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BIOTECHNOLOGY FOR HUMAN LIFE AND HEALTH—THE SPECIAL CASE FOR A NEGLIGENCE-ONLY RULE TO PROMOTE CRITICAL INNOVATION

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I. INTRODUCTION

Biotechnologically produced medical products are of exceptional value to humankind, and the research that produces them promises large spill-over benefits to human life and health. While biotechnology may seem to hold mysteries, scientists conclude that biotech medical products are no more dangerous than medical products made by conventional means. Indeed, they are likely to result in fewer by-product harms because of their unique ability to target diseased cells while not harming healthy cells.[1] The probable dynamic contributions of biotech research and product development should counsel hospitable legal rules.

Biotech products have not yet resulted in reported harm. When harm should occur and litigation should follow, plaintiffs are likely to invoke rules of strict product liability. Since biotech medical products are usually developed in the form of drugs and vaccines, jurists are likely to apply the legal rules applicable to other drugs and vaccines, or perhaps even rules of stricter liability.

We write this article in anticipation of such litigation. We reflect on the present state of the product liability system and ask whether the system is flexible enough to accommodate high technology, high social value products with positive spill-over benefits but some unforeseen and unforeseeable harms. This category might describe most traditionally made drugs and vaccines. It certainly describes biotech medical products.

The main conclusion of our article is that strict and quasi-strict product liability rules have a bias in favor of the status quo. They put extra costs on those who are foresightful and creative. While strict liability rules also have benefits, such as the internalization of costs and compensation for injured persons, the time has come to recognize a category in which the dynamic benefits lost by a regime of strict liability are likely to overwhelm the static benefits. Exactly where the two lines

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1. *See, e.g.*, Kolata, *In the War on Cancer, A New Kind of Weapon*, N.Y. Times, May 7, 1991, at B5, col. 1; S. BURRILL & K. LEE, BIOTECH 91: A CHANGING ENVIRONMENT 29 (1990) (referring to products such as tissue plasminogen activator, erythropoietin, alpha-interferon, human growth hormone, a hepatitis C blood test, and the introduction of a test for the cystic fibrosis gene). *See also* Fisher, *Biologists Re-Engineer Antibodies*, N.Y. Times, Mar. 5, 1991, at C1, col. 6.

cross is impossible to tell. But it is possible to begin the process of reining in strict and quasi-strict liability rules with a "best case" for a negligence-only rule governing the design of biotech medical products. A "best case" is a very high social value product with large positive spill-over benefits from the research and development that underlies the product.[2] Biotech medical products fit this description, and we argue here for a negligence-only rule, freed even from the case-by-case examination often accorded traditionally made drugs. In view of the hospitable treatment we urge for biotech medical products, we suggest that producers acknowledge their social and ethical responsibilities to discover and proceed upon early warning signals of danger and harm.

Section II of this article introduces certain biotechnologically designed products and alternative liability rules. Section III discusses the expansiveness of U.S. regulatory law and the search for limits. Section IV describes the evolution of tort law and the growing importance of the Restatement (Second) of Torts and comment k. Section V examines the costs and benefits of alternative liability rules. Finally, Section VI concludes with a note on social responsibility.

II. BIOTECHNOLOGY AND ALTERNATIVE LIABILITY RULES

On the frontiers of medical engineering, superior products are made with biotechnology, which involves the manipulation of living organisms.[3] Biotechnology can substitute for traditional methods in the production of vaccines for humans, medical diagnostic products, veterinary medicines, and products to improve livestock and agricultural yields and quality. In medicine, biotechnology makes it possible to create drugs that target cell receptors precisely, changing the functions of diseased or distorted cells without touching the normal cells. As a result, biotechnologically-produced drugs are less likely to have debilitating side effects than are traditionally produced drugs.[4]

Biotech research has resulted in a number of important, currently available drugs, including: the first hepatitis-B vaccine; tissue plasminogen activator, a compound that dissolves blood clots developing after heart attacks and strokes; and human growth hormone, used as a

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2. Another "best case" for reform in the same direction is the case of a high social value product that has been screened for safety by specified and competent administrative agencies. *See* Grundberg v. Upjohn Co., 318 P.2d 89 (Utah 1991). *See also* Wilson v. Piper Aircraft Corp., 282 Or. 61, 577 P.2d 1322 (1978) (Linde, J., concurring).

We do not deal centrally in this article with examples other than biotech medical products, but we encourage the search for similar examples.

3. *See* Kolata, *supra* note 1.

4. *See id. See also* Fisher, *supra* note 1.

substitute for natural hormone to help reverse infantile dwarfism.[5] Biotechnology may also help to cure cystic fibrosis, the most common inherited fatal disease.[6] Other currently researched biotech drugs may provide a cure for a number of different cancers.[7] Biotech researchers are also studying a number of possible cures for AIDS.[8] The President's Council on Competitiveness has singled out biotechnology as a principal area in which excessive government restrictions should be avoided.[9]

Like all products, biotech medical products may cause unexpected harms. We propose that liability for unforeseeable harms be imposed on the designer only if there was a failure to exercise due care.[10] We argue that the imposition of strict liability as defined by section 402A of the Restatement (Second) of Torts,[11] or even a case-by-case inquiry to determine whether strict liability should apply, is likely to impose too high a cost on society in lost research and development to justify the rule.[12]

A narrower alternative would be to develop law within the context of comment k of Section 402A,[13] which is interpreted as exempting certain

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5. *See Biotechnology; The Promise and Peril of a New Age*, WorldPaper, Nov. 1990, at 10. *See also* Kolata, *supra* note 1.

6. *See Gene Therapy Cures Cystic Fibrosis in Lab*, Chicago Tribune, Sep. 21, 1990, at 1.

