Bowers*, 478 U.S. at 188 n.1.

195. In a five to four decision, the Court upheld the statute as applied to acts of sodomy which had been performed by two consenting, adult, homosexual men within the bedroom of one of their homes. The Court's opinion was written by Justice White and joined by Chief Justice Burger together with Justices Powell, Rehnquist, and O'Connor. Justice Blackmun's dissenting opinion was joined by Justices Brennan, Marshall, and Stevens.

196. *Roe*, 410 U.S. at 152.

197. *Id.* (quoting Palko v. Connecticut, 302 U.S. 319, 325 (1937)). The Court also has defined as "fundamental" those liberties which are "'deeply rooted in this Nation's history and tradition.'" *Bowers*, 478 U.S. at 192 (White, J.) (quoting Moore v. East Cleveland, 431 U.S. 494, 503 (1977) (plurality opinion delivered by Powell, J.)); Thornburgh v. Am. College of Obstetricians and Gynecologists, 476 U.S. 747, 791 (1986) (White, J., dissenting) (quoting *Moore*, 431 U.S. at 503).

In Michael H. v. Gerald D., ___ U.S. ___, 109 S. Ct. 2333 (1989) (plurality opinion), Justice Scalia appeared to offer a new, more restrictive view of the liberties protected by the due process clause: "In an attempt to limit and guide interpretation of the Clause, we have insisted *not merely* that the interest denominated as a 'liberty' be 'fundamental' (a concept that in isolation is hard to objectify), *but also* that it be an interest traditionally protected by our society." *Id.* at 2341 (emphasis added). Unfortunately, however, this view seems to distort our present jurisprudence in at least three ways.

This test was designed to prevent the justices from interpreting the Constitution according to their own values or preferences;[198] but, at least on some level, the determination of what is "fundamental" requires a subjective interpretation of our nation's history, tradition, or values.[199]

First, it seems to suggest that due process only protects unspecified liberties if those liberties can be deemed to be fundamental. To the contrary, however, the liberty guaranteed by the due process clause extends to both "ordinary" liberties and "fundamental" liberties. To be sure, ordinary liberties are entitled only to ordinary judicial protection while fundamental rights are entitled to heightened protection; but, this is not to say that the protection of the due process clause extends only to fundamental rights. *See infra* notes 201-203 and accompanying text.

Second, Justice Scalia's interpretation of our due process jurisprudence seems to equate a conclusion with a method of analysis by insisting that a protectable liberty must be defined as "'fundamental'" *and* "an interest traditionally protected by our society." Justice Scalia also fails to suggest how a right can be fundamental apart from its reference to some type of tradition or other standard of measurement.

Finally, Justice Scalia's narrow, exclusively historical approach appears to depart from the Court's more interpretive tradition. Further explanation will demonstrate the point.

In *Michael H.*, the putative natural father of a child born to the wife of another man raised a due process challenge to California Evidence Code § 621 which creates a statutory presumption that "the issue of a wife cohabiting with her husband, who is not impotent or sterile, is ... a child of the marriage," and only allows the presumption to be challenged by the husband or wife. CAL. EVID. CODE § 621 (Deering 1986), *quoted and discussed in Michael H.*, 109 S. Ct. at 2338-39. The putative natural father claimed that he had a liberty interest in his relationship with the child, and that the interest was infringed by the state.

In analyzing whether the claimed liberty was an interest traditionally protected by our society, Justice Scalia further explained his due process methodology: "We refer to the most specific level at which a relevant tradition protecting, or denying protection to, the asserted right can be identified." *Id.* at 2344 n.6 (joined only by Rehnquist, C.J.); *see id.* at 2346-47 (O'Connor J., joined by Kennedy, J., concurring in all but footnote 6 and criticizing this very specific, historical mode of analysis). Accordingly, Justice Scalia analyzed the claimed right in terms of the "historical traditions specifically relating to the rights of an adulterous natural father," *Id.* at 2344 n.6; that is, "the societal tradition regarding the natural father's rights vis-a-vis a child whose mother is married to another man." *Id.*; *see also id.* at 2342-44 (discussing this tradition). Not surprisingly, Justice Scalia concluded that the liberty interest was not fundamental, and upheld the statute. *Id.* at 2344-46.

Hopefully, Justice Scalia's new methodology will not win the day. For a sharp critique of Justice Scalia's opinion, *see id.* at 2349-59 (Brennan, J., dissenting) (arguing, among other things, that the relevant liberty interest was a more general interest in "parenthood"); *see generally* Grey, *Do We Have an Unwritten Constitution?*, 27 STAN. L. REV. 703 (1975) (thoughtful defense of the kind of constitutional adjudication in which courts go beyond the interpretation of norms which are implicit in the text and original history of the Constitution, and accept their role in expounding basic ideals of liberty and fair treatment).

198. *Bowers*, 478 U.S. at 191-92; *see also* Palko v. Connecticut, 302 U.S. 319, 325-28 (1937) (Cardozo, J.) (concept of ordered liberty refers to our basic principles of liberty and justice).

199. *See, e.g., Michael H.*, 109 S. Ct. at 2349 (Brennan, J., dissenting) ("reasonable people can disagree about the content of particular traditions, and ... even about which traditions are relevant to the definition of 'liberty'"); *compare, e.g., Bowers*, 478 U.S. at 191-94 (White, J.) (right to engage in consensual "homosexual sodomy" is neither "'implicit in the concept of ordered liberty'" (quoting *Palko*, 306 U.S. at 325-26) nor "'deeply rooted in this Nation's history and tradition'" (quoting *Moore*, 431 U.S. at 503)) *with id.* at 206, 213-14

Further, adjudicating the constitutional boundaries of the privacy right entails a basic question of political philosophy: Who is sovereign, the individual or the state, when an intimate decision with moral and political overtones is in issue? Those justices who have upheld or would expand the right of privacy have resolved the issue in favor of the individual, while those who have or would restrict the privacy right have tipped the balance in favor of the state.[200]

The results of this analysis are of more than theoretical concern. If a right is deemed fundamental, then any state action which limits the right is subject to strict judicial scrutiny. In other words, to be upheld, such a burdensome action must serve a "'compelling state interest'"[201] and "be narrowly drawn to express only the ... interest[] at stake."[202] On the other hand, if a right is not deemed "fundamental," any state action which burdens the right is subject to only minimal scrutiny and will be upheld if it is rationally related to a legitimate state interest.[203]

(Blackmun, J., dissenting) (liberty at stake is "fundamental interest all individuals have in controlling the nature of their intimate associations with others" and deprivation of this right threatens "the values most deeply rooted in our Nation's history").

200. Justice Stevens and Justice White addressed this issue in *Thornburgh*. Concurring with the majority, which invalidated a statutory scheme designed to inhibit the abortion decision, Justice Stevens argued in defense of individual sovereignty:

> Roe v. Wade ... places the primary responsibility for decision in matters of childbearing squarely in the private sector of our society. ...
>
> In the final analysis, the holding in *Roe v. Wade* presumes that it is far better to permit some individuals to make incorrect decisions than to deny all individuals the right to make decisions that have a profound effect upon their destiny .... [T]he lawmakers who placed a special premium on the protection of individual liberty have recognized that certain values are more important than the will of a transient majority.

Thornburgh v. American College of Obstetricians and Gynecologists, 476 U.S. 747, 781-82 (1986) (Stevens, J., concurring).

Dissenting, Justice White argued in favor of state sovereignty:

> Abortion is a hotly contested moral and political issue. Such issues, in our society, are to be resolved by the will of the people, either as expressed through legislation or through the general principles they have already incorporated into the Constitution they have adopted .... I would return the issue to the people by overruling Roe v. Wade.

Id. at 796-97 (White, J., dissenting).

201. Roe v. Wade, 410 U.S. 113, 155 (1973) (quoting Kramer v. Union Free School Dist., 395 U.S. 621, 627 (1969) and Sherbert v. Verner, 374 U.S. 398, 406 (1963), and citing Shapiro v. Thompson, 394 U.S. 618, 634 (1969)); *see also* Carey v. Population Servs. Int'l, 431 U.S. 678, 685-86, 688-89 (1977).

202. *Roe*, 410 U.S. at 155 (citations omitted); *see also Carey*, 431 U.S. at 685-86, 688-89.

203. *See* Hodgson v. Minnesota, ___ U.S. ___, 110 S. Ct. 2926, 2937 (1990) (plurality portion of opinion by Stevens, J. and joined by Brennan, J.) ("[u]nder any analysis, the Minnesota [abortion] statute cannot be sustained if the obstacles it imposes are not reasonably related to legitimate state interests").

While the distinction between strict scrutiny and minimal scrutiny has become well established, not every Supreme Court case is defined in these terms. *See, e.g.*, Cruzan v. Director, Missouri Dep't. of Health, ___ U.S. ___, 110 S. Ct. 2841, 2851-52 (1990) (right to refuse medical treatment may be inferred as a liberty interest under the due process clause of the fourteenth amendment, and an alleged violation of the right must be "'determined

Despite the controversies associated with the privacy right and *Roe* in particular, it seems unlikely that the Court would entirely abolish those aspects of the right which have become an accepted part of our jurisprudence and generally protect individual decisions related to child rearing and education, family relationships, procreation, marriage and contraception.[204] Nevertheless, the Court may have begun to retreat from the frontiers of privacy adjudication. In several recent cases, the Court has refrained from deciding an issue on privacy grounds and instead has resolved the issue in terms of the liberty interest directly guaranteed by the due process clause of the fourteenth amendment.[205]

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by balancing [the individual's] liberty interests against the relevant state interests'") (quoting Youngberg v. Romeo, 457 U.S. 307, 321 (1982)).

Further, the appropriate level of review may be debated in any given case. Indeed, this has become another battleground of the abortion debate. In *Akron*, for example, Justice O'Connor acknowledged that abortion was a fundamental right in some circumstances, City of Akron v. Akron Center for Reproductive Health, Inc., 462 U.S. 416, 459 (1983) (O'Connor, J., concurring), but argued that strict scrutiny is only triggered in abortion cases if a statute "unduly burdens" the abortion decision. *Id.* at 461-66. This argument, however, appears to misread prior cases by confusing the threshold inquiry with the conclusion of an analysis. To be sure, a statute must burden, restrict, or impinge on a right —to some debatable extent—before any judicial review is triggered. However, the burden only becomes "undue" if it fails to meet the appropriate level of scrutiny. This seems apparent in the cases cited by Justice O'Connor. *See, e.g., id.* at 461 n.8.

In *Webster*, the plurality formed by Chief Justice Rehnquist, Justice White, and Justice Kennedy entirely abandoned the compelling state interest test and upheld a Missouri statute which required a physician to perform certain tests to determine viability, on the ground that the statute "permissibly further[ed] the State's interest in protecting potential human life," Webster v. Reproductive Health Servs., ___ U.S. ___, 109 S. Ct. 3040, 3057 (1990), and was "reasonably designed to ensure that abortions [were] not performed where the fetus [was] viable—an end which all concede is legitimate." *Id.* at 3058. Dissenting, Justice Brennan criticized the "permissibly furthers" test as "nothing more than a dressed-up version of rational basis review, [the] Court's most lenient level of scrutiny." *Id.* at 3076 (Brennan, J., dissenting). Further, Justice Brennan critiqued "[t]his newly minted standard," *id.*, on the ground that it posed "the *question* that courts must answer in abortion cases, not the standard for courts to apply." *Id.* (emphasis in original). Hence, the *Webster* plurality, like Justice O'Connor, appears willing to substitute conclusions for analysis—in all but the most extreme cases—in order to give the states more leeway in the abortion arena.

204. *See, e.g.*, Bowers v. Hardwick, 478 U.S. 186, 190-91 (1986) (relying on the established reach of the privacy right, including the abortion right, to argue that the right of privacy did not extend to "homosexual sodomy").

205. *See infra* notes 216-224 and accompanying text; *Cruzan*, 110 S. Ct. 2841. In *Cruzan*, the Court upheld a Missouri requirement that life-sustaining treatment could only be withdrawn from a patient in a persistent vegetative state based on clear and convincing evidence that, while competent, the patient had expressed the desire to have treatment withdrawn in such circumstances. The Court analyzed the right to refuse treatment "in terms of a Fourteenth Amendment liberty interest," 110 S. Ct. at 2851 n.7 (citing *Bowers*, 478 U.S. at 194-95), and specifically declined to follow the "many state courts [which] have held that a right to refuse treatment is encompassed by a generalized constitutional right of privacy." *Id.*; *see also id.* at 2851-52.

On one level, at least in theory there are several reasons why this kind of shift should not really change the adjudication of privacy or liberty issues. First, the right of privacy is derived from the concept of liberty guaranteed by the fourteenth amendment[206] and the Court has relied on due process cases to establish the present scope of the privacy right.[207] Second, like the privacy right, a right claimed to be a substantive liberty under the due process clause can be deemed fundamental and thus entitled to strict judicial protection.[208] Third, procreative rights already have been defined as fundamental under the due process clause. In *Skinner v. Oklahoma ex rel. Williamson*[209]—before the privacy right was recognized—the Court established that "procreation"[210] was "one of the basic civil rights of man"[211] and "a basic liberty,"[212] "fundamental to the very existence and survival of the race."[213] Hence, laws which infringed that right were subject to strict scrutiny.[214] Further, the Court has acknowledged that *Griswold*, *Eisenstadt*, and *Roe* established a fundamental right under the due process clause "to decide whether or not to beget or bear a child."[215]

Nevertheless, within the context of the abortion debate, the shift from a privacy analysis toward a liberty analysis seems to reflect the disarray within the Court and the uncertain future of *Roe v. Wade*. In *Webster v. Reproductive Health Services*,[216] Chief Justice Rehnquist, Justice White, and Justice Kennedy formed a plurality arguing that abortion was an ordinary "liberty interest protected by the Due Process Clause"[217]

In *Bowers*, the Court rejected the argument that the right of privacy extends to either "homosexual sodomy," *see supra* notes 193-195 and accompanying text, or "any kind of private sexual conduct between consenting adults." *Bowers*, 478 U.S. at 191. Further, as an entirely separate point, the Court declined to find a fundamental right to engage in homosexual sodomy within the substantive liberties directly guaranteed by the due process clause of the fourteenth amendment. *Id.* at 191-95.

206. *Roe*, 410 U.S. at 153; *Akron*, 462 U.S. at 426-27.

207. *See Roe*, 410 U.S. at 152-53 (right of privacy extends to child rearing and education, citing Pierce v. Soc'y of Sisters, 268 U.S. 510 (1925) (statute restricting private education violated liberty guaranteed by the fourteenth amendment)); Meyer v. Nebraska, 262 U.S. 390 (1923) (statute which restricted teaching of foreign language violated liberty guaranteed by fourteenth amendment)).

208. *Bowers*, 478 U.S. at 191-95.

209. 316 U.S. 535 (1942) (Douglas, J.).

210. *Id.* at 541.

211. *Id.*

212. *Id.*

213. *Id.*

214. *Id.* (invalidating Oklahoma law which provided for sterilization of some convicted felons).

215. Bowers v. Hardwick, 478 U.S. 186, 190 (1986).

216. ___ U.S. ___, 109 S. Ct. 3040 (1989).

217. *Id.* at 3058.

rather than a fundamental right.[218] Following this definition, the three justices relaxed the standard of review, arguing that a Missouri statute was constitutional because it was "reasonably designed to ensure that abortions [were] not performed where the fetus is viable—an end which all concede is legitimate."[219]

In *Hodgson v. Minnesota*,[220] Justices Stevens and Brennan also formed a plurality stating that "[a] woman's decision to beget or to bear a child is a component of her liberty that is protected by the Due Process Clause of the Fourteenth Amendment."[221] However, unlike the *Webster* plurality, the *Hodgson* plurality relied on the liberty interest to argue in favor of individual choice and preserve some kind of meaningful line between the individual and the state. As the plurality explained, "[T]he regulation of constitutionally protected decisions ... must be predicated on legitimate state concerns other than disagreement with the choice the individual has made."[222] Hence, even though a state might favor childbirth over abortion, that "value judgment"[223] would not provide "adequate support ... for simply substituting a state decision for an individual decision that a woman has a right to make for herself."[224]

Thus, one can neither deny nor ignore the controversies inherent in our privacy jurisprudence and the uncertain future of the abortion right. Nevertheless, the right of privacy and right to liberty guaranteed by the fourteenth amendment staunchly protect a basic procreative freedom. To be sure, the limits of such freedom must be defined on a case by case basis, but the right to reproductive freedom is secured by our constitutional principles.

B. Procreative Freedom Should Extend to Procreative Decisions Regarding the Preembryo

The right to reproductive freedom should give the progenitors a fundamental right to make decisions regarding the preembryo.[225] On one level, many decisions regarding the preembryo appear to be ordinary medical decisions which, like other medical decisions, must be analyzed in terms of standard medical practice and the medical goals to be achieved (such as curing infertility). However, these decisions may implicate basic procreative choices: for example, whether any given

218. *Id.*
219. *Id.*
220. ___ U.S. ___, 110 S. Ct. 2926 (1990).
221. *Id.* at 2936.
222. *Id.* at 2937.
223. *Id.*
224. *Id.*
225. *Accord* Andrews, *supra* note 30, at 358-61, 366, 402, 404-405.

preembryo is transferred with the hope of initiating a pregnancy, frozen for the possibility of future use, or discarded.

Further, it is hard to conceive of any state interest which would be sufficiently compelling to override the progenitors' decision making freedom.[226] There is a genetic link between the progenitors and the preembryo which does not exist between the preembryo and any other persons or entity. Further, for at least some people, this link may be significant in terms of the historical and physical continuity between generations, the implications of kinship, or the potential relationship of parents with children. Indeed, the progenitors may perceive this link as not only immediate and personal, but also symbolic of our human condition and hope for the future.

By comparison, the state has an important—but attenuated—interest in the preembryo. The state represents a collective body, and the direct, biological link between the progenitors and the preembryo is lacking. Further, unlike each progenitor, the preembryo cannot be counted as a sovereign member of the state. The preembryo is human in nature and entitled to respect. However, it simply has not developed to the point where it can be considered part of the body politic as an autonomous individual.

Hence, the progenitors' reproductive rights should stand as a bulwark against the efforts of states, such as the state of Louisiana, to force "extra" preembryos to be given up for "adoptive implantation."[227] The state interest in forcing adoption would consist of giving the preembryo a chance to develop further. However, as indicated above, the relationship between the progenitors, the preembryo, and the state gives the progenitors—not the state—the right to determine the preembryo's future life possibilities. The state would trammel that right without sufficient cause if it were to force unwilling progenitors to give up their preembryo for adoption.[228] Indeed, the prospect of state interference evokes the chilling image of the totalitarian state, so well illustrated by literary works such as *1984*[229] and *The Handmaid's Tale*.[230]

In *Davis*, the Tennessee Court of Appeal upheld the importance of the progenitors' constitutional rights. Citing *Skinner*, the court observed that the "right to procreate is [a] 'basic civil right[]'";[231] and, conversely,

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226. *Accord* Andrews, *supra* note 30, at 361-65.
227. LA. REV. STAT. ANN. § 9:130 (West Supp. 1990).
228. *Accord* Andrews, *supra* note 30, at 405-06.
229. G. ORWELL, 1984 (1949).
230. M. ATWOOD, THE HANDMAID'S TALE (1986).
231. Davis v. Davis, No. 180 (Tenn. Ct. App. Sept. 13, 1990) (LEXIS, States library, Tenn. file) at 5.

under *Griswold, Eisenstadt,* and *Carey v. Population Services International,*[232] that "an individual has a right to prevent procreation."[233] Hence, the court determined that an award of the preembryos to Mary Sue Davis for implantation, against the will of Junior Davis, was "impermissible state action in violation of Junior's constitutionally protected right not to beget a child where no pregnancy has taken place."[234] Further, the court concluded that "ordering implantation against the will of either party"[235] could not be justified by any compelling state interest.[236] Indeed, the court was so repelled by the notion of forced implantation that, in a footnote, it referred to the control of reproduction in Nazi Germany as "[a] haunting reminder of the evils of uncontrolled state action."[237]

Outside the zone of reproductive privacy, the state would have more leeway to enact reasonable regulations regarding the preembryo for such regulations would be justified if they were rationally related to a legitimate state goal.[238] However, before turning to one such area, research policy regarding IVF and the preembryo,[239] we must examine a difficult problem that remains: the relative weight of the progenitors' rights when their procreative desires conflict.

C. When the Progenitors Cannot Agree to a Procreative Decision, Preembryo Loss Will Be the Unfortunate Result

Within the context of the abortion decision, the relative weight of the progenitors' rights has been established: the woman alone has the right to decide. In *Planned Parenthood v. Danforth,*[240] the Supreme Court held that a spouse could not be given the right to veto the abortion

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232. 431 U.S. 678 (1977).
233. *Davis,* (LEXIS, States library, Tenn. file) at 5.
234. *Id.*
235. *Id.*
236. *Id.*
237. *Id.* at 6 n.7.
238. This requirement is based on the due process clause of the fifth amendment (applicable to the federal government) and the due process clause of the fourteenth amendment (applicable to the states). *See* Bolling v. Sharpe, 347 U.S. 497, 500 (1954) (construing due process clause of fifth amendment and holding that racial "[s]egregation in public education is not reasonably related to any proper governmental objective, and thus it imposes . . . a burden that constitutes an arbitrary deprivation of . . . liberty"); Village of Euclid, Ohio v. Ambler Realty Co., 272 U.S. 365, 395 (1926) (adjudicating municipal zoning laws under due process clause of fourteenth amendment and stating that the ordinance could only be stricken if it was "clearly arbitrary and unreasonable, having no substantial relation to the public health, safety, morals, or general welfare"); *see also* Moore v. East Cleveland, 431 U.S. 494, 498 & n.6 (1977) (affirming and elaborating on principle enunciated in *Euclid*).
239. *See infra* notes 250-356 and accompanying text.
240. 428 U.S. 52 (1976).

decision.[241] The Court was sensitive to the husband's interest in the pregnancy, the importance of the marital relationship, and the affect of the abortion decision on the relationship.[242] Nevertheless, the Court balanced the relative rights of husband and wife in favor of the wife:

> We recognize, of course, that when a woman, with the approval of her physician but without the approval of her husband, decides to terminate her pregnancy, it could be said that she is acting unilaterally. The obvious fact is that when the wife and the husband disagree on this decision, the view of only one of the two marriage partners can prevail. *Inasmuch as it is the woman who physically bears the child and who is the more directly and immediately affected by the pregnancy, as between the two, the balance weighs in her favor.*[243]

The situation differs when the preembryo is maintained *in vitro* or frozen. To be sure, the woman who has undergone the medical procedures necessary to retrieve her oocytes has invested more in the reproductive process than the man who has provided his sperm by way of ejaculation. Further, from the time a preembryo is transferred into the uterus, the woman would be "more directly and immediately affected" by the hoped for pregnancy. Nevertheless, while the preembryo is maintained *in vitro* or frozen, the man and woman appear to have an equal interest in the preembryo. At that point, the woman's bodily integrity is not at issue, and both have an equal genetic link with the preembryo. Thus, when confronted with a decision regarding the preembryo, as opposed to the abortion decision, there does not appear to be as compelling a reason to favor the woman's procreative choice over that of her male partner.[244]

Alternatively, there are many reasons to favor the rights of the progenitor, male or female, who does not wish to continue the reproductive process. Clearly, a woman could not be forced to undergo a preembryo transfer. As the Court of Appeal recognized in *Davis*, such an act would violate a woman's most basic procreative freedom. Further, a forcible transfer would be a battery (or bodily invasion performed without the woman's consent).[245] It would be absurd, for a woman would retain the right to abort any resulting pregnancy[246] and yet be

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241. *Id.* at 69-71.
242. *Id.* at 69-70.
243. *Id.* at 71 (emphasis added).
244. *Accord* J.A.M.A. Report, *supra* note 15, at 2486 (report prepared by Committee on Medicolegal Problems and Council on Ethical and Judicial Affairs of American Medical Association).
245. *See* Cobbs v. Grant, 8 Cal. 3d 229, 239-41, 104 Cal. Rptr. 505, 511-12 (1972) (medical procedure performed without consent constitutes battery).
246. *See* Roe v. Wade, 410 U.S. 113, 152-55, 162-66 (1973).

obliged to undergo a transfer procedure. Furthermore, from a woman's perspective, such a procedure might be akin to rape.[247]

Other scenarios are also disturbing. What if a woman desires to undergo a transfer procedure but the man no longer wants to become a father (like Mary Sue Davis and Junior Davis at the time of trial)? What if the man wants to have the preembryo transferred into a willing, gestational surrogate, with the understanding that he will raise any live born child, but the ova provider will not agree to the arrangement? What if either progenitor wants to donate the preembryo for adoption, but the other does not (like Mary Sue Davis and Junior Davis at the time of appeal)?

The common question raised by these possibilities is whether one progenitor can force the other to become a genetic parent against his or her will. In *Davis*, the trial court resolved the issue in favor of Mary Sue Davis, but the Court of Appeal concluded that "implantation" could not be ordered against the will of either progenitor. This conclusion appears correct. As a matter of constitutional law, it does seem that neither progenitor should be forced to become a parent against his or her will. Genetic ties may form a powerful bond between an individual and his or her progeny even if the progenitor is freed from the legal obligations of parenthood. Thus, forcing one to become a genetic parent may work a quiet form of violence and violate a vital freedom.[248]

This analysis of constitutional principles implies that a progenitor who does not want the reproductive process to continue should have a right to veto the desires of the progenitor who does, for the state's interest in the preembryo is insufficient to override the privacy rights of either progenitor. Hence, if one progenitor wants to continue with the reproductive process but the other does not, the preembryos should be allowed to deteriorate and die. This result may seem harsh to the extent that it favors the reproductive choice of one progenitor over the other or

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247. A criminal rape may also constitute a civil battery. Delia S. v. Torres, 134 Cal. App. 3d 471, 480, 184 Cal. Rptr. 787, 793 (1982).

248. Likewise, Professor Robertson argues that, as a general rule, the right to avoid reproduction should take priority over the right to reproduce because unwanted parenthood may impose significant financial and psychosocial burdens on an individual. Robertson, *supra* note 30, at 476-81. However, Robertson would carve an exception to the rule if the party who desires to reproduce will not have an "alternative opportunity to reproduce because the pleasures of parenthood will be deeper and more intense than the discomfort of unwanted biologic offspring." *Id.* at 481.

The J.A.M.A. Report also concludes that one progenitor's "choice not to have offspring should not be overriden by another person's desire to have offspring," J.A.M.A. Report, *supra* note 15, at 2486, and that, regardless of whether preembryos are used, donated, or discarded, both progenitors must consent to the manner of disposition. *Id.* at 2486-87. However, the Report does not resolve the issue of how disputes should be resolved when the progenitors cannot agree to one course of action. *See id.* at 2487.

to the extent that it favors a choice which allows a preembryo to be lost. Nevertheless, this result also seems to reflect the nature of the decision making process when natural reproduction is assisted by IVF.

IVF makes it possible to separate the genetic, gestational, and social aspects of parenthood in ways never before possible. Any number of individuals may share the traditional functions of parenthood: the woman and man who provide the egg and sperm, the woman who bears the child, and the individuals who raise the child. Further, the basic procreative process can be manipulated in ways never before possible: ova can be retrieved from a woman's body, fertilization can be achieved *in vitro*, preembryos can be sustained *in vitro* (at least to some point), and preembryos can be cryopreserved for future use.

When the component parts of the reproductive process can be isolated, controlled, and extended over time, there are many points for individual decision making. "The decision whether to bear or beget a child" can no longer be conceived as an isolated decision to engage in sexual intercourse, use contraceptives, or have an abortion. Instead, the decision must be seen as an ongoing process, from both a medical and personal point of view, subject to uncertainty and changing circumstances.[249] During this process, each progenitor remains dependent on the other; and the preembryo's continued development remains dependent on the consent of each.

In sum, given the relationship between the state, the progenitors, and the preembryo, a deadlock between the progenitors should be resolved by allowing the preembryos to deteriorate and die. Preembryo loss is the price of the progenitors' freedom and mutual dependence. The price may be high, but it seems necessary to preserve our most personal rights and the integrity of our most personal relationships.

V. OUTSIDE THE ZONE OF REPRODUCTIVE FREEDOM: TOWARD A COMPREHENSIVE RESEARCH POLICY

A. The Preembryo Can Play a Unique Role as a Research Subject

The preembryo can play a critical and varied role as a research subject. The preembryo is a necessary subject in research designed to

249. For a similar analysis of the consent process involved with IVF, *see* J.A.M.A. Report, *supra* note 15, at 2486-87. Professor Robertson also argues that "[b]ecause so many contingencies could intervene to change original plans, creation of embryos alone should not be taken as an irrevocable commitment to reproduction." Robertson, *supra* note 30, at 475.

improve the efficacy of IVF.[250] For example, the culture medium used to nourish fertilized eggs is based on animal research, usually involving mice, so further research with human zygotes or preembryos might improve the culture medium and, therefore, the success rate of IVF.[251] Further, research involving the preembryo might improve the clinical diagnosis of infertility, contraceptive technology, genetic diagnosis, and the medical management of congenital malformations.[252]

The unique nature of the preembryo also holds enormous promise for other kinds of research. Certain cells of the preembryo are totipotent: that is, they have the capacity to divide and differentiate into one or more of the many different cells comprising the human organism.[253] Hence, research with the preembryo might be designed to study cell differentiation and malignancy.[254] Also, preembryo research might be designed to culture specific cells and tissues with the hope of enhancing transplantation therapy.[255] If such cultures could be produced, it might be possible to alleviate two problems that now plague human transplants: scarce resources and rejection because of immunological incompatibility.[256]

At present, the ethical and legal status of research involving the preembryo remains uncertain. There is a void in federal policy and a number of state laws are designed to prevent nontherapeutic research with certain categories of the unborn. The state of the law will be explained in more detail below and guidelines will be suggested to define the preembryo's role as a research subject.

B. The State of the Law

1. *THE VOID IN FEDERAL POLICY*

The issue of research involving the preembryo has been simmering within the federal government, in the form of research involving *in vitro* fertilization and preembryo transfer, since the mid-1970's. Given the politics of the abortion debate, the issue has yet to be resolved.

In 1974, the Department of Health, Education and Welfare ("HEW") (now Health and Human Services or "HHS") promulgated regulations which applied to all research involving human subjects conducted or

250. INFERTILITY IN AMERICA, *supra* note 8, at 7; C. GROBSTEIN, *supra* note 3, at 78-80.

251. INFERTILITY IN AMERICA, *supra* note 8, at 15, 19-20; *see also* Beardsley, *Aborted Research*, SCI. AM., Feb. 1990, 16.

252. C. GROBSTEIN, *supra* note 3, at 80; HEW Report, *supra* note 160, at 35,039.

253. C. GROBSTEIN, *supra* note 3, at 68; HEW Report, *supra* note 160, at 35,039.

254. C. GROBSTEIN, *supra* note 3, at 68; HEW Report, *supra* note 160, at 35,039.

255. C. GROBSTEIN, *supra* note 3, at 68-69.

256. *Id.* at 69.

funded by HEW.[257] In general, research institutions were required to establish an Institutional Review Board ("IRB") to review and approve research protocols and to review the research while in progress.[258] One criterion of approval was the informed consent of the research subject.[259]

In 1975, HEW promulgated additional regulations regarding fetal research,[260] and defined the "fetus" as "the product of conception *from the time of implantation* ... until a determination is made, following expulsion or extraction ... that it is viable."[261] Hence, these regulations did not apply to research with the preembryo; and, rather than promulgate any specific guidelines, HEW provided for additional review by an Ethical Advisory Board on a case by case basis: "No application ... involving human *in vitro* fertilization may be funded ... until the application ... has been reviewed by the Ethical Advisory Board and the Board has rendered advice as to its acceptability from an ethical standpoint."[262]

An Ethical Advisory Board ("EAB") was appointed in September 1977, more than two years later,[263] and convened in 1978.[264] The board was asked to review a research application concerning IVF.[265] Then, following the birth of Louise Brown, the first person to be born as a result of IVF, the board was asked to expand its review of the pending application to consider "the scientific, ethical, legal and social issues surrounding human *in vitro* fertilization and embryo transfer in general."[266] An extensive study followed and the EAB's report was published in June 1979.[267]

In September 1980, the EAB lapsed when its charter and funding were allowed to expire.[268] There have been many efforts, supported by scientists within HHS, major scientific and medical associations, and

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257. 45 C.F.R. § 46.101(a) (1989); *see generally id.* §§ 46.101-46.124.

258. *See id.* §§ 46.102(h), 46.103, 46.107-46.115.

259. *Id.* §§ 46.111(a)(4), 46.111(a)(5), 46.116, 46.117.

260. *See generally id.* §§ 46.201-46.211; Fletcher & Schulman, *supra* note 27, at 6-7 (concise overview of events leading to adoption of fetal research regulations).

261. 45 C.F.R. § 46.203(c) (emphasis added).

262. *Id.* § 46.204(d). The regulations define *in vitro* fertilization as "any fertilization of human ova which occurs outside the body of a female, either through a mixture of donor human sperm and ova or by any other means." *Id.* § 46.203(g).

263. HEW Report, *supra* note 160, at 35,037.

264. Fletcher & Schulman, *supra* note 27, at 7.

265. HEW Report, *supra* note 160, at 35,034.

266. *Id.*

267. *See id.*

268. INFERTILITY IN AMERICA, *supra* note 8, at 6. Apparently, the EAB was allowed to lapse by mistake because an HEW official mistakenly advised Congress that an EAB would not be necessary in view of the newly appointed President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. Hence, money was reprogrammed from the EAB to the Commission. INFERTILITY IN AMERICA, *supra* note 8, at 6; Fletcher & Schulman, *supra* note 27, at 8.

other government bodies to reconstitute the EAB or to allow funding for IVF research without EAB approval.[269] However, the EAB has not been renewed and the regulation that requires EAB review of IVF research has not been lifted. The politics of preembryo research continue to implicate the volatile "right to life" debate and, in order to avoid that controversy, HHS appears to have succumbed to a policy of inaction.[270]

Accordingly, federal policy has been characterized by a *de facto* moratorium on HEW or HHS research involving IVF, extending from 1975 (when EAB review was required) to 1978 (when the EAB was convened), and then from 1980 (when the EAB lapsed) through the present writing in 1990. As a result, federal funds have not been available for IVF research;[271] the United States lags behind other countries in such research;[272] and, as a treatment for infertility, IVF remains more expensive—and ineffective—than it might be otherwise.[273] Further, without an EAB, the federal government lacks the forum—contemplated by existing regulations—in which controversial research proposals could be studied and evaluated within the context of an ongoing public dialogue regarding the ethical implications of federal research policy.[274]

2. *THE PATCHWORK OF STATE LAW*

State laws are plagued by inconsistency and uncertainty. A number of state statutes are designed to prevent nontherapeutic research with certain categories of the unborn. Some statutes specifically ban research

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269. *See* INFERTILITY IN AMERICA, *supra* note 8, at 13-18 (summarizing history of these efforts); *id.* at 21-22, 29 (urging HHS to exempt IVF research from EAB review and to establish an EAB which will be able to function effectively and review more controversial research proposals); *see also* Fletcher & Schulman, *supra* note 27, at 10-11.

270. INFERTILITY IN AMERICA, *supra* note 8, at 18-19.

271. For example, without an EAB, one investigator has not been able to obtain approval—or funding—for a well regarded study, using human zygotes or preembryos, which is designed to improve the culture medium used in IVF and hence the efficacy of IVF. *Id.* at 15, 19-20; Beardsley, *supra* note 251, at 16; INFERTILITY IN AMERICA, *supra* note 8, at 6-7. Further, according to one estimate, "100 IVF-related grant proposals would be submitted to NIH every year if such research was fundable." INFERTILITY IN AMERICA, *supra* note 8, at 7.

272. INFERTILITY IN AMERICA, *supra* note 8, at 7 (major developments are occurring in countries such as Australia and the United Kingdom); *see also* Bearsdley, *supra* note 251, at 16 (noting that "Sweden and Canada, in particular, are making headway").

273. INFERTILITY IN AMERICA, *supra* note 8, at 19-20. In the absence of federal funding, IVF research has been supported through the private sector by university medical centers, large pharmaceutical companies, and private foundations. *Id.* at 19; *see also* Beardsley, *supra* note 251, at 16. At least some of these costs are passed on to patients in the form of medical fees. INFERTILITY IN AMERICA, *supra* note 8, at 19. Also, according to one source, the lack of federal funding has made foundations and pharmaceutical companies "skittish about sponsoring such work." Beardsley, *supra* note 251, at 16.

274. *See* 45 C.F.R. § 46.204(a)-(c) (1989) (describing structure and function of EAB); INFERTILITY IN AMERICA, *supra* note 8, at 21-22; Fletcher & Schulman, *supra* note 27, at 6, 11.

with any embryo or fetus subject to the abortion procedure. For example, a California statute makes it unlawful "to use any aborted product of human conception ... for any type of scientific or laboratory research or for any other kind of experimentation or study, except to preserve the life and health of the fetus."[275] Others not only seek to proscribe research in the abortion setting, but also to regulate more broadly research with the embryo, fetus, or neonate. For example, a Michigan statute prohibits nontherapeutic research with an embryo or fetus known to be the subject of a planned abortion (unless the research is designed to protect the mother's life) as well as nontherapeutic research with "a live human embryo, fetus, or neonate [if] the research substantially jeopardizes the life or health of the embryo, fetus, or neonate."[276]

Some statutes also contain specific provisions regarding IVF. For example, the Maternal, Fetal and Infant Experimentation Act of New Mexico defines a "fetus" as a "product of conception from the time of conception until the expulsion or extraction of the fetus or the opening of the uterine cavity,"[277] and proscribes nontherapeutic research as follows:

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275. CAL. HEALTH & SAFETY CODE § 25956(a) (Deering 1988); *see also* ARK. STAT. ANN. § 20-17-802(b)(1) (1987); ARIZ. REV. STAT. ANN. § 36-2302A (1986); FLA. STAT. ANN. § 390.001(6) (West 1986); IND. CODE ANN. § 35-1-58.5-6 (West 1986); KY. REV. STAT. ANN. § 436.026 (Baldwin 1988); MO. ANN. STAT. § 188-037 (Vernon 1983); MONT. CODE ANN. § 50-20-108 (3) (1985) (banning nontherapeutic research with "premature infant born alive"); NEB. REV. STAT. § 28-346 (1989) (banning nontherapeutic research with "premature infant aborted alive"); OHIO REV. CODE ANN. § 2919.14 (Anderson 1987); OKLA. STAT ANN. tit. 63, § 1-735 (West 1984); 18 PA. CONST. STAT. ANN. §§ 3216 (a), (c) (Purdon 1990 Supp.); WYO. STAT. § 35-6-115 (1977 republished edition) (banning the sale, transfer, distribution, or giving away of "any live or viable aborted child for any form of experimentation").

276. MICH. COMP. LAWS § 333.2685 (1989); *see also* LA. REV. STAT. ANN. § 14:87.2 (West 1986) (no experimentation on human embryo or fetus *in utero* except to preserve the life or improve the health of the embryo or fetus); MASS. ANN. LAWS ch. 112, § 12J(a)(I) (Law. Co-op. 1985) (no research with "any live human fetus," but proscription does not apply if the procedures are directed to the fetus *in utero*, the procedures "do not substantially jeopardize the life or health of the fetus," and the fetus is not the subject of a planned abortion; likewise, proscription does not apply to diagnostic procedures designed to preserve the life or health of the fetus or mother); ME. REV. STAT. ANN. tit. 22, § 1593 (1980) (banning experimentation with "any live human fetus, whether intrauterine or extrauterine, or any product of conception considered live born"); MINN. STAT. ANN. §§ 145.421-145.422 (West 1989) (prohibiting research with "human conceptus," defined as "any human organism, conceived either in the human body or produced in an artificial environment ... from fertilization through the first 265 days thereafter," unless the research is therapeutic or harmless to the conceptus); N.D. CENT. CODE § 14-02.2-01 (Supp. 1989) (same general prohibition as Mass.); R.I. GEN. LAWS § 11-54-1 (1989 Supp.) (same general prohibition as Mass.); UTAH CODE ANN. § 76-7-310 (1990 replacement) (no experimentation with "[l]ive unborn children").

Some statutes are less restrictive. *See* S.D. CODIFIED LAWS ANN. § 34-23A-17 (1986 revision) (only prohibiting "[e]xperimentation with fetuses without written consent of the woman); TENN. CODE ANN. § 39-15-208 (Supp. 1990) (prohibiting research "upon an aborted fetus without the prior knowledge and consent of the mother").

277. N.M. STAT. ANN. § 24-9A-1(c) (1978 & Supp. 1989).

> No fetus shall be involved as a subject in any clinical research activity unless the purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs or no significant risk to the fetus is imposed by the research activity.[278]

"Clinical research" is defined to include "research involving human *in vitro* fertilization"[279] but not "human *in vitro* fertilization performed to treat infertility."[280] However, IVF performed to treat infertility is defined to be outside the scope of clinical research only if the "procedure ... include[s] provisions to insure that each living fertilized ovum, zygote or embryo is implanted in a human female recipient."[281]

Arguably, each of these statutes could be interpreted to inhibit IVF. For example, each could be construed to prohibit any formal research protocol or IVF technique which contemplates preembryo loss. Thus, each of these statutes could make it unlawful to conduct any type of procedure which might not be directed toward the continued survival or development of a particular preembryo.

Although each statute must be analyzed individually, similar state statutes have been held unconstitutional. In *Margaret S. v. Edwards*,[282] the following provision of a Louisiana statute was at issue: "No person shall experiment on an unborn child or a child born as the result of an abortion, whether the unborn child or child is alive or dead, unless the experimentation is therapeutic to the unborn child or child."[283] A federal appellate court held that the statute violated the due process clause of the fourteenth amendment because the terms "experiment" and "experimentation" were impermissibly vague.[284] As the court explained, no meaningful distinction could be drawn, based on the statutory language, "between experimentation and testing, or between research

278. N.M. STAT. ANN. § 24-9A-3(a) (1978 & Supp. 1989).
279. *Id.* § 24-9A-1(D).
280. *Id.*
281. *Id.* A Minnesota statute regulating research with the "human conceptus," *see supra* note 276 and accompanying text, does not specifically mention IVF but defines the conceptus as "any human organism, conceived either in the human body or produced in an artificial environment other than the human body." MINN. STAT ANN. § 145.421, subd. 2 (West 1989). Hence, the statute would apply to research with the preembryo created through *in vitro* fertilization.

The Pennsylvania legislature has taken a different approach, apparently deciding to avoid the issues raised by IVF. The legislature mentioned IVF in its fetal experimentation statute, *see supra* note 275, but specifically stated that nothing in the statute should be "construed to condone or prohibit the performance of *in vitro* fertilization and accompanying embryo transfer." 18 PA. CONS. STAT. ANN. tit. 18, § 3216 (c) (Purdon 1990 Supp.)
282. 794 F.2d 994 (5th Cir. 1986).
283. *Id.* at 998 (quoting LA. REV. STAT. ANN. § 40:1299.35.13 (West 1977 & Supp. 1990)).
284. *Id.* at 998-99.

and practice."[285] To be sure, some procedures might be considered "'experimental'"[286] and some might be considered "'standard,'"[287] but a very broad area of medical practice is defined by a process in which experimental procedures become standard procedures, "a gradual process of observing the results, confirming the benefits, and often modifying the technique."[288]

In *Lifchez v. Hartigan*,[289] a class of physicians, specializing in reproductive endocrinology and fertility counseling, challenged an Illinois statutory provision which banned nontherapeutic fetal experiments but permitted IVF. In relevant part, the statute read as follows:

> No person shall sell or experiment upon a fetus produced by the fertilization of a human ovum by a human sperm unless such experimentation is therapeutic to the fetus thereby produced.... Nothing in this subsection ... is intended to prohibit the performance of *in vitro* fertilization.[290]

The federal district court struck down the statute on the ground that the terms "experimentation"[291] and "therapeutic"[292] were vague.[293] As the court explained, the term "experimentation" has a number of medical and scientific definitions, including: pure research where the only goal is to increase knowledge and there is no direct benefit to the human subject,[294] procedures which lack sufficient testing to produce a predictable outcome or veer from current practice,[295] standard

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285. *Id.* at 999.
286. *Id.*
287. *Id.*
288. *Id.*
289. 735 F. Supp. 1361 (N.D. Ill. 1990).
290. *Id.* at 1363-64 (quoting ILL. REV. STAT. ch. 38, para. 81-26, § 6(7) (1989)).
291. *Id.* at 1364.
292. *Id.*
293. An earlier version of the statute was enjoined on the ground that it was unconstitutionally vague. Charles v. Carey, 579 F. Supp. 377, 383 (N.D. Ill. 1983) (granting preliminary injunction); Charles v. Carey, 579 F. Supp. 464, 476 (N.D. Ill. 1983) (granting permanent injunction). The statute made it a felony to "'use or sell any fetus or premature infant *aborted alive* for any type of scientific, research, laboratory or other kind of experimentation either prior to or subsequent to any abortion procedure except as necessary to protect or preserve the life and health of such premature infant aborted alive ...'" 579 F. Supp. at 383 (quoting Illinois Abortion Law of 1975, as amended, § 6(3)) (emphasis added by the court). As the district court explained, the term, "aborted alive," was impermissibly vague because it could refer to "'only the most minimal of life signs in a nonviable fetus or ... the capability of sustained survival.'" *Id.* (quoting Charles v. Carey, 627 F.2d 772, 791 (7th Cir. 1980) (striking other portions of the Illinois Abortion Law)).
294. *Lifchez*, 735 F. Supp at 1364-65.
295. *Id.* at 1365.

procedures when performed by any particular person for the first time,[296] and "any medical therapy where the practitioner applies what he [or she] learns from one patient to another."[297]

The statutory vagueness forced the physicians to guess whether various activities were unlawful.[298] For example, the physicians performed amniocentesis and chorionic villi sampling, diagnostic procedures designed to identify genetic anomalies in the developing fetus.[299] Amniocentesis was no longer considered experimental, but chorionic villi sampling was;[300] so like the *Margaret S.* court, the *Lifchez* court observed that experimental procedures may become routine over time.[301]

Likewise, IVF and related procedures were affected. To be sure, the statute allowed for *in vitro* fertilization, but if fertilization occurred *in vivo* and the preembryo was flushed from the uterus of one woman and transferred to the uterus of another, the procedure might not be "therapeutic" for the preembryo involved.[302] Likewise, if the genetic screening of a preembryo maintained *in vitro* was followed by the destruction of a defective preembryo, the screening procedure might not be considered therapeutic.[303]

Further, experiments designed to improve IVF might exceed the statutory definition of "*in vitro* fertilization" and might not be therapeutic for every preembryo. Again, by way of example, super-ovulation techniques may reduce the quality of the ova produced or the quality of the uterine lining, so it is more difficult for the preembryo to implant.[304] Hence, some experiments might not be of any benefit to the preembryos involved because some experiments might fail; for example, experiments designed to improve super-ovulation or to determine the most effective shape of the laboratory container in which IVF occurs or the most effective growth medium in which ova are fertilized.[305]

The *Lifchez* court also struck down the statute on the ground that it restricted a woman's right of reproductive privacy. In a brief, cogent analysis, the court reviewed the various aspects of reproductive privacy,

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296. *Id.*
297. *Id.*
298. *Id.* at 1364, 1376.
299. *Id.* at 1366-67.
300. *Id.*
301. *Id.* The court warned lawmakers of their responsibility to recognize "the fundamental progression from 'experiment' to 'routine,'" and to describe unlawful actions with particularity. *Id.* at 1367.
302. *Id.* at 1367-68.
303. *Id.* at 1368.
304. *Id.* at 1368-69.
305. *Id.* at 1369.

observed that the Illinois statute would prohibit chorionic villi sampling and the kind of preembryo transfer in which a preembryo is washed from one woman's uterus and transferred to another's, and concluded that both procedures were protected by the right of privacy.[306] As the court explained, if the right of privacy protects the right to prevent pregnancy by using contraceptives, it protects the right to establish a pregnancy through preembryo transfer.[307] Likewise, if the privacy right protects the right to abort during the first trimester, it protects the right to undergo chorionic villi sampling, a procedure which would be performed during the first trimester and would produce information relevant to the abortion decision.[308]

Hence, state laws offer little real guidance, if any, in the area of IVF research. A number of state statutes are designed to prevent non-therapeutic research with some category of the unborn. By and large, however, these statutes remain uncertain in scope and application, and may be subject to constitutional challenge. Given this dismal situation, the void in federal policy, and the volatile political climate surrounding any issue regarding the unborn, a thoughtful, comprehensive policy is necessary to guide research in this burgeoning field.

C. The Case for Preembryo Research

1. *RESEARCH CAN BE JUSTIFIED BY THE COMMON GOOD AND INFORMED CONSENT*

As a general proposition, research involving the preembryo, whether therapeutic or nontherapeutic, can be justified by the common good.[309] For the purpose of this argument, "research" will be used in the

306. *Id.* at 1376-77.

307. *Id.* at 1377.

308. *Id.*

309. The argument developed here applies to research with the zygote (one cell fertilized egg) as well as to research with the preembryo. The preembryonic period begins with the first cell division and continues until the primitive streak appears—some 14 days after conception—and a single, biological entity begins to develop. *See supra* notes 46-59 and accompanying text. Hence, the argument is consistent with the position, supported by various advisory groups, that research involving the preembryo should be allowed up to 14 days after conception. *See* HEW Report, *supra* note 160, at 35,057 (supporting IVF research without preembryo transfer if "[n]o embryos will be sustained *in vitro* beyond the stage normally associated with the completion of implantation (14 days after fertilization)"); Ontario Law Reform Comm'n, Ministry of the Attorney General, II Report on Human Artificial Reproduction and Related Matters 216 (1985) (recommending, with respect to research involving the preembryo, that "no fertilized ovum outside the body should be allowed to develop beyond fourteen days after fertilization"); Warnock Report, *supra* note 160, § 11.22, at 66 (recommending, based on formation of primitive streak, that preembryo neither "be kept alive ... nor ... used as a research subject beyond fourteen

sense defined by the HHS regulations, namely, "a *systematic* investigation designed to develop or contribute to *generalizable* knowledge."[310] This definition includes "pure" research and clinical research in which a subject might derive some benefit, but does not include an experimental therapy performed outside the scope of a research protocol, an accepted therapy which an individual performs for the first time, or the more general process of observation and reflection through which an individual may enhance his or her clinical judgment or professional expertise. This definition grounds research in the common good and research, as such, is designed to advance human knowledge and thus advance the human condition.[311]

Nevertheless, when research involves a human subject, such research can proceed only with the informed consent of the research subject. This principle is fundamental both in ethics and in law.[312] If an adult subject cannot consent, his or her "legally authorized representative"[313] must consent.[314] If the subject is a child, special provisions must be made for the child's "assent,"[315] if possible, and the

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days after fertilisation"); The Committee to Consider the Social, Ethical and Legal Issues Arising from In Vitro Fertilization, Victoria, Australia, Report on the Disposition of Embryos Produced By In Vitro Fertilization § 3.29, at 47 (1984) [hereinafter the Waller Report] (chaired by Professor Louis Waller) (concluding that any preembryo used for research "shall not be allowed to develop beyond the stage of implantation, which is completed 14 days after fertilization. It is after this stage that the primitive streak is formed ...."), *reprinted in* III Bioethics Reporter (1985), Legislation 226; Ethics Comm. of Am. Fertility Soc'y, *supra* note 42, at 63S (concluding "that it seems prudent ... not to maintain human preembryos for research beyond the 14th day of postfertilization development").

310. 45 C.F.R. § 46.102(e) (1989) (emphasis added).

311. *See generally* H. Jonas, *Philosophical Reflections on Experimenting with Human Subjects*, in EXPERIMENTATION WITH HUMAN SUBJECTS 1, 13-14 (P. Freund ed. 1969); PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, COMPENSATING FOR RESEARCH INJURIES 11-12 (1982).

312. The informed consent of the research subject is required by federal regulations and some states. *See* 45 C.F.R. § 46.116 (1989) (HHS' general requirements for informed consent); CAL. HEALTH & SAFETY CODE §§ 24172-24176 (Deering 1988) (informed consent to medical experimentation required by California law); N.Y. PUB. HEALTH LAW §§ 2440-2444 (McKinney 1975). The principle of informed consent is also critical to international codes of research ethics. *See* II Trials of War Criminals, Before the Nuremberg Military Tribunals Under Control Council No. 10 181 (1949) (Nuremberg Code) (stating that "[t]he voluntary consent of the human subject is absolutely essential" as a moral, ethical, and legal principle of research); Eighteenth World Med. Assembly, 271 NEW ENG. J. MED. 473 (1964) (Declaration of Helsinki) (informed consent of research subject set forth as basic principle).

313. 45 C.F.R. § 46.116.

314. *Id.*

315. *Id.* §§ 46.402(b), 46.404, 46.405(c), 46.406(d), 46.407(b)(iii), 46.408(a), (e).

parents' "permission."[316] If the subject is a fetus, the consent of both the mother and father is necessary.[317]

Likewise, if the subject is a preembryo, the progenitors' consent should be required. Whether or not the preembryo is a "human subject"[318] within the meaning of the HHS regulations, the preembryo is a human entity with a unique status. Hence, respect for the preembryo demands that research involving the preembryo incorporate the principle of informed consent; and, given the primary relationship between the progenitors and the preembryo, the right to give or withhold consent should rest with the progenitors. Further, if a research decision reflects a procreative decision, the progenitors' right to consent should be protected as a function of their right of privacy.

Thus, at a minimum, research involving the preembryo can be justified if it is designed to serve the common good and only proceeds with the informed consent of the progenitors.[319] Nevertheless, another issue remains: whether the preembryo's unique status requires any special limits on preembryo research.

2. *LIMITS ON RESEARCH DEPEND ON A CAREFUL BALANCE OF RISK, BENEFIT, AND THE NATURE OF THE KNOWLEDGE TO BE GAINED*

The question of limits can be illuminated by the HHS regulations governing research with human subjects, but cannot be resolved by a mechanical extension of those principles. The HHS regulations define the areas of permissible research in terms of risk, benefit, and the nature of the knowledge to be gained. For example, the risk to an adult subject must be minimized to the greatest extent possible[320] and must be reasonable in terms of both the "anticipated benefits ... to subjects, and the importance of the knowledge that may reasonably be expected to result."[321]

When a child serves as a research subject, the analysis is more elaborate. If the research only presents a "minimal risk,"[322] the research can proceed without any special consideration.[323] If the research presents

316. *Id.* §§ 46.402(c), 46.405(c), 46.406(d), 46.407(b)(2)(iii), 46.408(b)-(d).
317. *Id.* §§ 46.208(b)-46.209(d).
318. *Id.* § 46.102(f).
319. For an argument supporting research which neither harms nor demeans the preembryo, *see* Robertson, *supra* note 30, at 504-06.
320. 45 C.F.R. § 46.111(a)(1) (1989).
321. *Id.* § 46.111(a)(2).
322. *Id.* § 46.404.
323. *See id.*

"more than minimal risk"[324] but "holds out the prospect of direct benefit"[325] to the child, the risk must be "justified by the anticipated benefit."[326] Further, the "relation of the anticipated benefit to the risk"[327] must be "at least as favorable ... as that presented by available alternative approaches."[328] If the research presents more than minimal risk but does not hold out the prospect of direct benefit, the risk may only constitute a "minor increase over minimal risk,"[329] the research experience must be "reasonably commensurate"[330] with the child's experience in other areas of life,[331] and the research must be "likely to yield generalizable knowledge about the [child's] disorder or condition which is of vital importance for the understanding or amelioration of the ... disorder or condition."[332] Finally, if the research does not fit into any of these categories, it may proceed if it "presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children,"[333] and "will be conducted in accordance with sound ethical principles."[334]

When the fetus is involved as a research subject, the regulations are even more stringent and are designed to ensure that every fetus is treated equally, regardless of its status in terms of the abortion decision.[335] Hence, research can only be directed toward the fetus *in utero* if it satisfies the following criteria:

> (1) The purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.[336]

Further, the regulations subordinate research to the natural processes of fetal life and death. If research is directed toward the fetus *ex utero*, one must ascertain whether the fetus is viable. If this determination has not been made, the research can proceed only if "[t]here will be no

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324. *Id.* § 46.405.
325. *Id.*
326. *Id.* § 46.405(a).
327. *Id.* § 46.405(b).
328. *Id.*
329. *Id.* § 46.406(a).
330. *Id.* § 46.406(b).
331. *See id.*
332. *Id.* § 46.406(c).
333. *Id.* § 46.407(b)(2)(i).
334. *Id.* § 46.407(b)(2)(ii).
335. *See* 42 U.S.C. § 289g(b) (1988) (risk standard to be "the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term").
336. 45 C.F.R. § 46.208(a) (1989).

added risk to the fetus"[337] or "[t]he purpose of the activity is to enhance the possibility of survival of the ... fetus to ... viability."[338] If the fetus is nonviable, the "[v]ital functions of the fetus [can] not be artificially maintained"[339] and, conversely, experimental activities cannot be used "which of themselves would terminate the heartbeat or respiration of the fetus ...."[340] In all cases, except where the research is designed to enhance the survival of the fetus to viability, the research must be designed to develop "important biomedical knowledge which cannot be obtained by other means ...."[341]

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337. *Id.* § 46.209(a)(1).

338. *Id.* § 46.209(a)(2); *see also* 42 U.S.C. § 289g(a)(2) (1988).

339. 45 C.F.R. § 46.209(b)(1); *see also* 42 U.S.C. § 289g(a)(1) (1988).

340. 45 C.F.R. § 46.209(b)(2).

341. *Id.* §§ 46.209(a)(1), 46.209(b)(3); *see also* 42 U.S.C. § 289g(a)(2) (1988). The HHS Secretary is authorized to modify or waive the requirements imposed by the fetal research regulations with the approval of an Ethics Advisory Board. 45 C.F.R. § 46.211. This authority, however, has become illusory for at least several reasons. First, the EAB existed for only a brief period (from 1978-1980) and has been defunct for years. *See supra* notes 260-270 and accompanying text. Second, any modifications or waivers under § 46.211 were subject to a statutory moratorium from November 20, 1985, through November 4, 1990. 42 U.S.C. § 289g(c)(2) (West Supp. 1990) (including Historical and Statutory Notes). Third, an effort to review the waiver standard recently failed at the Congressional level. In 1985, a bicameral Biomedical Ethics Board (the "Board") was established to "study and report to ... Congress ... on the ethical issues arising from the delivery of health care and biomedical and behavioral research ...." 42 U.S.C. § 275(c)(1); *see id.* § 275(a)-(c) (establishment of Board, membership, reports, etc.). As part of this task, the Board was directed to appoint a Biomedical Ethics Advisory Committee (the "Committee"), *see id.* § 275(d); and the Committee, in turn, was directed to study "the nature, advisability, and biomedical and ethical implications of exercising any waiver of the risk standard ...," *id.* § 289g(c)(1), applicable to all HHS research involving human subjects, including the fetus. *See id.*; 45 C.F.R. § 46.102(g). The Committee's report was due by November 4, 1990, 42 U.S.C. § 289g(c)(1), the same day the moratorium on modifications or waivers for fetal research was scheduled to end. *Id.* § 289g(c)(2).

Unfortunately, the Board and Committee were paralyzed by abortion politics. Hilts, *Abortion Debate Clouds Research on Fetal Tissue*, N.Y. Times, Oct. 16, 1989, § A, at 19, col. 1. Appointments to the Board and Committee were so controversial that it took a year to appoint the Board and another 2-1/2 years to appoint the Committee. *Id.* Then, in 1989, the Board's funding expired, INFERTILITY IN AMERICA, *supra* note 8, at 7; and, in October 1989, all Committee work stopped. Hilts, *supra*.

Hence, given the restrictions on fetal research, federal funding has been confined to research that presents no more than "minimal risk" to the fetus or is therapeutic to the fetus. *See* 45 C.F.R. §§ 46.206(a)(2), 46.207(a), 46.208(a), 46.209(a), (b); Hansen & Sladek, *Fetal Research*, 246 SCIENCE 775, 777 (1989); Fletcher & Schulman, *supra* note 27. As a result, at least some fetal research has been stymied, *see* Fletcher & Schulman, *supra* note 27, at 8-9, 11, and further research may advance slowly. Hansen & Sladek, *supra*.

This situation needs to be considered thoughtfully, for fetal research now holds the promise of continued advancement in the diagnosis of fetal disorders such as inherited chromosomal abnormalities, metabolic deficiencies, and anatomical malformations, as well as the development of surgical therapies designed to treat—*in utero*—disorders involving a single organ system or an isolated congenital malformation, and the assessment of the safety and efficacy of medications for both the fetus and pregnant

How should risk, benefit, and the value of knowledge be weighed in the context of research involving the preembryo? The HHS regulations generally define "minimal risk" to mean "that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."[342] Any given preembryo is subject to relatively great risk. The rate of preembryo loss which occurs naturally is relatively high. Within the context of IVF, the rate of loss is even higher. Hence, when the preembryo is involved, the concept of risk is more extreme than it is for an adult, child, or even a developing fetus: the likelihood of continued existence is highly uncertain.

Further, when evaluating risk in terms of the preembryo, it seems appropriate to consider whether or not the research will be followed by preembryo transfer. If the research will be followed by preembryo transfer, the preembryo should not be exposed to unnecessary risk by the research. In other words, the research should not increase the risk inherent in the natural process or the techniques of assisted reproduction.

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woman. *Id.* at 775-77. Hence, fetal research now offers a number of therapeutic benefits to both the fetus and pregnant woman.

Likewise, fetal tissue research holds great promise but has been stymied by the abortion controversy. Fetal tissue research differs from research with the living fetus in that it involves studies with tissues or cells which have been derived from a dead fetus after a spontaneous or induced abortion. *Id.* at 775, 777. Fetal cells, cultured and grown in the laboratory, have been used to study gene regulation as well as cell interaction, function, differentiation, and growth. *Id.* at 777. Also, fetal cells have been used to develop and test vaccines and to determine whether new drugs are teratogens or carcinogens. *Id.* Further, the transplantation of fetal cells has been studied as a therapeutic tool to treat insulin-deficient diabetes mellitus, neurodegenerative disorders such as Parkinson's and Alzheimer's disease, and even immune deficiencies of other fetuses *in utero*. *Id.* at 777-79.

Technically, fetal tissue research is beyond the scope of the fetal research regulations and left to the regulation of any applicable state or local laws. *See* 45 C.F.R. § 46.210. However, in November 1989, HHS Secretary Louis W. Sullivan announced a permanent ban on federal funding for research involving the transplantation of fetal tissue derived from an elective abortion. Beardsley, *supra* note 251, at 16. The ban was surprising because a panel convened by the National Institutes of Health had concluded that federal support for research involving fetal tissue transplantation would be an acceptable public policy provided that the research would not be used to induce a woman to have an abortion. *Id.* Many other studies were in accord. *See, e.g.*, COUNCIL ON SCIENTIFIC AFFAIRS AND COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, *Medical Applications of Fetal Tissue Transplantation*, 263 J. A.M.A. 565, 568-69 (1990) [hereinafter *Medical Applications of Fetal Tissue Transplantation*].

Hence, although fetal research and fetal tissue research offer enormous benefits, federal research policy continues to be dominated by the abortion debate. Federal policy needs to be examined more thoughtfully in terms which address the unique concerns raised by research in these areas, but such an examination is beyond the scope of this Article.

342. 45 C.F.R. § 46.102(g) (1989).

The research need not be therapeutic to the preembryo, but it should not jeopardize the preembryo's chance to develop into a healthy child. On the other hand, a greater level of risk seems acceptable if the preembryo will not be transferred. In that event, the preembryo must always be treated with respect, but greater risk will neither diminish the preembryo's chance to develop further nor jeopardize its healthy development. Indeed, Grobstein argues that "carefully considered research"[343] with a preembryo which will not have a chance to develop further will allow the preembryo to "realize part of its human heritage and potential by fulfilling a significant and unique role in the human family."[344]

The concept of benefit to the research subject—a second variable in current federal regulations—also depends on whether the preembryo involved in research will be transferred. If the preembryo will not be transferred, benefit to the preembryo is not in issue. However, if the preembryo will be transferred, the benefit offered by the research is certainly relevant to the research design.

When relevant to the preembryo, the concept of benefit may require different levels of analysis. On one level, the analysis seems to be relatively basic and, like the analysis of risk, to focus primarily on the preembryo's chance to survive, implant, and continue developing. However, at some point in the future it may become necessary to consider the therapeutic benefits of genetic engineering. Genes, which are composed of the DNA molecule, govern each cell's structure and function.[345] If the DNA structure of a particular gene is faulty, the gene may malfunction and cause a genetic disease such as cystic fibrosis, sickle

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343. C. GROBSTEIN, *supra* note 3, at 82.

344. *Id.*; *accord* Jones & Schrader, *supra* note 3, at 191.

In contrast to the notions of risk proposed here, current federal regulations only allow the fetus to be involved in research if the research is designed "to meet the health needs of the mother or the particular fetus, [and] the risk to the fetus is minimal." 45 C.F.R. § 46.206(a)(2) (1989). The risk is not allowed to vary, depending on whether or not the fetus is to be aborted, and the same standard applies while the nonviable fetus, *ex utero*, is dying.

Nevertheless, it seems that the standard of risk should be allowed to vary in preembryo research. Even compared to the developing embryo and fetus, the preembryo is a unique biological entity: uniquely situated, having a unique relationship with its progenitors, and, whether measured in terms of natural reproduction or assisted reproduction, given only a slim chance of continued development. Hence, whatever level of risk may be appropriate in fetal research, the standard of risk in preembryo research must be analyzed in terms of the preembryo's own status and situation.

345. Nat'l Insts. of Health, Dep't of Health & Human Servs., Recombinant DNA Research; Actions Under Guidelines, 55 Fed. Reg. 7,438, 7,439 (Mar. 1, 1990) (public information brochure regarding human gene therapy, prepared by the Human Gene Therapy Subcommittee of the Recombinant DNA Advisory Committee ("RAC") of the National Institutes of Health ("NIH")).

cell anemia, or hemophilia.[346] Research in "human gene therapy"[347] is designed to alleviate or even cure a genetic disease by inserting a normal gene into the DNA of a cell with a malfunctioning gene.[348] Hence, with further research, it may become possible to treat genetic disorders in the preembryo.[349] If so, the concept of benefit will have to be expanded to consider factors related to the treatment of disease and the alleviation of suffering.[350]

A third variable in the federal regulations concerns the nature and value of the knowledge to be gained by research. In general, risk must always be proportionate to the importance of the knowledge to be gained,[351] and this relation is specially defined in special circumstances. If research presents greater than minimal risk to a child, it must be likely to yield knowledge "which is of vital importance for the understanding or amelioration of the subjects' disorder or condition,"[352] or "present[] a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children."[353] When the fetus is involved as a research subject, the purpose of the activity must generally be to develop "important biomedical knowledge which cannot be obtained by other means."[354]

Likewise, in the context of preembryo research, risk should be justified by the importance of the knowledge to be gained. By necessity,

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346. *Id.*

347. *Id.*

348. *Id.* at 7,438-39. Human gene therapy may affect "somatic" cells (non-reproductive cells) or "germ line" cells (reproductive cells including eggs in women and sperm in men). *Id.* At present, the NIH will fund research involving somatic cell gene therapy, but will not fund research involving germ line alterations. *Id.* at 7,444 ("Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA into the Genome of Human Subjects," prepared by the Human Gene Therapy Subcommittee and approved by the RAC). As the NIH has explained, "The purpose of somatic cell gene therapy is to treat an individual patient ... [while] [i]n germ line alterations, a specific attempt is made to introduce genetic changes into the germ ... cells of an individual, with the aim of changing the set of genes passed on to the individual's offspring." *Id.* One concern regarding somatic cell research, however, is that somatic cell changes may be transmitted unintentionally from an individual to his or her offspring. *Id.*

349. *See* Warnock Report, *supra* note 160, § 12.15, at 74; Waller Report, *supra* note 309, §§ 3.14-3.16, at 39-40.

350. The concept of benefit could also become highly controversial if a research proposal was designed to "enhance" or alter the preembryo's natural genome in order to produce specific characteristics in the potential child. For example, such research might be designed to produce children who were taller than they would be otherwise. Presently, such research remains speculative and futuristic, but is cause for concern. *See* Warnock Report, *supra* note 160, § 12.16, at 74.

351. 45 C.F.R. § 46.111(a)(2) (1989).

352. *Id.* § 46.406(a)(c).

353. *Id.* § 46.407(b)(2)(i).

354. *Id.* §§ 46.208(a), 46.209(a)(1), 46.209(b)(3).

this will involve a subjective, value oriented determination. Some knowledge will be worth the risk; some will not. Further, it seems appropriate to limit preembryo research to situations where important knowledge "cannot be obtained by other means." Arguably, this limitation is consistent with our respect for the preembryo and will help to maintain our respect. No matter how important the knowledge to be gained, the preembryo should not be treated as a commodity to be used whenever convenience or whim demands.

Nevertheless, by analogy to the regulations regarding children, it does not seem appropriate to limit research which presents relatively high risk to the preembryo to situations where the knowledge to be gained will be important to a "disorder or condition" of the preembryo or to "a serious problem affecting the health or welfare" of preembryos. Basic medical or scientific research involving the preembryo appears to be justified by the preembryo's unique status. Our duties toward the preembryo differ from our duties toward children.[355] Further, the preembryo deserves our serious respect, but children have legal rights[356] and warrant special protection as vulnerable research subjects.[357] Hence, a wider scope of research appears justified in the case of preembryos than in the case of children.

3. *SUGGESTED GUIDELINES*

The analysis of risk, benefit, and knowledge can be summarized in a set of proposed regulations. First, if research involving the preembryo does not involve any particular risk to the preembryo or only involves minimal risk, the research should be able to proceed with the informed consent of the progenitors. In this context, "minimal risk" would be

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355. Parents have the right and duty to care for and nurture their children. *See* Prince v. Massachusetts, 321 U.S. 158, 166 (1944), Pierce v. Soc'y of Sisters, 268 U.S. 510, 535 (1925). However, if parents abuse or neglect their children, the state has the right and duty under its *parens patrie* power to protect the children's well being. *See Prince*, 321 U.S. at 166-67; Bowen v. Am. Hosp. Ass'n, 476 U.S. 610, 627 & n.13 (1986) (plurality opinion by Stevens, J.).

356. *See supra* note 148 and accompanying text.

357. Although commentators have developed different theories to justify or limit research with children, there is some general accord that children are special research subjects deserving special consideration. *See* P. RAMSEY, THE PATIENT AS A PERSON 11-19 (1970) (nontherapeutic research with children cannot be justified because children lack the capacity to give a true consent); McCormick, *Proxy Consent in the Experimental Situation*, 18 PERSP. BIOLOGY & MED. 2, 13-14 (1974) (consent on behalf of children can be justified "when a particular experiment would involve no discernable risks, no notable pain, no notable inconvenience, and yet hold promise of considerable benefit"); Fried, *Children as Subjects for Medical Experimentation*, in RESEARCH ON CHILDREN 107, 111-15 (J. van Eys ed. 1978) (research with young children can be justified if inter alia there is a close connection between the child and the benefit produced by the research).

defined to mean a risk to the preembryo, equivalent in kind and/or degree, to the risk normally associated with reproduction, whether measured by natural processes or alternative technologies.

Second, if the research would involve greater than minimal risk to the preembryo and would be followed by preembryo transfer, the risk should be justified by the anticipated benefit to the preembryo. In this context, the relation between risk and benefit would be critical, and "benefit" would refer to the preembryo's chance for survival, implantation, continued development, or even, at some point in the future, to the treatment of genetic disease. Hence, research involving greater than minimal risk would be justified if it would be expected to improve the preembryo's chance to be born alive or free from genetic disease.

Third, if the research would involve greater than minimal risk to the preembryo and would not be followed by preembryo transfer, the research should be justified by the development of important knowledge which cannot be obtained by other means. Benefit would not be an issue; instead, the nature of the knowledge to be gained would be critical. For example, given the current research in animal breeding, it might be possible someday to transfer human preembryos into chimpanzees or gorillas so these primates can serve as "surrogates" for the purpose of gestation and birth.[358] Such a phenomenon would be highly controversial and implicate many basic values, assumptions, and goals. Hence, it would be critical to evaluate the nature of the knowledge to be gained by a study designed to achieve this goal.

Finally, beyond these proposed regulations, two general restraints on preembryo research seem justified: preembryos should not be bought or sold for research[359] and preembryos should not be created solely for research. The former point seems almost self-evident as a principle of bioethics. By way of either law or policy analysis, commercial transactions are either banned or disfavored in the settings of organ transplantation,[360] surrogacy,[361] and fetal tissue transplantation.[362]

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358. INFERTILITY IN AMERICA, *supra* note 8, at 21.

359. *Accord,* Robertson, *supra* note 30, at 512-14.

360. *See, e.g.*, 42 U.S.C.A. § 274e (a) (West Supp. 1990) (organs for use in human transplantation cannot be sold through interstate commerce); CAL. HEALTH & SAFETY CODE §§ 7150-7156.5 (Deering Supp. 1990) (providing for donation of cadaver organs as a gift under the Uniform Anatomical Gift Act); CAL. PENAL CODE §§ 367f(a), (d), (e) (Deering 1985) (banning the commercial brokerage of human organs); Caplan, *Blood, Sweat, Tears and Profits: The Ethics of the Sale and Use of Patient Derived Materials in Biomedicine,* 33 CLINICAL RES. 448, 448-50 (1985).

361. *See, e.g.*, Matter of Baby M, 109 N.J. 396, 537 A.2d 1227 (1988).

362. *See e.g.*, CAL. HEALTH & SAFETY CODE § 7150.1(b) (Deering Supp. 1990) ("decedent" defined to include a fetus for purpose of donating all or part of a human body,

The latter point seems consistent with our principles of constitutional law and public policy. The progenitors have a right to make reproductive decisions free from state interference, and this right should protect their right to conceive, freeze, transfer, donate, or discard a preembryo as part of the reproductive process. However, a decision to create a preembryo solely for research would exceed this protected domain. Moreover, the creation of preembryos solely for research can be criticized on policy grounds for it can be argued that the preembryo would become nothing more than a commodity to be produced, used, and discarded at will. As a result, our humanity would be denigrated and the research would be devalued.[363]

VI. CONCLUSION

As technology has advanced toward the edge of life, it has become necessary to look beyond the bright lines which usually define legal analysis. To define the legal status of the preembryo, we must look beyond our familiar concepts of "property" and "person" and account for the phenomenon of human development. To define the rights of the progenitors—relative to the preembryo, the state, and each other—it is necessary to examine and affirm our basic freedoms vis-a-vis the state. In doing so, however, it has become necessary to realize that freedom can only be exercised within the context of human relationships; that human relationships imply connections and interdependence; and that reproductive freedom must account for the phenomena of assisted reproduction and human development, phenomena which involve

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including tissue, under the Uniform Anatomical Gift Act); *Medical Applications of Fetal Tissue Transplantation*, *supra* note 341, at 568-69.

363. *See* Annas, *The Ethics of Embryo Research: Not as Easy as It Sounds*, 14 LAW, MED. & HEALTH CARE 138, 138, 139-40 (1986). Commentators are divided. *See* Warnock Report, *supra* note 160, §§ 11.20-11.30, at 66-69 (members of committee divided over issue but agreed that it should be resolved by legislation); Waller Report, *supra* note 309, §§ 3.26-3.31, 6.14, at 46-47, 60 (acknowledging dissenting views but recommending that preembryos should not be created solely for research because they would be created solely as a means to an end); Ethics Comm. of Am. Fertility Soc'y, *supra* note 42, at 63S (some research may require production of preembryos solely for the research). The state of Victoria, Australia has enacted legislation to deal with the issue. *See* Buckle, Dawson & Singer, *The Syngamy Debate: When Precisely Does a Human Life Begin?*, 17 LAW, MED. & HEALTH CARE 174 (1989) (discussing the Infertility (Medical Procedures) Act and the Infertility (Medical Procedures) (Amendment) Act, enacted in 1984 and 1987; the former followed the Waller Committee and only allowed ova to be fertilized outside the body for the purpose of implantation, while the latter allows ova to be fertilized outside the body "for experimental procedures 'from the point of sperm penetration prior to but not including the point of syngamy,'" *id.* at 180, with syngamy referring to the point at which a new genotype is formed and the process of fertilization is complete).

change and extend over time.[364] Finally, to define a policy adequate to guide IVF research and research with the preembryo, we must look beyond the polarized lines of the abortion debate and define the role of the preembryo within the larger human community.

As our jurisprudence expands to accommodate the implications of change and human relationships, our familiar assumptions are tested and patterns of reasoning are disrupted. However, as our jurisprudence expands, it also becomes more dynamic, responsive to the challenge of technology and to the shared meaning of our human situation.[365]

364. *See generally* Minow, *Interpreting Rights: An Essay for Robert Cover*, 96 YALE L. J. 1860, 1874-94 (1987) (developing an "interpretive" approach to rights in which rights arise within the context of human relationships, depend on human communities for recognition, and provide a language for community discourse regarding roles, relationships, and responsibility).

365. *See generally*, Martin & 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, 253-61 (1989) (discussing these themes within the context of our world view which arguably is shifting from the mechanistic view generated by the scientific revolution of the sixteenth and seventeenth centuries toward a more organic view).