7. *See Biotech Firms Struggle to Turn Their Research into Healthcare*, San Diego Bus. J., Dec. 10, 1990, § 1, at 18. *See also* Kolata, *supra* note 1; Bernstein, *Genentech Tests Mab as Cancer Treatment*, 3 BIOWORLD 68 (Apr. 8, 1991) (reporting phase I clinical trials of monoclonal antibody to treat patients with breast and ovarian cancers).

8. *See* S. BURRILL & K. LEE, BIOTECH '92: PROMISE TO REALITY 14–20 (1991); Waldholz, *Gene Implants Destroy Cancer in Lab Rodents*, Wall St. J., Nov. 1, 1991, at B1, B8.

9. *See Competitiveness Council Biotechnology Study Says Japan, Europe Gaining on United States*, 8 Int'l Trade Rep. (BNA) 326 (Feb. 27, 1991).

Biotechnology has seldom been a subject of litigation. It was a subject of litigation, and was favorably treated, in Moore v. Regents of the Univ. of Cal., 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990), *cert. denied*, __ U.S.__, No. 90–1037 (1991 WL 254322). The court considered whether Moore, a university hospital patient, had any basis for claiming compensation or restitution of the profits allegedly made by his treating physician, the university and others from a cell line developed from his surgically removed diseased spleen and patented and developed commercially without his explicit consent. It held that Moore can maintain a cause of action, not for conversion of property but for breach of a duty of disclosure of a physician's research or economic interests. *See* Dorney, *Moore v. The Regents of the University of California: Balancing the Need for Biotechnology Innovation Against The Right of Informed Consent*, 5 HIGH TECH. L.J. 333 (1990). For various perspectives on *Moore*, *see Symposium: Moore v. Regents*, 9 BIOTECH L. REP. 239 (1990).

10. We would not curtail liability in the case of a negligently designed product, since the threat of liability for negligence is an important incentive to make safe products.

11. *See* RESTATEMENT (SECOND) OF TORTS § 402A (1965) (strict liability applies to "product[s] in a defective condition unreasonably dangerous to the user").

12 . We are not scientists, however, and we do not attempt to make the scientific case. This would require one to muster the data on availability of insurance, costs of insurance, size of jury awards, incidence of court or jury error (for example, in finding causation where it does not exist), or quantification of the benefits of innovation that would exist in the absence of ex post liability rules.

13. *See infra* text accompanying note 36.

products from strict liability. The problem with this approach is that it begins on the wrong foundation. It presumes that strict liability is the rule and that freedom from it is an exception. Moreover, the insistence on putting comment k into the center of the universe draws one into the highly contentious area of interpreting the quarter-century old text of a comment to a secondary source, rather than arguing on the basis of principle.

In a 1989 article,[14] one of the present authors and a co-author argued that the rule of a then-recent California Supreme Court case,[15] which construed comment k to exempt all prescription drugs from strict liability, should be applicable to the design of biotechnologically produced prescription drugs. In this article, we examine the state of the literature and jurisprudence two years later, and we build upon the previous article's proposal for a negligence-only rule. First, we take stock of the general problem of overregulation and the perceived need to scale back regulatory barriers that chill innovation.

III. THE LIMITS OF AMERICAN LAW

A quarter of a century ago the United States had an uncontested dominant economic position in the world. Today, America's power has faded.[16] Its trading partners in Germany, Japan, Korea and elsewhere have absorbed large segments of American markets.[17] Abroad, U.S. firms no longer present the feared "American Challenge" documented by J.J. Servan-Schrieber in his 1968 book.[18]

Many explanations have been offered for this fall from power of American business. Some analysts ascribe the phenomenon merely to the fact that our trading partners have finally recovered from the devastation of World War II, and competition is at last on a more equal footing.[19] Others add that market power at mid-century brought complacency, and American business sat back on its laurels while Europe and Asia more than caught up.[20] Still others have asserted that "too much" law is a central problem of the United States. They argue that the fear of antitrust, tort and employee discrimination suits has stifled the innovation and

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14. Traynor & Cunningham, *Emerging Product Liability Issues in Biotechnology*, 3 HIGH TECH. L.J. 149 (1989).

15. Brown v. Superior Court, 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988).

16. M. PORTER, THE COMPETITIVE ADVANTAGE OF NATIONS (1990); F.M. SCHERER & D. ROSS, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE (3d ed. 1990); R. REICH, THE WORK OF NATIONS: PREPARING OURSELVES FOR 21ST CENTURY CAPITALISM (1991).

17. *Id.*

18. J.J. SERVAN-SCHRIEBER, THE AMERICAN CHALLENGE (1968).

19. *See* B. FRIEDMAN, DAY OF RECKONING: THE CONSEQUENCES OF AMERICAN ECONOMIC POLICY (1989).

20. *See* F.M. SCHERER & D. ROSS, *supra* note 16.

efficiency of American firms, and that only radical surgery to cut back law will "free" American firms to compete in the world marketplace.

For antitrust and civil rights law, blame is put on the Warren Court for following the guiding light of pluralism, access and diversity at the cost of efficiency.[21] For tort law, blame is put on "the Founders" of strict product liability.[22]

As with Mark Twain's reflections on the rumors of his death, the claims of crisis are greatly exaggerated.[23]. The rhetoric of crisis is often heard from individuals who do not like the core concept of strict liability.[24] Nonetheless, the critics of "expansive law" have spoken more than a germ of truth.

By about 1970 certain bodies of law, including torts and antitrust, had expanded beyond the bounds that their policy goals would justify. The expanded law undoubtedly deterred some socially progressive activity and increased the costs of available products.[25] Antitrust law

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21. *See, e.g.*, R. BORK, THE TEMPTING OF AMERICA: THE POLITICAL SEDUCTION OF THE LAW (1990); R. BORK, THE ANTITRUST PARADOX: A POLICY AT WAR WITH ITSELF (1978).

22. *See, e.g.*, P. HUBER, LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES (1988).

23. *See* S. Clemens, Cable From Europe to the Associated Press (1897), *quoted in* BARTLETT'S FAMILIAR QUOTATIONS 625 (15th ed. 1980). *See* Henderson & Eisenberg, *The Quiet Revolution in Product liability: An Empirical Study of Legal Change*, 37 UCLA L. REV. 479 (1990).

24 . *See* O.W. HOLMES, JR., THE COMMON LAW, LECTURE III (1881) (liability should be linked with personal responsibility; people should be liable only for what they could and should have prevented; more extensive law is an intrusion on personal freedom). For modern articulations of the same principle, *see* R. NOZICK, ANARCHY, STATE, AND UTOPIA (1974) and T.R. MACHAN, INDIVIDUALS AND THEIR RIGHTS (1989).

25. *See* T. DUNGWORTH, PRODUCT LIABILITY AND THE BUSINESS SECTOR: LITIGATION TRENDS IN FEDERAL COURTS (1988) (empirical study of the Institute for Civil Justice of the Rand Corporation); G. EADS & P. REUTER, DESIGNING SAFER PRODUCTS: CORPORATE RESPONSES TO PRODUCT LIABILITY LAW AND REGULATION 21 (1983); *Product Injuries*, in 1 REPORTER'S STUDY TO THE AMERICAN LAW INSTITUTE, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY 255 (1991); *Product Defects and Warnings*, in 2 REPORTER'S STUDY TO THE AMERICAN LAW INSTITUTE, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY 33 (1991); K. VISCUSI, REFORMING PRODUCTS LIABILITY (1991). *See also* Browning-Ferris Indus. of Vermont, Inc. v. Kelco Disposal, Inc., 492 U.S. 257, 282 (1989) (O'Connor, J., concurring in part and dissenting in part) ("[t]he threat of such enormous [punitive damage] awards has a detrimental effect on the research and development of new products.").

Research along the foregoing lines may provide empirical data that will reinforce or explain or modify the intuitive judgment of the authors that strict liability tends to limit the availability of adequate and reasonably-priced liability insurance, to increase the exposure of young companies to liability they cannot sustain, and to impair incentives for research and innovation in health care. *See* Gastel, *Product Liability Tort Reform*, INS. INFO. INST. (April 1991) ("A 1988 Conference Board survey of 500 chief executive officers shows actual or threatened product liability suits caused 36 percent of surveyed companies to discontinue products, 15 percent to lay off workers and 8 percent to close plants"; also that a recent report of the AMA indicates that "several companies have stopped producing vaccines because of the threat of lawsuits"). *See also* Priest, *The Current Insurance Crisis and Modern Tort Law*, 96 YALE L. J. 1521 (1981); Giges, *Marketers Feel Product Liability Pressure: Risks Crimp Launch of New Items*, ADVERTISING AGE, May 12, 1986, at 3; *OTA [Office of Technology Assessment] Takes a Long Second Look at U.S. Role in Global Bio-Economy*,

provides good examples. The law expanded through judicial opinions particularly in the 1960s and early 1970s. By the 1970s many business persons feared that joint ventures among competitors might be illegal *per se*.

Responding to the problem of expansive antitrust law, the Supreme Court limited its excesses between the mid-1970s and the mid-1980s by working at its margins. In so doing, the Court tried to assure that the law would not chill conduct that promised the delivery of more, better or cheaper goods to consumers.[26]

Special reform came in the area of high technology and innovation. Congress enacted the National Cooperative Research Act of 1984[27] to assure that R&D joint ventures would be facilitated and would not be condemned on their face. Also, the act reduced the quantum of damages available for certain R&D joint ventures that cause competitive harm. Moreover, in antitrust cases in general, courts began to err on the side of facilitating inventiveness rather than compensating plaintiffs.

We propose a similar course in product liability. Change should occur at the margin to induce important innovation, thus recreating an atmosphere hospitable to the prudent development of high social value products, particularly biotech products for medical uses. Tort law shall be preserved at the core of this system.

Biotechnology Newswatch at 8 (May 1, 1989); *Lawmakers Hear Call For Changes in U.S. Biopolicy*, BIOTECHNOLOGY NEWSWATCH, Jan. 6, 1986, at 4 (reporting comment by Warren C. Hyer, Managing Director of the Association of Biotechnology Companies, that without product liability insurance, the biotechnology company "is not only worried about its survival in the event of a lawsuit," but also "it can't enter clinical trials with medical institutions that require the producer to cover the risk of product problems").

The Institute for Civil Justice of the RAND Corporation has commenced a study of the economic effects of product liability law that is currently framed to include a case study of the pharmaceutical industry. It will focus on the factors that shape corporate perceptions of liability exposure and on the issue of how to measure the indirect effects of the liability system on corporate behavior. The ICJ may seek empirical data about what drugs were discontinued because of liability concerns; how information about potential liability exposure is communicated to research and developmental departments in drug companies; what research efforts were undertaken or stopped as a result of liability concerns; what information was furnished to the FDA and what correlation, if any, such disclosures and the FDA response have on a manufacturer's decision to pursue clinical testing or terminate research and investigation; the effect of the attenuation of the learned intermediary doctrine for certain drugs on the development of new drugs; and what drug companies' reactions are to changes in the law or to jury verdicts. (This paragraph is based in part on Mr. Traynor's awareness of the project as a member of ICJ's Board of Overseers and in part on his telephone conversation on May 9, 1991 with Mark Peterson, one of the researchers on the project.)

26. *See* Fox & Sullivan, *Antitrust—Retrospective and Prospective: Where Are We Coming From, Where Are We Going?*, 62 N.Y.U. L. REV. 936 (1987).