ARTICLE

THE JUDICIAL IMPROVEMENTS AND ACCESS TO JUSTICE ACT: NEW PATENT VENUE, MANDATORY ARBITRATION AND MORE

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I. INTRODUCTION

This Article discusses the impact of the Judicial Improvements and Access to Justice Act upon the practice of intellectual property law.[1] According to Chief Justice Rehnquist, the Act is "the most significant legislation affecting the Federal courts since the early part of the decade."[2]

The Act contains three sections, the last of which contains ten titles which make various substantive and technical amendments to parts of the United States Code affecting federal jurisdiction and procedure. The focus of this Article is upon four titles of the Act which contain items relevant to the practice of intellectual property law. First, the Article discusses changes in corporate venue. Second, the Article analyzes the significance of Title IX which sets up a procedure both for consensual and mandatory non-binding arbitration of disputes filed in certain federal district courts. Finally, the Article informs the reader of several miscellaneous provisions of the Act. These provisions include: Title II which modifies the federal courts' diversity jurisdiction; Title V which modifies the jurisdiction of the Federal Circuit Court of Appeals; and three sections of Title X which abolish divisional venue in civil cases, significantly alter the procedures for removal from state court, and also make miscellaneous technical amendments to sections of the judicial code covering patents, copyrights and trademarks.

II. CORPORATE VENUE

A. The Pieces of the Puzzle

For intellectual property law practitioners, the corporate venue amendment is the most significant of all the changes made by the Act. Prior to the Act, the general corporate venue provision (28 U.S.C. § 1391(c)) read as follows:

> (c) a corporation may be sued in any judicial district in which it is incorporated or licensed to do business or is doing business, and such

1. Judicial Improvements and Access to Justice Act, Pub. L. No. 100-702, 102 Stat. 4642 (1988) (codified at scattered sections of 28 U.S.C.) [hereinafter the Act].

2. *Court Reform and Access to Justice Act, Hearings Before the Subcomm. on Courts, Civil Liberties, and the Administration of Justice of the Comm. on the Judiciary, House of Representatives*, 100th Cong., 1st & 2d Sess. 901 (1987 & 1988) [hereinafter *Subcommittee Hearings*], at 901. When finally passed by Congress, the name of the legislation would be changed to "The Judicial Improvements and Access to Justice Act."

> judicial district shall be regarded as the residence of such corporation for venue purposes.[3]

As amended, section 1391(c) now reads as follows:

> (c) *for purposes of venue under this chapter,* a defendant that is a corporation shall be deemed to reside in any judicial district in which it is subject to personal jurisdiction at the time the action is commenced. In a state which has more than one judicial district and in which a defendant that is a corporation is subject to personal jurisdiction at the time an action is commenced, such corporation shall be deemed to reside in any district in that state within which its contacts would be sufficient to subject it to personal jurisdiction if that district were a separate state, and, if there is no such district, the corporation shall be deemed to reside in the district within which it has the most significant contacts.[4]

The first obvious alteration worked by the new corporate venue provision is to merge the personal jurisdiction and venue inquiries.[5] If a corporation is subject to personal jurisdiction in a particular federal judicial district, that is, if the corporation is subject to general jurisdiction in the district,[6] or has minimum contacts with the district,[7] then venue is proper, without more. In a situation where the corporation does not have "minimum contacts" with any one district in a multi-district state, yet is subject to the court's personal jurisdiction because its aggregate contacts with the state satisfy due process, the statute requires that venue is proper in the district which has the most "significant" contacts with the defendant and the action.[8]

The major impact on patent law of the amendment to the general venue statute, however, is found in its opening clause: "For purposes of venue under this chapter...." If Congress meant what it said, that section 1391(c)'s definition of residence applies to all venue provisions in Chapter 87 of the Judicial Code, the Act would erase some 100 years of precedent in patent venue cases under 28 U.S.C. § 1400(b) and its predecessors.[9]

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3. 28 U.S.C. § 1391(c) (1976) (amended 1989).

4. 28 U.S.C. § 1391(c) (1989) (as amended by the Act, *supra* note 1, § 1013, 102 Stat. at 4669).

5. *See* Nabisco Brands, Inc. v. Conusa Corp., 892 F.2d 74 (M.D.N.C. 1989); Siegel, *Changes in Federal Jurisdiction and Practice Under the New Judicial Improvements and Access to Justice Act*, 123 F.R.D. 399, 405-07 (1989).

6. *See* Helicopteros Nacionales De Columbia, S.A. v. Hall, 466 U.S. 408, 414-15 & n.9 (1984).

7. *See Helicopteros*, 466 U.S. at 414 & n.8.

8. 28 U.S.C. § 1391(c) (1989) (as amended by the Act, *supra* note 1, § 1013, 102 Stat. at 4669); Siegel, *supra* note 5, at 406-07.

9. 28 U.S.C. § 1400(b) reads as follows:

> (b) Any civil action for patent infringement may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business.

Decades ago, in *Fourco Glass Co. v. Transmirra Products Corp.*,[10] the Supreme Court held that section 1400(b) "is the sole and exclusive provision controlling venue in patent infringement actions, and that it is not to be supplemented by the provisions of 28 U.S.C. § 1391(c)."[11] It is significant to note that the *Fourco Glass* Court placed considerable weight on the "Revisors' notes" in reaching its decision that the 1948 revision and codification of the Judicial Code did not expand patent venue.[12]

B. The Rules of Construction

Whether patent venue has been changed by the Act's amendment of section 1391(c) is one of statutory interpretation. Therefore, the ground rules of statutory interpretation must be understood. When one analyzes the cases in the Federal Circuit on the question of how statutes are interpreted, the following, rather amorphous, "rules" appear:

(1) The court must start with and be guided by the express and plain language of the statute to determine the meaning intended.

(2) If the language is plain, there is usually no need to analyze legislative history; provided, that if the plain meaning of the statute leads to irrational results or would thwart the statute's obvious purpose, then an analysis of legislative intent is required. This is but another way of saying that a statute whose meaning is plain creates a presumption that it will be enforced as written unless legislative intent clearly to the contrary is found.

(3) Statutes dealing with narrow and precise subject matters control over those dealing with general matters which would otherwise subsume

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28 U.S.C. § 1400(b) (1989).

10. 353 U.S. 222 (1957).

11. *Id.* at 229; *see also* Stonite Prods. Co. v. Melvin Lloyd Co., 315 U.S. 561 (1942).

12. *Fourco Glass*, 353 U.S. at 225-28; *see also id.* at 229 (Harlan, J., dissenting). The Federal Circuit has relied in the past on the insights of legislative drafters, or persons with significant input into statutory language, even if those persons were *not* members of Congress. *See, e.g.*, Atari, Inc. v. JS & A Group, Inc., 747 F.2d 1422, 1433 n.6 (Fed. Cir. 1984) (testimony before the Federal Circuit Judicial Conference of a Justice Department official, who participated in drafting the legislation at issue, given weight in interpreting 28 U.S.C. § 1295). In interpreting statutes, the Federal Circuit has also looked to the intent of persons outside of Congress when Congress was responding to the concerns or proposals of that outside party. *See* United States v. John C. Grimberg Co., 702 F.2d 1362, 1369-71 (Fed. Cir. 1983) (en banc) (Congress was responding to legislative concerns of the Justice Department; therefore, the Justice Department's view accorded some weight in the analysis of legislative intent); *see also* Summit Airlines, Inc. v. Teamsters Local Union No. 295, 628 F.2d 787 (2d Cir. 1980) (intent of the draftsman of a statute, although the draftsman was not a member of Congress, entitled to "great weight"); United States v. Oates, 560 F.2d 45, 68 (2d Cir. 1977) (Advisory Committee's notes to the Federal Rules of Evidence relied upon to interpret those rules).

the specialized statute; provided, that clear evidence of legislative intent prevails over this and any other "rule" of statutory construction.

(4) Congress is presumed to be aware of the way a statute it is amending has been interpreted by the courts.[13]

The analysis therefore begins with the amendment's "plain meaning." It is beyond debate that the plain language of amended section 1391(c) extends its definition of corporate residence to section 1400(b). The statute expressly states that the definition of "reside" set forth therein is used "for purposes of venue under this chapter." This "chapter" is, of course, Chapter 87 of Title 28,[14] which contains sections 1391 through 1412. The plain meaning of amended section 1391(c) is that a corporation resides (as that term is used in both sections 1391(c) and 1400(b)) in any judicial district in which it is subject to personal jurisdiction.[15] Nevertheless, this plain meaning can be overcome if the legislative history plainly and unmistakably indicates that congress could not have intended for corporate residence under sections 1391(c) and 1400(b) to be equivalent.

C. The Legislative History

A review of the published legislative material associated with the Act[16] sheds no direct light on whether Congress intended for the new

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13. *See generally* Glaxo Operations UK Ltd. v. Quigg, 894 F.2d 392, 395-96 (Fed. Cir. 1990); Madison Galleries, Ltd. v. United States, 870 F.2d 627, 629-32 (Fed. Cir. 1989); Johns-Manville Corp. v. United States, 855 F.2d 1556, 1559-62 (Fed. Cir. 1988), *cert. denied*, ___ U.S. ___, 109 S. Ct. 1342 (1989); Neptune Mut. Ass'n, Ltd. v. United States, 862 F.2d 1546, 1549 (Fed. Cir. 1988); Martin J. Simko Constr., Inc. v. United States, 852 F.2d 540, 542 (Fed. Cir. 1988); Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1426 (Fed. Cir. 1988); Horner v. Merit Sys. Protection Bd., 815 F.2d 668, 674-76 (Fed. Cir. 1987); Reid v. Dep't of Commerce, 793 F.2d 277, 281-83 (Fed. Cir. 1986); Aceto Chem. Co., Inc. v. United States, 465 F.2d 908, 913 (C.C.P.A. 1972).

14. 28 U.S.C. § 1391(c) is contained within the following chapter of the Judicial Code: "Chapter 87—DISTRICT COURTS; VENUE." *See* 28 U.S.C. §§ 1391-1440 (1989).

15. It should be noted that Congress obviously knows how to define the scope of a statute's application in terms of titles, subtitles, chapters, sections and subsections. *See, e.g.*, 38 U.S.C. § 1801 (1979); 26 U.S.C. § 2502(c) (1986) ("for purposes of this chapter"); 28 U.S.C. § 594 (1984); 26 U.S.C. § 3402 (1986) ("for purposes of this subsection"); 38 U.S.C. § 1801 (1979) ("for purposes of this section"); 26 U.S.C. § 1223 (1982) ("for purposes of this subtitle"). Furthermore, in the Act itself Congress has shown that if its intent is to limit the scope of a statute, it is capable of saying so. *See* the Act, *supra* note 1, § 203(a), 102 Stat. at 4646 (wherein it is written: "for the purposes of this section [1332(a)], section 1335, and section 1441"); *see also id.* § 1016(a), 102 Stat. at 4669 (wherein it is written: "for purposes of removal under this chapter").

16. The Act was originally introduced as H.R. 3152 in 1987. In May of 1988, H.R. 3152 was reported out of the House Judiciary Committee's Subcommittee on Courts, Civil Liberties and the Administration of Justice with an amendment in the nature of a substitute. This amended version of H.R. 3152 was introduced as a "clean bill," known as H.R. 4807, and went before the full Committee of the Judiciary and eventually was

definition of "reside" in amended section 1391(c) to apply to section 1400(b). The legislative history does contain a single clue which eventually leads to the conclusion that the corporate venue amendment was indeed intended to apply to patent venue under section 1400(b). The single clue is found in the pedigree of the corporate venue amendment. On August 6, 1987, Representative Kastenmeier introduced H.R. 3152 in the first session of the 100th Congress.[17] As originally drafted, H.R. 3152 (then called the "Court Reform and Access to Justice Act of 1987"), did not propose any alteration to corporate venue.[18] The corporate venue amendment was proposed, not by the Subcommittee, but by the Judicial Conference of the United States,[19] transmitted to the Subcommittee via the testimony of Judge Elmo B. Hunter, chairman of the Committee on Court Administration of the Judicial Conference of the United States.[20] In his testimony to the subcommittee, there was no discussion of patent venue.

The official congressional explanation for the corporate venue amendment, contained in the House Report, is but a verbatim adoption of the Judicial Conference position as reflected in Judge Hunter's prepared statement.[21] Nothing else about the corporate venue amendment is found in the Subcommittee Hearings or the House Report.[22]

If we stop here and step back to review the rules of statutory construction,[23] the amended statute has a plain meaning which is not contradicted by anything in its legislative history. Thus, the inquiry could end here. Because the corporate venue amendment to section 1391(c) by its own explicit terms applies to all of Chapter 87 of Title 28, including section 1400(b), and given nothing to the contrary in the legislative history, a corporation may be sued for patent violations in any judicial district wherein personal jurisdiction over the defendant exists.

To stop at this point leaves a nagging question unanswered—so nagging, in fact, that some reasonable jurists have incorrectly concluded that section 1400(b) remains aloof from the general venue provision; and that *Fourco Glass* survives intact.[24] Again, falling back on those malleable

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enacted and signed into law. The Subcommittee Hearings (*see supra* note 2) were conducted before the change in the House Resolution number. *See* H. R. REP. NO. 100-889, 100th Cong., 2d Sess. 24-26 (1988) [hereinafter House Report].

17. *See id.*

18. *See Subcommittee Hearings, supra* note 2, at 452-515.

19. *See id.* at 65; House Report, *supra* note 16, at 70.

20. *See Subcommittee Hearings, supra* note 2, at 3.

21. House Report, *supra* note 16, at 66, 70.

22. No Senate Report was submitted with the Act. *See id.* at 70.

23. *See supra* text accompanying note 13.

24. A few federal district courts have addressed this venue question. These courts were fragmented. In the following cases, the district courts held that the new amendment

"rules" of construction, one could argue that the legislative background should have been more transparent if Congress had intended to overrule almost a century of patent venue jurisprudence.[25] In other words, something more than ignorance of *Fourco Glass* and its progeny should be evident somewhere in the legislative background of the Act.[26] Yet even the skeptics will accept the amended section's plain meaning after a look "behind the scenes" at the evolution of the corporate venue amendment.

As set forth above, there is no doubt that the corporate venue amendment originated in the Judicial Conference of the United States. The Judicial Conference provides strong evidence that drafters of the corporate venue amendment intended it to cover the entirety of chapter 87 of title 28, and that the use of the word "chapter" in the amendment's opening clause was not accidental or the result of ignorance.[27]

In 1984, the Subcommittee on Federal Jurisdiction of the Judicial Conference requested that Judge William W. Schwarzer, of the United States District Court for the Northern District of California, prepare a proposed amendment to 28 U.S.C. § 1391(c) to address perceived problems in the area of corporate venue. In response, on February 22,

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does not alter the existing *Fourco Glass* venue rule: Joslyn Mfg. Co. v. Amerace Corp., 729 F. Supp. 1219 (N.D. Ill. 1990); Doelcher Prods., Inc. v. Hydrofoil Int'l, Inc., 14 U.S.P.Q.2d 1067 (D. Md. 1989). In other cases, the district courts found that the amendment to section 1391(c) changed the law of patent venue: Regents of the Univ. of California v. Eli Lilly & Co., 734 F. Supp. 911 (N.D. Cal. 1990); Century Wrecker Corp. v. Vulcan Equip. Co., 733 F. Supp. 1170 (E.D. Tenn. 1989). The Court of Appeals for the Federal Circuit has recently resolved this conflict, holding that the amendment did in fact alter the law of patent venue by allowing suit anywhere the corporate defendant is subject to personal jurisdiction. VE Holding Corp. v. Johnson Gas Appliance Co., 16 U.S.P.Q.2d 1614 (Fed. Cir. 1990) (adopting the argument presented in this section of the Article). The authors of this Article argued the *VE Holding* case before the Federal Circuit.

25. Although such explicitness in the Legislative History would be helpful, Congress is neither (1) obligated to specifically state that its amended language either means something different from the old language, Volkswagen of Am., Inc. v. United States, 340 F. Supp. 983, 989 (Cust. Ct. 1972), *aff'd per curiam*, 494 F.2d 703 (C.C.P.A. 1974); Cellas v. United States, 18 C.C.P.A. 237, 241 (1930); United States Cordage Co. v. United States, 18 C.C.P.A. 23, 25 (1930); Am. Mfrs. v. United States, 15 Ct. Cust. App. 355, 358 (1928); Strouse, Adler & Co. v. United States, 3 Ct. Cust. App. 184, 186 (1912); Acme Shear Co. v. United States, 386 F. Supp. 513, 517 (Cust. Ct. 1974); or (2) obligated to explicitly state that it intends an amendment to "overrule" past judicial decisions, *see* Redding v. Comm'r of Internal Revenue, 630 F.2d 1169, 1182 (7th Cir. 1980), *cert. denied*, 450 U.S. 913 (1981).

26. Even if Congress were to be "ignorant" of the changes its amendment would work in application, the Supreme Court and the Federal Circuit's predecessor have found such "ignorance" to be an insufficient ground for ignoring the plain meaning of a statute. Barr v. United States, 324 U.S. 83, 90 (1945); Sears, Roebuck & Co. v. United States, 504 F.2d 1400, 1402 (C.C.P.A. 1974).

27. *Fourco Glass* placed great emphasis on the intent of the drafters and the Revisors' notes. It is thus more than appropriate to investigate the intent of the Judicial Conference subcommittee which actually drafted the language in question. *See supra* note 11 and accompanying text.

1985, Judge Schwarzer submitted a proposed amendment to the Subcommittee on Federal Jurisdiction along with an earlier memorandum he authored on the general subject of corporate venue.[28] Judge Schwarzer's proposal to amend the corporate venue statute was as follows:

> *For the purposes of Subsections (A) and (B)*, a corporation, whether a plaintiff or a defendant, shall be deemed to reside in any judicial district in which it is subject to personal jurisdiction at the time the action is commenced. In a state having more than one judicial district, a corporation shall be deemed to reside in a district only to the extent that the corporation's contacts within that district would be sufficient to subject it to personal jurisdiction if that district were a separate state.[29]

Significantly, this draft submitted to the Subcommittee on Federal Jurisdiction would have limited the application of section 1391(c)'s definition of "reside" quite considerably—it would apply only to sections 1391(a) and (b).

Thereafter, on March 1, 1985, the Hon. Charles B. Simons, Jr., Chief Judge of the United States District Court for the District of South Carolina, and member of the Subcommittee on Federal Jurisdiction, forwarded Judge Schwarzer's proposal to Edward H. Cooper, of the University of Michigan law school, who was the reporter for the Judicial Conference's Subcommittee on Federal Jurisdiction.[30] A copy of the proposed amendment was also forwarded to the clerk of the Supreme Court for placement on the agenda for the June, 1985 meeting of the Subcommittee on Federal Jurisdiction to be held in Santa Fe, New Mexico.[31]

In July of 1985, the Subcommittee on Federal Jurisdiction issued its report of the Santa Fe meeting. The full Subcommittee recommended that section 1391(c) be amended in substantially the manner suggested by Judge Schwarzer. Significantly, the Subcommittee's recommendation modified Judge Schwarzer's proposal by greatly extending the

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28. Memorandum from Judge Schwarzer (Feb. 22, 1985) (a copy of this memorandum is on file at the *High Technology Law Journal* office).

29. *Id.*

30. In addition, Professor Cooper (along with Charles Alan Wright and Arthur R. Miller) is the author of an authoritative treatise on Federal Practice and Procedure. *See* C. WRIGHT, A. MILLER & E. COOPER, FEDERAL PRACTICE AND PROCEDURE: JURISDICTION (1st ed. 1976).

31. *See* Letter to the Honorable William W. Schwarzer from the Honorable Charles E. Simons, Jr. (Mar. 1, 1985) (a copy of this letter is on file at the *High Technology Law Journal* office).

definitional reach of section 1391(c).[32] Where Judge Schwarzer's proposal limited the definition of corporate residence to "the purposes of Subsections (A) and (B)" of section 1391, the Subcommittee recommended that the new definition of corporate residence be "for purposes of venue under this chapter."[33] It is thus clear that the extension of section 1391(c)'s definition of residence was deliberate. This evolution is convincing evidence that the drafters intended the new definition to apply to all of chapter 87, including section 1400(b).[34]

Furthermore, Professor Cooper, as official reporter for the Subcommittee on Federal Jurisdiction, drafted a Memorandum which addresses the proposal to amend section 1391(c).[35] In the Cooper Memorandum, the intent of the drafters of the corporate venue amendment is made indisputable:

> *Other Venue Provisions.* The definition of corporate residence in § 1391(c) now provides a basis for applying the substantial number of venue statutes enacted as part of various substantive federal laws. As a matter of caution, *the proposal limits its definition of residence to the venue provisions gathered in Chapter 87 of the Judicial Code, 28 U.S.C. §§ 1391 through 1412. If the proposal were enacted in its present form, it would be necessary to recreate definitions of residence for the specialized venue statutes.* It may be that little is lost by this change, but it is a question that deserves some reflection.[36]

It simply cannot be written any clearer. The reporter for the drafters of the language which was eventually enacted into law stated that the new definition of residence in section 1391(c) applies to every venue section in chapter 87; from section 1391, including section 1400(b),

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32. Report of the Subcommittee on Federal Jurisdiction (June, 1985) (a copy of this report is on file at the *High Technology Law Journal* office). The pertinent part of the Report states:

> Recommendation:
>
> Your Subcommittee accordingly recommends that 28 U.S.C. § 1391(c) be amended to read as follows:
>
> (c) *for purposes of venue under this chapter* a corporation, whether a plaintiff or defendant, shall be deemed to reside in any judicial district in which it is subject to personal jurisdiction at the time the action is commenced. In a state having more than one judicial district, a corporation shall be deemed to reside in a district only to the extent that the corporation's contacts within that district would be sufficient to subject it to personal jurisdiction if that district were a separate state.

Id.

33. The "chapter" containing section 1391 also contains sections 1392 through 1412, including, of course, the patent venue statute, section 1400(b). *Supra* note 14.

34. *Cf.* Russello v. United States, 464 U.S. 16, 23-24 (1983) ("Where Congress includes limiting language in an earlier version of a bill but deletes it prior to enactment, it may be presumed that the limitation was not intended.").

35. Memorandum from Professor Edward H. Cooper to Members of the Subcommittee on Federal Jurisdiction (Dec. 4, 1986) (a copy of this memorandum is on file at the *High Technology Law Journal* office).

36. *Id.* at 4 (emphasis added).

through the end of the chapter, section 1412. Professor Cooper also understood the proposed amendment's effects on the specialized venue statutes. He noted that if the specialized venue statutes were to use definitions of residence other than the new definition found in section 1391(c), it would be necessary for Congress to "recreate" other definitions for the specialized statutes.[37]

D. The Solution

The legislative history establishes that the definition of corporate residence in newly amended section 1391(c) was indeed intended to apply to its patent venue counterpart, as well as to all other venue provisions in chapter 87. Now, in a patent case, a corporate defendant may be sued in any judicial district wherein it is subject to personal jurisdiction.

III. ARBITRATION

Title IX of the Act amends Title 28 of the United States Code to insert an entirely new chapter: "Chapter 44 – Arbitration."[38] The new chapter became effective May 16, 1989.[39] Title IX also contains an automatic repeal of the entire chapter, effective on November 19, 1993, with the reservation that an action referred to arbitration on or before that date shall continue under the chapter's provisions until the action is concluded.[40] As presently written, the arbitration rules are confined to ten federal districts,[41] with the provision for ten additional districts to be designated by the Judicial Conference of the United States.[42] It is now possible for a trademark, copyright or even a patent case to be referred to mandatory arbitration.

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37. It is interesting to note that Professor Cooper was a long time advocate of repealing the patent venue statute entirely. *See* C. WRIGHT, A. MILLER & E. COOPER, *supra* note 30, § 3823, at 135 ("The statute [28 U.S.C. § 1400(b)] ought to be repealed, and patent cases treated in the same fashion as federal question cases generally."). He was not alone. *See, e.g.*, American Law Institute, Study of the Division of Jurisdiction between State and Federal Courts, Official Draft, 1969, at 219-21; Wydick, *Venue in Actions for Patent Infringement*, 25 STAN. L. REV. 551 (1973).

38. *See* 28 U.S.C. §§ 651-658 (1989) (as added by the Act, *supra* note 1, § 901(a), 102 Stat. at 4659-64).

39. *See* the Act *supra* note 1, § 907, 102 Stat. at 4664.

40. *See id.* § 906, 102 Stat. at 4664.

41. These ten districts include N.D. Cal., M.D. Fla., W.D. Mich., W.D. Mo., D.N.J., E.D.N.Y., M.D.N.C., W.D. Okla., E.D. Pa., and W.D. Tex. 28 U.S.C. § 658(1) (1989) (as added by the Act, *supra* note 1, § 901(a), 102 Stat. at 4662).

42. 28 U.S.C. § 658(2) (1989) (as added by the Act, *supra* note 1, § 901(b), 102 Stat. at 4662). These new district courts may not, however, refer cases to arbitration without consent of the parties. *See id.* § 651(a) (as added by the Act, *supra* note 1, § 901(a), 102 Stat. at 4659).

The new 28 U.S.C. § 652 sets out actions that may be referred to arbitration, actions that may not be referred without consent of the parties, and certain actions excepted from arbitration.[43] Under 28 U.S.C. § 652(a)(1)(A), courts included in the arbitration chapter are given the power to refer any civil action to arbitration if the parties consent.[44] Significantly, 28 U.S.C. § 652(a)(1)(B) empowers the initially designated courts to refer any civil action to arbitration,[45] even in the face of the parties' opposition, if the relief sought in the case is limited to money damages in an amount less than $100,000, exclusive of interest and costs.[46] There are exceptions to the mandatory arbitration provision of 28 U.S.C. § 652(a)(1)(A) for actions based on alleged violations of the United States Constitution, or actions based, in whole or in part, on civil rights statutes.[47] Exemptions from arbitration are found at 28 U.S.C. § 652(c) for those cases where the "objectives" of arbitration would not be realized because of complex or novel legal issues, because legal issues predominate over factual issues, or for other "good cause."[48]

The new arbitration statute also provides that a court may appoint arbitrators who will have various powers over the arbitration hearing, and who have duties to the court. Arbitrators will have the power to conduct the hearing, administer oaths and make awards.[49] The arbitrator also is empowered to issue subpoenas for the appearance of witnesses and production of documents at an arbitration hearing.[50] In so far as timing is concerned, the statute requires that the arbitration hearing begin no later than 180 days after the filing of an answer but, in the absence of consent, the hearing shall not commence until at least 30 days after the district court has decided any pending dispositive motions, or motions to join necessary parties.[51] These time periods may be altered by the court for good cause shown.[52]

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43. *Id.* §§ 652(a), (b) & (c) (as added by the Act, *supra* note 1, § 901(a), 102 Stat. at 4659-60).

44. *Id.* § 652(a)(1)(A) (as added by the Act, *supra* note 1, § 901(a), 102 Stat. at 4659).

45. This is subject to certain exceptions and exemptions discussed in the next paragraph. The "initially designated courts" are set out *supra* at note 41.

46. 28 U.S.C. § 652(a)(1)(B) (1989) (as added by the Act, *supra* note 1, § 901(a), 102 Stat. at 4659). This amount can go as high as $150,000 in those districts which, as of the date of the Act, already had court-annexed arbitration under local rule, and which local rule had a ceiling above $100,000. *See* the Act *supra* note 1, § 901(b), 102 Stat. 4663.

47. 28 U.S.C. § 652(b) (as added by the Act, *supra* note 1, § 901(a), 102 Stat. at 4660).

48. *Id.* § 652(c) (as added by the Act, *supra* note 1, § 901(a), 102 Stat. at 4660).

49. *Id.* § 653(a) (as added by the Act, *supra* note 1, § 901(a), 102 Stat. at 4660).

50. *Id.* § 653(c) (as added by the Act, *supra* note 1, § 901(a), 102 Stat. at 4660). The issue of discovery in actions referred to arbitration is not addressed by the statute.

51. *Id.* § 653(b) (as added by the Act, *supra* note 1, § 901(a), 102 Stat. at 4660).

52. *Id.*

An arbitration award is filed with the clerk of the district court and entered as a judgment of the court after the time within which to request a trial *de novo* has expired.[53] Judgment on an award has the same effect as an ordinary judgment in a civil action, except that the award cum judgment is not subject to review by appeal or otherwise.[54]

As alluded to above, the new statute provides for a trial de novo after the decision by the arbitrator.[55] A trial *de novo* is secured merely by filing a written demand for it within 30 days after the arbitration award is filed with the district court.[56] After the demand for trial *de novo* is made, the action is placed back on the court's docket and the case is treated as if it never was referred to arbitration.[57] Section 655(b) specifically provides that restoration to the court docket preserves any right to trial by jury and the case's place on the court calendar which it would have occupied had there been no arbitration.[58]

The new arbitration rules contain a number of hazards to those seeking trials *de novo*. These hazards are liability for costs and the possibility that unfavorable evidence proffered at the arbitration hearing might make its way into evidence at trial. These hazards, the consequences of which can be devastating, should serve to discourage demands for trials *de novo*. The first hazard is contained at 28 U.S.C. § 655(c), which is euphemistically entitled "LIMITATION ON ADMISSION OF EVIDENCE."[59] This subsection states that, at the trial *de novo*, the court shall not admit any evidence that there has been an arbitration proceeding, the nature or amount of any award, or any matter concerning the conduct of the arbitration proceeding—unless the evidence would otherwise be admissible under the Federal Rules of Evidence.[60] The section limiting admission of evidence is far from a blanket rule of non-admissability. In fact, the section is quite circular in nature. Once the section is examined, it really says very little other than the obvious proposition that nothing about the arbitration is admissible at the trial *de novo* unless it is admissible under the Federal Rules of Evidence. Put positively, everything at the arbitration is admissible at the trial *de novo* if such evidence is admissible under the Federal Rules of Evidence.

53. *Id.* § 654(a) (as added by the Act, *supra* note 1, § 901(a), 102 Stat. at 4660-61).
54. *Id.*
55. *Id.* § 655 (as added by the Act, *supra* note 1, § 901(a), 102 Stat. at 4661).
56. *Id.* § 655(a) (as added by the Act, *supra* note 1, § 901(a), 102 Stat. at 4661).
57. *Id.* § 655(b) (as added by the Act, *supra* note 1, § 901(a), 102 Stat. at 4661).
58. *Id.*
59. *Id.* § 655(c) (as added by the Act, *supra* note 1, § 901(a), 102 Stat. at 4662).
60. *Id.* The parties may also stipulate to admissibility of these matters. *Id.*

The fact of arbitration and the nature of the award may, in fact, be inadmissible at trial.[61] However, as to everything said in arbitration testimony or placed into evidence, the key question is whether Rule 408 of the Federal Rules of Evidence[62] applies. It is unlikely that arbitration would be considered a "compromise negotiation."[63] Perhaps this is why Vermont Rule of Evidence 408 has been amended to specifically include mediation: "Evidence of conduct or statements made in compromise negotiations, including mediation, is likewise not admissible...."[64]

Because it appears that Rule 408 will be inapplicable to the arbitration, testimony and documents introduced at the hearing, classified as "not hearsay" under the Federal Rules of Evidence,[65] will be admissible as substantive evidence at the trial *de novo*. To paraphrase what Mr. Miranda should have been told, "anything you say at the arbitration may be used against you at trial."[66]

The second category of risks in seeking a trial *de novo* are financial. Seeking a trial *de novo* creates the risk of being charged with your opponent's arbitration costs should one lose the trial *de novo*.[67] Furthermore, the court can require the party seeking a trial *de novo* to post

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61. *Cf.* State of Missouri ex rel. State Highway Comm'n v. Meadows, 444 S.W.2d 225, 226 (Mo. App. 1969) (nature of award in a condemnation proceeding before county commissioners inadmissible at the trial *de novo*).

62. Rule 408 reads in relevant part:

> Evidence of (1) furnishing or offering or promising to furnish, or (2) accepting or offering or promising to accept, a valuable consideration in compromising or attempting to compromise a claim which was disputed as to either validity or amount, is not admissible to prove liability for or invalidity of the claim or its amount. Evidence of conduct or statements made in compromise negotiations is likewise not admissible.

FED. R. EVID. 408.

63. *See* Hansell v. Farmers' Mut. Hail Ins. Ass'n of Iowa, 209 Iowa 378, 383, 228 N.W. 88, 90 (1929).

64. VT. R. EVID. 408 (1985). As the Reporter's Notes to the 1985 Vermont Amendment state: "The language is broad enough to cover statements made by the mediator as well as statements of the parties. Prohibiting the use of statements made during mediation should aid the openness and effectiveness of the process." *Id.*

65. FED. R. EVID. 801(d); *see* United States v. Smith, 776 F.2d 892, 897 (10th Cir. 1985) (testimony from prior trial of same matter not hearsay); United States v. Russell, 712 F.2d 1256, 1258 (8th Cir. 1983) (prior testimony before grand jury is not hearsay); State ex rel. City of Warrensburg v. Stroh, 690 S.W.2d 215, 216-17 (Mo. App. 1985) (admissions against interest at condemnation hearing before county commissioners admissible at trial *de novo*).

66. One must also be careful of how the award is drafted. A convincing argument can be made that any recitals in the award which are not objected to, or worse, which are agreed to, are admissible in a subsequent trial as admissions against interest. *Cf.* C.I.T. Corp. v. Waltrip, 70 S.W.2d 206, 206 (Tex. Civ. App. 1934) (writ dismissed without judgment); Cauble v. Cauble, 2 S.W.2d 967, 969-70 (Tex. Civ. App. 1927) (writ dismissed without judgment); Wootton v. Jones, 286 S.W. 680, 685 (Tex. Civ. App. 1926) (recitals in prior judgments).

67. 28 U.S.C. § 655(d)(1)(A) (1989) (as added by the Act, *supra* note 1, § 901(a), 102 Stat. at 4661).

a bond equal to those arbitration costs.[68] Even more costly, section 655(e) provides that the court may impose costs and reasonable attorneys' fees against the party demanding a trial *de novo* if the party who sought the trial *de novo* wins, but fails to win an award which is "substantially more favorable" than the arbitration award[69] and if that party's conduct in seeking a trial *de novo* was in "bad faith."[70]

IV. MISCELLANEOUS PROVISIONS

This section discusses a number of technical changes made by the Act. Title II modifies the federal courts' diversity citizenship jurisdiction. Title V modifies the jurisdiction of the Federal Circuit Court of Appeals. Title X, entitled "Miscellaneous Provisions," contains several important amendments for the intellectual property practitioner, including: section 1001 abolishing divisional venue in civil cases; section 1016 setting out various amendments to removal procedure from state court to federal court; and section 1020 making technical amendments to 28 U.S.C. § 1338 and other federal jurisdictional statutes applicable to patent, trademark and copyright actions.

A. Changes in Diversity Jurisdiction

Title II of the Act is entitled "Federal Jurisdiction—Diversity Reform" and contains three sections. The first, section 201(a), increases the "amount in controversy" requirement in diversity cases from $10,000 to $50,000.[71] New subsection 1332(c)(2), added by section 202 of the Act, deems a legal representative of a decedent, infant or incompetent to be a citizen of the same state as the person who is represented.[72] Finally, section 203 of the Act amends 28 U.S.C. § 1332(a) by clarifying that for purposes of diversity jurisdiction, interpleader and removal, a permanent resident alien is deemed a citizen of the state in which he or she is domiciled.[73] In all cases, the changes in diversity jurisdiction made by Title II were effective on May 16, 1989.[74]

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68. *Id.* § 655(d)(1)(B) (as added by the Act, *supra* note 1, § 901(a), 102 Stat. at 4661).

69. *Compare id. with* FED. R. CIV. P. 68.

70. 28 U.S.C. § 655(e) (1989) (as added by the Act, *supra* note 1, § 901(a), 102 Stat. at 4662).

71. *See id.* § 1332(a) & (b) (as amended by the Act, *supra* note 1, § 201(a), 102 Stat. at 4646). It is interesting to note that the jurisdictional amount for diversity cases had not increased since 1958, and when adjusting for inflation, $10,000 in 1958 is equivalent to $37,921 in 1986. Thus, in real terms, the jurisdictional amount is not much higher than in 1958. *See Subcommittee Hearings, supra* note 2, at 1111.

72. 28 U.S.C. § 1332(c)(2) (1989) (as amended by the Act, *supra* note 1, § 202, 102 Stat. at 4646).

73. *Id.* § 1332(a) (as amended by the Act, *supra* note 1, § 203, 102 Stat. at 4646).

74. *See* the Act, *supra* note 1, § 203(b), 102 Stat. at 4646.

B. Jurisdiction of the Federal Circuit

The Act has expanded the jurisdiction of the United States Court of Appeals for the Federal Circuit in a way which will, however, only indirectly affect intellectual property practitioners.[75] This new provision grants the Court of Appeals for the Federal Circuit exclusive jurisdiction over appeals from interlocutory orders of district and territorial courts which grant or deny, in whole or in part, a motion to transfer an action to the United States Claims Court.[76] As with any increase in the Federal Circuit's case load, this amendment may tend to increase the time within which appeals in patent cases are processed.

C. Divisional Venue

Previously section 1393 of the Judicial Code provided that when one sued a resident of the particular division within a federal district, that defendant had to be sued in the particular division in which the defendant resided. The divisional venue section read as follows:

> **§ 1393. Divisions; Single Defendant; Defendants in Different Divisions.**
>
> (a) except as otherwise provided, any civil action, not of a local nature, against a single defendant in a district containing more than one division must be brought in the division where he resides.
>
> (b) any such action, against defendants residing in different divisions of the same district or different districts in the same state, may be brought in any of such divisions.[77]

Section 1001 of the Act repeals section 1393 in its entirety,[78] effective February 17, 1989.[79] The abolition of divisional venue is significant in a state such as Texas which has seven divisions in each of its four federal districts.[80] The abolition of divisional venue will facilitate the practices, be they pernicious or salutary,[81] of judge and forum "shopping." Regardless of what one calls it, "shopping" is an important aspect of properly representing a client.[82] It may be that a particular judge has

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75. Title V of the Act amended 28 U.S.C. § 1292(d) adding new subparagraph (4)(a). *See* the Act, *supra* note 1, § 501, 102 Stat. at 4652.

76. 28 U.S.C. § 1292(d)(4) (1989) (as added by the Act, *supra* note 1, § 501, 102 Stat. 4652).

77. 28 U.S.C. § 1393 (1976).

78. *See* the Act, *supra* note 1, § 1001(a), 102 Stat. at 4664.

79. *Id.*

80. *See* 28 U.S.C. § 124 (1989).

81. This depends on whether your audience consists of judges or trial lawyers.

82. *See generally* C. WRIGHT, A. MILLER & E. COOPER, *supra* note 30, § 3823, at 225 (choice of forum is thought particularly important in patent cases and forum shopping is thus regarded as critical).

expertise in intellectual property cases, yet he or she is located in a division within the district where the defendant does not "reside." Or perhaps the venire in one division is more "liberal," "conservative" or "sophisticated." Even docket conditions can vary greatly from division to division within the same district.