27. 15 U.S.C. §§ 4301–05 (Supp. II 1984).

IV. AN EVOLUTION—TORT LAW, STRICT PRODUCT LIABILITY, AND COMMENT K

There are lessons to be learned from contemplating expansive law. The major lessons are that law should not expand beyond its goals and that expansions should be worth their costs. The cost of lost innovation in medical products is high indeed. We turn, then, to the goals and evolution of tort law.

Tort law has several purposes. At first designed simply to resolve incendiary disputes in a fair and legitimate way, the early writ of trespass protected the integrity of person and property against direct invasions. People were liable for the harms they caused. But the law shifted to a negligence-only rule during the industrial revolution. Applying the philosophy of Oliver Wendell Holmes and encouraging the growth of railroads and industry, one court decreed that liability would fall on people and businesses only when they had the choice, the chance, and the moral imperative to prevent the harm they caused.[28]

A. Strict Product Liability

In the mid-twentieth century, however, long past the pains of industrialization, a new need arose. Products were mass produced and mass distributed. Sometimes these products caused injuries to users, and victims demanded accountability. The new societal need was expressed nowhere more eloquently than by Justice (later Chief Justice) Roger Traynor, concurring in *Escola v. Coca-Cola Bottling Co.*:

> Even if there is no negligence, however, public policy demands that responsibility be fixed wherever it will most effectively reduce the hazards to life and health inherent in defective products that reach the market. It is evident that the manufacturer can anticipate some hazards and guard against the recurrence of others, as the public cannot. Those who suffer injury from defective products are unprepared to meet its consequences. The cost of an injury and the loss of time or health may be an overwhelming misfortune to the person injured, and a needless one, for the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business. It is to the public interest to discourage marketing of products having defects that are a menace to the public. If such products nevertheless find their way into the market it is to the public interest to place the responsibility for whatever injury they may cause upon the manufacturer, who, even if he is not negligent in the manufacture of the product, is responsible for its reaching the market. However intermittently such injuries may occur and however haphazardly they may strike, the risk of their occurrence is a constant

28. *See* M. HORWITZ, THE TRANSFORMATION OF AMERICAN LAW 1780–1860 (1977); O.W. HOLMES, JR., THE COMMON LAW 77 et seq. (1881). *See also* Fox, *A Century of Tort Law: Holmes, Traynor and Modern Times*, Trial, July 1989, at 78.

> risk and a general one. Against such a risk there should be general and constant protection and the manufacturer is best situated to afford such protection.[29]

In Chief Justice Traynor's formulation, interests of efficiency, fairness, expectations, and legitimacy all coalesced. First, if the cost of defects in mass produced and distributed products were borne by the manufacturer, the manufacturer alone would have the necessary skill, knowledge, and incentive to make a safer product. Second, if the product bore its own costs, an externality would be internalized and price signals would be clearer and more efficient. Third, if the manufacturer paid the costs, justice to the manufacturer would be done in those cases where the manufacturer's negligence produced the defect but as a practical matter the victim could not prove it. In such cases, deterrence would be increased.[30] Finally, strict liability would serve the interests of compensating the victim, who normally did not have the chance to avoid injury from products that were placed in the stream of distribution.

The Chief Justice made the fair assumption that manufacturers subject to this new conception of product liability would be able to obtain insurance and to pay reasonable rates. The cost of accidents would therefore be borne and distributed efficiently by a company that would presumably continue to thrive if its product was useful. There was no reason to suppose that the manufacturer would not continue to produce or improve the product, for the profit was normally sufficient to induce the investment.

The Chief Justice's insight led to the modern rule of strict product liability, incorporated into Section 402A of the Restatement (Second) of Torts. Section 402A or some variant of it was adopted by state courts throughout the country. The general rule for product defects today is the rule of Section 402A, namely, that sellers of products are strictly liable for all harms proximately caused by their products' defects.[31] The rule applies even if the seller has exercised all possible care.

It is now axiomatic that under a rule of strict product liability the focus of the inquiry is on the defective nature of the product rather than on the seller's conduct. If a plaintiff is able to prove that a product is defective and (in most jurisdictions) unreasonably dangerous, and that

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29. 24 Cal. 2d 453, 462, 150 P.2d 436, 440–441 (1944). *See also* Traynor, *The Ways of Defective Products and Strict Liability*, 32 TENN. L. REV. 363 (1965).

30. The manufacturer would prefer to pay for the safety precaution than for the cost of injuries.

31. Section 402A provides:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm caused to the ultimate user or consumer to his property if
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> (a) the seller is engaged in the business of selling such a product, and
>
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

the defect proximately caused an injury to the plaintiff, the seller is liable.[32]

B. Policy Advantages and Disadvantages of Strict Product Liability

There are policy advantages to strict liability for all products, including biotech medical products. With a blanket strict liability rule, the standard of liability is clear. This leads to greater efficiency in investment decision-making and the conservation of judicial and litigation time.[33] Most importantly, the product internalizes the cost of its harms, and injured persons are compensated.

Moreover, it can be argued that victims are especially worthy of compensation in the case of harms from biotech products. Because of the newness and even perceived mysteriousness of biotechnology, which supposedly has prospects of causing science-fiction type misfortunes, victims may feel themselves to be "guinea pigs" of society.

On the negative side, however, products that bear the costs of strict liability necessarily cost more, which may make important medical products unaffordable. Also, the demand function may not allow the price increases necessary to cover the extra costs of insurance. Alternatively, insurance may become unavailable or insufficient and high tort judgments may force inventive firms out of the market, costing society the loss of investment in research, development, and production.[34] We will never know what pathbreaking products would have emerged in an environment more hospitable to inventiveness.