Using the Northern District of Texas as an example, if one wanted to sue a company headquartered in Dallas, one can now bring the action not only in Dallas, but in Fort Worth, Lubbock, Amarillo, Abilene, San Angelo or Wichita Falls.[83] Abolition of divisional venue therefore opens numerous new fora which were otherwise closed for a particular case.[84]

D. Removal Procedures

1. *GENERAL REQUIREMENTS*

Section 1016 of the Act makes several "improvements" in removal procedure. Section 1016(a) adds a new sentence to 28 U.S.C. § 1441(a), instructing that for purposes of removal, citizenship of defendants sued "under fictitious names" are to be ignored.[85] This is a congressional reversal of *Bryant v. Ford Motor Co.*[86] Section 1016(b) changes the name of the document which effects removal. The old "Petition for Removal" has been replaced with a "Notice of Removal." Another formal requirement, that of verifying the Petition (now Notice) of Removal, has been eliminated, although the Notice is subject to Rule 11 of the Federal Rules of Civil Procedure.[87] Also, a removal bond is no longer required.[88]

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83. 28 U.S.C. § 124(a)(1) (1989). Of course, the action could be transferred from any division to any other division. *See id.* §§ 1404(a) & (b); Williams v. Hoyt, 556 F.2d 1336, 1341 (5th Cir. 1977), *cert. denied*, 435 U.S. 946 (1978). It must be remembered, however, that under section 1404, plaintiff's forum choice is almost always honored. *See* C. WRIGHT, A. MILLER & E. COOPER, *supra* note 30, § 3848, at 239. And, many of the section 1404(a) factors simply will not be as compelling in a situation where the transfer is sought to a courthouse within the district rather than across several states or cross-country.

84. Prior to this amendment, two federal district courts had held that patent cases were not subject to section 1393 anyway. *See* Clopay Corp. v. Newell Cos., 527 F. Supp. 733, 741 (D. Del. 1981); Technograph Printed Circuits v. Packard Bell Elecs., 290 F. Supp. 308, 323-24 (S.D. Cal. 1968). The repeal of section 1393, however, certainly allows this practice, obviating the need to rely on two, somewhat dated, district court holdings; these are not the most substantial grounds on which to operate.

85. 28 U.S.C. § 1441(a) (1989) (as amended by th Act, *supra* note 1, § 1016(a), 102 Stat. at 4669). The fictitious defendant provision became effective on the date of the President's signature, November 19, 1988, but has been found to be retroactive in application. *See* Kruso v. Int'l Tel. and Tel. Corp., 872 F.2d 1416, 1425 (9th Cir. 1989).

86. 844 F.2d 602 (9th Cir. 1987) (en banc), *cert. denied*, ___ U.S. ___, 110 S. Ct. 1126 (1990).

87. 28 U.S.C. § 1446(a) (1989) (as amended by the Act, *supra* note 1, § 1016(b), 102 Stat. at 4669).

88. *Id.* § 1446 (as amended by the Act, *supra* note 1, § 1016(b)(3), 102 Stat. at 4669).

Section 1016 of the Act also imposes additional time limitations on removal and remand. These changes present some interesting questions, and have already divided the courts.

2. *REMOVAL TIME*

Section 1016 of the Act imposes new and additional time limitations on removals. Under prior law, a case could be removed from state court at virtually *any* time, if the case were removed within 30 days after first becoming removable[89]—even if the case first became removable *years* after it was filed.[90] Section 1446(b) as amended now contains a "statute of limitations" for removal, but for diversity actions only.[91] Section 1446(b) now provides that a diversity action may not be removed more than one year after the action is commenced.[92]

3. *REMAND TIME*

Another significant procedural change made by section 1016(c) of the Act was amending section 1447(c) to limit the time within which certain Motions to Remand can be filed. As amended, section 1447(c) now provides that a motion to remand based on "any defect in removal procedure" must be made within 30 days after the filing of the Notice of Removal.[93]

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89. Depending upon when the case first becomes removable, 30 days is not *always* allowed for removal. In fact, in one case, waiver of the right to remove was found where the defendant waited 15 minutes to one hour to file a removal petition after the non-diverse party was voluntarily dropped. *See* Walker v. AT&T Co., 684 F. Supp. 475, 477 (S.D. Tex. 1988).

90. For instance, if the only non-diverse party is dropped by the plaintiff, thus creating diversity jurisdiction, the case could be removed at that time. 28 U.S.C. § 1446(b) (1989) (as amended by the Act, *supra* note 1, § 1016(b)(3), 102 Stat. at 4669). Of course, the dropping of the non-diverse party must be the voluntary act of the plaintiff, or diversity jurisdiction still will not attach. *See, e.g.*, Whitcomb v. Smithson, 175 U.S. 635 (1900); DeBry v. Transamerica Corp., 601 F.2d 480, 486 (10th Cir. 1979); Weems v. Louis Dreyfus Corp., 380 F.2d 545 (5th Cir. 1967); Todd Holding Co., Inc. v. Super Valu Stores, Inc., 744 F. Supp. 1025 (D. Colo. 1990); Walker v. AT&T Co., 684 F. Supp. 475 (S.D. Tex. 1988); Higgens v. Pittsburgh-Des Moines Co., 635 F. Supp. 1182 (S.D. Tex. 1986).

91. The retroactivity of the one-year limitation has been the subject of a great deal of judicial exploration, with varying results depending upon the precise posture of the action at the time of the Act's passage. *See* Wilson v. Gen. Motors Corp., 888 F.2d 779, 781-82 (11th Cir. 1989) (and cases cited therein).

92. 28 U.S.C. § 1446(b) (1989) (as amended by the Act, *supra* note 1, § 1016(b)(2)(B), 102 Stat. at 4669). For the purposes of determining when the one-year removal limitation period begins, the fact that other defendants are added later on in the case is irrelevant. The one-year period begins when the action was filed against the initial defendant. *See* Royer v. Harris Well Serv., Inc., 741 F. Supp. 1247 (M.D. La. 1990).

93. 28 U.S.C. § 1447(c) (1989) (as amended by the Act, *supra* note 1, § 1016(c)(1), 102 Stat. at 4670).

An interesting question which has arisen under the new 30-day limitation on motions to remand involves whether, in light of the amendment, a court retains the power (after the 30-day period has expired) to remand a case *sua sponte* for defects in removal procedure. The resolution to this question pits the Third Circuit against the Northern District of Texas.[94]

It appears that because of the first sentence of section 1447(c), courts addressing the issue have fixated on the question of whether a *sua sponte* remand is, or is not, equivalent to a "motion" to remand, albeit the court's own "motion." The Third Circuit treated the two as substantially similar and held that after the 30 day limit, the court had no power to remand the case because of removal defects. The Northern District of Texas held the opposite way. Yet, this whole discussion of whether a "motion" is at issue seems to miss the point. The focus should *not* be on the first sentence of section 1447(c):

> A motion to remand the case on the basis of any defect in removal procedure must be made within 30 days after the filing of the notice of removal under section 1446(a);

but upon the *second* sentence, which states that:

> If at any time before final judgment it appears that the district court lacks subject matter jurisdiction, the case shall be remanded.

Given the present statutory scheme and the ruling case law,[95] the analysis must focus on whether there is a specific statutory *authorization* to remand a case. Certainly, one ground for removal could have been untimeliness. However, a removal is "untimely" *only* if the complaint is made within the statutorily authorized time to complain. After that time has past, the statute no longer authorizes remand on the basis of that defect. After that authorization has faded away, the only ground for remand (whether on motion or *sua sponte*) contemplated by section 1447(c) is lack of subject matter jurisdiction. Therefore, because the court *has jurisdiction* when only a procedural defect is at issue, a court cannot take it upon itself to remand the case.[96] This conclusion is bolstered by a recent Fifth Circuit decision which succinctly stated that a court may consider remand *only* if the parties raise the issue; conversely, a court

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94. *Compare* Air-Shields, Inc. v. Fullam, 891 F.2d 63, 65 (3rd Cir. 1989) (court may *not* remand *sua sponte* for removal defects more than 30 days after motion for removal), *with* FDIC v. Loyd, 744 F. Supp. 126, 135-36 (N.D. Tex. 1990) (court *may* remand *sua sponte* for removal defects).

95. *See, e.g.*, Thermtron Prods., Inc. v. Hermansdorfer, 423 U.S. 336 (1976).

96. This is closely akin to the famous *Thermtron* case, where the Supreme Court authorized mandamus to order a district court to vacate its order of remand which was based upon grounds for remand not authorized by statute, *i.e.* crowded docket conditions. *Id.*

must consider the existence of subject matter jurisdiction on its own motion.[97]

Therefore, the result reached by the Third Circuit in *Air-Shields* is the correct one; after the 30-day period for filing procedural remand motions, a court cannot remand a case to state court *sua sponte* for defects in removal procedure.

4. *THE INTERPLAY BETWEEN THE NEW TIME LIMITS*

Fascinating questions are presented when the new "statutes of limitations" on removal and remand collide. The problem situation is as follows: a defendant removes the case later than one year after it was filed, but the plaintiff fails to move to remand the case within the 30 day limit. The statutory question is, of course, whether removal outside of the one-year limit is a "procedural" defect. The few courts which have faced this situation have reached opposite results.

Without discussion, the District Court for the Northern District of California held that a plaintiff waives any complaint about a removal outside of the one-year limit if a motion to remand is not made within 30 days of the Notice of Removal.[98] The Eastern District of Wisconsin, after a thorough analysis, reached the same result.[99] The District Court for the Northern District of Illinois reached the opposite result. After doing its own analysis of the language of the statute and its legislative history, the Illinois court held that the one-year limitation is *jurisdictional* and is not waived by failure to move to remand within 30 days.[100]

The Illinois District Court opinion in *Foiles* appears to be incorrect. While the *Foiles* court is correct in pointing out that section 1446(b) states clearly and emphatically that a diversity case may not be removed after one year,[101] the significance of this language *vis-a-vis* a waiver argument is problematic. A statute of limitations, when pleaded and proven, completely extinguishes a cause of action on the merits. Yet even this draconian advantage may be waived by someone entitled to assert it. The Federal Rules of Civil Procedure even mention statutes of limitations specifically in Rule 8(c) as an affirmative defense which must be pleaded. Certainly, time limitations on removal should be entitled to no more sanctity than are statutes of limitations on the merits of claims.

Furthermore, the *Foiles* court's alternative—making the one-year limitation on removal *jurisdictional* and not subject to waiver—is wholly

97. Ziegler v. Champion Mortgage Co., 913 F.2d 228, 230 (5th Cir. 1990).
98. Gray v. Moore Business Forms, 711 F. Supp. 543 (N.D. Cal. 1989).
99. Leidolf v. Eli Lilly & Co., 728 F. Supp. 1383 (E.D. Wis. 1990).
100. Foiles v. Merrell Nat'l Laboratories, 730 F. Supp. 108 (N.D. Ill. 1989).
101. *Id.* at 110.

unjustified given that the similar 30-day limitation on removing any then removable action, which limitation is located in the same subsection of the statute (section 1446(b)), is clearly *non-jurisdictional* and subject to waiver.[102]

The *Foiles* court also ignored the fact that the one-year removal limitation was placed in section 1446, a section solely concerned with removal *procedure*. Although this "location" was noted, the court stated that "Congress is not required ... to write and amend its statutes with the kind of semantic exactitude valued by lawyers."[103] Perhaps if section 1446 were the *only* removal statute, the court would have a point. The court simply ignored that fact that if Congress indeed meant for the one-year removal limitation to be jurisdictional, the limitation would have been placed in section 1445 (non-removable actions), or at least in section 1441(a) (removability of diversity actions).[104]

The one-year limitation is not jurisdictional, and failure to move to remand a case based upon that defect is subject to waiver. The statutory scheme and the case law surrounding it does not jibe with any other construction.

5. *POST-REMOVAL JOINDER OF PENDENT PARTIES*

New subsection (e) to section 1447 was added by the Act, addressing certain joinders of parties after removal. Section 1447(e) deals with the rather complex jurisdictional situation where, after removal, the plaintiff seeks to join additional defendants whose joinder would have destroyed subject matter jurisdiction had the party been joined at the beginning. For the first time, Congress has taken an explicit position on the "pendent party" jurisdiction question,[105] at least in the removal context. Section 1447(e) provides that, in the post-removal pendent party situation, the court may deny joinder, or permit the joinder and remand the action to the state court.[106] Note that the statute does not permit

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102. *See, e.g.*, Wilson v. Gen. Motors Corp., 888 F.2d 779, 781-82 (11th Cir. 1989) (and cases cited therein); Fristoe v. Reynolds Metals Co., 615 F.2d 1209, 1212 (9th Cir. 1980); Woodlands II on the Creek Homeowners Ass'n v. City Sav. and Loan Ass'n, 703 F. Supp. 604, 607 (N.D. Tex. 1989) (and cases cited therein).

103. *Foiles*, 730 F. Supp. at 111.

104. 28 U.S.C. §§ 1441(a), 1445 (1988).

105. Although an in-depth examination of the complex field of pendent-party federal jurisdiction is beyond the scope of this Article, essential reading on this topic includes Finley v. United States, 490 U.S. 545 (1989), and Alumax Mill Prods. v. Congress Fin. Corp., 912 F.2d 996, 1005-07 (8th Cir. 1990).

106. 28 U.S.C. § 1447(e) (1989) (as added by the Act, *supra* note 1, § 1016(c)(1), 102 Stat. at 4670). Added section 1447(e) also provides that a post-joinder order of remand may require the payment of just costs and expenses, including attorneys' fees.

joinder of these "pendent parties" unless the case is then remanded to state court.[107]

E. Technical Amendments

The only technical amendments of even limited interest to the intellectual property practitioner are the insertion, into various copyright-related sections of the Judicial Code, of the terms "exclusive rights in mask works" and "mask works."[108]

V. CONCLUSION

The Judicial Improvements and Access to Justice Act contains several revolutionary changes in the legal environment in which intellectual property law is practiced. No more will the first several months and several thousands of dollars of a patent suit against a corporation be spent fighting over venue. Even after venue has been resolved, you may find yourself trying the case in front of an arbiter, rather than a federal judge. Divisional venue rules have also been abolished. Thus, if venue is proper in a federal district, suit may be brought in any division of that district. And, if your case is in state court (perhaps a common law unfair competition claim or a trade mark case), yet diversity jurisdiction exists, the Act makes changes in the procedures which must be followed to both remove and remand such a case. The Act also imposes new "statutes of limitations" before which certain removals and all remand motions must occur.

Simply put, it is essential for every practitioner to have a firm grasp on the Act, the most significant legislation relating to the federal courts in decades.

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107. *See, e.g.*, Righetti v. Shell Oil Co., 711 F. Supp. 531 (N.D. Cal. 1989).

108. *See* 28 U.S.C. § 1338 (as amended by the Act, *supra* note 1, § 1020(a)(4)(A), 102 Stat. 4671-72, by adding new subsection (c), which reads: "subsections (a) and (b) apply to exclusive rights in mask works under chapter 9 of title 17 to the same extent as such subsections apply to copyrights."). The section heading for 28 U.S.C. § 1338 was also amended to include "mask works," as were sections 1295(a)(1) and 1400(a). *See* the Act, *supra* note 1. A new subsection (e) was also added to section 1448, which is identical to new section 1338(c). *Id.*

COMMENT

MOORE V. THE REGENTS OF THE UNIVERSITY OF CALIFORNIA: BALANCING THE NEED FOR BIOTECHNOLOGY INNOVATION AGAINST THE RIGHT OF INFORMED CONSENT

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I. INTRODUCTION

In just a few short years, advancements in the science of biotechnology[1] have made it possible to derive new medicines from human tissue. The potential profitability of these medicines has sparked great debate over whether the donors of these tissues must be informed that a commercial product may be developed using their cells and whether they have any right to compensation for such use.

The controversial case of *Moore v. The Regents of the University of California*[2] has become the focus of this debate. Unfortunately, the opinion of the California Court of Appeals was narrowly focused on the issue of whether or not the law should treat human body parts and other human tissue as a form of tangible personal property.[3] This narrow focus obscured the three crucial issues raised by the *Moore* case: 1) Should the scope of the doctrine of informed consent be modified to include the right to be informed of any potential use of one's excised tissue to create commercial products?; 2) Do individuals have the right to refuse to consent to the use of their bodily tissue in this manner?; and 3) Should persons whose tissues are used to create a commercially valuable product have the right to compensation for such use?

The California Supreme Court properly turned the focus of the *Moore* case to these issues when it held that although there was no cause of action for conversion of human tissue, Mr. Moore could maintain an action against his treating physician for lack of informed consent to the use of his tissue for biotechnical research.[4] This Comment will suggest,

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1. The term "biotechnology" has been defined to include "any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses." OFFICE OF TECHNOLOGY ASSESSMENT, COMMERCIAL BIOTECHONOLOGY: AN INTERNATIONAL ANALYSIS, U.S. CONG., PUB. NO. OTA-BA-218, at 3 (1984).

2. 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990), *reh'g denied*, Moore v. The Regents of the Univ. of California, No. S006987 (Cal. Supreme Ct. Aug. 30, 1990) (1990 CAL. LEXIS 3975, States library, Cal file). *See infra* Section III for a discussion of the facts and the procedural history of the case.

3. The Appellate Court merely held that Mr. Moore had adequately stated a cause of action for conversion and remanded to the trial court for consideration of the remaining causes of action. Moore v. The Regents of the Univ. of California, 215 Cal. App. 3d 709, 722, 249 Cal. Rptr. 494, 502 (1988), *rev'd*, 51 Cal. 3d 120, 128, 793 P.2d 479, 483, 271 Cal. Rptr. 146, 150 (1990).

4. *Moore*, 51 Cal. 3d at 147, 793 P.2d at 497, 271 Cal. Rptr. at 164.

however, that the court's holding provides only a partial resolution of these issues.

Section II will describe the technology underlying the science of biotechnology because understanding the technology is crucial to understanding the issues presented by the *Moore* case. Section III of this Comment will discuss the facts and the procedural history of the *Moore* case in order to illustrate how the case squarely presents these three issues. In addition, this section will suggest that many other cases will be affected by the outcome of *Moore*. Section IV will analyze various sources of "property" rights in the human body in order to demonstrate that there are several reasons why it is inappropriate to treat human body parts as tangible personal property, and to explain why the California Supreme Court expressly refused to do so. Section V will analyze the doctrine of informed consent and why the Supreme Court held that it applies to the *Moore* case. In addition, this section will demonstrate that further modifications of the doctrine of informed consent to medical treatment and of existing guidelines for informing research subjects of the risk and benefits of research that is conducted on them are needed in order to respond to the use of human tissue in biotechnology research and product development. Finally, Section VI will briefly address the complicated issue of whether or not the initial source of the tissue should receive compensation for the use of that tissue.

II. THE TECHNOLOGY

The science of biotechnology encompasses several new and different scientific technologies that enable researchers to solve the mysteries of our genetic make-up, and develop novel new drugs which have the potential to benefit many people.[5] As with other developments in technology,[6] biotechnology has created new legal, public policy, and ethical dilemmas which can only be solved satisfactorily if one understands the underlying techniques used in biotechnology research, and is familiar with the various types of human tissue which are used in such research.[7]

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5. For a general discussion of the state of the biotechnology industry, see OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 1, at 119-253.

6. For example, the legal issues surrounding the use of fetal tissue in research can also only be understood if the underlying technology is first explained. *See* Terry, *Politics and Privacy: Redefining the Ethical and Legal Issues in Fetal Tissue Transplantation*, 66 WASH. U.L.Q. 523 (1988).

7. The types of tissue that are used in various forms of biotechnology research are important because any new rights or remedies created to deal with the issues raised by the *Moore* case must be integrated with an already complex system for the regulation of the use of human tissue or organs in research or medical treatment. *See infra* Section VI.

There are three main types of technologies that are employed in the science of biotechnology.[8] The first, and most basic, is cell culture technology.[9] Most established cell cultures are derived from cancerous tissue samples.[10] Developing immortal human cell cultures is a difficult and time consuming process. Still, scientists do not fully understand why any particular culture is successful.[11] These cell cultures are essential in many types of commercial and non-commercial research. For example, they can be used as a "biological factory to produce large or small quantities of a substance," or to test the toxicity of various compounds.[12] It is the patenting of such a cell culture that is at issue in the *Moore* case.[13]

The second technique is known as hybridoma technology. As the name suggests, hybridomas are cells that are created by the fusion of two different types of cells, usually a tumor cell and a cell that is an efficient producer of certain antibodies.[14] Hybridomas are used to produce individual antibodies in a greater quantity than possible by other means.[15] The results of the hybridoma process are more commonly known as monoclonal antibodies.[16]

The third type of technology is known as recombinant DNA technology.[17] This is perhaps the most dramatic of these techniques, because it usually involves the direct manipulation of the genetic material

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8. OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS, U.S. CONG., PUB. NO. OTA-BA-337, at 31 (1987) [hereinafter OWNERSHIP OF HUMAN TISSUES AND CELLS].

9. A cell culture is defined as a continuous culture of cells that can survive in a laboratory, independent of the source of the cells, for an indefinite period of time. *Id.* at 31-35. Hence, they are referred to as "immortal."

10. *Id.* at 33.

11. *Id.* at 32-34.

12. *Id.* at 35.

13. An examination of the patent granted for the "Mo cell-line" shows both the efforts that were expended to establish the cell-line, and the unique properties of the cell-line. Moore v. The Regents of the Univ. of California, 215 Cal. App. 3d 709, 754-68; 249 Cal. Rptr. 494, 516-30 (1988) (U.S. Patent No. 4,438,032 reproduced in Appendix A), *rev'd*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990).

14. A tumor cell is usually fused with a B lymphocyte that has been isolated from spleen or lymph node tissue. The B lymphocyte is a specialized type of white blood cell that secretes one specific kind of antibody in response to the presence of a specific foreign substance. When the B lymphocyte is fused with the immortal tumor cells, the resulting hybridoma is capable of continuously producing the beneficial antibody proteins. OWNERSHIP OF HUMAN TISSUES AND CELLS, *supra* note 8, at 37-38.

15. E. ANTEBI & D. FISHLOCK, BIOTECHNOLOGY STRATEGIES FOR LIFE 74 (1986).

16. For a detailed discussion of the development of monoclonal antibodies and related subjects, see *id.*, ch. 6.

17. In 1953, Francis Crick, James Watson and Maurice Wilkens discovered the double helix structure of the DNA (deoxyribonucleic acid). DNA contains the genetic code for all living creatures and is comprised solely of combinations of a four letter chemical "alphabet." For a detailed description, see E. ANTEBI & D. FISHLOCK, *supra* note 15, at 43.

(the DNA) of the cell.[18] Recombinant DNA technology uses a variety of techniques to isolate a single piece of DNA and insert it into a rapidly growing cell, thereby creating large amounts of that DNA segment of interest.[19]

Currently, the human tissue needed for the various types of biotechnology research is derived from a number of different sources. Patients receiving medical treatment are a common source of tissue. This tissue may be removed incident to medical treatment, or solely for research purposes.[20] In addtion, replenishing tissue and other bodily fluids may be obtained from healthy individuals according to accepted research principles.[21] Finally, of course, cadavers are the only possible source of tissue from many organs, both healthy and diseased.[22]

This brief discussion of the science of biotechnology illustrates several important factors that must be kept in mind when determining what judicial and legislative action should be taken to regulate the use of human tissue in biotechnology research. First, it takes an enormous skilled effort on the part of the researchers, as well as a certain amount of luck, to produce a successful commercial product. A significant amount of research is done on tissue that has no particular commercial value.[23] Second, unlike the *Moore* case, it is common for a successful product to be developed from multiple sources of tissue.[24] Third, since the tissue needed for biotechnology research comes from many types of sources, any permanent solution to the issues posed by the *Moore* case must be integrated with existing statutory schemes to regulate the sale of blood, procurement of organs for transplant, research protocols, etc.[25] For example, society must decide if it is desirable to allow the sale of organs for biotechnology research but not for transplant. Finally, it must be remembered that patients undergoing treatment for cancer are a crucial source of tissue for biotechnology research.[26] What rights do they have to be informed of the uses to which their excised tissue is put, and do they have any right to compensation for its use?

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18. OWNERSHIP OF HUMAN TISSUES AND CELLS, *supra* note 8, at 41.
19. *Id.* at 41-44.
20. *Id.* at 51. As suggested above, the cells from cancer patients are an indispensable source of tissue.
21. *Id.* For a discussion of the limits of current research guidelines, see *infra* Section V, Part B.
22. OWNERSHIP OF HUMAN TISSUES AND CELLS, *supra* note 8, at 51.
23. *Id.* at 55.
24. *Id.*
25. *See infra* Section VI.
26. *See infra* Sections V and VI.

III. DISPUTES OVER THE OWNERSHIP OF CELL-LINES

As long as there is the potential for economic profit from genetically engineered cell-lines, there will be lawsuits over the right to profit from those cell-lines. Although the *Moore* case was the first to go to trial, it was not the first dispute over the ownership of cell-lines. Nor is it likely to be the last. At least one lawsuit has been on hold awaiting the ruling of the California Supreme Court.[27]

A. Cases Prior to *Moore*

Prior to *Moore*, there were at least three other reported disputes over the ownership of cell-lines that were all settled out of court.

The first two disputes did not involve the actual tissue donors. In the first case, a researcher at Stanford University claimed the ownership of a cell-line which he created.[28] The case was settled without resolving the ownership of the cell-line.[29]

The second dispute arose between the University of California and the pharmaceutical company of Hoffman-LaRoche. The dispute was over the use of a cell-line developed by researchers at UCLA Medical Center, which was subsequently used by Genentech (under contract to Hoffman-LaRoche) to isolate large quantities of the interferon gene.[30] In 1983, this dispute was also settled out of court.[31]

Prior to *Moore*, there was at least one case where a claim to the ownership of a patented cell-line was based on the tangible contribution of human tissue from which the cell-line was developed. This case also involved the development of a patented cell line by researchers at the University of California. In 1981, Dr. Hagiwara suggested that researchers at the University of California, San Diego use the lymph cells of his mother, who was being treated for cervical cancer.[32] Mrs. Hagiwara's cells were used to develop a hybridoma cell-line that secreted

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27. Following the Appellate Court's reinstatement of Mr. Moore's suit, a woman named Gina Potts filed a complaint in Superior Court for Santa Clara County alleging that Genentech, Inc., The Regents of the University of California, her doctors and her hospital used her blood and placenta without her consent in the development of the drug TPA (tissue plasminogen activator). Complaint, Potts v. Genentech, Inc., (Cal. Sup. Ct., County of Santa Clara, filed Nov. 1, 1988) (No. 670331). This complaint was filed but not formally served on the defendants. The parties were awaiting the ruling of the California Supreme Court on the *Moore* case before taking further action. Interview with Gary H. Ritchey, Esq., Cooley Godward Castro Huddleson & Tatum, Palo Alto, California (Apr. 16, 1990).

28. OWNERSHIP OF HUMAN TISSUES AND CELLS, *supra* note 8, at 25.

29. *Id.*

30. *Id.*

31. *Id.* at 26.

32. *Id.*

anti-tumor antibodies.[33] In a subsequent dispute, the Hagiwaras asserted tangible personal property rights in the cell line. In 1983, the Hagiwaras and the University reached a settlement whereby the University retained all patent rights and the Hagiwaras were given an exclusive license to exploit the patent in Asia.[34] The dispute between the University of California and the Hagiwaras serves to illustrate that the dispute over the rights to a human cell-line in the *Moore* case is not unique and can be expected to arise again as the development of genetically engineered pharmaceuticals increases.

B. Facts and Procedural History of *Moore*

In 1976, John Moore was referred to the UCLA Medical Center for treatment of a relatively rare form of blood cancer known as hairy cell leukemia.[35] At the Medical Center he was seen by Dr. Golde, who recommended that Mr. Moore's spleen be removed. This was the only known treatment for the disorder.[36] Mr. Moore signed a standard surgical consent form for the therapeutic procedure. This consent form did not include any mention of research being performed on the excised tissue.[37] However, Mr. Moore's third amended complaint alleged that Dr. Golde noted in his medical record, before the surgery, "his desire to have a portion of plaintiff's fresh spleen placed in a sterile container and removed from the operating room for his independent research purposes."[38]

Apparently, the operation was a success and Mr. Moore's condition "stabilized."[39] Over the next seven years, Mr. Moore traveled to the UCLA Medical Center from his home in Seattle approximately twelve times for follow-up visits.[40] During each visit, blood samples were

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33. *Id.* It is important to note that, unlike the cell-line in the *Moore* case, hybridoma cell-lines are always created from cells from more than one donor. This makes it much harder for a plaintiff to prove that his or her tissue was the source of the cell-line. In fact, it is usually the case that the cells in a commercially valuable cell-line were obtained from multiple donors. *See infra* Section III.

34. *Id.* at 26.

35. *The Use of Human Biological Materials in the Development of Biomedical Products: Hearings Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 99th Cong., 1st Sess. 241 (1985) (statement of John Moore) [hereinafter *Hearings*].

36. *Id.* At the time of the surgery, Mr. Moore's spleen weighed approximately 22 pounds whereas a normal spleen weighs around half of a pound.

37. *Id.* Exhibit A at 267.

38. Third Amended Complaint, Moore v. The Regents of the University of California, (Cal. Sup. Ct., County of Los Angeles, filed in 1984) (No. 513755). [hereinafter Third Amended Complaint].

39. *Hearings, supra* note 35, at 241.

40. *Id.*

obtained. Mr. Moore claims that when he asked if he could have the blood samples taken in Seattle and sent to Dr. Golde (in order to save money), Dr. Golde said that would not be a good idea and that he would be able to find grant money to pay Mr. Moore's expenses.[41]

In September of 1983, during one of these follow up visits, Mr. Moore was asked to sign a form consenting to the use of his blood for research purposes.[42] The consent form included a portion where the individual was to circle either "I do", or "I do not" "voluntarily grant to the University of California any and all rights I, or my heirs, may have in any cell-line or any other potential product which might be developed from the blood and/or bone marrow obtained from me."[43]

Mr. Moore has testified before the House of Representatives Subcommittee on Science and Technology that, during this visit, he formed the impression that he was being given "vague" and "patronizing" answers to his questions about whether there were any ongoing efforts to commercialize his tissue. Mr. Moore claims that this treatment led him to circle the "I do not consent" option on the consent form.[44] Mr. Moore has stated that, after he left UCLA Medical Center, Dr. Golde and his secretary made repeated efforts to get him to re-sign the consent form "correctly" and that this fact finally caused him to see an attorney who commenced the investigation which lead to the filing of the current lawsuit.[45]

On March 20, 1984, Dr. Golde and his researcher, Shirley Quan, received a patent for the "Mo cell-line"; this cell-line was developed solely from Mr. Moore's tissue.[46] The patent was assigned to the University of California.[47] The University and Dr. Golde also entered into agreements with Genetics Institute and Sandoz Pharmaceutical to develop commercial products from the Mo cell-line.[48] As of the date of the patent, nine potential products had been developed from the Mo cell-line.[49]

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41. *Id.*

42. Mr. Moore did sign an identical consent form on an earlier visit in April of 1983. *Id.*

43. Moore v. The Regents of the Univ. of California, 215 Cal. App. 3d 709, 769, 249 Cal. Rptr. 494, 531 (1988) (quoting from a copy of the consent form reproduced in Appendix B of the opinion), *rev'd*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990).

44. *Hearings, supra* note 35, at 242.

45. *Id.* at 242-43.

46. *Moore*, 215 Cal. App. 3d at 757, 249 Cal. Rptr. at 519 (U.S. Patent No. 4,438,032 reproduced in Appendix A).

47. *Id.* at 755, 249 Cal. Rptr. at 517.

48. *Hearings, supra* note 35, at 243-44.

49. *Moore*, 215 Cal. App. 3d at 762, 249 Cal. Rptr. at 524.

The complaint alleges that, in addition to the payment of fees to the University, part of which were used to pay Dr. Golde's salary, Dr. Golde received options to acquire 75,000 shares of Genetics Institute stock for a total of $750 in exchange for his consulting services.[50]

In 1984, Mr. Moore filed a Third Amended Complaint in Superior Court for the County of Los Angeles, alleging causes of action for conversion, lack of informed consent, breach of a quasi-contract, breach of the implied covenant of good faith and fair dealing, intentional infliction of emotional distress, negligent misrepresentation, interference with prospective advantageous economic relationships, and slander of title, and requesting an accounting and declaratory relief.[51]

The first trial court to hear a motion to dismiss sustained the joint demurrers of the Regents, Dr. Golde and Ms. Quan on the first cause of action for conversion.[52] In addition, the court held that, because the first cause of action was incorporated into the remaining causes of action, the demurrers to the remaining causes of action were sustained as well.[53]

The court gave four reasons for its ruling. First, that the complaint failed to allege that Mr. Moore did not know or have reason to know that any tissue removed incident to treatment at UCLA Medical Center might be used for research.[54] Second, that the complaint failed to allege that the defendants knew of the potential commercial value of Mr. Moore's cells and "had formed the intent to commercially exploit such substances" prior to the surgery.[55] Third, that Mr. Moore failed to allege that he had consented only to the removal of his spleen for therapeutic purposes.[56] Fourth, that Mr. Moore had failed to attach either a copy of the consent form for the splenectomy or the September 1983 consent form as exhibits to the complaint.[57]

The Court of Appeals reversed the trial court and held that the demurrer to the conversion cause of action had been improperly

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50. Third Amended Complaint, *supra* note 38. The value of this stock has been estimated to be approximately two million dollars.

51. *Id.*

52. Note that the second trial court later sustained the demurrers of Genetics Institute and Sandoz under a similar rationale. *Moore*, 215 Cal. App. 3d at 720-21, 249 Cal. Rptr. at 501.

53. *Id.* at 720, 249 Cal. Rptr. at 501.

54. *Id.*

55. *Id.* Note that paragraphs 8 through 15 of the complaint do allege that the defendants were in a position to recognize the unique properties of Mr. Moore's cells during pre-operative testing, that such testing did take place and that, prior to surgery, the defendants arranged to obtain a portion of Mr. Moore's spleen without his consent. *See* Third Amended Complaint, *supra* note 38.

56. *Moore*, 215 Cal. App. 3d at 720, 249 Cal. Rptr. at 501.

57. *Id.* The majority of the Appellate Court held that there is no authority requiring documents be attached to a complaint. *Id.* at 736, 249 Cal. Rptr. at 512.

sustained and that Mr. Moore had properly stated a cause of action for conversion.[58] In support of its holding, the court stated that:

> The rights of dominion over one's body, and the interests one has therein, are recognized in many cases. These rights and interests are so akin to property interest that it would be subterfuge to call them anything else.[59]

The California Supreme Court granted review of the case.[60] The Supreme Court subsequently held that "the allegations of Moore's third amended complaint state a cause of action for breach of fiduciary duty or lack of informed consent, but not conversion."[61]

Until this ruling, the debate engendered by the *Moore* case had concentrated on the issue of whether Mr. Moore could state a cause of action for the conversion of human tissue. The opinion of the Supreme Court demonstrates, however, that the fundamental issue in the *Moore* case is whether a person has the right to be informed of how tissues that are removed from his or her body will be used and disposed of.

IV. PROPERTY RIGHTS IN THE HUMAN BODY

A. Intangible Property Rights in Human Tissue

The patent in the Mo cell-line is an intangible property right.[62] In *Diamond v. Chakrabarty*, the United State Supreme Court for the first time held that certain living cells that met the standard of novelty, unobviousness and usefulness qualified for patent protection.[63]

It is important to realize that patent rights are only available to the inventor who reduces his idea to practice.[64] "Products of nature," no matter how exceptional, cannot be the subject of patent protection.[65] Thus, patent protection is not available for human tissue in its unaltered form, and the fact that patent protection has been granted to the inventor of a cell-line (or other genetically engineered substance) has no bearing on what rights the source of the original tissue may possess in that tissue.[66]

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58. *Id.* at 722, 249 Cal. Rptr. at 502.
59. *Id.* at 725, 249 Cal. Rptr. at 505.
60. 252 Cal. Rptr. 816, 763 P.2d 479 (1988).
61. Moore v. The Regents of the Univ. of California, 51 Cal. 3d 120, 147, 793 P.2d 479, 497, 271 Cal. Rptr. 146, 164.
62. Intangible assets such as patents are defined as "property that is a right." BLACK'S LAW DICTIONARY 808 (6th ed. 1990).
63. 447 U.S. 303, 309-10 (1980). For an overview of the requirements for patenting biotechnology inventions see I. COOPER, BIOTECHNOLOGY AND THE LAW, ch. 2 (1985).
64. 35 U.S.C. § 102(g) (1988).
65. I. COOPER, *supra* note 63, § 3.02.
66. Wagner, *Human Tissue Research: Who Owns The Results?*, 3 COMPUTER & HIGH TECH. L. J. 233, 236 (1987).

B. Tangible Personal Property Rights

The California Court of Appeals faced a difficult task when it was forced to rely upon existing legal doctrine to rule on the novel questions presented by the *Moore* case.[67] It appears that one reason the Court turned to property law to define the rights and obligations of the parties in *Moore* is that few legal concepts are potentially as broad in their application as the concept of property.[68]

In keeping with a broad definition of property, the California Civil Code defines property in the following manner: "The ownership of a thing is the right of one or more persons to possess and use it to the exclusion of others. In this Code, the thing of which there may be ownership is called property."[69] In defining tangible personal property, the California Civil Code provides, "Every kind of property that is not real is personal."[70]

The Court of Appeals used both the common law concept of the expansive bundle of rights associated with property interests, as well as the all-encompassing definition of property contained in the California statutes, to support its holding that there is a tangible personal property right in human tissue.[71] The Appellate Court opinion makes clear that the underlying principle guiding the Court of Appeals is that human beings must have the right to control the disposition of their tissue and bodily parts. The court stated that: "A patient must have the ultimate power to control what becomes of his or her tissues. To hold otherwise would open the door to a massive invasion of human privacy and dignity in the name of medical progress."[72]

However, as will be discussed below, creating tangible personal property rights in human tissue will have legal consequences that go beyond merely granting individuals the right to exert dominion and control over their excised tissue.

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67. See *infra* Section V for a discussion of the problems encountered by the court when trying to apply the doctrine of informed consent in the context of the *Moore* case.

68. For example, the court noted that "As a matter of legal definition, 'property' refers not to a particular material object but to the right and interest or domination rightfully obtained over such object, with the unrestricted right to its use, enjoyment and disposition. In other words, [in] its strict legal sense ... 'property' is nothing more than a collection of rights." Moore v. The Regents of the Univ. of California, 215 Cal. App. 3d 709, 725, 249 Cal. Rptr. 494, 504 (1988) (citing 63A AM. JUR. 2D, *Property*, § 1, at 228 (1984)), *rev'd*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990).

69. CAL. CIV. CODE § 654 (West 1982). These general property statutes were enacted in 1872 and have not been amended since.

70. CAL. CIV. CODE § 663 (West 1982).

71. *Moore*, 215 Cal. App. 3d at 723-32, 249 Cal. Rptr. at 503-09.

72. *Id.* at 728, 249 Cal. Rptr. at 506.