C. Comment k—the Recognition that Strict Liability Should not Apply to All Products

Since the adoption of the principle of strict product liability, the tension between the goals of promoting useful conduct and of

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32. *See* Brown v. Superior Court, 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1980); Toner v. Lederle Laboratories, 112 Idaho 328, 732 P.2d 297 (1987); Feldman v. Lederle Laboratories 97 N.J. 429, 430, 479 A.2d 374, 375 (1984).

There are two accepted tests for proof of design defects. The consumer expectations test, as articulated in the Restatement, specifies that a product is unreasonably dangerous and therefore defective if it is more dangerous than would be expected by a reasonable consumer. *See* RESTATEMENT (SECOND) OF TORTS § 402A comment i (1965). The risk/benefit or danger/utility test specifies that a product is defective if the "magnitude of the danger outweighs the utility of the product." W. KEETON, D. DOBBS, R. KEETON & D. OWEN, PROSSER AND KEETON ON THE LAW OF TORTS 699 (5th ed. 1984). *See also* Barker v. Lull Eng'g Co., 20 Cal. 3d 413, 573 P.2d 470, 143 Cal. Rptr. 225 (1978).

33. "It is much simpler to use a test for product actionability in strict liability design cases that avoids any issue of negligent conduct. The same position may be taken in the failure-to-warn cases." Wade, *On the Effect in Product Liability of Knowledge Unavailable Prior to Marketing*, 58 N.Y.U. L. REV. 734, 749 (1983).

34. *See supra* note 25.

compensating victims has been apparent. By definition, strict liability resolves the tension in favor of compensating victims. The resolution was apparently driven by an intuition that the cost of the trade-off in lost incentives would not be too great. For one category of products, however, the American Law Institute recognized that the cost of the trade-off *was* too great. To correct for this problem, the ALI adopted comment k in 1965.[35]

Comment k states:

> k. *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and use of the vaccine are justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurances of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products ... is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful product, attended with a known but apparently reasonable risk.[36]

Unfortunately, the apparent purpose of comment k has been undermined and its implied limits ignored. The most plausible reason for the existence of comment k is a concern not to undercut the incentives to research, develop, produce and market products of high social value, especially medical products. The examples given of products to which comment k applies are drugs and vaccines, and the examples of risks are medical. The comment does not itself state why the products described should not be subject to the extra costs of strict liability. The reason is certainly not that drug and vaccine makers are less likely than other producers to be blameworthy; not only is there no reason to suspect that this proposition is true, but blameworthiness is by definition irrelevant to strict liability. The reason is not that injuries from "drugs, vaccines and the like" are unavoidable whereas injuries from other products, such as

35. RESTATEMENT (SECOND) OF TORTS § 402A comment k (1965).
36. *Id.*

asbestos, are avoidable. There is no basis for distinguishing degrees of avoidability. The reason is not that injuries caused by vaccines and drugs are more likely to be inherent in the product itself, even a perfectly made product, for the last sentence of the comment specifically includes the case of impurities in new drugs attributable to the lack of time to detect and remove the impurities.

The tone and examples of the comment lead to a rather simple conclusion: there are some products that are simply too critical to society to be burdened with the costs of accidents that are not the producer's fault. Tort rules should not delay the design, manufacture and sale of these products after the producer has taken all due care. The comment suggests that such products are not subject to strict liability under section 402A. It does not suggest the less favorable alternative of a presumptive strict liability rule with gateways for exemption. Much less does the comment reveal any indication that it was intended to someday gain the prominence of a statute. Still, the law has taken a turn in that direction.

D. Judicial Interpretation of Comment k

Over the years, a body of law developed regarding comment k's application to prescription drugs and vaccines, the closest analogy thus far to biotech medical cases. The courts adopted a case-by-case approach to comment k in both prescription drug and vaccine cases.[37] To avoid strict liability, the cases required the defendant to satisfy a two-pronged inquiry. First, the defendant had to prove[38] that it minimized risks and that the product was "incapable of being made safe given the present state of human knowledge."[39] Second, the defendant had to prove that on balance the product was socially beneficial[40] and that there was no safer alternative.[41] This second prong is a risk/benefit test with a post hoc twist.[42] A manufacturer "might be held strictly liable for harmful

37. *See, e.g.*, Patten v. Lederle Laboratories, 676 F. Supp. 233, 236–37 (D. Utah 1987) (DPT vaccine); Graham by Graham v. Wyeth Laboratories, 666 F. Supp. 1483, 1496 (D. Kan. 1987) (DPT vaccine); Ortho Pharmaceutical Corp. v. Heath, 722 P.2d 410, 415 (Colo. 1986) (oral contraceptive); Toner v. Lederle Laboratories, 112 Idaho at 340, 732 P.2d at 308 (1987) (DPT vaccine); Feldman v. Lederle Laboratories 97 N.J. at 447, 479 A.2d at 383 (1984) (tetracycline).

38. The burden of proof has been placed on the seller. *See, e.g.*, Hill v. Searle Laboratories, 884 F.2d 1064, 1068 (8th Cir. 1989) (IUD); Allen v. G.D. Searle & Co., 708 F. Supp. 1142, 1149 (D. Or. 1989) (IUD); *Patten*, 676 F. Supp. at 237; *Toner*, 112 Idaho at 338, 732 P.2d at 302–03.

39. *Hill*, 884 F.2d at 1068.

40. In *Hill*, the court required defendant to prove that the product "possesses such a high degree of social need . . . that its use is warranted." *Id.*

41. *See, e.g.*, *Allen*, 708 F. Supp. at 1149; *Patten*, 676 F. Supp. at 237; *Toner*, 112 Idaho at 337, 732 P.2d at 302–03.