1. *CONVERSION*

Conversion is defined as "any act of dominion wrongfully exercised over another's personal property in denial of or inconsistent with his rights therein."[73] It is interesting to note that, originally, intangible property rights could not be the subject of an action for conversion.[74] Currently, the law has developed to the point where intangible rights in a document (e.g. a check or stocks) can be the subject of a conversion.[75]

However, the expansion of the doctrine of conversion has never been extended to include all types of personal property. Courts have refused to find conversion of an intangible personal property right, such as an ordinary debt, the good will of a business, or an idea.[76] California courts have followed this general rule and limited the types of personal property that could be subject to a cause of action for conversion. For example, in *Olschewski v. Hudson*,[77] the court held that, while a list of customers was protectible property, it was not tangible personal property and could not be the subject of an action for conversion.[78] Likewise, Prosser and Keeton state that, although commentators have urged that conversion be expanded to apply to all types of property, both tangible and intangible, it is preferable to fashion other remedies to "protect people from having intangible values used and appropriated in unfair ways."[79]

The fundamental reason that conversion has not been extended to apply to intangible property is the harsh nature of the remedy for conversion. The rationale for protecting intellectual property rights is to encourage the development of new inventions, creations or commercial endeavors that will benefit society.[80] Hence, intangible property rights must balance the amount of protection needed to encourage innovation against the benefit to society of competition and of free access to the fruits of subsequent innovation.[81]

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73. W. PROSSER & W. KEETON, PROSSER AND KEATON ON TORTS § 15, at 92 (5th ed. 1971); *see also* CAL. CIV. CODE § 1712 (West 1989).

74. W. PROSSER & W. KEETON, *supra* note 73, § 15, at 91.

75. *Id.*

76. *Id.* at 92.

77. 87 Cal. App. 282, 262 P. 43 (1927).

78. *Id.* at 286, 262 P. at 45; *see also* Vuich v. Smith, 140 Cal. App. 453, 35 P.2d 365 (1934) (leasehold interest); Italiani v. Metro-Goldwyn-Mayer Corp., 45 Cal. App. 2d 464, 114 P.2d 370 (1941) (plagiarism of a literary composition is a separate tort and not the subject of a suit for conversion).

79. W. PROSSER & W. KEATON, *supra* note 73, at 92.

80. Bonito Boats, Inc. v. Thunder Craft Boats, 489 U.S. 141, 146 (1989).

81. A similar rationale is applied to determine the extent of patent and trademark protection. *See, e.g.*, Aro Mfg. Co. v. Convertible Top Replacement Co., 377 U.S. 476, 522

It will be demonstrated below that, because the statutes for conversion were designed solely to provide a remedy for another's taking of a personal possession,[82] conversion is not an appropriate cause of action for the wrongful use of human tissue in biotechnology research. This is due to the presence of important, competing public policy considerations in biotechnology research, such as encouraging beneficial technological innovation and protecting individual autonomy.[83] One example of this is found in the measure of damages for a conversion. The California Civil Code provides for the following damages:

> [F]irst—The value of the property at the time of the conversion ... or, an amount sufficient to indemnify the party injured for the loss which is the natural, reasonable and proximate result of the wrongful act complained of and which a proper degree of prudence on his part would not have averted; and
> Second—A fair compensation for the time and money properly expended in pursuit of the property.[84]

This statute would appear to limit a plaintiff like Moore's recovery to whatever he or she could establish was the value of the removed organ or tissue at the time of its removal.

However, while it is true that, as the dissenting opinion of the Appellate Court suggests,[85] there are serious difficulties inherent in attempting to determine what value to place on diseased tissue in its unaltered state, it is not the case that, under an action for conversion, a person would be limited to the provisions of California Civil Code section 3336. Section 3336 merely sets forth a *presumption* of damages. Both the dissent and the majority for the Appellate Court opinion in the *Moore* case failed to note that the California Civil Code also provides for the remedy of specific performance when tangible property is wrongfully taken and made into a new product.[86]

(1963) (Black, J., dissenting); *In re* Morton-Norwich Pro Inc., 671 F.2d 1332, 1341 (C.C.P.A. 1982).

82. *Olschewski*, 87 Cal. App. at 287, 262 P. at 45. While it is certainly the case that a person's tissue is not analogous to the good-will of a business or a trademark, it is true that there are ethical and public policy concerns implicated by the commercial use of human tissue that could not have been contemplated in 1872 by the drafters of California's statutes on conversion.

83. Note that this section of the analysis deals only with the appropriateness of applying the doctrine of conversion to human tissue. Whether their should be a right to control the disposition of one's tissue is dealt with in Section VI, *infra*, under the doctrine of informed consent.

84. CAL. CIV. CODE § 3336 (West 1982).

85. Moore v. Regents of the University of California, 215 Cal. App. 3d 709, 747-48, 249 Cal. Rptr. 494, 536-37 (1988) (George, J., dissenting), *rev'd*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990).

86. "In all cases where one whose material has been used without his knowledge, in order to form a product of a different description, can claim an interest in such product, he

More importantly, conversion is a strict liability tort.[87] In other words, "[t]he foundation for the action of conversion rests neither in the knowledge nor the intent of the defendant."[88] If the California Supreme Court were to have allowed an action for conversion in the *Moore* case, the practical implication of strict liability under California Civil Code section 1032 would have been that the ownership of the Mo cell-line (and all products derived therefrom) would revert to Mr. Moore.[89] In other words, the researcher, Ms. Quan, and the pharmaceutical companies would be strictly liable, along with the treating physician and the hospital, no matter what knowledge they actually possessed concerning how the original tissue sample was obtained.

It has been suggested that the doctrine of accession would also apply to the *Moore* case.[90] Under California law:

> If one makes a thing from materials belonging to another, the latter may claim the thing on reimbursing the value of the workmanship, unless the value of the workmanship exceeds the value of the materials, in which case the thing belongs to the maker, on reimbursing the value of the materials.[91]

However, Civil Code section 1028 is not applicable in a situation where the materials of another are willfully used without the owner's consent.[92] Therefore, accession would not be a remedy in the *Moore* case, because the tissue was knowingly used without Mr. Moore's consent.[93]

In other words, the application of tangible personal property law to the *Moore* case would not allow for any apportionment of the benefit among Moore (the owner of the tissue) and the researchers (in recognition of their contribution to value of the cell-line). This result would be directly contrary to the articulated policy of the Supreme Court of California to foster the creation of new prescription drugs. This policy

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has an option to demand either restitution of his material in kind, in the same quantity, weight, measure, and quality, or the value thereof; or where he is entitled to the product, the value thereof in place of the product." CAL. CIV. CODE § 1032 (West 1982).

87. Henderson v. Security Nat'l. Bank, 72 Cal. App. 3d 764, 770-71, 140 Cal. Rptr. 388, 391 (1977); *see generally* 5 WITKIN, SUMMARY OF CALIFORNIA LAW, § 624 (4th ed. 1988).

88. *Moore*, 215 Cal. App. 3d at 722, 249 Cal. Rptr. at 503 (quoting City of Los Angeles v. Superior Ct., 85 Cal. App. 3d 143, 149, 149 Cal. Rptr. 320 (1978)).

89. This is assuming that he succeeds in establishing that his tissue was taken without his consent, that there was no abandonment, etc.

90. Note, *Toward The Right Of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue*, 34 UCLA L. REV. 207, 253 (1986) (authored by Roy Hardiman) [hereinafter *Toward the Right of Commerciality*].

91. CAL. CIV. CODE § 1028 (West 1982).

92. "The foregoing sections of this Article are not applicable to cases in which one willfully uses the materials of another without his consent; but, in such cases, the product belongs to the owner of the material, if its identity can be traced." CAL. CIV. CODE § 1031 (West 1982).

93. *See supra* text accompanying note 38.

was articulated in the case of *Brown v. Superior Court*.[94] In *Brown*, the court reasoned that, because of the public interest in the "development, availability, and reasonable price of drugs," a drug manufacturer's liability for design defects should not be governed by a standard of strict liability.[95] Instead, the court held that the appropriate standard of liability is one of negligence, as is suggested in Comment k to section 402A of the Restatement (Second) of Torts.[96]

In its opinion in the *Moore* case, the California Supreme Court held that both the policy considerations underlying the holding in *Brown* and the difficulty of assessing damages, made it inappropriate for the courts to extend liability for conversion to include taking human tissue.[97] The court stated:

> Indeed, this is a far more compelling case for limiting the expansion of tort liability than *Brown*. In *Brown*, eliminating strict liability made it more difficult for plaintiffs to recover actual damages for serious physical injuries resulting from their mothers' prenatal use of the drug diethylstilbestrol (DES). In this case, by comparison, limiting the expansion of liability under a conversion theory will only make it more difficult for Moore to recover a highly theoretical windfall. Any injury to his right to make an informed decision remains actionable through the fiduciary-duty and informed-consent theories.[98]

2. *LIABILITY FOR PRODUCT DEFECTS*

An additional reason for refusing to treat human tissue as property is the fear that the source of the tissue could be liable for defects in the tissue that cause injury. This concern has led states to enact laws that provide that other biological materials are not property. For example, concern over the possibility of strict liability being imposed on the sources of blood used for transfusions and various blood products, as well as on the third-party blood banks and blood product companies, has

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94. 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988).

95. *Id.* at 1061, 751 P.2d at 477, 245 Cal. Rptr. at 418.

96. *Id.* In general, Comment k provides that drug manufacturers should not be held liable for a drug's side effects if they could not have known of the defect, under the existing scientific knowledge that was available at the time the drug was distributed. *Id.* at 1058-59, 751 P.2d at 475-76, 245 Cal. Rptr. at 416-17. For a comprehensive analysis of the *Brown* opinion, as well as its application to biotech drugs, see Traynor & Cunningham, *Emerging Product Liability Issues In Biotechnology*, 3 HIGH TECH. L.J. 149 (1988).

97. Moore v. The Regents of the Univ. of California, 51 Cal. 3d 129, 142-47, 793 P.2d 479, 493-97, 271 Cal. Rptr. 146, 160-64 (1990). The California Supreme Court stated that the legislature was best suited to decide whether users of cell lines should be liable for "failing to investigate the consensual pedigree of their raw materials...." *Id.* at 147, 793 P. 2d at 496, 271 Cal. Rptr. at 163.

98. *Id.* (citation omitted).

motivated both the courts and most legislatures to label blood as a "service" instead of a "good" (i.e. a type of tangible property).[99]

California law provides that:

> The procurement, processing, distribution, or use of whole blood, plasma, blood products, and blood derivatives for the purpose of injecting or transfusing the same, or any of them, into the human body shall be construed to be, and is declared to be, *for all purposes whatsoever*, the rendition of a service by each and every person, firm, or corporation participating therein, and shall not be construed to be, and is declared not to be, a sale of such whole blood, ... for any purpose whatsoever.[100]

California courts have interpreted this statute to be a codification of the holding in *Perlmutter v. Beth David Hospital*,[101] that a hospital's furnishing of blood to a patient was a service, not a sale, and thus not subject to strict liability on a warranty theory.[102] At the time *Perlmutter* was decided, strict lability in tort did not exist.[103] However, in *Shepard v. Alexian Bros. Hosp.*, the court held that section 1606 applied to strict liability in tort as well.[104] Subsequent cases have held that section 1606 exempts both blood banks[105] and blood product manufacturers[106] from strict liability for defective blood or blood products.

The rationale behind section 1606 is the need to promote an adequate supply of blood.[107] As the California Supreme Court made clear in the *Brown* opinion,[108] there is an equally strong policy to promote the development and supply of new drugs. Therefore, in light of the fact that section 1606 makes no distinction between the person compensated for the use of her blood and the hospital or blood products company, the

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99. See *infra* section VI for a discussion of the separate issue of whether the source of the blood, organ or other tissue is entitled to compensation.

100. CAL. HEALTH & SAFETY CODE § 1606 (West 1988) (emphasis added).

101. 308 N.Y. 100, 123 N.E.2d 792 (1954). For California cases interpreting *Perlmutter* and section 1606, see McDonald v. Sacramento Medical Found. Blood Bank, 62 Cal. App. 3d 866, 869, 133 Cal. Rptr. 444, 445 (1976); Shepard v. Alexian Bros. Hosp., 33 Cal. App. 3d 606, 610, 109 Cal. Rptr. 132, 134 (1973).

102. *Perlmutter*, 308 N.Y. at 107, 123 N.E.2d at 795.

103. Note, *Hepatitis, AIDS and the Blood Product Exemption from Strict Product Liability in California: A Reassessment*, 37 HASTINGS L.J. 1101, 1108 n.49 (1986) (authored by Pamela T. Westfall).

104. *Shepard*, 33 Cal. App. 3d at 610, 109 Cal. Rptr. at 133.

105. Klaus v. Alameda-Contra Costa County Medical Ass'n Blood Bank, 62 Cal. App. 3d 417, 418, 133 Cal. Rptr. 92, 92-93 (1976).

106. Fogo v. Cutter Laboratories, 68 Cal. App. 3d 744, 752, 137 Cal. Rptr. 417, 422 (1977). For a criticism of the application of section 1606 to blood product manufacturers see Note, *supra* note 103, at 1119-29. *Cf.* Note, *Liability for Transfusion-Transmitted Disease*, 14 WM. MITCHELL L. REV. 141 (1988) (authored by Lynn Shodahl).

107. *Klaus*, 62 Cal. App. 3d at 419, 133 Cal. Rptr. at 92-93.

108. *See supra* notes 94-96 and accompanying text.

supply of blood for biotechnology research and product development should also be treated as a service and not as the sale of property.

California law also exempts the donor of a body part from liability for "any injury or damage that may result from the making or the use of the anatomical gift."[109] However, Health & Safety Code section 7155.5(d) does not apply to situations where the individual did not make a "gift" of her tissue.[110] This suggests that, if human tissue is considered alienable property, an individual can be held liable for defects in that tissue.[111]

In summary, the Supreme Court correctly refused to treat human tissue and body parts as a form of tangible personal property that can be subject to a cause of action for conversion. There is no precedent in either statutory or judicial law that supports doing so. Furthermore, the extension of the doctrine of conversion to parts of the human body would cause strict liability to be imposed on suppliers of genetically engineered drugs, a result that is directly contrary to the stated policy of both the California courts and legislature. Finally, treating the human body as property opens up difficult and largely unanswered questions regarding the nature of the liability of the "owner" of tissue to individuals who are injured by defects in that tissue.

C. Quasi-Property Rights in the Human Body

The California Supreme Court has stated that the "term property is sufficiently comprehensive to include every species of estate, real and personal, and everything which a person can own and transfer to another. It extends to every species of right and interest capable of being enjoyed as such upon which it is practicable to place a money value."[112]

It has been argued that, although it may be inappropriate to treat the human body as tangible personal property, it is still properly the subject of some other property right.[113] The most commonly cited

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109. CAL. HEALTH & SAFETY CODE § 7155.5(d) (West Supp. 1989). This section replaced CAL HEALTH & SAFETY CODE § 7155.6, repealed by 1988 Cal. Stat. ch. 1905, § 1, which paralleled section 1606 and provided that donated tissue was treated as a service.

110. *Cf.* CAL HEALTH & SAFETY CODE § 1606 (West 1988), which would appear to protect both the paid and unpaid donor of blood in California. See *infra* Section VI for a discussion of the limited circumstances under which the use of paid blood donors is allowed in California.

111. It is likely that the paid source of the tissue would be held to a negligence standard of liability. *See* Note, *supra* note 106, at 161.

112. Yuba River Power Co. v. Nevada Irrigation Dist., 207 Cal. 521, 523, 279 P. 128, 129 (1929).

113. Martin & 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, 238-44 (1989); *Toward the Right of Commerciality*, *supra* note 90 at 260-64.

precedents for this type of treatment are the common law recognition of a quasi-property right in dead bodies and the right of publicity.

1. *THE LAW OF DEAD BODIES*

Under early English common law there was no property right in a dead body.[114] The earliest laws controlling the disposition of a corpse were a reaction to infamous cases in England, where persons were murdered in order to sell the corpses to medical schools.[115] Courts now recognize a limited right to control the disposition of the corpse for the purposes of burial and to recover damages for the mishandling of dead bodies.[116] However, Dean Prosser states that this "dubious property right" possesses none of the attributes of traditional property.[117] "It seems obvious that such property is something evolved out of thin air to meet the occasion, and that in reality the personal feelings of the survivors are being protected, under a fiction likely to deceive no one but the lawyer."[118]

Nonetheless, the Court of Appeals in *Moore* cited to California cases that found such a right in a dead body as support for the proposition that there is a property interest in the human body.[119]

The severe limitations on the so-called "quasi-property right" do not seem to support giving human tissue the full extent of rights granted tangible personal property. Nor does this right provide any precedent for allowing persons to be compensated for the use of their tissue.[120] However, the existence of a quasi-property right in dead bodies provides support for the underlying rationale of the Court of Appeals, which is that human beings have a right to control what becomes of their body.[121]

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114. *Toward the Right of Commerciality*, *supra* note 90, at 225-26.

115. R. SCOTT, THE BODY AS PROPERTY 4-12 (1981).

116. O'Donnel v. Slack, 123 Cal. 285, 55 P. 906 (1899); Enos v. Snyder, 131 Cal. 68, 63 P. 170 (1900); Cohen v. Groman Mortuary, Inc., 231 Cal. App. 2d 1, 41 Cal. Rptr. 481 (1963).

117. E.g., it can not be conveyed and has no pecuniary value. W. PROSSER AND W. KEETON, *supra* note 73, § 12, at 59.

118. *Id.*

119. Moore v. The Regents of the Univ. of California, 215 Cal. App. 3d 709, 724-26, 249 Cal. Rptr 494, 504-05 (1988), *rev'd*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990). The court noted that the limits placed on the disposition of a corpse "reflect significant public health concerns, rather than a legislative policy against a property interest in a living body. We see no inconsistency between the cases dealing with dead bodies and our conclusion." *Id.* at 726, 249 Cal. Rptr. at 505.

120. See *infra* Section VI.

121. See *supra* text accompanying notes 58-59.

2. *THE RIGHT OF PRIVACY/PUBLICITY*

The Restatement (Second) of Torts recognizes four separate actions under the general heading of the Right to Privacy: appropriation of name or likeness, unreasonable intrusion, public disclosure of private facts, and false light in the public eye.[122]

Commentators have suggested that the appropriation of the name or likeness aspect of the right to privacy provides individuals with the right to recover damages for the unauthorized commercial use of their cells.[123] The tort of appropriation of the right to one's name or likeness has been more commonly called the right of publicity.[124] The effect of this right is:

> to recognize or create an exclusive right in the individual plaintiff to a species of trade name, his own, and a kind of trade mark in his own likeness. It seems quite pointless to dispute whether such a right is to be classified as property; it is at least clearly proprietary in its nature. Once protected by the law, it is a right of value upon which the plaintiff can capitalize by selling licenses.[125]

California has a statutory counterpart to the right of privacy/publicity which provides that "any person who knowingly uses another's name voice, signature, photograph, or likeness in any manner, on or in products, merchandise or goods ... without such person's prior consent ... shall be liable" to the injured party.[126]

In *Lugosi v. Universal Pictures*,[127] the California Supreme Court expressly refused to decide whether the right of appropriation was a property right as defined in California Civil Code section 654.[128] The Court went on to hold that the right to recover for the misappropriation

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122. RESTATEMENT (SECOND) OF TORTS §§ 652A-E (1977); *see also* Prosser, *Privacy*, 48 CAL. L. REV. 383, 384 (1963).

123. Martin & Lagod, *supra* note 113, at 232-44; *Toward the Right of Commerciality*, *supra* note 90, at 259.

124. Zacchini v. Scripps-Howard Broadcasting Co., 433 U.S. 562, 564 (1976) (interpreting Ohio law).

125. W. PROSSER & W. KEETON, *supra* note 73, § 117, at 854 (footnotes omitted).

126. CAL. CIV. CODE § 3344(a) (West Supp. 1990). This statute provides, among other things, that the damages recoverable for its violation include the profits attributable to the unauthorized use, as well as attorney's fees. *Id.* "The statute applies only to use of a person's name, voice, signature, photograph or likeness and does not extend to the use of human tissue." *Id.*

127. 25 Cal. 3d 813, 603 P.2d 425, 160 Cal. Rptr. 323 (1979) (holding that the right to exploit one's name and likeness is personal and cannot be exercised by the decedent's heirs).

128. *Id.* at 818-19, 603 P.2d at 428, 160 Cal. Rptr. at 326.

of one's name or likeness was personal and that it must be asserted during one's lifetime.[129]

In response to the holding in *Lugosi*, the California legislature enacted Civil Code Section 990, which extended the protection of Civil Code section 3344 to the likeness of a deceased person.[130] Civil Code section 990 expressly states that the rights it provides are "property rights."[131] In *Midler v. Ford Motor Co.*,[132] the Ninth Circuit cited to Civil Code section 990(b) as support for its statement that "[b]y analogy, the common law rights [in the use of one's likeness] are also property rights."[133]

Although the express terms of Civil Code sections 3344 and 990 do not apply to the use of an individual's tissue, they do suggest that the right of publicity is indeed a kind of property right. Yet, the crucial question is not whether the right of publicity is a type of quasi-property right,[134] but whether the right of publicity is the appropriate vehicle for the protection of an individual's right to control the disposition of her body.

The right of publicity is different from the other three privacy-based rights, in that the other three rights are based on a "direct wrong of a personal character, resulting to an injury to the feelings."[135] One commentator has suggested that:

> [T]he right of publicity is a species of the right of privacy, rather than an entirely separate interest.... Furthermore, when the right of publicity or the right of privacy is violated, the gravamen of the tort is the same: An individual's identity has been used without his or her consent for another's advantage. Hence, the only real difference ... seems to be whether one seeks to exploit or prevent the public use of his or her identity. In the former instance, the right is used offensively as a sword; in the latter instance, the right is used defensively as a shield.[136]

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129. *Id.* at 824, 603 P.2d at 431, 160 Cal. Rptr. at 329; *see supra* note 70 and accompanying text.

130. CAL. CIV. CODE § 990(a) (West Supp. 1990).

131. *Id.* § 990(b).

132. 849 F.2d 460 (9th Cir. 1988) (construing California law, the court held that, although Bette Midler had no cause of action under Civil Code § 3344 where the defendant used a singer whose voice sounded like Ms. Midler's, there was a cause of action at common law).

133. *Id.* at 463.

134. Under California law, even if the right to publicity is considered a type of property, it is not a type of tangible personal property that would properly be the subject of a cause of action for conversion. *See supra* notes 73-98 and accom-panying text.

135. Lugosi v. Universal Pictures, 25 Cal. 3d 813, 833, 603 P.2d 425, 437, 160 Cal. Rptr. 323, 335 (1979) (Bird, C.J., dissenting) (quoting Fairfield v. American Photography Equip. Co., 138 Cal. App. 2d 82, 291 P. 2d 194 (1955)).

136. Martin & Lagod, *supra* note 113, at 235.

However, as noted by the United States Supreme Court, the underlying rationales of the rights are very different. The Court has explained that the right of publicity does not involve the mere use of a person's attractiveness to enhance a product, it involves the "appropriation of the very activity by which the entertainer acquired his reputation in the first place."[137] The Supreme Court further stated that the protection of the right of publicity:

> is more than a desire to compensate the performer for the time and effort invested in his act; the protection provides an economic incentive for him to ake the investment required to produce a performance of interest to the public. This same consideration underlies the patent and copyright laws long enforced by this Court.[138]

Dissenting in *Lugosi*, Justice Bird also recognized that the right of publicity "intrudes on interests distinctly different than those protected by the right of privacy."[139] She went on to note that "the loss may well exceed the mere denial of compensation for the use of the individual's identity. The unauthorized use disrupts the individual's effort to control his public image, and may substantially alter that image."[140]

As defined by both the California and the United States Supreme Court, the right to publicity is designed to protect a public figure's investment in his or her public persona, in order to encourage people to invest in developing that persona. In this way, the right of publicity is more than just an "offensive sword" that is used to protect an individual's privacy. It is a mechanism to reward an individual's efforts to create valuable rights in his or her persona. If this right were to be extended to protect the commercial use of human tissue, the courts would be implicitly stating that it is desirable for the individual to treat his or her body as a commercial product. This is fundamentally inconsistent with the way we currently treat other potentially valuable uses of the human body.[141]

Perhaps more importantly, the vast majority of individuals are not equipped to discover and develop any potential commercial value that might exist in their cells. Therefore, the rationale behind the right of publicity simply does not apply to the use of human tissues in biotech drugs. Furthermore, extending the right to such situations would

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137. Zacchini v. Scripps-Howard Broadcasting Co., 433 U.S. 562, 576 (1976).

138. *Id.*

139. *Lugosi*, 25 Cal.3d at 834, 603 P. 2d at 437, 160 Cal. Rptr. at 335 (Bird, C.J., dissenting).

140. *Id.* at 835, 603 P.2d at 438, 160 Cal. Rptr. at 336.

141. *See infra* Section VI. Even though we do allow some compensation for the use of human tissue in very limited circumstances, the general rule is not to allow compensation to be paid to tissue donors.

conflict with the public policy of rewarding the efforts of the inventors of these drugs.[142]

Another fundamental problem with the right to publicity is that the right would not be violated until a successful commercial product is created. Due to the fact that most biotechnology research does not result in the development of a successful commercial product,[143] this right fails to protect the rights of the vast majority of persons whose tissues are used in biotechnology research to decide whether their cells will be commercialized.

The California Supreme Court gave a more basic reason for finding that the right of publicity cases were irrelevant to the issue of conversion. The court stated:

> Not only are the wrongful publicity cases irrelevant to the issue of conversion, but the analogy to them seriously misconceives the nature of the genetic materials and research involved in this case. ... [T]he goal and result of the defendants' efforts has been to manufacture lymphokines. Lymphokines, unlike a name or a face, have the same molecular structure in every human being and the same important functions in every human being's immune system.[144]

The courts' and commentators' focus on whether there is a property right in human tissue and, if so, what the nature of that right is, has obscured the underlying issues of the *Moore* case. Society's two important goals of protecting individual autonomy as well as furthering the ability of researchers to conduct potentially valuable research (both commercial and noncommercial) in a way that leaves them free from future claims of impropriety, will be better served by the imposition of a clear right that attaches at the time that the tissue is first removed.[145] Even though the use of human tissue does not fit into a recognized right of privacy cause of action, it is recognized that there is a zone of privacy protected by the Constitution. "It embraces not only the interests protected by the common law action..., but it also protects to a

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142. *See supra* text accompanying notes 80-81.

143. *See supra* text accompanying note 23. In addition, the classic case of the right to publicity involves the use of a person's face or voice. This type of use involves relatively simple problems of proof that are resolved by showing the offending picture or recording. Similarly, in *Moore*, it is relatively easy to show that the "Mo cell-line" was created using only Mr. Moore's cells. *See supra* text accompanying note 46. This is in contrast to the problems of proof that would be encountered in the more common situation where the cells of more than one individual are used to create a single product. *See supra* note 33 and accompanying text.

144. Moore v. The Regents of the Univ. of California, 51 Cal. 3d 120, 138-39, 793 P.2d 479, 489-90, 271 Cal. Rptr. 146, 154-55 (1990).

145. The California Supreme Court recognized this fact when it held that Mr. Moore had a cause of action under informed consent law. *Id.* at 147, 793 P.2d at 497, 271 Cal. Rptr. at 164.

considerable extent the autonomy of the individual to make certain important decisions of a very personal nature."[146] It is this right to make important decisions of a personal nature that the Court of Appeals was trying to protect in the *Moore* case. In this way, it is an individual's interest in making such decisions that is analogous to the quasi-property right to control the disposition of a corpse.[147] The most effective way to protect this right for all patients and research subjects is to expand both the common law and statutory rules of informed consent.

V. INFORMED CONSENT

In the *Moore* case, the alleged injuries occurred during the course of a relationship that was both therapeutic and research-oriented in nature.[148] Therefore, the Supreme Court reasonably focused on examining whether the common law duty of informed consent imposes a duty of doctors to inform patients of possible research on, and commercial exploitation of, their tissue. The court held that:

> [A] physician who is seeking a patient's consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose personal interests unrelated to the patient's health, whether research or economic, that may effect his medical judgement.[149]

In order to understand the Court's holding, this section will analyze the doctrine of informed consent. In addition, this section will examine the scope of the statutory and regulatory duty of informed consent as it is currently applied to medical researchers and suggest some changes that should be made in this area.

A. The Treating Researcher/Physician's Duty of Informed Consent

Originally, the failure to obtain consent for medical treatment was considered subject to a cause of action in battery for unconsented touching.[150] This cause of action was generally limited to situations where the treatment itself was performed without the patient's consent.[151]

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146. W. PROSSER & W. KEETON, *supra* note 73, § 117, at 866.

147. Analogous to the right in a dead body, the right to control the disposition of one's bodily tissue does not necessarily include the right of alienation or of conveyance, however damages can be recovered for violation of this right. *See supra* note 116 and accompanying text.

148. *See supra* Section III B.

149. *Moore*, 51 Cal. 3d at 131, 793 P.2d at 485, 271 Cal. Rptr. at 152.

150. Schultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 YALE L.J. 219, 224 (1985). For a description of the tort of battery, see W. PROSSER & W. KEATON, *supra* note 73, § 9, at 39-42. For an analysis of the doctrine of informed consent to medical

The advantage of a battery-type cause of action was that "the patient's wishes take priority over even the fully competent recommendation of a doctor, unless an exception applies."[152] Professor Shultz, however, cites two primary reasons why the tort of battery has become disfavored by many courts in informed consent cases. First, in most cases of medical treatment, the patient did consent to some form of medical treatment.[153] Second, battery is an intentional tort and in most informed consent cases, doctors are not acting with antisocial intent; the issue instead is the failure of the physician to provide enough information about the risks of treatment, as well as the alternative medical treatments available.[154]

> [T]o hold that such uninformed consent was invalid, thereby subjecting doctors to actions for battery, threatened to yield unacceptably harsh results. Given the absolute nature of battery, the narrowness of its defenses, and the breadth of its remedies, doctors could end up paying significant damages after providing faultless medical treatment, simply because some minor informational aspect of the consent process was questioned.[155]

Due to these difficulties, it became more common over time for the doctrine of informed consent to be treated as a subset of doctors' professional malpractice law, rather than as a type of battery.[156]

The physician's traditional duty, under the professional malpractice standard, was to inform the patient of all risks that a physician would customarily disclose under the circumstances.[157] The adoption of this standard effectively substituted the doctor's judgement for the patient's.[158] Recognition of this fact lead the California Supreme Court to hold in *Cobbs v. Grant* that "there is a duty of reasonable disclosure of the

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treatment, see Schultz, *supra; see also* Studer, *The Doctrine of Informed Consent: Protecting the Patient's Right to Make Informed Health Care Decisions*, 48 MONT. L. REV. 85, 86-88 (1987).

151. Schultz, *supra* note 150, at 226. In the case of *Schloendorff v. Society of New York Hospital*, Justice Cardozo stated that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable for damages." 211 N.Y. 125, 127, 105 N.E. 92, 93 (1914), *overruled by* Bing v. Thunig, 2 N.Y. 2d 656, 163 N.Y.S. 3, 143 N.E.2d 3 (1957).

152. Shultz, *supra* note 150, at 224 (footnotes omitted).

153. *Id.* at 225.

154. *Id.*

155. *Id.*

156. *Id.* at 226; Studer, *supra* note 153, at 87-88; *see also* Salgo v. Leland Stanford Jr. Univ. Board of Trustees, 154. Cal. App. 2d 560, 317 P.2d 170 (1957).

157. W. PROSSER & W. KEETON, *supra* note 73, § 117, at 191.

158. Cobbs v. Grant, 8 Cal. 3d 229, 243-44, 502 P.2d 1, 10, 104 Cal. Rptr. 505, 514 (1972). The seminal case in this area is Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972), *cert. denied*, 409 U.S. 1064 (1972). "Respect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose on themselves." *Id.* at 784.

available choices with respect to proposed therapy and of the dangers inherently and potentially involved in each."[159] As way of guidance as to what constitutes reasonable disclosure, the court stated that:

> In sum, the patient's right of self-decision is the measure of the physician's duty to reveal. That right can be effectively exercised only if the patient posseses adequate information to enable an intelligent choice. 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. Thus the test for determining whether a potential peril must be divulged is its materiality to the patient's decision.[160]

However, in *Cobbs*, the court also clearly established that the requisite causal connection between the plaintiff's injury and the failure to inform is only satisfied when it "is established that had revelation been made consent to treatment would not have been given."[161] In other words, unless the patient would not have elected to have the treatment if full disclosure had been given, there is no cause of action for lack of informed consent. This would effectively prevent recovery in a case like *Moore*, unless the plaintiff can show she would have refused treatment if she had known of possible commercialization of her cells.[162]

Yet, the doctrine of informed consent has been expanded in California to create a duty to inform that goes beyond mere disclosure of the risks of a given course of treatment. In *Truman v. Thomas*,[163] the California Supreme Court extended the duty of disclosure required under the patient-oriented standard of informed consent to include the duty to advise a patient who refuses to undergo a risk-free diagnostic test of all "material risks of which a reasonable person would want to be informed before deciding not to undergo the procedure."[164]

More importantly, in *Jamison v. Lindsay*,[165] the plaintiff claimed that the failure to disclose that some of the tissue from her ovarian tumor was of a type that some pathologists considered to be malignant or pre-malignant was a breach of the duty of informed consent because she was entitled to know of the potential malignancy so that she could choose to

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159. *Cobbs*, 8 Cal. 3d at 243, 502 P. 2d at 10, 104 Cal. Rptr. at 514.

160. *Id.* at 245, 502 P.2d at 11, 104 Cal. Rptr. at 515 (citing *Canterbury*, 464 F.2d at 786).

161. *Id.* at 245, 502 P.2d at 11, 104 Cal. Rptr. at 515.

162. Note that in his complaint Mr. Moore did allege that he would have sought treatment elsewhere if he had known of Dr. Golde's research. *See* Third Amended Complaint, *supra* note 38.

163. 27 Cal. 3d 285, 611 P.2d 902, 165 Cal. Rptr. 308 (1980).

164. *Id.* at 292, 611 P.2d at 906, 165 Cal. Rptr. at 312 (trial court erred in refusing to give jury instruction on the issue of negligence of a doctor who refused to warn of risks of not having a pap smear).

165. 108 Cal. App. 3d 223, 166 Cal. Rptr. 443 (1980).

seek further medical treatment.[166] Although the Court of Appeals denied recovery by rejecting the plaintiff's proposed jury instructions,[167] it opened the door to a broader definition of the duty of informed consent when it held that it would be proper to give a jury instruction that stated; "it is the duty of a physician or surgeon to disclose to the patient all relevant information to enable the patient to make an informed decision whether to seek additional treatment following surgery."[168] The holding in *Jamison* provides support for the proposition that there is an ongoing duty of disclosure that applies to information discovered by a physician after the consent to surgery has been validly obtained. It would be consistent with the reasoning of *Jamison* to impose upon a physician who is in an ongoing therapeutic relationship with a patient, the duty of informing the patient of the ongoing efforts to commercialize his cells.

The rationale behind the duty of informed consent is that the patient's right of self-decision (regarding whether or not to undergo medical treatment) compels the disclosure of all information regarding the treatment that is material to that patient's decision-making process.[169] If it is recognized that the decision to have a portion of one's body used for research, as well as in commercial products, is encompassed in an individual's right to privacy,[170] the failure of the physician to disclose such research causes a cognizable injury to the patient and should be sufficient to create a cause of action for lack of informed consent.

The Supreme Court correctly noted that:

> [A] physician who treats a patient in whom he also has a research interest has potentially conflicting loyalties. ... The possibility that an interest extraneous to the patient's health has affected the physician's judgment is something that a reasonable patient would want to know in deciding whether to consent to a proposed course of treatment.[171]

An alternative legal theory that could be used to protect a patient's right to control what research is performed on her body (or its parts), could be found in the an expansion of the tort of battery. Despite the more common use of a negligence-based cause of action in California, a cause of action for battery can still be maintained against a physician.

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166. *Id.* at 229, 166 Cal. Rptr. at 446.
167. *Id.* at 230-31, 166 Cal. Rptr. at 446-47.
168. *Id.* at 230, 166 Cal. Rptr. at 447 (citation omitted).
169. *See supra* text accompanying note 160.
170. *See supra* text accompanying notes 145-146.
171. Moore v. The Regents of the Univ. of California, 51 Cal. 3d 120, 130, 793 P.2d 479, 484, 271 Cal. Rptr. 146, 151 (1990). The court went on to note that even though the "disclosure of research and economic interests may corrupt the patient's own judgment by distracting him from the requirements of his health," the patient has a basic right "to ... 'make the ultimate informed decision.'" *Id.* at 131, 793 P.2d at 484, 271 Cal. Rptr. at 151 (citing Cobbs v. Grant, 8 Cal. 3d 229, 243 (1972)).

Unfortunately, in *Cobbs v. Grant*,[172] the California Supreme Court explicitly limited the battery cause of action to those cases where "a doctor performs an operation to which the patient has not consented."[173] This limitation on the tort of battery is derived from the theory that there must be an unconsented-to touching in order to maintain an action for battery.[174] Such a limitation would appear to bar the application of the doctrine in a case such as Mr. Moore's, where there was a valid consent to surgery.

However, at least one court has held that the tort of battery applied to a case where there was no unconsented-to touching. In *Mink v. The University of Chicago*,[175] the plaintiffs were given the drug diethylstilbestrol ("DES"), as part of their regular prenatal treatment, without their knowledge.[176] The court held that a negligence action could not be maintained because the plaintiffs did not allege any personal physical injury.[177] However, the court also held that the plaintiffs had stated a valid cause of action for battery.[178] The court noted that: "[P]roof of the technical violation of the integrity of the plaintiff's person by even an entirely harmless, but offensive, contact entitles him to a vindication of his right...."[179] In addition, the court adopted a more narrow definition of what would qualify as a valid consent to treatment by the patient. The court stated that "the scope of the plaintiff's consent is crucial to their ultimate recovery in a battery action. The defendant's privilege is limited at least to acts substantially similar to those to which the plaintiff consented."[180]

Under the rationale of the *Mink* court, a patient such as Mr. Moore, whose tissue was used for research without his consent, would be entitled to seek "vindication" of the invasion of his privacy right, even though he did not suffer any physical injury. A valid consent to medical treatment would not also constitute consent to research or consent to the commercialization of the patient's tissues.

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172. 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972).

173. *Cobbs*, 8 Cal. 3d at 240, 502 P.2d at 8, 104 Cal. Rptr. at 512. A requirement for the tort of battery is that there be an unconsented-to touching of the patient by the physician. *See supra* note 150 and accompanying text.

174. *See supra* note 151.

175. 460 F. Supp. 713 (N.D. Ill. 1978).

176. *Id.* at 715.

177. *Id.* at 722. The alleged injury was mental anxiety and emotional distress caused by the increased risk of cancer to the plaintiff's children. *Id.* at 716.

178. *Id.* at 722.

179. *Id.* at 718 (citing to W. PROSSER & W. KEETON, THE LAW OF TORTS, § 9, at 35 (4th ed. 1971)).

180. *Id.* at 718.

An expanded battery theory would protect the rights of patients whose tissues are used for research by a treating physician, whether or not that research yielded a commercially viable product. Furthermore, under this approach, the researcher/physician could obtain a consent in advance of the research that includes consent to possible commercialization, thereby avoiding any impracticality associated with a requirement that the physician obtain an additional consent when it is proven that a given tissue sample has commercial applications.[181] However, under the rational of the *Mink* court, consent to research should not implicitly include consent to the commercialization of one's tissue, unless the consent expressly provided for that possibility.