42. The drug "must survive two risk/benefit challenges, first by the judge and then by the jury." Brown v. Superior Court, 44 Cal. 3d 1049, 1068, 751 P.2d 470, 482, 245 Cal. Rptr. 412, 424 (1980).

side effects because a trial judge could decide, perhaps many years later, that in fact another product which was available on the market would have accomplished the same result."[43]

Many of the cases rely on *Toner v. Lederle Laboratories*,[44] the facts and analysis of which have contributed to an understanding of the jurisprudence of comment k. In *Toner*, a child received Tri-Immunol, a vaccination against diphtheria, pertussis and tetanus. The child suffered permanent damage to his spine and became paralyzed from the waist down.

According to the court in *Toner*, the manufacturer would be strictly liable unless it established three preconditions to gaining an exemption from strict liability under comment k. First, the manufacturer had to show that the product was "properly prepared, and accompanied by proper directions and warning." Second, it had to prove that the product's risk was "in fact unavoidable." Finally, it had to prove through a risk/benefit analysis that the product was one "apparently useful and desirable" for the public.

Despite the court's acknowledgment that strict liability could undermine incentives to develop new drugs,[45] it rejected blanket immunity from strict liability as an approach "counter both to the express language of comment k and to common sense."[46] Mixing ex ante and ex post considerations, the court declared that it did not "serve society that an unavoidably unsafe product, which has occasional or fractious benefit, should enjoy insulation from strict liability in tort when the product's predominant effects are detrimental to individual and public safety."[47]

Ultimately, the court in *Toner* upheld a judgment on a jury verdict finding that the manufacturer did meet its burden in proving comment k exemption from strict liability. The court held, however, that the manufacturer could nonetheless be found negligent for marketing its DPT vaccine when it might have developed and sought FDA approval for a DPT vaccine prepared by a safer methodology.

The cases state that risk/benefit analysis should occur as of the time the product is distributed to the plaintiff. But clearly and by definition, the test is not a normal ex ante negligence test.

43. *See id.* at 1067-68, 751 P.2d at 482, 245 Cal. Rptr. at 423. *See also*, Belle Bonfils Memorial Blood Bank v. Hansen, 665 P.2d 118, 123 (Colo. 1983).

44. 112 Idaho 328, 732 P.2d 297 (1987). *Toner* was decided after the intermediate court decision but before the California Supreme Court had affirmed and expanded upon that decision in *Brown*.

45. *Id.* at 338–339, 732 P.2d at 307–308, (citing Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment k*, 42 WASH. & LEE L. REV. 1139, 1141 (1985) ("The public policy of encouraging the production of new and hopefully efficacious drugs is not compromised by imposing a reasonable standard on manufacturers to be responsible for new developments and risks in drugs they have marketed.")).

46. *Id.* at 340, 732 P.2d at 309.

47. *Id.* at 336–337, 732 P.2d at 305–06 (quoting Willig, *The Comment k Character: A Conceptual Barrier to Strict Liability*, 29 MERCER L. REV. 545, 575 (1978)).

Accordingly, under the widely adopted analysis of *Toner*, a drug or vaccine seller must compose a detailed defense in every tort action based on product design. In effect, the seller must jump the *Toner* hurdles to receive negligence-only treatment.[48]

E. *Brown v. Superior Court:* A Blanket Exemption from Strict Liability for Prescription Drugs

In 1988 the California Supreme Court departed from the *Toner* approach in *Brown v. Superior Court*,[49] a consolidation of product liability cases against manufacturers of diethylstilbestrol ("DES"). The court rejected the usual case-by-case approach to determine whether DES was "unavoidably unsafe" within the meaning of comment k. It determined that prescription drugs that are designed with care but still cause harm are all unavoidably unsafe as a matter of law. The court concluded that prescription drugs are not subject to strict liability for allegedly defective design. The court's reasoning is particularly cogent:

> Perhaps a drug might be made safer if it was withheld from the market until scientific skill and knowledge advanced to the point at which additional dangerous side effects would be revealed. But in most cases, such a delay in marketing new drugs—added to the delay required to obtain approval for release of the product from the Food and Drug Administration—would not serve the public welfare. Public policy favors the development and marketing of beneficial new drugs, even though some risks, perhaps serious ones, might accompany their introduction, because drugs can save lives and reduce pain and suffering.
>
> If drug manufacturers were subject to strict liability, they might be reluctant to undertake research programs to develop some pharmaceuticals that would prove beneficial or to distribute others that are available to be marketed, because of the fear of large adverse

48. *See* 2 REPORTER'S STUDY TO THE AMERICAN LAW INSTITUTE, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY 47–57 (1991); T. DUNGWORTH, *supra* note 25. *See also* Traynor & Cunningham, *supra* note 14.

In some jurisdictions, in design cases, strict liability can be avoided not only by comment k treatment but also or alternatively by proof of a "state of the art" defense. Some courts hold that a seller cannot be held liable for a defect that was undetectable given the state of scientific knowledge at the time the product was sold. Conversely, however, if detection was scientifically possible, the defendant would be strictly liable even though it did not know of the defect and exercised all due care. *See, e.g.*, George v. Celotex Corp., 914 F.2d 26 (2d Cir. 1990). Other jurisdictions reject a state of the art defense because such a defense introduces principles of negligence into areas carved out for strict liability. *See, e.g.*, Hayes v. Ariens Co., 462 N.E.2d 273, 277 (Mass. 1984); Beshada v. Johns-Manville Products Corp., 90 N.J. 191, 202, 447 A.2d 539, 546 (1982) (asbestos).

49. 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988). Doctors prescribed the drug to prevent miscarriages. Ingested during pregnancy, the drug allegedly caused injury to women *in utero* and to their offspring. The plaintiffs, the offspring of mothers who had used the drug during their *in utero* development, alleged that the manufacturers had knowledge that DES "contained a cancer-causing substance" and failed to warn consumers of the potential harm, as well as asserting no fault theories.

> monetary judgments. Further, the additional expense of insuring against such liability—assuming such insurance would be available—and of research programs to reveal possible dangers not detectable by available scientific methods could place the cost of dedication beyond the reach of those who need it most.[50]

F. The Aftermath of *Brown*

Since *Brown*, approximately a dozen states have interpreted comment k in strict liability claims involving drugs. Most of the published opinions deal with the question of whether a defendant-manufacturer can obtain a pretrial ruling, as in *Brown*, that strict liability is not applicable as a matter of law to the design of prescription drugs or medical devices. After *Brown* and until the Supreme Court of Utah decided *Grundberg v. Upjohn Co.*[51] in 1991, the courts systematically ruled that the defendant-manufacturer can assert comment k as a defense to strict liability only after a case-by-case determination as to whether, for example, the product was unavoidably unsafe and had such high social value that it should be available despite the potential harm.[52] Thus, the *Brown* rule rejecting the case-by-case approach and requiring a blanket negligence-only rule remains a distinct minority rule in the United States.[53] Moreover, in the aftermath of *Brown*, no judicial opinion other than *Grundberg* has given more than cursory discussion to the impact of strict liability on incentives in the prescription drug industry.

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50. The court continued:

> Dean Prosser summed up the justification for exempting prescription drugs from strict liability as follows:
>
> > The argument that industries producing potentially dangerous products should make good the harm, distribute it by liability insurance, and add the cost to the price of the product, encounters reason for pause, when we consider that two of the greatest medical boons to the human race, penicillin and cortisone, both have their dangerous side effects, and that drug companies might well have been deterred from producing and selling them.
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> 44 Cal. 3d at 1063–1064, 751 P.2d at 479, 245 Cal. Rptr. at 420.

51. 813 P.2d 89 (Utah 1991).

52. Hill v. Searle Laboratories, 884 F.2d 1064, 1068–1069 (8th Cir. 1989); Allen v. G.D. Searle & Co., 708 F. Supp. 1142, 1149–1150 (D. Or. 1989); Kociemba v. G.D. Searle & Co., 695 F. Supp. 432, 435–436 (D. Minn. 1988); Pollard v. Ashby, 793 S.W.2d 394, 400 (Mo. App. 1990); White v. Wyeth Laboratories, Inc., 40 Ohio St. 3d 390, 533 N.E.2d 748, 752 (1988); Castrignano v. E.R. Squibb & Sons, Inc., 546 A.2d 775, 781 (R.I. 1988). The issue of the applicability of comment k may arise in a pretrial motion, for example, for summary judgment, and the court may decline to rule on the issue as a matter of law but remand to the jury to do a risk/benefit analysis.

53. *See* Lindsay v. Ortho Pharmaceutical Corp., 637 F.2d 87, 90–91 (2d Cir. 1980) (oral contraceptives). *But see* Jones v. Lederle Laboratories, 695 F. Supp. 700, 706 (2d Cir. 1988) (involving DPT vaccine, the court suggested that the fact-finder must do a risk/utility analysis); Moore v. Vanderloo, 386 N.W.2d 108, 117 (Iowa 1986) (oral contraceptive); McKee v. Moore, 648 P.2d 21, 23 (Okla. 1982) (IUD); Terhune v. A.H. Robins Co., 90 Wash. 2d 9, 16–17, 577 P.2d 975, 979 (1978) (IUD).

Grundberg involved several causes of action in negligence and strict liability against Upjohn, the manufacturer of the drug Halcion. Ilo Grundberg was taking Halcion to treat her case of insomnia. Consistent with Upjohn's recommendations, Grundberg's doctor prescribed a dosage of .5 milligram. When Grundberg took the drug at this dosage, she allegedly experienced intoxication, depersonalization, and homicidal compulsion. While suffering from these side-effects, Grundberg shot and killed her mother.

The personal representative of the mother's estate sued Upjohn in federal court. The federal court certified to the Utah Supreme Court the questions: Does Utah adopt the "unavoidably unsafe" exemption to strict product liability as set forth in comment k, and if so are all FDA-approved prescription drugs within the "unavoidably unsafe" exemption as a matter of law, or should the determination be made on a case-by-case basis?

The Court did adopt the "unavoidably unsafe" exemption and agreed with *Brown's* rejection of the case-by-case approach. For prescription drugs approved by the FDA, the court held that:

> In light of the strong public interest in the availability and affordability of prescription medication, the extensive regulatory system of the FDA, and the avenues of recovery still available to plaintiffs by claiming inadequate warning, mismanufacture, improper marketing, or misrepresenting information to the FDA, we conclude that a broad grant of immunity from strict liability claims based on design defects should be extended to FDA-approved prescription drugs in Utah."[54]

But *Grundberg* criticized *Brown's* "apparent attempt to use the plain language of comment k as the vehicle for exempting all prescription drugs from strict liability rather than relying on the policies underlying that comment."[55] Arguing on the basis of comment k's underlying policies, the court stated:

> Because prescription drugs are chemical compounds designed to interact with the chemical and physiological processes of the human body, they will almost always pose some risk of side effects in certain individuals. Despite these risks, new drugs are continually approved by the FDA because of their social benefit in saving lives and alleviating human suffering. The health care system and general standard of living in this country, for example, would be seriously impaired without such essential drug products as antibiotics that allow quick recovery from ailments that were once debilitating or even fatal....

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54. 813 P.2d at 99. It bears noting that the FDA has a "volume of new products in the pipeline," including many that "are much more complex scientifically than their earlier counterparts." *Biotech Pipeline: Bottleneck Ahead*, 254 SCIENCE 369 (1991). Reliance on the FDA regulatory system will require resources sufficient to the task.

55. 813 P.2d at 95.