The fiduciary nature of the doctor-patient relationship[182] provides further support for holding the treating physician liable for the failure to inform a patient that the doctor is performing research upon his or her tissue, research which may prove quite lucrative to the physician. The dual role of researcher and healer creates an inherent conflict of interest for the physician. The California Supreme Court recognized that a doctor's fiduciary duty imposes an obligation to disclose a conflict of interest, such as profiting from commercially valuable research on a patient.[183]

Although it was an expansion of prior law to hold that informed consent law expressly required full disclosure of all research performed on a patient (or in tissue removed from that patient), doing so was in accord with the basic principles behind informed consent doctrine. The rationale behind the holdings in *Truman v. Thomas*[184] and *Jamison v. Lindsay*[185] provided the grounds for such an expansion of the scope of informed consent.

Alternatively, in the future, courts could follow the rationale of the *Mink* court[186] and hold that there is a cause of action for battery when the

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181. It is true that, especially in the doctor-patient relationship, where the balance of power is extremely unequal, a written consent is always open to challenge on the ground that it was improperly obtained. However, this alone is not sufficient a reason to deny an important individual right.

182. RESTATEMENT (SECOND) OF AGENCY § 387 (1957); Shultz, *supra* note 150, at 259-63.

183. The California Supreme Court explained that that the term "fiduciary" did not mean that the physician was the patient's financial advisor. It "signifies only that a physician must disclose all facts material to the patient's decision because "certain professional interests may effect personal judgement." Moore v. The Regents of Univ. of the California, 51 Cal. 3d 120, 131 n.10, 793 P.2d 479, 485 n.10, 271 Cal. Rptr. 146, 152 n.10 (1990). This description of the physician's fiduciary duty is similar to the duty to disclose conflicts of interest that is imposed on attorneys.

184. 27 Cal. 3d 285, 611 P. 2d 902, 165 Cal. Rptr. 308 (1980).

185. 108 Cal. App. 3d 223, 166 Cal. Rptr. 443 (1980).

186. *See supra* text accompanying note 180.

scope of consent given to medical treatment did not specifically include consent to research and commercialization of one's cells.

B. Statutory and Regulatory Treatment of Informed Consent

The failure of the common law doctrine of informed consent to protect research subjects has meant that the primary protection from unauthorized research being performed upon a patient has been found in federal regulations and state statutes.

In *Moore*, the Supreme Court held that because the hospital, Ms. Quan (Golde's researcher) and the biotechnology companies were not physicians, they did not have a duty to obtain Moore's informed consent to medical procedures. The Court further stated that, in order to hold these defendants liable, Moore would have to prove that they were liable under some theory of secondary liability.[187]

This means that when the researcher is not also the patient's treating physician, the *Moore* case does not impose any duty to inform the patient that her tissue is being used for potentially lucrative biotechnology research. In such a case, the tissue source must turn to existing state and federal guidelines for protection.

Unfortunately, these statutes and regulations, while affirming the broad principle that informed consent must be obtained for all research on human subjects, were drafted to protect people from the dangers of physical and mental experimentation on their bodies. Therefore, they do not necessarily require obtaining valid consent for the commercial development of excised tissue.

The regulations which control the use of research subjects in federally funded research are contained in Parts 21 and 45 of the Code of Federal Regulations. These regulations provides that experiments on human subjects funded or conducted by the federal government can only be performed if the subject is first informed of all the potential risks and the benefits of the experimentation.[188]

Unfortunately, it is not at all clear that these regulations automatically apply in a case like the *Moore* case. First, as with the common law doctrine of informed consent, the concept of risks and benefits is limited to those of a physical nature.[189] Second, these regulations may be modified, or waived altogether, when a research

187. *Moore*, 51 Cal. 3d at 133-34, 793 P.2d at 486, 271 Cal. Rptr. at 153-54. Examples are found in employee-employer or joint-venture realtionships. *Id.* at 133-34 n.12, 793 P.2d at 486 n.12, 271 Cal. Rptr. at 153-54 n.12.

188. 45 C.F.R. §§ 46.101-46.103 (1989).

189. 12 C.F.R. § 50.25 (1990).

project involves minimal risk.[190] Minimal risk exists where the risks of harm encountered in the proposed research are not greater in magnitude than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.[191] Under this standard, Mr. Moore did not encounter any additional physical risks beyond those that he was subjected to in the course of necessary surgery. In fact, the federal informed consent guidelines are generally not applied to cases where research is performed on tissue removed incident to necessary surgery. Therefore, Dr. Golde's actions did not necessarily violate federal guidelines.[192]

In order to protect the right of individuals to determine whether their body tissue will be commercialized, it is necessary to revise the federal regulations to define the commercialization of tissue used in biotechnology research as a risk and/or benefit to the research subject. Furthermore, the definition of minimal risk must be revised to explicitly include biotechnology research that has potential commercial applications.[193] The right to be informed of what type of research is being performed on one's tissues should not depend only on whether the researcher happens to be the donor's treating physician.

In California, laws regulating human experimentation were enacted under the Protection of Human Subjects in Medical Experimentation Act.[194] The Act mirrors federal regulation and is designed to provide minimal protection when research is not covered by federal regulations. As with the federal regulations, the Act provides that, for consent to research to be valid, the subject must be given a written statement that includes, among other things: information on "the nature and the purpose of the experiment";[195] a description of the attendant risks and discomfort reasonably to be expected from the experiment;[196] information as to any potential benefits to the subject that is reasonably to be expected

190. 45 C.F.R. § 46.102 (1989).

191. *Id.* § 46.102(g).

192. *Cf.* Martin & Lagod, *supra* note 113, at 226-32.

193. For an in depth critique of the federal guidelines, which includes several additional excellent suggestions for revision, see Delgado & Leskovac, *Informed Consent In Human Experimentation: Bridging The Gap Between Ethical Thought And Current Practice*, 34 UCLA L. REV. 67 (1986). The authors list four important rationales that support a broader definition of informed consent in human experimentation: (1) the risks of experimentation cannot be ascertained in advance; (2) there is no reason the defer to medical expertise because it does not exist in experimental settings; (3) experimentation often provides no certain benefit to the subject and; (4) the researcher and the subject often have conflicting interests. *Id.* at 88-92. It is reason number 4 that is at the heart of the *Moore* case.

194. CAL. HEALTH & SAFETY CODE §§ 24170 - 24172 (West 1984).

195. *Id.* § 24172(a).

196. *Id.* § 24172(c).

from the experiment;[197] the opportunity to ask questions; and instructions that the patient can withdraw from the experiment at any time.[198] Unfortunately, these requirements have also been traditionally considered to apply only to physical risks and benefits. As with the federal regulations, the California Legislature should revise the Act to explicitly provide that a subject must be fully informed of any potential for the commercialization of her tissue.

VI. SHOULD INDIVIDUALS BE ALLOWED TO SELL THEIR TISSUE?

Until this point, this Comment has confined its analysis to the issue of whether individuals have a right to control what becomes of their excised tissue and how that right should properly be enforced. Although the California Supreme Court established in *Moore* that a physician must disclose any interests that he might have that will affect a patient health, the Court did not address the issue of whether or not a patient has the right to sell her own tissue.[199] This section will explore a possible legal framework within which to analyze this issue. In addition, this section will examine the current scheme for regulating the use of bodily products and organs for medical research and treatment.

In order to properly accommodate the competing public policy considerations of individual autonomy and of furthering the development of science that is of potential benefit to mankind, it is important to distinguish the right to control the disposition of one's tissue from the right to sell that tissue. The Court of Appeals recognized this dichotomy when it stated that "[w]e are not called upon to determine whether use of human tissue or body parts ought to be 'gift based' or subject to a 'free market.' That question of policy must be determined by the legislature."[200]

The policy issue of whether there should be a "free market" in human tissue used for biotech products and research is extremely complex. In order to achieve a satisfactory solution, the California legislature must first understand the complicated and contradictory nature of the existing federal and state regulations and statutes that already control various uses of human tissue and body parts. Second, the

197. *Id.* § 24172(d).
198. *Id.* § 24172(g) & (h).
199. Moore v. The Regents of the Univ. of California, 51 Cal. 3d 120, 133, 793 P.2d 479, 487, 271 Cal. Rptr. 146, 154 (1990).
200. Moore v. The Regents of the Univ. of California, 215 Cal. App. 3d 709, 724, 249 Cal. Rptr. 494, 504 (1988), *rev'd*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990).

Legislature must reconcile the contradictions that currently exist in the regulation of the sale of human tissue.

In the long run, better results will be achieved with rules that are fashioned with a clear policy rationale to govern the scope of the permissible limits on the commodification of the human body. In subsection A, I attempt to provide a theoretical basis for such a policy. Then, in subsection B, I examine current federal and state controls on the sale of human tissue. Finally, subsection C suggests two possible alternative approaches to the regulation of the sale of tissue for biotechnology research.

A. Doctrinal Treatments of the Commodification of Personhood[201]

Theorists have strongly disagreed on the degree of commodification[202] of the human body that is tolerable in a society that seeks to protect individual autonomy. At one extreme is the position of universal commodification.[203] Proponents of this view suggest that all things can be conceived of as commodities, and that individual freedom is equated with unrestricted choice as to what goods to trade in.[204] At the other extreme is Marxist theory, which suggests that "the market ought not to exist and that social interactions involving production and consumption should be reconceived in a non-market way."[205]

Professor Radin contends that the vision associated with traditional liberal values in western society is called pluralism.[206] Under the pluralist view, there is a realm of alienable property rights and inalienable political or individual rights.[207] However, competing with that view is the notion of "negative liberty," that is the right to be let alone, as long as one does not hurt anyone else. [208] The inevitable result of negative liberty is that restraints on alienation are thought to be paternalistic. It follows that this

201. The discussion in this section is based on the analytical framework developed by Professor Margaret Radin in *Market Inalienability*, 100 HARV. L. REV. 1849 (1987).

202. In a narrow sense, the term "commodification" means the actual buying and selling of human tissue and body parts. In its broader sense, the term also refers to "the practice of thinking about interactions as if they were sale transactions." *Id.* at 1859.

203. *Id.* at 1859.

204. *Id.* at 1860-61. Posner, a major proponent of this system, suggests all things scarce should be subject to property rights and thus saleable. R. POSNER, ECONOMIC ANALYSIS OF LAW 29-33 (3rd ed. 1986). Posner has also advocated the creation of a market for the selling of babies. *Id.* at 139.

205. Radin, *supra* note 201, at 1870.

206. *Id.* at 1887.

207. In other words, certain personal rights are so central to our idea of personhood, that they may not be sold (commodified) without diminishing individual autonomy. *Id.* at 1888-98.

208. *Id.* at 1888.

concept of negative liberty comes into direct conflict with the principle that full human freedom requires that some individual rights not be commodified.[209]

Professor Radin suggests that a proper reconciliation of the competing principles of negative liberty and the protection of individual rights is achieved by allowing the individuals to make gifts of aspects of the self that are central to personhood, and by not allowing the sale of such intimate aspects of the self.[210] Professor Radin uses prostitution, surrogacy and baby selling as examples involving commodification of the person.[211]

However, Professor Radin also proposes an important limiting principle to the noncommodification of personhood. She suggests that when a given aspect of personhood is already commodified, prohibiting persons from selling that aspect of their personhood places them in a double bind of powerlessness, thereby reducing the individual's power of autonomy.[212]

In such a case, Professor Radin suggests that the individuals should be allowed to sell that aspect of the person, but that the market should be regulated to reduce the negative effects to aspects of personhood.[213]

B. Existing Regulation of the Sale of Human Tissue and Body Parts

As was discussed above, the tissue used in biotech research comes from blood and other replenishing body fluids, from tissue and organs removed incident to surgery and from cadavers.[214] Although they were not drafted with biotechnology research in mind, there are various regulations which apply to the sale of each of these sources of tissue.

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209. *Id.* at 1903.

210. *Id.* at 1907-14. Professor Radin notes that the goal of a rule of noncommodification of personhood is to ensure free choice. It is crucial to note that, as Professor Radin points out, "to the extent that [a rule of noncommodification] equates poverty with coercion, the prophylactic argument requires a corollary in welfare rights." *Id.* at 1911. While I strongly agree with this argument, I also believe that noncommodification of intimate aspects of personhood is a principle that serves to protect the individual dignity of all persons.

211. *Id.* at 1911.

212. *Id.* at 1912-17.

213. For example, she suggests that a woman be allowed to engage in prostitution because sex is already so commodified in society. However, to reduce the negative effect on a woman's personhood, pimping should be prohibited. *Id.* at 1921-25. Professor Radin goes on to conclude that both baby selling and surrogacy are not sufficiently commodified to warrant allowing woman to be compensated. *Id.* at 1925-36.

214. OWNERSHIP OF HUMAN TISSUE AND CELLS, *supra* note 8, at 51; *see supra* notes 20-22 and accompanying text.

The sale of blood and other replenishing bodily fluids is not prohibited under existing state or federal law.[215] California law was amended in 1986 to make it unlawful to use blood from a compensated individual for a transfusion, unless no suitable blood is available from a donor.[216] However, this appears to be more a reaction to the spread of the AIDS virus than a policy against the sale of blood. In fact, income from the sale of blood remains exempt from California income tax.[217] It is currently legal, in California, for an individual to sell his blood to researchers for use in biotechnology research.

Federal law makes it "unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce."[218] The definition of human organ is quite broad and includes replenishing tissue, such as skin and bone marrow.[219] The statute was amended in 1988 to include fetal tissue in the definition of the term human tissue.[220] The definition of what constitutes a human organ under federal law seems to contemplate the prohibition of sale of most types of organs and tissue. Furthermore, the definition of a human organ seems to be broad enough to include most types of human tissue and organs that are used in biotechnology research. However, 42 U.S.C. § 274e only applies to the use of human organs for transplantation. Therefore, technically, there is no current federal prohibition on the sale of human tissue and organs for biotechnology research.

California has adopted the Uniform Anatomical Gift Act ("UAGA") to regulate the use of human tissue in transplantation.[221] The drafters of the UAGA were simply not concerned with the issue of whether organs may be sold. The purpose of the Act was to increase the supply of organs donated after death by making it easier for a person to consent to donation.[222] The only prohibition in California on the sale of human organs that is contained in California's UAGA is that "a person may not knowingly, for valuable consideration, purchase or sell a part for

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215. OWNERSHIP OF HUMAN TISSUE AND CELLS, *supra* note 8, at 76; *see supra* notes 20-22 and accompanying text.

216. CAL. HEALTH & SAFETY CODE § 1626 (West Supp. 1989).

217. CAL. REV. & TAX. CODE § 33 (West 1987).

218. 42 U.S.C. § 274e(a) (West Supp. 1990).

219. "The term 'human organ' means the human, (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, skin or any subpart thereof or any other human organ (or any subpart thereof, including that derived from a fetus) as specified by the Secretary of Health and Human Services or by regulation." *Id.* § 274e(c).

220. *Id.*

221. CAL. HEALTH & SAFETY CODE §§ 7150-7155 (West Supp. 1990).

222. OWNERSHIP OF HUMAN TISSUE AND CELLS, *supra* note 28, at 75.

transplantation, [or] therapy... if removal of the part is intended to occur after the death of the decedent."[223]

In fact, it appears that California law allows an individual to sell his or her own organs or tissue if the removal will not occur after the individual's death.[224] This result is contained in California Penal Code, section 367f,[225] which makes it unlawful to "acquire, receive, sell, promote the transfer of ... any human organ for the purposes of transplantation, for valuable consideration."[226] However, section 367f does not apply to the person from whom the organ is removed, nor to the person who receives the transplant.[227] The net effect, under California and federal law, is to allow an individual to sell his or her nonvital organs or other tissues, for the purposes of human transplantation, as long as interstate commerce is not affected, no profit is received by any third party broker, and the organs will not be removed after the source's death.[228]

C. Commodification of the Individual for Biotechnology Research

The sale of human organs and tissue involves aspects of the self that are central to personhood.[229] Federal law reflects this fact when it prohibits the sale of human organs and tissue for transplantation, but allows people to choose whether to donate organs for this purpose.[230] This would suggest that, under Professor Radin's analysis, human organs should be market-inalienable for the purpose of use in biotechnology research.[231]

However, the fact that researchers and physicians can currently reap great profits from products developed from human tissue already results in a partial commodification of the human body. The fact that blood can clearly be sold for the purposes of biotechnology research,[232]

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223. CAL. HEALTH & SAFETY CODE § 7155(a) (West Supp. 1988).

224. Note that this argument assumes that such a sale does not affect interstate commerce. Also, if a court were to hold that 42 U.S.C. § 274e preempts state law, this argument would no longer be valid. However, to date, there has been no such holding.

225. CAL. PENAL CODE § 367f (West 1988).

226. *Id.* § 367f(a).

227. *Id.* § 367f(e).

228. This result is not surprising in light of the underlying purposes of the UAGA.

229. *See supra* notes 202-213 and accompanying text.

230. *See supra* notes 218-220 and accompanying text. The California statute prohibiting the removal of organs after death also reflects this fact. *See supra* notes 221-228 and accompanying text.

231. Note that it does not follow from this conclusion that human beings do not have the right to control the use of their tissue. In a gift based system, the right to alienate tissue remains, but this right does not include the right to receive compensation.

232. *See supra* text accompanying notes 215-217.

along with the fact that the sale of human body parts by an individual is permitted under certain circumstances in California, lends further support to the proposition that the sale of human body parts is an area in which there is incomplete commodification.[233] This incomplete commodification presents a serious risk that patients and research subjects will be placed in exactly the type of "double-bind of powerlessness" that is described by Professor Radin.[234] This double-bind is especially acute for seriously ill patients because they are often in need of money, and also because their lives are often completely dependent on their physician's judgement.

There are two potential solutions to this problem. The first is to try to equalize the balance of power between the physician/researcher and the patient by allowing the patient to sell his or her tissue. The problem with this approach is that when there is such a disparity of power between the patient and the physician, the patient may not feel free to forcefully assert his or her right to compensation. In addition, merely paying some compensation to the patient may not be sufficient to adequately resolve any conflict of interest that the physician may have between his own research and the treatment needs of the patient.[235]

The Supreme Court correctly noted, however, that "progress in medicine often depends upon physicians, such as those practicing at the university hospital where Moore received treatment, who conduct research while caring for their patients."[236] Given that prohibiting a physician from profiting from research done on their patients could have a devastating effect on the development of new advances in medicine, the second approach, and the approach that will be the most effective in protecting individual autonomy, is to amend federal and state law to clearly require a researcher to inform a patient of potential commercial uses of his or her research. Furthermore, research subjects should be allowed to profit from the use of their tissue.

VII. CONCLUSION

The *Moore* case raised several important questions concerning the effect advances in biotechnology will have on an individual's right to control the disposition of his body. As is the case with other advances in technology, it is important for the courts and legislature to insure that

233. *See supra* text accompanying note 202.

234. *See supra* text accompanying note 212.

235. For a suggestion that the federal regulations be amended to provide that a physician receiving federal funds should not be allowed to profit from the research so funded, see Delgado & Leskovac, *supra* note 193, at 126.

236. Moore v. The Regents of the Univ. of California, 51 Cal. 3d 120, 130, 793 P.2d 479, 484, 271 Cal. Rptr. 146, 151 (1990).

individual autonomy will not be diminished by new scientific discoveries. However, it is also important for society to encourage innovation that will be of benefit to all people.

The California Supreme Court took an important first step in accommodating this balance when it held in *Moore* that the law of informed consent to medical treatment requires a physician to disclose all research interests. In order to protect all research subjects, the federal and state laws regulating informed consent to research must be amended to provide that individuals be told of potential commercial applications of research performed on their tissues. Furthermore, individuals must have the right to refuse to consent to such research, if they so desire.

Finally, it must be remembered that the right to control is distinct from the right to profit. The goal of individual autonomy will best be served by prohibiting individuals from selling their tissue. However, given that our current system of medical research and advancement depends on research done by researchers who expect to profit from successful results, it is not just to prohibit the tissue donor from receiving compensation while the researcher profits. Therefore, those who provide tissue to be used in biotechnology research should have the right to receive compensation for its use. Otherwise, as the general public grows to perceive that they are being mined for profit by their treating physician and other researchers, the integrity of the doctor-patient relationship will be irreparably damaged and more and more people may refuse to provide biological materials needed for research.

COMMENT

SCANNING INTO THE FUTURE OF COPYRIGHTABLE IMAGES: COMPUTER-BASED IMAGE PROCESSING POSES A PRESENT THREAT

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I. INTRODUCTION

Traditionally, infringing upon copyrighted photographs and drawings was an easy task. An infringer hired a competent artist or photographer to recreate the image, and then the unlicensed copy was put to use. Today, swiftly advancing computer technology is making traditional processes for infringement seem slow and laborious. This new computer technology, namely digital scanning and image processing, has created a need to refine the tests for copyright infringement.

Digital scanning and image processing in the computer graphics and photography industries parallels digital sound sampling in the music industry. The inadequacy of current copyright law to protect still images and the lack of photograph infringement cases should be addressed by a plaintiff-oriented approach to copyright infringement lawsuits, providing still images actual protection and encouraging artists to protect their images. Image processing technology has made extra-judicial protection necessary for artists, both to enable people to use artists' work without infringing copyrights and to compensate artists for the use of their work.

Section II of this comment provides an introduction to the relevant computer technology and its capabilities, costs, and applications. Section III presents the copyright and ethical problems that have arisen and are expected to arise with the use of this technology. Then in Section IV, the traditional approach to determining copyright infringement is discussed. This section reviews the applicability of the traditional approach to the problem of infringement through digital scanning and image processing, followed by a discussion of the fair use exception. Section V proposes a change in the traditional approach that would compensate for the increased infringement potential of this new technology. Section VI compares image processing and digital music sampling. Finally in Section VII, this author suggests that artists organize a national registry, similar to those in the music industry, in order to protect their work and collect royalties.

II. THE TECHNOLOGY

Image-processing is "the alteration and analysis of a picture for such purposes as enhancement and recognition."[1] Image processing products and their functions fall into four major categories: electronic photography cameras (input or image capturing devices), playback and recording systems (processing devices such as computers), still-image printers (output devices), and image transmission systems (for communication between processing devices).[2]

In order to process images, an image must first exist. Although images can be created on computers without any outside source,[3] this Comment will focus solely on the capture and alteration of existing images. Most often, an image (usually a photograph) is inputted to a computer for processing by using an electronic camera which digitally scans the image.[4] To scan is "to digitize, or convert, a real-world image, such as a photograph or text, into ... data on a computer. The resulting digital image is also called a scan."[5] Electronic cameras, or scanners, come in several forms, including laser scanners,[6] CCD cameras,[7] and fax machines.[8]

An important feature of scanning devices is the degree of resolution they achieve in the copies they make. This resolution is expressed in the number of component parts, or pixels, into which an image is divided[9] — the more pixels, the finer the detail in the picture.[10]

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1. Spalding & Dawson, *Finding the Titanic,* BYTE, Mar. 1986, at 96, 110.

2. Birkmaier, *SV High and Low,* AUDIO-VISUAL COMM., Mar. 1989, at 28, 28.

3. A computer user may create an image from "scratch" by using the computer program to directly generate each element of his or her art work. Hanselman & Gordon, *New Library of Software Packages Advances Image Processing,* GRAPHIC ARTS MONTHLY, Mar. 1985, at 116, 116.

4. Abernathy & Weiss, *Gray Expectations,* MACUSER, June 1989, at 170, 170.

5. *Id.* Basically, a scanner records a two dimensional image in computer memory using the same technology that a digital audio tape uses to record sound. *See infra* text accompanying notes 188-195.

6. Streano, *Retouching History?,* PUB. REL. J., Mar. 1986, at 8, 8; Garneau, *Laser-based Electronic Cameras: Some Newspapers Praise Them, Others Can't Afford Them,* EDITOR & PUBLISHER, Nov. 5, 1988, at 18P.

7. One Kodak CCD (charge-coupled device) has a resolution of 1.4 million picture elements (pixels). Galluzzo, *Kodak Breaks Million Pixel Barrier with New Image Sensor,* MODERN PHOTOGRAPHY, Sept. 1986, at 28. A CCD is a device which produces an electrical voltage in relation to the type and amount of light striking it. *Id.*

8. Fax machines use scanners to capture and convert images to digital signals and then send those images over telephone lines to a computer or another fax machine. Fitzpatrick, *Facts About Fax,* 43 J.AM. SOC'Y CLU & CHFC 15, 15 (1989).

9. "Resolution—the maximum number of pixels that a scanner can fit into an inch. The higher the resolution, the more fine details you can see in an image." This is usually expressed in dots per inch (dpi), where a dot is the equivalent of a pixel. Abernathy & Weiss, *supra* note 4, at 170. "Resolution: In image processing, the number of bits of

Once an image has been digitized through the scanning process, a computer can manipulate the image.[11] Computer memory, computer disk, magnetic tape, and other common means electronically store the digitized image.[12] Once stored, the memory of the computer must contain the proper image processing program in order to process the image. Such programs are quite common. "Systems for image processing range over almost all of the computer field—from Apples and IBM Personal Computers (PCs), through small minicomputers, to mainframe installations."[13]

The extent to which an image can be manipulated during storage depends on the type of image processing program that is used. "[S]oftware lets users ... electronically process in much the same way one might in a conventional darkroom—but without the time and materials."[14] Undoubtedly, such programs put a new face on photography, and go beyond darkroom capabilities.[15]

What can a typical image processing program do? In general, such programs can crop, retouch, cut and paste, change contrast, change brightness, outline, distort elements of an image, rotate an image, blur an image, sharpen or enhance edges, airbrush, smooth textures, add textures, change from positive to negative (and vice versa), highlight, enlarge, reduce, change tint, posterize (to group similar gray values), alter threshold (to change all grays to either black or white), merge two images, or change an image's background.[16]

These possible manipulations result from a computer's ability to take each pixel in an image and individually recolor, reorganize, alter, or

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accuracy or number of gray levels that can be represented in a pixel; for example, 8 bits = 256 levels, 6 bit = 64 levels." Spalding & Dawson, *supra* note 1, at 110. "Pixel: The smallest unit of storage in a digital image...." *Id.*

10. Pixels number in the millions, depending on the system, and each pixel element can be individually signaled for color and brightness. Streano, *supra* note 6, at 8.

11. Video images may also be digitized for computer using an imaging board. Spiegelman, *AST Board Eases Process of Bringing Images from Video Camera to Mac II*, PC WEEK, Aug. 15, 1988, at 18.

12. *See* Hanselman & Gordon, *supra* note 3, at 116.

13. Star, *Introduction to Image Processing*, BYTE, Feb. 1985, at 163, 164. The capabilities of these programs will be discussed *infra* at text accompanying notes 16-25.

14. Hanselman & Gordon, *supra* note 3, at 118.

15. *Id.*; Antonoff, *Image Capture for Business*, PERSONAL COMPUTING, Apr. 27, 1990, at 101, 101-102.

16. Hanselman & Gordon, *supra* note 3; Thompson, *Industrial-Strength Color Processing*, BYTE, Apr. 1989, at 97; Dawson, *Doing It Digitally*, AUDIO-VISUAL COMM., Feb. 1988, at 19; *XEROX- IMAGING; (XRX) Xerox Imaging Systems to Market Electronic Darkroom for Desktop Publishing on IBM PC and PS/2 Platforms*, BUS. WIRE, Sept. 12, 1989; Sussman, *Graphics Software Traces Scanned Objects*, PC WEEK, Mar. 1, 1988, at 19; Fiderio, *The Electronic Darkroom*, BYTE, Mar. 1989, at 104; Streano, *supra* note 6; Brand, Kelly & Kinney, *Digital Retouching*, WHOLE EARTH REV., July 1985, at 42.

combine it with another pixel to enhance the image or form an entirely new image.[17] Many computer programs can manipulate 256 levels of gray.[18] In order to alter color, some programs have a "palette" of 16.7 million colors from which to choose.[19]

Certain procedures are easier than others. For instance, eliminating an object in the background of a photograph is a simple process.[20] Wholesale operations such as enlarging, reducing, or changing an image from positive to negative are also categorized as "easy." On the other end of the scale, pixel-by-pixel manipulation is relatively time consuming. Yet a computer's ability to alter a photograph's smallest elements can create the most unique and radical effects.[21] For example, a person's eyes, closed in the photograph, can be opened, and his or her eye color changed.[22]

Once scanned, processed, and then reprinted, alterations made to a photo can be undetectable.[23] Arguably, if a copy has enough alterations, its source material will be unidentifiable. Image processing produces extremely accurate and realistic copies.[24] National magazines have used image processing to alter photographs which their readers would assume were unchanged. *National Geographic Magazine*, for instance, manipulated

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17. Streano, *supra* note 6, at 8; *see also* Brand, Kelly & Kinney, *supra* note 16.

18. Hanselman and Gordon, *supra* note 3, at 118.

19. Spiegelman, *supra* note 11; Picarille, *Color Highlights Graphics Show: New Releases Allow Color Separations, Video Imaging*, PC WEEK, Apr. 24, 1989, at 23, 30.

20. Streano, *supra* note 6, at 8; Reveaux, *I Second That Emulsion*, MACUSER, Jan. 1989, at 201, 202; Brand, Kelly & Kinney, *supra* note 16, at 42.

21. *See, e.g.*, Hanselman & Gordon, *supra* note 3, at 118.

22. Streano, *supra* note 6, at 8. A photograph in the *San Jose Mercury News* appeared to show Michael Dukakis surrounded by George Bush, Jesse Jackson, and Ronald Reagan at a dais displaying a Dukakis-Bush campaign poster. The photograph had been altered. Heads had been brought in from other photographs, the poster's lettering had been reversed and changed, Dukakis' watch had been moved, and his daughter's and wife's jacket colors switched. Rosenburg, *Computers, Photographs and Ethics*, EDITOR & PUBLISHER, Apr. 8, 1989, at 40, 40.

23. Streano, *supra* note 6, at 8; *see also* Brand, Kelly & Kinney, *supra* note 16.

24. Brand, Kelly & Kinney, *supra* note 16. Photorealistic models can be created on a computer. Brown & Verity, *The Graphics Revolution*, BUS. WEEK, Nov. 28, 1988, at 142, 143. Computers can be programmed to put correct shadows, calculated from an imaginary light source, into images. Sherman, *The Latest Generation of Computers Can Generate Images that Will Help Us in Future Generations*, MODERN PHOTOGRAPHY, Jan. 1985, at 20, 21.

Recently in Los Angeles, a man was accused of creating $100 million worth of fake art, including fake Renoirs, and bilking art investors out of millions. It is possible to spot such a fake, but "it often takes an expert who's been around for 30 years to determine ... whether a color sequence is wrong." Some of the fakes were "produced with sophisticated and costly laser scanning equipment that can 'duplicate prints with a margin of error that is very slim.'" Sahagun & Woodyard, *Art Fraud Suspect's Bail Cut*, L.A. Times, Sept. 30, 1989, § 2 (Metro), at 3, col. 2. It seems this scanning equipment, even though costly, was put to profitable use. The scanned images were transferred to a lithograph plate or silkscreen process after they were scanned. *Id.*

the pyramids in the background of a photograph of Egypt so that all the pyramids would fit on the magazine's cover.[25]

Once an image has been scanned, stored, and manipulated, it can be outputted to a variety of media. These include digital cameras,[26] printers,[27] photographic prints,[28] slide negatives,[29] transparencies for overhead projectors,[30] lithographs,[31] and silkscreens.[32]

Output can also take the form of transmission to another system.[33] This type of intersystem communication is usually accomplished via phone lines using standard modem communication software.[34]

The cost of digital scanning and image processing technology has decreased significantly and is expected to continue falling. Fax machines cost one fifth what they did five years ago.[35] Today, consumers can purchase an advanced scanner for around $2000.[36] Memory chips cost one thirtieth of what they did in 1980 and have much greater capacity.[37] This additional storage capacity translates into an ability to store larger numbers of more detailed pictures.[38] Image processing programs for home computers cost in the neighborhood of $500.[39] Electronic publishing systems have become so cheap that small businesses can

25. Brand, Kelly & Kinney, *supra* note 16, at 43. (The pyramids were moved in the Feb. 1982 edition of *National Geographic Magazine*). In *National Geographic Magazine*, April 1982, a hat was added to the person on the cover. *Id.* In December 1983, *PopularScience* substituted the background from one photo for the background of the cover photograph. *Id.* at 46. In *The New York Times Magazine*, April 1983, a technician electronically filled a photograph with shrubbery. The *New York Times* claimed it did not notice until later. *Id.* In the cover photo of one issue of *Rolling Stone Magazine*, Miami Vice's Don Johnson's pistol and shoulder holster were electronically removed. Seymour, *Let Me Scan Just This One Picture*, PC, Jan. 12, 1988, at 77, 77.

26. Birkmaier, *supra* note 2, at 37.

27. *Id.*

28. Picarille, *supra* note 19, at 30.

29. *Id.*

30. *Id.*

31. Sahagun & Woodyard, *supra* note 24.

32. *Id.*

33. Hanselman & Gordon, *supra* note 3, at 122.

34. Rosenburg, *Digital Transmission of Photos*, EDITOR & PUBLISHER, Nov. 5, 1988, at 14P.

35. Fitzpatrick, *supra* note 8, at 15.

36. Abernathy & Weiss, *supra* note 4, at 172.

37. Brown & Verity, *supra* note 24, at 144.

38. *Id.*

39. MacVision software was introduced at $399. Miley, *Big Frame Hunters*, MACUSER, Mar. 1989, at 35, 35. GraphistPaint II was priced at $495. Martinez, *GraphistPaint II*, MACUSER, Apr. 1989, at 45, 45. Picture Publisher was priced at $595. Thompson, *supra* note 16, at 97. PhotoMac was priced at $695. Fiderio, *supra* note 16, at 105. Image Studio 1.5 was priced at $495. Reveaux, *supra* note 20, at 208. Digital Darkroom 1.0 was priced at $295. *Id.*

economically produce their own advertisements.[40] In 1988, the value of shipments of hardware and software used in computer graphics systems reached $9.1 billion. Such shipments are expected to grow to $27 billion by 1993.[41] Image processing systems are also becoming more powerful; today a $7,000 personal computer with software can outperform a $100,000 graphics workstation from 1980.[42]

In addition to the low cost and ease of manipulating scanned images, scanners can process images with remarkable speed. State-of-the-art scanners can scan 120 office documents per minute.[43] Within six hours, one can convert a photo into a full size billboard.[44] Recording photographic subjects directly in digital form using a special camera, rather than scanning an intermediary photographic print, could soon be viable.[45]

III. COPYRIGHT AND ETHICAL PROBLEMS: A FOCUS ON PUBLISHING AND COMPUTERS

The publishing industry and the computer industry are breeding most of the copyright problems based on image processing. Publishers and computer hackers alike are grappling with the legal and ethical difficulties posed by image processing, often at the expense and distress of photographers and other image producers.

A. Publishing

Traditionally, readers trusted magazines to use unaltered photographs. With the changes in technology, however, publishers can alter any photograph available to them. Responding to criticism for moving pyramids on its cover,[46] *National Geographic Magazine's* editor maintained that the alteration merely established a new point of view from which the photo could have been taken.[47] The news industry, as a source of documentary images, generally agrees that "[e]lectronic manipulation is acceptable only in efforts to improve design elements, as seen in the *National Geographic* example, but not to [re]arrange actual

40. Hammonds, *These Desktops are Rewriting the Book on Publishing*, BUS. WEEK, Nov. 28, 1988, at 142, 142.
41. Brown & Verity, *supra* note 24, at 143.
42. *Id.* at 144.
43. *Kodak Unveils New Products for the Imaging System of Today...and Tomorrow*, BUS.WIRE, June 13, 1989.
44. *Putting Byte into Billboards*, TIME, May 11, 1987, at 57, 57.
45. Hammonds, *supra* note 40, at 156.
46. *See supra* text accompanying note 25.
47. Streano, *supra* note 6, at 8.

events."[48] Other than this position, very little agreement exists as to what ethical standards press photographers should use.[49] Moreover, the advertising industry has implemented fewer and less rigorous ethical restraints on scanning and image processing than the news industry.[50]

B. Computers

1. *ELECTRONIC BULLETIN BOARDS AND INFORMATION SERVICES*

Unauthorized use of images is now commonplace in the desktop publishing industry.[51] One writer humorously defined copyright in a personal computing magazine: "Copyright, n. The indisputable common-law privilege held since time immemorial by owners of optical scanners to reproduce anything they can get their hands on as clip art."[52] Computer bulletin boards and information services enable personal computer users with modems to send (upload) and retrieve (download) images (clip art) to and from these services' computers. Knowing that copyright infringement is taking place, the computer services post warnings to subscribers that submission or use of copyrighted material is illegal and should not be done without the appropriate permission.[53]

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48. *Id.*

49. "The National Press Photographers Association conference was concerned with technical aspects, ethical questions and managerial ... impact of computerized handling of photography. For its consideration of technology and ethics, the meeting probably produced no more agreement on ethical standards than now exists on technical standards." Rosenburg, *supra* note 34, at 40.

50. Streano, *supra* note 6, at 8. Legal remedies exist for false advertising and unfair competition. However, these only serve as outer boundaries in delineating ethical considerations and are only available if the harmed party is willing to resort to litigation.

51. Seymour, *supra* note 25.

52. Shapiro, *The Devils Desktop Publishing Dictionary*, MACWEEK, Oct. 25, 1988, at 102. "Clip art", prior to the computer age, referred to art that graphic artists clipped out of printed sources with scissors for use in their own artwork. In the computer context, clip art is a variation of the same thing except the artwork first must be digitized. A large market exists for selling volumes of digitized images on computer disk or "clip-art packages" for use in desktop publishing. Raskin, *PC-based Clip Art: Instant Images*, PC MAGAZINE, Oct. 17, 1989, at 149.

53. Shapiro, *Copywrongs on Consumer Info Networks? Posting of Scanned Images on Electronic Services Infringes Copyrights*, MACWEEK, Aug. 30, 1988, at 20, 20.

DIALOG is an accessible computer database which contains TRADEMARKSCAN (graphic representations of trademarks digitized from the *Official Gazette of the U.S. Patent and Trademark Office* available with accompanying text of applications and registrations). Chadwick, *Dialog Comments on Imaging Capabilities: An Interview with Fred Zappert*, ONLINE, May 1989, at 28; Thompson, *DIALOGLINK and TRADEMARKSCAN—Federal: Pioneers in Online Images*, ONLINE, May 1989, at 15. Using TRADEMARKSCAN, "[b]usiness users can compile and monitor portfolios of their own and competitors' trademarks." *Id.* at 21. Obviously, users can also use it to steal or infringe trademarks!

Beyond warnings, these computer services generally take two approaches to copyright infringement. First, some conference services do not enforce the warnings and do not monitor the system for copyrighted images. They argue that the service "is a common carrier, like the phone company, and as such is not responsible for the content it carries."[54] Second, conference services that publish images as well as carry them monitor their services as best they can, but often find it impossible to recognize copyrighted material. These systems operators contend "that they could not purge the graphic files and remain competitive."[55] In response to magazine complaints about infringements taking place, some services argue that "because no one can mistake a scanned copy for an original, the copyright holder is not hurt."[56] At best, the argument is weak, and considering the capabilities of image processors, this position would likely fail if maintained as a defense.[57] Other services hope to use the fair use exception to avoid liability.[58]

2. *INDIVIDUAL USERS*

Computer users are engaging in unauthorized use of image processing because the computer industry lacks standards to guide them.[59] The industry needs and wants guidelines, as evidenced by trade magazine articles that attempt to tackle the problem.[60] These magazines provide inconclusive advice and discussion about this dilemma.[61]

In the meantime, computer users stumble along. Many small businesses create their own advertisements by using desktop publishing programs to manipulate scanned images.[62] In some cases the computer manuals for these programs demonstrate cut and paste techniques without warning the reader about possible copyright infringement.[63]

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54. Shapiro, *supra* note 53, at 20.
55. *Id.* at 23.
56. *Id.*
57. *Id.*
58. *Id.* In short, the fair use doctrine allows a defendant who has copied a work to escape liability if he has not copied a substantial portion of the work or if his copy fulfills a different function from that of the plaintiff's work. For a more detailed discussion of the fair use doctrine, see *infra* text accompanying notes 91-97.
59. *See* Rosenthal, *Use an Image, Prepare for a Shootout*, MACWEEK, June 13, 1989, at 16.
60. *See, e.g., id.*; Seymour, *supra* note 25; Shapiro, *supra* note 53.
61. *Compare* Coale, *Setting up Shop*, MAC USER, Oct. 1988, at 275, 279 (recommending use of a scanner) *with* Rosenthal, *supra* note 59, at 16 (warning of danger of using scanned images). Computer pornographers, although faced with the very sensitive issue of distributing obscene material, are "far more concerned about the copyright violations involved in the scanning and distribution of nudes [than in the pornography issue]." Lander, *It Was Bound to Happen: Sex Enters Computer Age*, NEWSDAY, Feb. 26, 1989, at 75.
62. Hammonds, *supra* note 40, at 154.
63. Beamer, *OmniPage makes OCR a Snap*, MACWEEK, Nov. 22, 1988, at 42.

C. Injury to Photographers

While computer users and photographers debate who owns the copyright to composite or altered images,[64] photographers are also voicing other concerns. For instance, the American Society of Magazine Photographers is concerned about its members' financial stake in processed images and about the integrity of those images.[65] As the copyright holders, photographers do not want anyone else to tamper with their images for either commercial or aesthetic reasons.[66] Other photographers hypothesize that digitizing to create as well as to infringe upon images could make photography unprofitable. In addition, the art of photography could lose its outstanding and creative people, resulting in reused, boring images without individual creative spark.[67]

IV. THE TRADITIONAL APPROACH TO COPYRIGHT INFRINGEMENT AND ITS APPLICATION TO IMAGE PROCESSING

A. The Traditional Approach to Copyright Infringement

The traditional court approach to copyright infringement actions is helpful in determining how copyright concepts will be applied to copying through image processing technology.

Courts have traditionally required three elements in a copyright infringement case.[68] First, the plaintiff must prove that the defendant had access to the plaintiff's work.[69] Second, the material at issue must be

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64. *See* Streano, *supra* note 6, at 10.

65. Seymour, *supra* note 25, at 77-78.

66. Shapiro, *More on Copyright*, MACWEEK, Oct. 11, 1988, at 27, 27. Authors of visual works have also attempted to preserve the integrity of their works even where they no longer hold the copyright. For example, the Director's Guild maintains, and a federal report found, that alteration and colorization of films has adverse effects on films and injures the reputation of directors. Honan, *Federal Report Criticizes the Coloring of Films*, N.Y. Times, Mar. 16, 1989, Business, at C22, col. 1. This problem is known as the "moral rights issue" and has been a growing issue in art in recent years. Artists claim to hold the moral rights of paternity and integrity in the work that they create. Artists, when they do not own or have sold the copyright to their creations, often seek to assert these moral rights when those creations are threatened with alteration. *See generally* Verbit, *Moral Rights and Section 43(a) of the Lanham Act: Oasis or Illusion?*, 9 COMM/ENT L. J. 383 (1987).

67. Streano, *supra* note 6, at 10.

68. *See* Cohen, *Masking Copyright Decisionmaking: The Meaninglessness of Substantial Similarity*, 20 U.C. DAVIS L. REV. 719, 728 (1987).

69. Gaste v. Kaiserman, 863 F.2d 1061, 1066 (2d Cir. 1988) ("Because copiers are rarely caught red-handed, copying has traditionally been proven circumstantially by proof of access and substantial similarity."); *see* Cohen *supra* note 68, at 728.

copyrightable material.[70] Copyright law protects only the expressions of ideas, not the ideas themselves.[71] Thus, the plaintiff must show that the material was an expression, not just an idea.[72] Third, the plaintiff must prove that the two expressions are substantially similar, with the trier of fact acting as an ordinary observer.[73] If the similarity exists, the defendant can still escape liability if the trier of fact finds that he or she fairly used the material.[74]

1. *COPYRIGHTABILITY OF STILL IMAGES*

Photographs and other images (e.g. drawings, paintings, lithographs) are copyrightable.[75] The concept of originality figures heavily in determining the differences between idea and expression in photographs.[76] Slavish copying of a photograph (e.g. xeroxes, photographs of photographs, or microfilm) is not considered original, so a work produced by one of these methods is not copyrightable.[77] Although every photograph could be considered an "original," for purposes of copyright, courts do not consider it original to reproduce a photograph by copying the technique and subject. The copyist is liable for infringement if a court cannot find any distinguishable variation from the original.[78] Generally a copyright on a photograph gives rights to all the copyrightable original elements. These elements include angle, perspective, choice of lens, and color patterns, but not the subject unless the subject itself is copyrightable.[79]

2. *SUBSTANTIAL SIMILARITY*

The determination of similarity between two works necessarily involves an attempt to grasp the difference between idea and expression.[80] This dichotomy is ambiguous.[81] It often involves

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70. Cohen, *supra* note 68, at 728.

71. 17 U.S.C. § 103 (1988); M. NIMMER, NIMMER ON COPYRIGHT, § 13.03[A] (1988). For further discussion, see *infra* text accompanying notes 80-82.

72. Cohen, *supra* note 68, at 730.

73. M. NIMMER, *supra* note 71, § 13.03[A]; *see also* Cohen, *supra* note 68, at 731.

74. 17 U.S.C. § 107 (1988); *see also* Cohen, *supra* note 68, at 731.

75. 17 U.S.C. § 103 (1988); Burrow-Giles Lithographic Co. v. Sarony, 111 U.S. 53 (1884).

76. M. NIMMER, *supra* note 71, § 2.08 [E][1].

77. Gracen v. Bradford Exchange, 698 F.2d 300, 305 (7th Cir. 1983); M. NIMMER, *supra* note 71, § 2.08[E].

78. Time Inc. v. Bernard Geis Assoc., 293 F. Supp. 130 (S.D.N.Y. 1968) (a sketch of the subject photograph would have been an infringing copy except that it was judged a fair use).

79. M. NIMMER, *supra* note 71, §§ 8.01[D], 2.18[H][2]; *see also Burrow-Giles Lithographic*, 111 U.S. at 60; Pagano v. Chas. Beseler Co., 234 F. 963, 964 (S.D.N.Y. 1916); Edison v. Lubin, Pa., 122 F. 240, 242 (C.C.A.Pa. 1903); *Bernard Geis Assoc.*, 293 F. Supp. at 143.

80. M. NIMMER, *supra* note 71, § 13.03[A].

determining the point at which a work embodying a common theme (an idea) rises to a level of originality at which it becomes an expression of that theme.[82]

Substantial similarity is also a rather amorphous concept.[83] Generally, similarity between two works is of two types. The first type, "comprehensive non-literal similarity,"[84] occurs when the structure or overall pattern of two works is the same. This similarity is likened to paraphrasing; no single element is *exactly* the same. It means that an "immaterial variation" does not justify allowing an infringer to escape liability.[85] Liability exists for comprehensive non-literal similarity.

The other type of similarity is "fragmented literal similarity," which describes a similarity in detail but not in overarching concept.[86] This situation occurs where some parts of the alleged copy are exactly the same (or nearly so). Liability turns on whether the copying was material, involved a substantial portion of the plaintiff's work, or both. Courts and commentators often use the doctrine of fair use to describe this type of value judgment.[87]

Ordinarily, the presence of dissimilar material in a defendant's work does not immunize him or her from liability for infringement unless the material indicates that the plaintiff's material is of minimal import quantitatively, qualitatively, or both.[88]

3. *TRADITIONAL APPROACHES TO SUBSTANTIAL SIMILARITY*

Courts have approached the question of substantial similarity in several ways. In most instances courts use the "ordinary observer" test, in which the spontaneous and immediate reaction of a lay observer, without aid or suggestion, determines whether substantial similarity exists.[89]

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81. *Id.*
82. *Id.*
83. *Id.*
84. *Id.* § 13.03[A][1]; *see also* Sheldon v. Metro-Goldwyn Pictures, Corp., 81 F.2d 49 (2d Cir. 1936) (judging substantial similiarity with respect to the whole of the copied portions, including non-copyrightable elements).
85. Nichols v. Universal Pictures, Corp., 45 F.2d 119, 121 (2d Cir. 1930); M. NIMMER, *supra* note 71, § 13.03[A][1].
86. M. NIMMER, *supra* note 71, § 13.03[A][2]; *see also* Alexander v. Haley, 460 F. Supp. 40 (S.D.N.Y. 1978) (trial court excluded scenes common to depictions of slavery, and once these scenes were eliminated found the works were not substantially similar).
87. M. NIMMER, *supra* note 71, § 13.03[A][2].
88. *Id.* § 13.03[B]; *see Sheldon*, 81 F.2d at 56 ("no plagiarist can excuse the wrong by showing how much of his work he did not pirate").
89. M. NIMMER, *supra* note 71, § 13.03 [E][1].

Courts also use the pattern test, where the original and alleged copy are dissected to determine individual points of similarity. The trier of fact compares these points and, based on that comparison, determines whether substantial similarity exists.[90]

4. *THE FAIR USE EXCEPTION*

The doctrine of fair use allows the trier of fact to find that the maker of a similar copy is not liable when (1) the similarity to the original is not substantial or (2) the defendant's work fulfills a different function from that of the plaintiff's.[91] The court weighs four factors in determining function. First, the court decides if the defendant used the material for a non-profit/educational or commercial purpose.[92] Second, the court must determine the nature of the material.[93] For example, a textbook prepared for a school market could not properly be copied for school use. Third, the court considers the amount and substantiality of the portion copied.[94] Lastly, the effect of the defendant's work on the plaintiff's potential market must be evaluated.[95] These four factors may be weighed independently,[96] and the most important factor is the last—impact on the plaintiff's market.[97]

5. *TRADITIONAL APPROACHES TO PROVING COPYRIGHT INFRINGEMENT*

The traditional three-step approach to proving copyright infringement is problematic. For instance, an ordinary observer lacks standards as to whether he or she should compare the works as whole, look to important parts, or look to the value of material copied.[98] In addition, the three-step approach fails to distinguish between the issue of copying and that of misappropriation or fair use.[99] Furthermore, the traditional approach requires duplicative determinations of substantial similarity, first for infringement and then for fair use.[100]

Several courts have recognized and attempted to address the problems with the traditional approach to proving copyright

90. Chafee, *Reflections on the Law of Copyright*, 45 COLUM. L. REV. 503, 513 (1945).
91. 17 U.S.C. § 107 (1988); *see also* M. NIMMER, *supra* note 71, §§ 13.05 [A], [B].
92. 17 U.S.C. § 107 (1988).
93. *Id.*
94. *Id.*
95. *Id.*
96. Hustler Magazine v. Haberman, 626 F. Supp. 201 (D. Mass. 1986).
97. M. NIMMER, *supra* note 71, § 13.05 [A][4]; Harper & Row v. Nation Enters., 471 U.S. 539 (1985); Sony Corp. of Am. v. Universal City Studios, Inc., 464 U.S. 417 (1984).
98. Cohen, *supra* note 68, at 741-49.
99. *Id.*
100. *Id.* at 735-47.

infringement. In *Arnstein v. Porter*,[101] using an analysis of substantial similarity under the traditional approach, the court attempted to overcome several of the problems in determining substantial similarity.[102] *Arnstein* used a two-step approach to determine substantial similarity. First, the court determined whether the defendant's work copied the plaintiff's work.[103] The court then did a critical analysis which probably included evaluating the idea/expression dichotomy, not an ordinary observer test.[104] Under the *Arnstein* approach, if the defendant's work is a copy, the court then applies the ordinary observer test to determine whether the copying constituted an improper appropriation (a theft of value beyond fair use).[105]

Another case, *Sid & Marty Krofft Television Productions, Inc. v. McDonald's Corp.*,[106] which referred to the *Arnstein*[107] approach, used a different two-step approach. The first step, an "extrinsic test," required a comparison of specific criteria such as subject matter, setting, type of artwork, and materials used in the works.[108] The second step, an "intrinsic test," used the ordinary observer approach to evaluate whether the similarities in expression justified holding the defendant liable.[109] This test is limited because it does not involve a critical analysis of the idea/expression dichotomy to determine whether substantial similarity exists.[110] Accordingly, the court probably misinterpreted *Arnstein*. The confusing overlap of substantial similarity and fair use also continued to exist in *Krofft* as it had in *Arnstein*.[111]

B. Application of the Traditional Approach to Infringement Through Image Processing

The traditional approach to determining substantial similarity, when applied to image processing cases, presents two problems. First, the approach lacks the sophistication to identify the changes made and decide whether those changes eliminate substantial similarity. Second,

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101. 154 F.2d 464 (2d Cir. 1946).
102. *Id.*; *see* M. NIMMER, *supra* note 71, § 13.03 [E][3]; Cohen, *supra* note 68, at 731.
103. *Arnstein*, 154 F.2d at 468-70; *see* M. NIMMER, *supra* note 71, § 13.03 [E][3]; Cohen, *supra* note 68, at 731.
104. *Arnstein*, 154 F.2d at 472-73; *see* M. NIMMER, *supra* note 71, § 13.03 [E][3]; Cohen, *supra* note 68, at 731.
105. *See* M. NIMMER, *supra* note 71, § 13.03 [E][3]; Cohen, *supra* note 68, at 732.
106. 562 F.2d 1157 (9th Cir. 1977).
107. *Krofft*, 562 F.2d 1164; *see* M. NIMMER, *supra* note 71, § 13.03 [E][3].
108. *Krofft*, 562 F.2d 1164; *see* M. NIMMER, *supra* note 71, § 13.03 [E][3].
109. *Krofft*, 562 F.2d 1164; *see* M. NIMMER, *supra* note 71, § 13.03 [E][3].
110. Cohen, *supra* note 68, at 755.
111. *Id.* at 757.

the approach cannot cope with the speed and ease that image processing lends to the task of infringing still images.

Because an infringer using image processing can steal small fragments of the original, the ordinary observer is easily fooled.[112] Theoretically, a copyright gives actual protection to the copyright holder against theft of the fruits of his or her labor. An audience's impression that the works are or are not similar does not necessarily accomplish this goal.[113] This test also fails to adequately distinguish between idea and expression and to evaluate specific details in a work.[114] One solution would be to limit the ordinary observer test to determining whether fair use exists.[115] That is, since the fair use doctrine requires a value judgment in evaluating whether the defendant misappropriated the expression, an ordinary observer could make the value judgment.

1. *PROBLEM #1: THE UNDETECTABILITY OF CHANGES—EMBRACING THE CAPABILITIES OF IMAGE PROCESSORS USING EXISTING CASE LAW*

a. The Pattern Test

Because of an image processor's ability to make subtle pixel-by-pixel changes, the average person cannot detect the changes.[116] As a result, a defendant who steals small fragments of the plaintiff's work may escape the ordinary observer test undetected. Therefore, courts are probably not justified in using the ordinary observer test for determining substantial similarity.

Alternatively, courts could use the pattern test and compare the individual elements of the images.[117] Courts could justify the use of this approach because copyrightability of photographs is based on individual elements such as angle and perspective.[118] This alternative test takes into account the subtle alterations created through image processing.

b. Substantial Similarity in Still Images

In comparing images, courts will encounter the problem of determining the extent to which an image can copy the expression from an original without crossing the threshold to infringement.

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112. M. NIMMER, *supra* note 71, § 13.03 [E][2].
113. *Id.*
114. Cohen, *supra* note 68, at 739.
115. *Id.* at 737 & n.66.
116. *See supra* text accompanying notes 16-25.
117. *See supra* text accompanying note 90.
118. *See supra* text accompanying notes 75-79.

Fortunately, some case law exists for those who wish to protect against image processors. In *Franklin Mint Corp. v. National Wildlife Art Exchange*[119] the court stated that copyright confers "the sole right to reproduce the work and to control all the channels though which ... [the] work, or any fragments of ... [the] work reach the market."[120] Applied to still images, "fragments" that are copied, no matter how small, can cause infringement.

However no such copying of fragments was found in *Franklin*. In that case, the plaintiff alleged that the defendant had made a copy of a scientific-style painting of a bird. The pictures were *very* similar, but no fragment was exactly the same. The court found that an "artist who produces a rendition with *photograph-like* clarity and accuracy may be hard pressed to prove unlawful copying by another who uses the same subject matter and the same technique."[121] The court concluded that the plaintiff's copyright was "weak" because artists possess so few ways to expressively paint a bird's anatomy. Thus, where the subject matter is limited in options for expression, a defendant can escape liability unless actual copying of a fragment can be proven.

Edwards v. Ruffner[122] involved a similar situation. The subject of the photographs was uncomplicated (a ballerina's feet in the fifth position). The court did not hold the defendant liable because the defendant had not reproduced any part of the protectable expression, such as angle or costuming.

Other cases may help plaintiffs impose liability on defendants who steal fragments of the plaintiff's work that make up only a small part of the defendant's work, such as *Foreign Car Parts, Inc. v. Auto World, Inc.*[123] and *Hedeman Products Corp. v. Tap-Rite Products Corp.*[124] Both cases involved defendant's use of plaintiff's material as a part of defendant's multi-page products catalog. In *Foreign Car Parts,* although plaintiff's material appeared on only one page of the catalog, the court held that the defendant had infringed.[125] In *Hedeman,* the court applied a test for the substantiality and materiality of the infringement to each component part of the catalog, not the catalog as a whole. This test questioned whether the defendant took the work at issue from the copyrighted source. Slight differences did not constitute a defense.[126] Similarly, in *Lynn Goldsmith v.*

119. 575 F.2d 62 (3d Cir. 1978).
120. *Id.* at 64 (quoting Chafee, *supra* note 90, at 505).
121. *Id.* at 66 (emphasis added).
122. 623 F. Supp. 511 (S.D.N.Y. 1985).
123. 366 F. Supp. 977 (M.D. Pa. 1973).
124. 228 F. Supp. 630 (D.N.J. 1964).
125. *Foreign Car Parts,* 366 F. Supp. at 977.
126. *Hedeman,* 228 F. Supp. at 631.

Peter Max,[127] the defendant had cut up a photograph of Mick Jagger and incorporated pieces of the photograph into an acrylic painting. The court noted that, had the plaintiff's copyright been valid, it may have held the defendant liable for infringement.[128]

The preceding line of cases does not consider situations where a defendant's copy involves different subject matter or an area where many possibilities for expression exist. Therefore, these cases do not provide adequate guidelines regarding the extent to which an image processor can copy without infringing on the artist's copyright. If there is no copying, there can be no infringement.[129] But how big is an infringing fragment? One pixel? Two pixels? This undoubtedly depends on both the fragment's recognizability and the outcome of an evaluation under the idea/expression test. Although undecided, courts will probably protect any small piece that a plaintiff can identify as coming from his or her photograph.

c. Case Law Analogous to Image Processor Functions

Court decisions in similar situations provide some indications about how courts may treat image processing cases. Photographic reproductions of portions of a copyrighted work, as can be performed by computer cut and paste, constitute infringement.[130] For those who may conglomerate stolen images to create an advertisement or catalog (e.g., small businesses), precedent exists for making substantial similarity comparisons of these component images individually.[131]

The tests for originality and infringement are different.[132] However, in determining what types of image processing prevent works from being substantially similar, courts may look at factors that have been considered in the context of deciding whether a derivative work is copyrightable. Enlargement or reduction, for instance, does not result in an "original" product even though it involves the effort of artistic scaling.[133] Adding

127. 213 U.S.P.Q. 1008 (S.D.N.Y. 1981); 1978-81 Copr.L.Dec. ¶ 25,248.

128. Related questions of fair use are discussed *infra* at text accompanying note 143.

129. Mazer v. Stein, 347 U.S. 201, 218 (1954).

130. Sub-contractors Register v. McGovern's Contractors and Builders Manual, 69 F. Supp. 507, 510 (S.D.N.Y. 1946).

131. "In mail-order catalog copyright infringement actions, the court must look not to the substantial similarity of the entire catalog, but at the substantial similarity of the very small amount of protectable parts." Haan Crafts Corp. v. Craft Masters, Inc., 683 F. Supp. 1234, 1243 (N.D. Ind. 1988).

132. *See, e.g.*, Sargent v. Am. Greetings Corp., 588 F. Supp. 912, 918 (N.D. Ohio 1984). "A work which makes non-trivial contributions to an existing one may be copyrighted as a derivative work and yet, because it retains the "same aesthetic appeal" as the original, render the holder liable for infringement of the original copyright." *Id.*

133. L. Batlin & Son, Inc. v. Snyder, 536 F.2d 486, 491 (2d Cir. 1976).

colors to a black and white photograph, another image processing capability, may create a copyrightable work depending on the extent and complexity of the colorization.[134] Similarly, those who colorize films using a complicated process with extensive color additions can copyright the film.[135] However, one cannot copyright a film by changing it from color to black and white.[136]

Great time and effort expended in copying an artwork does not necessarily make the result copyrightable.[137] The real test is whether the artist used independent effort—preferably great independent skill beyond physical skill or training.[138] Courts could use this test to distinguish between "easy" image processing (inverting an image or changing a color image to black and white), and, on the other end of the scale, "hard" image processing (pixel-by-pixel manipulation or colorizing an image).[139] While extensive "hard" image processing may produce an independently copyrightable image by underhandedly building on and infringing another image beyond the point of detection, courts can also consider the "tone and mood" of a photograph in determining substantial similarity.[140]

2. *PROBLEM #2: THE EASE AND SPEED OF COPYING*

A second problem facing the use of the traditional method of analysis is related to the quantity of alterations and the speed with which they can be made.[141] These two factors permit the production of numerous sophisticated altered copies, making multiple determinations of substantial similarity cumbersome. As discussed, the traditional approach often involves two determinations of substantial similarity: one for whether the defendant copied, and the other for whether his or her copy was a fair use.[142]

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134. *Compare Sargent*, 588 F. Supp. at 919 (whether plaintiff's coloring of defendant's line drawings was itself entitled to copyright protection presented a genuine issue of fact) *with* Hearn v. Meyer, 664 F. Supp. 832 (plaintiff's coloring of well-known public domain images not independently copyrightable).

135. 52 Fed. Reg. 23,443 (1987) (to be codified at 37 C.F.R. § 202) (proposed June 22, 1987).

136. Storm v. Kennington, Ltd., Inc., 223 U.S.P.Q. 790 (N.D. Cal. 1984).

137. *Hearn*, 664 F. Supp. at 839. Note that time is not an overwhelming factor in image processing.

138. *Sargent* 588 F. Supp. at 919; M. NIMMER, *supra* note 71, § 2.08[C][2].

139. In *Hearn*, the court found that huge amounts of time, effort, and craft did not constitute originality. *Hearn*, 664 F. Supp. at 839.

140. Kisch v. Ammirati & Puris, Inc., 657 F. Supp. 380, 384 (S.D.N.Y. 1987).

141. *See supra* text accompanying notes 16-25, 43-45.

142. *See supra* text accompanying note 100.

C. The Fair Use Exception

1. *APPLICABILITY TO IMAGE PROCESSING*

A defendant found to have copied will attempt to escape liability by claiming fair use.[143] Currently, no precedent clearly defines how material or substantial a stolen fragment must be to constitute infringement.[144] Considering that most still images are two dimensional, fixed to paper or canvas, and do not exceed the size of a large painting, one could argue that the copyrighted material is much more condensed than that in a book or film, for instance. Given that comparison, an artist should be able to protect even a small portion of his or her work. Such protection would deter unauthorized image processing.

2. *MARKETS AND IMPACT ON MARKETS*

The most important consideration in evaluating fair use of copyrighted material focuses on the impact of the infringement on the material's markets.[145] Presumably the same markets exist for processed images as exist for the unprocessed originals, including posters, magazines, books, art shows, art galleries, museums, television, and film.

It is important to emphasize that banks,[146] manufacturers,[147] doctors,[148] movie makers,[149] law enforcement agencies,[150] scientists,[151]

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143. *See supra* text accompanying notes 91-97.

144. *See supra* text accompanying notes 123-129.

145. *See supra* text accompanying notes 91-97.

146. Banks scan, store, transfer, and electronically compare signatures. *Signature Verification Products*, COMPUTERS IN BANKING, May 1989, at 96; *Database Incorporates Photos, Text*, PC WEEK, Mar. 1, 1988, at 28. A fax of a signature can be sent to a remote computer and compared with another signature in order to verify it for contracts, checks, or other documents. Fitzpatrick, *supra* note 8, at 15. Banks handle checks electronically after scanning them. Kantrow, *Electronic Check Handling Seen for 90's: Poll Finds 86% of Bankers Interested in Image Processing*, AM. BANKER, Apr. 19, 1989, at 6. Many financial institutions scan credit receipts to prevent fraud and improve billing. Brown & Verity, *supra* note 24, at 145. Moran, *Bank Finds Imaging System Pays Its Way*, COMPUTERWORLD, May 1, 1989, at 25.

147. Manufacturers scan and combine images into text files and then they can transfer the combined files between computers for parts inventories and quality control. *Database Incorporates Photos, Text, supra* note 146. Technicians using electronic access to engineer drawings can improve worker productivity. Brown & Verity, *supra* note 24, at 145.

148. *Database Incorporates Photos, Text, supra* note 146.

149. Future actors will be able to move in front of computer generated landscapes. Kemp, *Personal FX*, DISCOVER, Nov. 1988, at 74, 74. Film colorization is another use for image processing. *Id.* at 76. In film and video studios producers use scanning techniques to animate cartoons and models, manipulate live action, and create special effects. In time computers will be programmed to make feature length films. Brown & Verity, *supra* note 24, at 143.

businessmen,[152] lawyers,[153] and publishers[154] engage in widespread use of image processing technology. Commentators predict that, within the next five years, large companies will use this technology for presentations, archives, artwork and advertising files, communication systems, and security in 20 to 25 percent of their facilities.[155] For the most part, these uses do not create problems of copyright infringement. In the publishing and computer industries, however, many ordinary situations breed problems.[156]

A plaintiff must prove the effect of an unauthorized use of an image. Even when a plaintiff cannot prove conclusively the impact of the infringement, he or she can establish that the processed copy devalued the original. Because of the copy, the plaintiff may not be able to market the copy for image processing. Perhaps artists do not recognize the existence of a large future electronic market for images and that "unauthorized distribution deprives the copyright holder of any future gain through the electronic media."[157] Newspapers are finding that using images from electronic stock houses is cheaper than sending a staff photographer to take similar pictures. The proliferation of these stock houses indicates that newspapers desire greater access to these stock images.[158] National and international sales of image processing

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150. Police can digitize and manipulate mug shots for viewing by victims. Housman, *Boston Police Take Mug Books Electronic*, PC-COMPUTING, Sept. 1989. They also scan and electronically compare fingerprints. Jovanovitch, *Matching Technology to Police Needs*, N.Y. Times, Aug. 13, 1989, § 12, at 23, col. 1.

151. Scientists can decipher ancient writings through image processing. Stoll, *Scholars Use PCs to Decipher Ancient Writings*, PC WEEK, May 6, 1986, at 170. Researchers digitized and then enhanced degraded photographs to help locate the Titanic. Spalding & Dawson, *supra* note 1, at 102.

152. Antonoff, *supra* note 15. Digital scanning is used to create electronic filing cabinets in offices. Brown & Verity, *supra* note 24, at 144.

153. *Fast Document Retrieval*, PC WEEK, Aug. 28, 1989, at 76. Tangentially—"Photography has no place in ... any ... courtroom. For that matter, neither does film, videotape, or audio tape, in case [a party] plans to introduce in evidence other media susceptible to digital retouching." Brand, Kelly & Kinney, *supra* note 16, at 42.

154. *Color Systems for Design and Production*, THE SEYBOLD REP. ON PUBLISHING SYSTEMS, May 23, 1988, at 4. Image processing has made color proofing, previously a problem in newspaper publishing, easy because the photos are digitally stored and are easily adjusted and previewed. Esler, *Color Proofing*, GRAPHIC ARTS MONTHLY, Feb. 1989, at 44; *DDCP System: A Preview*, GRAPHIC ARTS MONTHLY, AND THE PRINTING INDUSTRY, Feb. 1989, at 90; Rosenberg, *Digital Color Proofing*, EDITOR & PUBLISHER, Sept 24, 1988, at 32C. Publishers use image scanning for newsgathering by digitizing photos and transmitting them all over the world. Miller, *A Letter from the Publisher*, TIME, Sept. 7, 1987, at 4; Sharbutt, *Shots Seen 'Round World Via Phone Line*, L.A. Times, June 7, 1989, pt. 6 (Calendar), at 1, col. 6.

155. *Electronic Still Imaging to Gross $540M in 1992*, EDN, July 7, 1988, at 315, 315.

156. *See supra* text accompanying notes 46-67.

157. Shapiro, *supra* note 66, at 27.

158. Rosenburg, *Servicing the Photo Customer*, EDITOR & PUBLISHER, Apr. 8, 1989, at 58, 58. Electronic stock photo agencies sell digitized photos. A low resolution version of the

equipment ranges into the billions of dollars.[159] One million desk top publishing systems are currently in use.[160] The people spending money on this equipment will need images to process.

Other potential markets for images include consumer information networks and electronic services, which make innumerable files (including digitized images) available to subscribers.[161] Presently, those who access these services show no limit to the types of images that are desirable.[162] These networks often use a copyright holder's image illegally and without compensation.[163] This free access to an image affects the copyright holder's ability to market the image to electronic stock houses.

Widespread distribution may also "wear out" an image. Abuse of images by unlicensed scanning, processing, and electronic distribution could make photography unprofitable.[164] Licensed electronic distribution, on the other hand, could create a profitable market for images, encouraging photography. Electronic use of scanned images could affect a copyright holder's print market as well,[165] extending even to unlicensed use in T-shirt making.[166]

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image (with the name of the photographer) is transmitted to the consumer as a preview; the agency transmits a high resolution image once the consumer has bought rights to the image. Streano, *supra* note 6, at 9.

159. Brown & Verity, *supra* note 24, at 143. 1988 shipments of hardware and software used in computer graphics systems equaled $9.1 billion, and are expected to grow to $27 billion by 1993. *Id.* Identified markets for images include real estate, retail, publishing, corporate, law enforcement, consumer, and government. The international market for still imaging equipment (equipment which processes and produces electronic still images) was estimated at $68.5 million in 1988, and predicted to grow to $542.6 million in 1992. *Electronic Still Imaging to Gross $540M in 1992*, *supra* note 155, at 315. Combined U.S. sales of image processing equipment are estimated to grow from $1.02 billion in 1988 to $1.58 billion in 1990. Lineback, *How Long Will It Take Image Processing to Blast Off*, ELECTRONICS, Feb. 19, 1987, at 65, 66; *see also supra* text accompanying notes 145-154.

160. Hammonds, *supra* note 40, at 154.

161. *See supra* text accompanying note 53.

162. Images from copyrighted and trademarked sources, ranging from M.C. Escher illustrations or *Sports Illustrated* and *Playboy Magazine* photographs to trademarked images of Mickey Mouse and Jessica Rabbit, show up on these networks. Shapiro, *supra* note 53, at 20.

163. *See supra* text accompanying notes 53-58.

164. Streano, *supra* note 6, at 10.

165. There is a large market for computer games, including computer pornography. One example is MacPlaymate, a computer game where the player can have simulated sex with a computer image. *Playboy Magazine* is currently suing the makers of this game for trademark infringement over the game's name, rather than suing over its content. Lander, *supra* note 61. However, it is possible that a person would buy the game rather than the magazine where the images were the same, making a copyright infringement action a real possibility.

166. Antonoff, *Not for Lasers Only*, PERSONAL COMPUTING, Aug. 1989, at 59, 62.

A court will weigh all the factors considered in a fair use analysis.[167] However, evidence that an illegally obtained copy affects the plaintiff's market should weigh heavily against a defendant's claim of fair use.

V. A PROPOSED NEW COURT APPROACH TO COPYRIGHT INFRINGEMENT OF STILL IMAGES

A. Access

Digital scanning technology poses a unique problem. An infringer only needs to have an original for a few minutes to successfully copy it. Additionally, the prevalence of image processing and the inability to detect its use in making copies makes image processing a potential hidden danger in all suits over still images. The issue is one of proof. For purposes of this Comment, I will assume access.

B. Professor Cohen's Approach

Courts have not resolved the problems of determining substantial similarity. Professor Amy Cohen, however, has proposed a new two-step test, revising the traditional approach of courts.[168]

The first step requires a determination of proof of copying.[169] This step focuses solely on specific similarities between the works and whether or not these similarities constitute ideas or expressions.[170] In other words, the trier of fact makes a determination of substantial similarity and does not consider the quantity of material copied.[171]

If similarities exist, the trier of fact then determines whether they are the result of copying. The degree to which similarities between the works indicates that copying occurred depends on several factors, including the type of subject (there is not much room for variation in a photograph of a famous subject, thus many similarities would have to be shown),[172] the extent of duplication of errors,[173] and whether the similarities are verbatim (there is little chance that verbatim errors are not copied).[174] The trier of fact also considers the defendant's access to the work. For

167. *See supra* text accompanying notes 91-97.
168. Cohen, *supra* note 68.
169. *Id.* at 758.
170. *Id.*
171. *Id.*
172. *Id.* at 759 & n.137.
173. *Id.* at 759 & n.139.
174. *Id.* at 759 & n.138.

instance, one can infer access from strikingly similar aspects. A positive determination of copying creates a *prima facie* case of infringement.[175]

The Ninth Circuit recently adopted an objective test of similarity of expression and idea as it pertained to literary works. In *Shaw v. Lindheim*,[176] the court changed the *Krofft* test for literary works so that an objective analysis of expression was included with an objective analysis of idea. Furthermore, *Shaw* identified eight objective components of expression which compose literary works.[177]

Once the plaintiff establishes a prima facie case of infringement under Cohen's test, the second step requires an analysis of the justification offered for the copying which parallels the fair use analysis. The burden shifts to the defendant to prove justification. This analysis starts with the extent of the similarities found in step one.[178] The trier of fact must then make a subjective determination[179] of the extent of the injuries and consider the factors governing fair use.[180] This determination weighs the purpose and character of the defendant's use, the nature of the copyrighted work, the social desirability of defendant's use, and the effect on the market for, or value of, the plaintiff's work.[181]

C. Modifying Cohen's Approach for Image Processing

Cohen's approach to determining substantial similarity does not adequately deal with image processing. However, a new approach to copyright infringement for still images could utilize the Cohen approach in a modified form. This proposed approach divides Cohen's first step into two parts, essentially adding an initial question to be asked prior to entering Cohen's proof of copying analysis.

The new first part would require the trier to determine whether, in comparing the two images, an ordinary observer would find that any part of the defendant's image is a copy of the plaintiff's image. This approach uses the ordinary observer test in its most basic sense, without explanation of idea or expression or a prolonged dissection of the photograph. "Copy" is defined as any similarity between the images which appears to be exact or nearly exact.

The new second part of this first step would retain Cohen's proof of copying analysis (i.e. all of her first step). However, the modified test

175. *Id.* at 760.
176. 908 F.2d 531 (9th Cir. 1990).
177. *Id.* at 539.
178. Cohen, *supra* note 68, at 760.
179. *Id.* at 761.
180. *Id.* at 762.
181. Harper & Row v. Nation Enters., 471 U.S. 539; Sony Corp. of Am. v. Universal City Studios, 464 U.S. 417 (1984); *see also* Cohen, *supra* note 68, at 763 & nn. 149-52.

would require the burden of proof for the copying analysis to shift if the plaintiff prevailed on the first step. Thus, the defendant must prove that he or she did not copy.

The second step in this new approach remains as Cohen proposed. If a *prima facie* case of copying results from step one, then the defendant must show justification for the copying.

D. Justifying the New Approach: Why it Will Work

Adding an initial ordinary observer test to Cohen's approach is not an insignificant modification. Many implications result.

First, as proposed, the ordinary observer does not compare the images as balanced wholes, but is allowed to find similarity in parts of the images. This prevents those who steal small but identifiable parts of an image from escaping the effect of this initial test.

Second, as proposed, the ordinary observer would make a positive initial finding of similarity only if the similarity is exact or nearly so. This allows defendants with photographs which fall into the comprehensive nonliteral similarity category to escape the test without the burden of proof shifting to them. In other words, defendants would not lose any of the protections that copyright law currently affords them.

Once the trier of fact decides that the defendant made an "exact" copy of an element or elements of a plaintiff's photograph, the defendant will have the burden of proving that he or she did not infringe. Defendants with photographs in the fragmented literal similarity category should usually fail this initial test. This may result in more defendants bearing the burden of proof than may deserve. However, those defendants who fail to pass the initial test because their subject is famous or popular should not be adversely affected. In such a case, the following proposed step—the detailed substantial similarity determination with an explanation of the idea/expression dichotomy (Cohen's step one)—will prevent a miscarriage of justice.

The proposed initial ordinary observer test targets only those who have used an image processor without troubling to completely disguise their sophisticated pixel-by-pixel manipulation, no matter how small the theft. However, this applies equally to those who use a camera, pen, or paintbrush to steal expression.[182]

In cases where the defendant stole an apparently insignificant part, this test does nothing to prejudice the defendant's ability to argue that he or she did not copy, although it forces the defendant to make that

182. Remember, this test needs to apply equally because of the inability to tell when an infringing image is result of image processing.

affirmative argument. Of course, the defendant may also argue fair use. The burden of proof remains with the defendant to prove fair use.

Shifting the burden of proof where the trier finds obvious copying, even if minute, is justifiable. Few cases result from photograph infringements because litigation is not currently viable, not because infringement does not exist. It is very tempting to steal copyrighted images.[183] The cost and trouble of suing individual infringers protects infringers.[184] With insufficient protection for a photographer's work in a mass infringement context, photographers lack economic incentive to enter or remain in the profession.[185] Therefore, shifting the burden of proof, in cases where copying is patently obvious, makes it easier for a plaintiff to protect his or her rights. Otherwise, image processing will greatly reduce the value of copyrighting an image.

Additional reasons justify the proposed new approach. Initially, the capabilities of image processors made substantial similarity determinations complex,[186] and Cohen's approach avoids duplicative determinations of substantial similarity.[187] It streamlines the litigation process to allow for more lawsuits. Furthermore, the suggested addition to Cohen's test addresses the problem of the ease, quantity, and quickness with which those seeking to infringe a copyrighted image can do so with an image processor.

E. A Hypothetical Example

A hypothetical situation illustrates more clearly the need for an approach beyond that of Cohen. My hypothetical consists of three photographs, one original and two copies. The location of all three photos is Tienamen Square in China. I assume that the plaintiff can easily prove access and that the copies have been scanned and processed. Copying is the issue.

The original photograph shows a student with a distinctive face and a soldier with a distinctive face. The soldier is bayoneting the student with his rifle. The background in the square includes other students, other soldiers, tanks, and smoke. This photo contains news value.

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183. Seymour, *supra* note 25, at 77.

184. *See* Shapiro, *supra* note 53, at 27.

185. *See* Streano, *supra* note 6, at 10. Digital scanning is already in the process of overrunning the typeface industry. Typeface fonts can be scanned, but since typefaces are not given copyright protection, typeface developers have watched horrified as their huge collections of typefaces, which were their advantage in business, have been speedily scanned by computer users. Bower, *Users in Control of Digitized Fonts*, MACWEEK, Feb. 14, 1989, at 58.

186. *See supra* text accompanying notes 116-140.

187. Cohen, *supra* note 68, at 761.

The first copy shows the same soldier bayoneting the same student. In the background of this photograph, however, all the smoke, tanks and other students and soldiers have been processed out to give the appearance of an otherwise empty square. Crying children in choir robes have been inserted by cut and paste, creating a symbolic and surreal new photograph. The photograph has lost its news value.

The second copy shows a student and soldier whose faces have been changed using sophisticated pixel-by-pixel manipulation of the original image. Additionally, the technician processed the bayonet out of the photograph, thus giving the appearance that the soldier is shooting the student at close range. The background in the square is the same as in the original except that it has been subtly altered to add or remove some students, soldiers, tanks, and smoke. The photograph retains its news value.

When the proposed new test is applied to the hypothetical, the first copy described above would run afoul of part one of step one. The obvious copying of part of the original photograph (the soldier and student with their poses exactly the same) would shift the burden on the defendant to prove he or she did not copy. The first copy communicates a distinctly different concept than the original (symbolic versus documentary), but the expression is the same (the original photographer's timing, choice of subjects, angle, etc.). This copy illustrates fragmented literal similarity. Moreover, because relatively simple image processing could produce this photograph, the infringer produced the copy rather easily.

The defendant will probably also lose at step two because the extent of similarities outweighs the distinctions. This copy probably fills a potential market for the photo, making it a poor candidate for the fair-use exception.

The second copy probably elicits a "no" answer from the question in part one of step one because nothing is exactly the same between the photographs. This copy embodies a comprehensive non-literal similarity. The defendant can argue that the plaintiff cannot protect the idea of photographing student protests and that individual expressive components of the copy are different from the plaintiff's original. Here the dissimilarity results from the defendant's "hard"[188] (pixel-by-pixel), albeit underhanded, image processing. This perhaps translates into independent original effort. But, while computerized equipment enables the defendant to "piggyback" upon the plaintiff at will, the defendant should produce something sufficiently "original" to pass an exacting ordinary observer test. This puts would-be infringers to the task of

188. *See supra* text accompanying notes 20-22.

making a large number of "hard" changes to escape liability for image theft. The number of changes necessary will rise in proportion to the uniqueness of the plaintiff's image. For this second photograph, because of the infamy of the plaintiff's subject, the test requires many exacting similarities in order to prove infringement.

Step two presents problems for both the plaintiff and the defendant. The defendant is impacting the plaintiff's market, but, on the other hand, the extent of the similarity between the defendant's and the plaintiff's photographs is small.

The maker of the first copy is easily caught under the new test. However, it is difficult to prove, even with the new test, that the second copy resulted from infringement. The new test forces the defendant to substantially alter the details of the photograph. The defendant ultimately steals mostly idea elements, even though his or her action is underhanded. The defendant knows that if he or she processes the plaintiff's expressive elements out of the infringing photograph, the plaintiff's loss of elements protected by copyright is minimized.

The hypothetical situation illustrates that computer image processing technology provides new opportunities for copyright infringement and presents new challenges to legal procedures, especially to insure the protection of original work.

VI. IMAGE PROCESSING COMPARED WITH DIGITAL SAMPLING

Digital scanning and image processing are the still image equivalents to digital sound sampling in music. "Digital sound sampling is a technique by which distinctive vocal or instrumental sounds may be recorded, analyzed and then played back to perform a song never actually executed by the original musician."[189] The music industry often uses sampling to increase artistic flexibility and eliminate the need for back-up musicians.[190] However, digital sampling in the music field results in more copyright infringements, more privacy for infringers, and more public acceptance of unauthorized copying.[191] Image processing has the same effect on the use of still images.

Digital music sampling, like digital scanning and image processing, uses affordable digital technology.[192] The sampling is done using digital

189. Note, *Digital Sound Sampling, Copyright and Publicity: Protecting Against the Electronic Appropriation of Sounds*, 87 COLUM. L. REV. 1723, 1725 (1987).

190. Fleischmann, *The Impact of Digital Technology on Copyright Law*, 23 NEW ENG. L. REV. 45, 55-56 (1988).

191. *Id.* at 46.

192. *Id.* at 56. Compact disc sales (digital recordings) have recently surpassed sales of analog phonograph records. *Id.* at 46.

audio tape machines (DATs).[193] Unlike still images, however, special codes can be integrated into songs. Pending legislation would incorporate into DATs an electronic computer chip which recognizes these special codes and prevents sampling from encoded songs.[194] Still images cannot be so encoded because the public generally does not access still images in digital form, and after they have been digitized and processed, they are usually outputted to a non-digital form.

Another important parallel between digital sampling and image processing is the problem of determining how much of a taking is a substantial or material theft. Courts have found as little as a six-note taking substantial.[195] This inquiry necessarily involves qualitative as well as quantitative weighing.[196] A California district court established that sampled sounds must be recognizable as being from the same performance that is carrying copyright protection.[197] This standard is transferred easily to the arena of image processing. It is probably unnecessary, however, due to the fact that an observer would not be able to find copying in a small stolen fragment of an image if it were not recognizable as being from the copyrighted source.

The threat that DATs have posed to music copyrights parallels the threat image processing and digital scanning pose to still-image copyrights.

VII. THE NEED FOR A NATIONAL REGISTRY TO COLLECT ROYALTIES AND PROTECT ARTISTS

Two organizations, the American Society for Composers, Authors and Publishers (ASCAP) and Broadcast Music Inc. (BMI), exist to license performances of their members' copyrighted material and distribute the collected royalties to those members. ASCAP currently has 45,000 members.[198] ASCAP and BMI keep track of the multitude of songs their registered members own and make big business out of collecting and distributing royalties for them. BMI claimed a gross income of approximately 250 million dollars in 1988.[199]

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193. *Id.* at 46.

194. Kawamura, *Digital Audio Tape Technology: A Formidable Challenge to the American Copyright System*, 4 AMER. U. J. INT'L. L. & POL'Y. 409, 411 & n.12 (1989).

195. Baxter v. MCA, Inc., 812 F.2d 421, 425 (9th Cir. 1987).

196. Comment, *Digital Sampling: Old-Fashioned Piracy Dressed Up in Sleek New Technology*, 8 LOY. ENT. L.J. 297, 323 (1988).

197. United States v. Taxe, 380 F. Supp. 1010, 1017 (C.D. Cal. 1974), *aff'd in relevant part* 540 F.2d 961 (9th Cir. 1976), *cert. denied*, 429 U.S. 1040 (1977).

198. Kozinn, *A Concert in Honor of ASCAP*, N.Y. Times, Oct. 29, 1989, § 1, pt. 2, at 66, col. 1.

199. Wheelock, *Dance and Exercise Studios Paying the Piper*, L.A. Times, Sept. 17, 1989, Calendar, at 56.

For publishers, a Copyright Clearing Center functions like ASCAP to monitor photocopying of copyrighted works and collect royalties.[200] This organization, formed in 1977, now represents 1,400 publishing organizations and their 110,000 publications.[201] For the month of June, 1988, the Center distributed one million dollars in royalties to its members.[202]

Computer users who want to digitize and process images have suggested that ASCAP and BMI "could be good models for the [graphic arts] industry to follow."[203] The fact that those who are potentially responsible for most of the copyright infringement through image processing are calling for an artists' organization makes the great urgency of the situation apparent.[204] In the absence of an organization to collect royalties, image processors are forced to steal images for want of someone to compensate for the use of those images.

Photography, painting, and graphic design are professions. As professionals, artists and their works are easily recognized and can be registered to form an organization like ASCAP, BMI, or the Copyright Clearing Center. The existence of ASCAP-type organizations proves their economic viability. Artists need an organization for the licensing of still images to allow them to profit fully from their works.

VIII. CONCLUSION

Courts need to modify copyright law to confront technological advances. The ordinary observer test, in its new proposed form that burdens copyright infringers with the problems of proof, would protect original work by providing some counterbalance to new, powerful and threatening computer technology. This proposal calls for the abandonment of the ordinary observer test to determine copying in an image and advocates a more critical comparison of expressive elements. Courts must streamline the traditional approach to copyright infringement determinations by eliminating duplicative legal determinations. Without change, computers will outstrip courts' ability to judiciously handle copyright infringement suits involving images. Because image processing and digital scanning have the potential to upset continued profitable still image production in much the same way that digital sampling has upset the music industry, it has become

200. Schroeder, *Music Licensing Firm Pressing Copyright Law*, ST. LOUIS BUS. J., Oct. 17, 1988, at 21A.
201. *Id.*
202. *Id.*
203. Shapiro, *supra* note 53, at 20; *see also* Rosenthal, *supra* note 59.
204. *See* Rosenthal, *supra* note 59.

imperative for artists to form an artists' organization to register and collect royalties for still images.

CASE UPDATE

The *Case Update* is a survey of recent state and federal court decisions which significantly relate to high technology. Cases are included either because they introduce new substantive law in areas which are important to a technology practice, or because they illustrate a new application of other areas of law to technology. The cases are organized below under appropriate headings. As many of the cases we report are quite complex or ongoing, the decisions reported herein are not necessarily final dispositions. This issue's *Case Update* covers cases decided from January through August, 1990.

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CIVIL PROCEDURE

License Agreement Exchanging 5% Interest in Patent for Licensee's Obligation to Sue Alleged Infringers Held Void Under New York Champerty Statute.

Refac Int'l, Ltd. v. Lotus Dev. Corp., 131 F.R.D. 56 (S.D.N.Y. 1990).

Forward Reference Systems, Ltd. ("FRS") assigned a 5% interest in its computer program patent to plaintiff Refac International, Ltd. ("Refac") in exchange for Refac's obligation to sue at least two alleged infringers of the patent. Under the agreement, FRS retained substantial control over the litigation. Defendants to Refac's subsequent suit sought dismissal for failure to join FRS as a necessary party.

Because the primary purpose of the agreement was to enable Refac to litigate on behalf of FRS, the district court determined that it violated New York's champerty statute. That statute, N.Y. Jud. Law § 489, prohibits buying or taking an assignment of any claim with the intent and for the purpose of bringing an action on that claim. The court also determined that Refac was not the real party in interest and ordered dismissal of the complaint, unless FRS voluntarily joined the action within 10 days as a necessary party pursuant to Fed. R. Civ. P. 19(a).

COPYRIGHTS

Rights in the Renewal Copyright Term Vest in the Successor when the Author Dies Before Commencement of the Renewal Period, Despite Agreement to the Contrary.

Stewart v. Abend, ___ U.S. ___, 110 S. Ct. 1750 (1990).

Defendants distributed "Rear Window," a motion picture derived from the story "It Had to Be Murder," and were sued for copyright infringement by plaintiff Abend, who owns the copyright to the story. Years earlier, defendants' predecessors in interest had purchased from the story's author the derivative motion picture rights to the story. During that period, 17 U.S.C. § 24 provided copyright protection for original works during an initial twenty-eight year term and a twenty-eight year renewal term. The author had agreed to renew the copyright in the original story and to assign the derivative motion picture rights for the renewal term to defendants' predecessors. However, he died before obtaining the renewal rights. The author's executor subsequently renewed the copyright and assigned the derivative rights to plaintiff. Defendants claimed that they could continue to use the existing derivative work beyond the initial term.

In denying defendants' claim, the Supreme Court held that, where the author dies before the commencement of the renewal term, the assignment of renewal rights must be made by the author's statutory successor. The Court found that, since the author had died before the expiration of the initial copyright term, all defendants' predecessors in interest possessed was an unenforceable expectancy. The Court rejected defendants' contention that the authorized creation of the derivative work partially extinguished plaintiff's rights. Thus, defendants were prohibited from exploiting their derivative work for as long as the original work remained outside the public domain.

"Misuse of Patent" Defense Adopted in Copyright Context.

Lasercomb Am., Inc. v. Reynolds, 911 F.2d 970 (4th Cir. 1990).

Plaintiff Lasercomb America, Inc. developed and copyrighted a computer program relating to the design and manufacture of steel rule dies. Plaintiff licensed copies of the program to defendants. Defendants subsequently made unauthorized copies of the software and marketed a similar program which almost entirely copied plaintiff's. Plaintiff brought suit for copyright infringement.

Defendants alleged "misuse of copyright" as a defense. Defendants claimed that plaintiff's standard licensing agreement impermissibly restricted licensees, in that it prohibited licensees from developing computer-assisted die making software on their own. (However, due in part to an oversight, defendants themselves had not actually signed such an agreement.) The trial court rejected the defense, extant in patent law, partly because it doubted the defense's existence in the area of copyright.

The court of appeals reversed. Invoking the history and public policy common to both patent and copyright law, it determined that the defense did indeed exist. The court also determined that the defense was available to parties who had not themselves been injured by the copyright misuse. Thus, defendants here were able to use the defense despite not being parties to the license agreement. Having recognized both the defense and defendant's standing to assert it, the court found that plaintiff did indeed misuse its copyright. The court held that plaintiff wrongfully suppressed licensee attempts to independently implement ideas expressed by its program, when it had only the right to protect against copying of the program's code. The court noted that the finding of misuse did not depend on whether plaintiff had also violated any antitrust laws.

Menu Command Structure of Spreadsheet Program Held Copyrightable.

Lotus Dev. Corp. v. Paperback Software Int'l, 740 F. Supp. 37 (D. Mass. 1990).

Plaintiff Lotus Development Corporation sued defendant Paperback Software International for copyright infringement, alleging that defendant's computer spreadsheet program, VP-Planner, infringed upon its program, Lotus 1-2-3. Defendant challenged the copyrightability of such spreadsheet programs.

The district court identified the issues as being whether the "non-literal" elements of the spreadsheet program were copyrightable and, if so, how such non-literal elements that are copyrightable may be

identified. By "non-literal" elements, the court meant elements of the program that could not be tangibly expressed in writing. For example, a literal element of a program would be its written code. Non-literal elements would include "the overall organization of a program, the structure of a program's command system, and the presentation of information on the screen." 740 F. Supp. at 46. The court recognized that the bulk of the creative work in programming often involves developing such non-literal elements. With respect to spreadsheet programs, the court noted that "creating a suitable user interface is a more difficult intellectual task, requiring greater creativity, originality, and insight, than converting the user interface design into instructions to the machine." *Id.* at 56.

The court interpreted the Copyright Act as extending copyright protection to "expressive" elements of computer programs, literal or non-literal, but not to the ideas embodied in the programs. The court applied a three-step test for determining whether a program possessed expressive elements that are copyrightable.

The first step required the court to formulate some conception or definition of the "idea" expressed in the work sought to be protected. In this case, the court defined the idea of Lotus 1-2-3, VP-Planner, and similar programs as being that of an "electronic spreadsheet." *Id.* at 65.

In the second step, the court must distinguish between essential and non-essential elements of expressing the idea. An expression that is essential to an idea merges with the idea and is not copyrightable. Non-essential expressions are those that are distinctive to a particular program. Here, the court noted that individual characteristics of the Lotus 1-2-3 command structure, such as the two-line moving cursor menu, the rotated L screen display, and the designation of a particular key to invoke the menu command system, were not distinctive. However, the court found that the "precise structure, sequence, and organization" of Lotus 1-2-3 were not obvious. *Id.* at 67. For example, the court found plaintiff's "choice of command terms, the structure and order of those terms, their presentation on the screen, and the long prompts" to be distinctive. *Id.* at 68.

The final step requires the court to determine whether the non-essential elements of the idea's expression form a substantial part of the program. Here, the court found that the above-enumerated distinctive elements of Lotus 1-2-3 were indeed substantial and, thus, held the program copyrightable.

CRIMINAL PROCEDURE

Testimony of Child Witness via One-Way Monitor is Constitutionally Permissible Where Face-to-Face Confrontation with Defendant Causes Witness Severe Emotional Distress.

Maryland v. Craig, ___ U.S. ___, 110 S. Ct. 3157 (1990).

Defendant Craig appealed convictions for sexual and physical abuse against a preschool child, claiming deprivation of rights guaranteed by the confrontation clause of the sixth amendment. The trial court, applying a Maryland statute, allowed a sexually abused child to testify in a separate room through a one-way television monitor which simultaneously displayed the testimony in the courtroom. The court invoked the procedure upon finding that face-to-face confrontation with defendant during testimony would cause the child to suffer such emotional distress that she would not be able to reasonably communicate.

The Supreme Court upheld the validity of the procedure, finding that the confrontation clause does not mandate face-to-face confrontation. The Court held that the clause attempts to ensure the reliability of evidence against a defendant by subjecting it to rigorous testing in an adversarial setting. While face-to-face testimony is preferred, it is not an indispensable element of the confrontation right and is not required when a conflicting state interest exists and when evidentiary accuracy is otherwise assured. Here, the state's interest in the physical and psychological well-being of child abuse victims was found to outweigh defendant's right to face her accusers in court.

Statute Allowing Roving Wiretap Does Not Violate Fourth Amendment Probable Cause and Particularity Requirements.

United States v. Silberman, 732 F. Supp. 1057 (S.D. Cal. 1990).

Federal agents obtained a court order authorizing a roving wiretap of telephone calls made by defendant Petti from various locations. Several calls to defendant Silberman were tapped. As a result, defendants were both indicted for money laundering. Defendants moved for an order suppressing evidence obtained through the wiretap surveillance. They claimed the statute authorizing the surveillance violates fourth amendment probable cause and particularity requirements.

Under the Omnibus Crime Control and Safe Streets Act of 1968, as amended in 18 U.S.C. § 2518(11), police may obtain an order authorizing a roving wiretap where (1) a federal officer applies for the order, (2) the

Attorney General approves the application, (3) the application shows the suspect is purposefully trying to thwart interception of his calls by changing facilities, and (4) a judge finds that the showing of purpose is adequate.

The district court, denying defendants' motion, rejected the claim that the statute violates the probable cause requirement prohibiting unreasonable searches and seizures, since the statute requires that the finding of probable cause be judicially determined. The court found that the statute merely modifies the requirement that the finding specify the exact location of the conversation to be tapped.

The court also rejected the claim that the statute violates the particularity requirement. The court noted that search and seizure orders need not precisely describe the physical location to be searched to satisfy this requirement. Although the particularity requirement prohibits general searches, it should be interpreted flexibly, in a manner accounting for the technological advances of modern society. The court found that where, as here, defendants used telephones at various and changing locations, the wide scope of the search authorized by the statute is constitutionally tailored to a legitimate end.

Video Surveillance of Crime Locale Violates Fourth Amendment Where Co-Tenant Consenting to Surveillance Is Not Present.

People v. Henderson, 220 Cal. App. 3d 1632, 270 Cal. Rptr. 248 (Ct. App. 1990).

Defendant Henderson allegedly operated a methamphetamine laboratory in a condominium owned by his accomplice's ex-brother-in-law, Hake, a DEA informant. Defendant's accomplice obtained Hake's permission to use the condominium for drug manufacture. Hake then authorized DEA agents, who had no search warrant, to set up a video surveillance system in the condominium. This system recorded defendant's illicit activities. The trial court denied defendant's standing to challenge the videotaped search and admitted the videotaped evidence, reasoning that Hake's consent as a co-tenant of the condominium legally authorized the DEA agents' entry onto and surveillance of the premises without a warrant.

The California Court of Appeal reversed, holding defendant had standing under federal law. The court found that, while the DEA agents properly obtained consent to enter the condominium, the fourth amendment bars evidence gathered in warrantless videotaping made while Hake was absent from the condominium. Under these

circumstances, defendant's reasonable expectation of privacy was abridged in violation of the fourth amendment.

Videotaped Surveillance of Pedestrians Is Admissible as Evidence of Identity in New York.

People v. Edmonson, 75 N.Y.2d 672, 554 N.E.2d 1254, 555 N.Y.S.2d 666 (1990).

Defendant Edmonson allegedly attacked a victim after meeting her on the street. While still in the hospital, the victim described defendant to the police and told them where he might be found. Using this information, the police randomly videotaped pedestrians at the identified locations, occasionally zooming in upon men fitting the description. The victim reviewed the videotape and, when defendant appeared, immediately identified him as her assailant. A day later, she again identified defendant in a lineup. Defendant challenged subsequent convictions of attempted murder and assault, claiming that the videotape of pedestrians was inadmissible as evidence of his identity.

The New York Court of Appeals found the videotape admissible as proof of identity, finding that it was not suggestive or prejudicial in content or in manner of presentation. The videotape did not single defendant out but presented him as one of many pedestrians and as part of a group of men fitting a general description. The videotape was simply a substitute for physical canvassing of the area by the victim. The court even preferred this method over the traditional use of "mug shots," since video-canvassing carries no inference that those pictured have criminal histories.

MEDICINE

Law Criminalizing "Experimentation upon a Fetus" Ruled Unconstitutionally Vague and in Violation of a Woman's Right to Privacy.

Lifchez v. Hartigan, 735 F. Supp. 1361 (N.D. Ill. 1990), *aff'd,* 914 F.2d 260 (7th Cir. 1990).

Plaintiff physicians specializing in reproductive endocrinology and fertility counseling initiated a class action suit challenging the constitutionality of a provision of the Illinois abortion law, Ill. Rev. Stat. ch. 38, para. 81-26. The statute provided that "[n]o person shall sell or experiment upon a fetus . . . unless such experimentation is therapeutic to

the fetus thereby produced." Plaintiffs attacked the statute on fourteenth amendment due process and right to privacy grounds.

The district court found the statute unconstitutionally vague in violation of due process. The court determined that the legislature's failure to define "experimentation" and "therapeutic" as used in the statute rendered the statute so vague that physicians could not know what actions would be deemed criminal. The court felt it unclear how the statute would apply to many accepted practices that could be ruled non-therapeutic to the fetus. Such practices might include, for example, embryo transfer and genetic screening. The court noted that many of today's "experiments" would be tomorrow's standard treatment.

The court also held that the statute unconstitutionally infringed upon a woman's privacy right in making reproductive choices free from governmental interference. In so holding, the court found that this privacy right included the right to such procedures as chorionic villi sampling (the taking of tissue from around the fetus to obtain information often used by a woman to determine whether to have an abortion) and embryo transfer.

Physician Must Inform Patient of Personal, Research, or Economic Interests in Excised Tissue, but Patient Does Not Retain a Property Interest in Such Tissue.

Moore v. The Regents of the Univ. of California, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990).*

As part of a treatment for hairy-cell leukemia, defendant physician Golde removed plaintiff Moore's spleen. Prior to the spleenectomy, without informing plaintiff, Golde arranged to obtain portions of plaintiff's spleen for research. Golde established a cell line from plaintiff's tissue. A patent to the cell line was assigned to defendant Regents of the University of California, and Golde, with other defendants, developed the cell line commercially. Plaintiff sued defendants for breach of defendant's fiduciary obligations and for conversion of tissue taken from plaintiff's spleen.

The California Supreme Court held that plaintiff stated a cause of action for breach of fiduciary duty. Physicians seeking patient consent to undergo medical treatment must disclose personal, research, or economic interests unrelated to the patient's health. Because personal interests may

* For a detailed analysis of Moore v. The Regents of the University of California, see the Comment by Maureen S. Dorney *supra*, *Moore v. The Regents of the Univ. of California: Balancing the Need for Biotechnology Innovation Against the Right of Informed Consent*, 5 HIGH TECH L.J. 333 (1990).

adversely affect the physician's medical judgment and thus conflict with the patient's interests, disclosure is required for obtaining the patient's informed consent to satisfy the physician's fiduciary duty.

However, the court held that plaintiff did not state a cause of action for conversion, finding that he retained no property interest in tissue after its removal from his body. The court doubted the legal validity of such a cause of action for a number of reasons. First, it found that reported case law lends no support for a conversion claim. Second, California statutory law limits a patient's interest in excised cells. Third, the court found that the cell line that was developed from plaintiff's spleen cells was "factually and legally distinct" from plaintiff's cells. 51 Cal. 3d at 141, 271 Cal. Rptr. at 159. Finally, the court took into account the potentially dampening effects of such liability upon scientific research and the adequacy of remedies available to plaintiff under his breach of fiduciary duty claim. Noting the complex policy issues involved, the court deferred to the Legislature the decision to extend such liability.

PATENTS

Patent Infringement Provision of 35 U.S.C. § 271(e)(1) Applies to Patented Medical Devices as well as to Drugs.

Eli Lilly and Co. v. Medtronic, Inc., ___ U.S. ___, 110 S. Ct. 2683 (1990).

Plaintiff Eli Lilly and Company filed an injunctive suit against defendant Medtronic, Inc., alleging that defendant's testing of a medical device infringed upon two of plaintiff's patents. Defendant responded that the testing was authorized by 35 U.S.C. § 271(e)(1), which was enacted by the Drug Price Competition and Patent Term Restoration Act of 1984 ("the 1984 Act"). Section 271(e)(1) authorizes the manufacture, use, or sale of a patented device "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." Defendant argued that its testing of the patented medical device was necessary to obtain pre-marketing approval of the device under the Federal Food, Drug, and Cosmetic Act ("FDCA"). Plaintiff countered that section 271(e)(1) applied only to drugs, not medical devices.

The Supreme Court held that section 271(e)(1) did indeed apply to medical devices. Although the Court found section 271(e)(1) ambiguous with respect to its scope of applicability, the Court found that the structure of the 1984 Act as a whole supported the section's applicability to medical devices.

The Court recognized that Congress enacted the 1984 Act to remedy two unintended distortions of the standard 17-year patent term brought about by the pre-market regulatory approval requirements of the FDCA. The first distortion occurred when an invention was subject to a lengthy approval process. The patent holder would not reap any financial gains during the early years of the 17-year term, because the invention had not yet received approval. The 1984 Act remedied this distortion by enacting 35 U.S.C. § 156, which extends by up to five years the 17-year patent protection term for drugs and medical devices subject to regulatory review.

The second distortion occurred at the end of the 17-year term, at which point patent holders, in effect, received an extension of the term: Since competitors could not begin the regulatory approval process until after the term's expiration, the patent holder's monopoly would continue during the years in which the competitor sought approval. The 1984 Act addressed this problem through the enactment of section 271(e)(1), which allows third parties to begin the approval process while the patent is still in effect.

The Court found that applying section 271(e)(1) only to drugs would allow a patentee of an FDCA-regulated non-drug invention to benefit from the latter distortion without the hindrance of the earlier distortion. Such an application would result in an aggravation of the monopolistic effects the 1984 Act was designed to remedy. Thus, the Court found that all inventions that are eligible for the term-extension benefit of 35 U.S.C. § 156 must also be subject to the non-infringement limitation of section 271(e)(1), and, similarly, such products that are not eligible for the term-extension benefit are excluded from the non-infringement limitation.

Patent Infringement Statute Does Not Abrogate States' Eleventh Amendment Immunity.

Chew v. California., 893 F.2d 331 (Fed. Cir. 1990), *cert. denied*, ___ U.S. ___, 111 S. Ct. 44 (1990).

Plaintiff Chew brought a patent infringement suit against the State of California, claiming that the State infringed upon her patent on a method for testing automobile exhaust emissions. Plaintiff argued that the State's eleventh amendment immunity from suit was abrogated by 35 U.S.C. § 271(a), which provides that "whoever" makes unauthorized use of a patented invention infringes upon the patent.

The court of appeals affirmed the lower court's holding that the general language in the patent statute does not curtail states' eleventh

amendment immunity. The court held that, while such immunity may be abrogated by Congress in the exercise of constitutionally delegated powers, there must be "unmistakable language in the statute itself" of Congress' intent to do so. 893 F.2d at 334.

The court also rejected plaintiff's further argument on appeal that barring her suit in federal court would result in a deprivation of her property without due process of law. The court held that, to the extent that plaintiff's claim involved Congress' failure to abrogate state immunity, the United States, not the State of California, was the proper party to be sued. To the extent that plaintiff's takings claim was based on the fourteenth amendment, the court found that a patent infringement suit was not the appropriate legal remedy.

"Actual Intent" Requirement for Establishing Active Inducement of Patent Infringement Requires Proof of More than Mere Knowledge of Infringement.

Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464 (Fed. Cir. 1990), *cert. denied*, ___ U.S. ___, 110 S. Ct. 1125 (1990).

Plaintiff Hewlett-Packard Company owned a patent relating to a device which creates two-dimensional plots, including charts and graphs. Defendant Bausch & Lomb Inc., through one of its divisions, sold devices incorporating the plotter technology patented by plaintiff. It later sold the division to a third party, Ametek, Inc. As part of this sale, it was agreed that (1) defendant would indemnify Ametek against liability for infringing upon plaintiff's patent, (2) defendant and Ametek would jointly work towards developing a plotter that would not infringe upon the patent, and (3) Ametek would not communicate with plaintiff concerning the infringed patent. Plaintiff subsequently sued defendant both for direct patent infringement and for actively inducing a third party to infringe.

The court of appeals, affirming the court below, held for plaintiff on its first claim but rejected the second. Although the court held defendant liable for infringement for the period prior to the sale, it found that plaintiff did not prove that defendant actually intended to cause Ametek itself to infringe upon the patent. The court reasoned that defendant's sale of plans for products infringing upon plaintiff's patent did not indicate such intent, because the plans were sold to Ametek as part of a much larger agreement and were related to a product comprising only a small portion of the sales governed by the agreement. Furthermore, the court noted, defendant had promised to work with Ametek to avoid infringement. Finally, the court found that defendant's agreement to

indemnify Ametek for infringement pursuant to the sale agreement, although insulating Ametek from the deterrent impact of patent laws, did not in itself evidence intent. On the contrary, defendant may have only been interested in selling its division at the highest possible price, regardless of infringement possibilities.

Invention of Novel Compounds Allows Patent on Seemingly Obvious Method of Their Use.

In re Pleuddemann, 910 F.2d 823 (Fed. Cir. 1990).

An inventor appealed from a rejection by the Patent and Trademark Office ("the PTO") of his process and method of use claims. The PTO had granted the inventor a patent for a new class of bonding agents that the inventor claimed imparted superior moisture resistance to certain materials. However, the PTO had rejected claims on the process or method of using the agents, finding the claims obvious in light of a prior patent involving a similar process using a different agent.

The court of appeals reversed the PTO's decision. The court noted that a single invention may be viewed legally as having different aspects, permitting claims to (1) the compounds themselves, (2) the method or process of making the compounds, and (3) the method or process of using the compounds for their intended use. The court found that the inventor's claims consisted both of a novel and non-obvious class of compounds and of development of methods of bonding and priming using these compounds. The court held that the PTO had erred in determining the obviousness of the method by assuming the separate existence of the compounds themselves as part of the prior art. The court distinguished this case from one where an inventor seeks a patent merely for the process of making (as opposed to using) a novel compound.

Court Employs New Test to Determine Whether a Patent Infringement Claim Under the Doctrine of Equivalents Can Survive a "Prior Art" Defense.

Wilson Sporting Goods Co. v. David Geoffrey & Assocs., 904 F.2d 677 (Fed. Cir. 1990).

Plaintiff Wilson Sporting Goods Co. sued defendants David Geoffrey & Associates and Dunlop Slazenger Corporation, alleging infringement of its patent on a method of positioning dimples on a golf ball. Although defendants did not use positioning schemes described in plaintiff's patent claims, plaintiff claimed that defendants were liable under the doctrine of equivalents. That doctrine provides for liability

where a product "performs substantially the same overall function or work, in substantially the same way, to obtain substantially the same overall result as the claimed invention." 904 F.2d at 683. Defendants responded that there was no principled difference between their golf balls and the prior art (consisting of golf ball design patents issued prior to plaintiff's patent).

The court of appeals ruled in favor of defendants. The court noted that a patentee can not obtain coverage under the doctrine of equivalents which could not have been obtained from the Patent and Trademark Office by literal claims. It then formulated the test for determining whether a prior art defense applies to an infringement claim under the doctrine of equivalents as whether one could visualize a hypothetical patent claim sufficient in scope to literally cover the accused product but not the prior art. After reviewing the technical merits of plaintiff's claims, the court concluded here that one could not.

TELECOMMUNICATIONS

Federal Law Does Not Require Electronic Communications Service Providers to Scramble Cellular Telephone Transmissions to Protect Against Their Interception.

Shubert v. Metrophone Inc., 898 F.2d 401 (3rd Cir. 1990).

After a third party intercepted plaintiff Shubert's cellular telephone transmissions, plaintiff brought suit against his phone service provider, defendant Metrophone, Inc., alleging violation of 18 U.S.C. § 2511(3)(a). That section prohibits providers of electronic communication services from intentionally divulging the contents of a communication to third parties. Plaintiff claimed that defendant was liable because it transmitted plaintiff's communication through a method susceptible to interception.

The district court dismissed the complaint for failure to state a claim upon which relief could be granted, and the court of appeals affirmed. The court held that section 2511(3)(a) does not impose a general duty upon a cellular service provider to encrypt or otherwise render its transmissions incapable of interception. The court found that transmission cannot be equated with intentional divulgence, even where the transmission may be readily intercepted.

Telephone Caller Identification Service Barred in Pennsylvania.

Barasch v. Pennsylvania Pub. Util. Comm'n, ____ Pa. ____, 576 A.2d 79 (1990).

The Pennsylvania Public Utility Commission approved a service allowing subscribers displayed access to caller's telephone numbers. The Commission found that such a service would reduce crime and prank phone calls. The ability to block the display was provided for certain calling parties, such as law enforcement agencies and persons who could demonstrate a need for such blocking to mitigate the risk of personal injury.

The Pennsylvania Supreme Court reversed the approval. The court held that the caller identification service violated 18 Pa. Cons. Stat. § 5771(a), which, with limited exceptions, prohibits the use of trap and trace devices. The court also held that the service violated state and federal constitutional privacy protections. It found telephone numbers, like telephone communication, to be private and subject to a reasonable expectation of privacy. The court even found potential privacy violations where callers are given the option of blocking display of their numbers.

TRADE/ANTITRUST

Tariff Act Does Not Prohibit Importation of Foreign Manufactured Products Using U.S. Patented Materials.

Amgen, Inc. v. United States Int'l Trade Comm'n, 902 F.2d 1532 (Fed. Cir. 1990).

Plaintiff Amgen, Inc. holds a patent covering certain recombinant DNA sequences, vectors, and host cells used to produce recombinant erythropoietin ("rEPO"), a product useful in treating anemia. Plaintiff has no patents on either rEPO itself or any process for making it. (The original patent claim included a claim for the process of making rEPO using these materials, but the process claim was rejected by the Patent and Trademark Office on the ground that it merely involved the application of an old process to new starting materials and was thus precluded by *In re Durden*, 763 F.2d 1406 (Fed. Cir. 1985).)

Plaintiff brought a claim before the United States International Trade Commission (the Commission) against a third party that was importing rEPO made in Japan with plaintiff's patented materials. Plaintiff claimed that the party was violating 19 U.S.C. § 1337(a)(1)(B)(ii), which prohibits the importation of articles produced "by means of a

process covered by the claims of a . . . patent." The Commission rejected plaintiff's claim, and plaintiff appealed.

The court of appeals framed the issue "as whether section 1337(a)(1)(B)(ii) was intended to prohibit the importation of articles made abroad by a process in which a *product* claimed in a U.S. patent is used." 902 F.2d at 1538. Looking to the language of the section and its legislative history, the court concluded that "a patent 'covering' a process is a patent containing at least one claim defining a process." 902 F.2d at 1538. Thus, because plaintiff's patent did not include a process claim, the court dismissed plaintiff's complaint.

A Computer Manufacturer that Services Its Own Product Is Not Liable for "Tying" when It Restricts Access to a Diagnostic Program It Designed for Use with Its Products.

Serv. & Training, Inc. v. Data Gen. Corp., 737 F. Supp. 334 (D. Md. 1990).

Plaintiff Service & Training, Inc. brought suit in order to enforce its claimed right to use a diagnostic software program developed and copyrighted by defendant Data General Corporation. Diagnostic software programs are used in the field maintenance and repair of computers, and the software in question was designed for servicing a computer marketed by defendant. During cross-motions for summary judgment, plaintiff alleged that defendant's restrictions on the use of the software violated the Sherman Act, specifically 15 U.S.C. §§ 1, 2.

The court rendered summary judgment against plaintiff's claim that defendant violated the prohibition on tying in 15 U.S.C § 1. Plaintiff claimed that defendant wrongfully tied access to the diagnostic software to defendant's computer maintenance services. In order to prove a tying claim, one must establish that there exists two separate and distinct products or services and an agreement conditioning the sale of one on the sale of the other. The court found that there existed no market for the software separate and independent from the servicing of defendant's computers; rather, the court viewed the software as a mere tool for such servicing.

Also, although finding a disputed issue of fact, the court expressed doubts as to whether defendant was liable for monopolization under 15 U.S.C. § 2. Plaintiff claimed that defendant monopolized the service market for defendant's computer through the restrictions on the diagnostic software. Monopolization requires both possession of monopoly power in the relevant market and the willful acquisition or maintenance of that power. The court found that there was some question as to whether defendant indeed possessed monopoly power.

However, the court noted that, if defendant raised the costs of its maintenance services to non-competitive levels, potential customers would arguably purchase their computer equipment from defendant's competitors. If so, then defendant could not be found to have monopoly power. Moreover, the court questioned whether plaintiff could prove that defendant "willfully" acquired what monopoly power it does possess in the service market. The court emphasized that plaintiff must show more than that defendant has developed a better diagnostic program than any other that is available.

Insurance Claims May Not Be Denied Based Solely on the Results of Polygraph Examinations.

Elder v. Coronet Ins. Co., 201 Ill. App. 3d 733, 558 N.E.2d 1312 (App. Ct. 1990).

Plaintiff Elder brought claims against defendant insurance companies for insurance claim rejections based solely on the results of a polygraph examination. The trial court dismissed plaintiff's claims.

The Illinois Appellate Court reversed, holding that plaintiff stated causes of action for both unfair and deceptive business practices. Although public policy allows investigatory use of polygraph examination under certain circumstances, it prohibits reliance on these sometimes flawed examinations in decision-making. Accordingly, the court held that the defendants' allegedly exclusive reliance on polygraph examination results violated public policy and unfairly oppressed and injured plaintiff. Furthermore, the court found defendants' non-disclosure of this practice to be deceptive.