> Despite inherent risks, *and in contrast to any other products*, society has determined that prescription medications provide a unique benefit and so should be available to physicians with appropriate warnings and guidance as to use. The federal government has established an elaborate regulatory system, overseen by the FDA, to control the approval and distribution of these drugs.... No other class of products is subject to such special restrictions or protections in our society (emphasis added by court).[56]

Most post-*Brown* cases involve actions for harms allegedly caused by DPT (the generic name for a vaccine against diphtheria, tetanus, and pertussis),[57] DES (diethylstilbestrol),[58] Chymodictin,[59] Myelogram,[60] Bendectin,[61] Carbamazepine,[62] Keflex,[63] and oral polio vaccine.[64]

Many other post-*Brown* cases involve G.D. Searle & Co., which designed and manufactured the Copper-7 (Cu-7) IUD.[65] The IUDs allegedly caused permanent infertility,[66] pelvic inflammatory disease

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56. *Id.* at 95, 96.

57. *White*, 40 Ohio St. 3d 390, 533 N.E.2d 748 (1988) (affirming court of appeals reversal of a jury verdict for plaintiff; adopting a case-by-case approach); Ackley v. Wyeth Laboratories, Inc., 919 F.2d 397 (6th Cir. 1990) (summary judgment affirmed on issue of negligent design pursuant to *White*).

58. Castrignano v. E.R. Squibb & Pons, Inc., 546 A.2d 775 (R.I. 1988) (adopting case-by-case approach to application of comment k in design-defect cases). On remand, jury found defendant liable. Castrignano v. E. R. Squibb & Pons, Inc., 900 F.2d 455 (1st Cir. 1990); Shirkey v. Eli Lilly & Co., 852 F.2d 227 (7th Cir. 1988).

59. Pollard v. Ashby, 793 S.W.2d 394 (Mo. App. 1990) (divided court affirms jury verdict for plaintiff and rejects *Brown*; argues that the ALI rejected a blanket provision in drafting Section 402A and comment k).

60. Savina v. Sterling Drug, Inc., 247 Kan. 105, 795 P.2d 915 (1990) (adopting a case-by-case determination and applying comment k to the drug; remanded on issue of warnings).

61. Daubert v. Merrell Dow Pharmaceutical, 711 F. Supp. 546 (S.D. Cal. 1989) (motion for summary adjudication of issues denied on issue of failure to warn). *See also* Coyle v. Richardson-Merrell, Inc., 526 Pa. 208, 584 A.2d 1383 (1991).

62. Williams v. Ciba-Geigy Corp., 686 F. Supp. 573 (W.D. La. 1988), *aff'd*, 864 F.2d 789 (5th Cir. 1988) (summary judgment for manufacturers upheld; rejected plaintiff's theory that Carbamazepine was "unreasonably dangerous per se" and therefore that its risk was always greater than its utility).

63. Jacobs v. Dista Products Co., 693 F. Supp. 1029 (D. Wyo. 1988) (failure to warn at issue).

64. Snawder v. Cohen, 749 F. Supp. 1473 (W.D. Ky. 1990) (failure to warn at issue).

65. On February 25, 1974, the Food and Drug Administration ("FDA") approved the Cu-7 IUD as a drug because it contains copper, a heavy metal. The Cu-7 IUD is an intrauterine copper strand used as a contraceptive and available through a physician's prescription only. The physician inserts the apparatus into a woman's uterus through the vagina and cervix where it remains until a physician removes it. At the time of its introduction, many women across America had ceased using oral contraceptives because of publicity regarding side effects. Hill v. Searle Laboratories, 884 F.2d 1064, 1065 (8th Cir. 1989) (referencing *Statement of Russell J. Thomsen, M.D., Hearings on Intrauterine Contraceptive Devices Before Subcomm. of the House Committee on Government Operations*, 93rd Cong., 1st Sess. (1973). *See also*, Allen v. G.D. Searle, 708 F. Supp. 1142, 1145 (D. Or. 1989) (motion for summary judgment denied; case-by-case determination accepted); Amore v. G.D. Searle, 748 F. Supp. 845, 847 (S.D. Fla. 1990) (motion for summary judgment denied; case-by-case determination accepted).

66. *See Amore*, 748 F. Supp. at 847.

including pelvic pain and bleeding, and infection of the upper genital tract including the uterus, fallopian tubes, and ovaries.[67] Also, it is alleged in some IUD cases that the polypropylene removal string retracted into the uterus.[68] In all of these cases, courts refused to take a blanket approach to comment k, citing the history and language of the comment and the need for a strict liability type of risk/benefit analysis.

These post-*Brown* opinions assert that the language of comment k necessitates a limited scope for derogation from Section 402A and that the language specifically precludes a blanket exemption. They posit that comment k states its own test[69] which indicates that not all drugs are worthy of exemption from strict liability.[70]

While the formulations in the various opinions contain different nuances, each court attempts to determine whether the social utility of the product outweighs its risk to society. Some of the opinions rely heavily on the history of comment k (much like one would rely on legislative history) to aid in construction.[71] Some jurists note that a blanket exemption for prescription drugs was proposed at an American Law Institute meeting and that that the motion was defeated.[72] They conclude that the drafters must have intended comment k not to offer such an exemption. These jurists parse the language in the comment the way one would parse statutory language, instead of recognizing the comment as elaboration on a principle in a secondary source that is under constant common law development. Thus, comment k becomes not only the freeze-dried product of an annual meeting of the ALI never to evolve in light of current needs, but it is frozen law. Meanwhile, the ALI itself rejects the notion of treating the Restatement as a statutory code.[73]

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67. *Allen*, 708 F. Supp. at 1145.

68. Adams v. G.D. Searle, 16 Fla. L. Week 233, 1991 WL 3575 (1991) (reversed summary judgment for defendant holding that comment k involves a mixed question of law and fact to be determined by the jury).

69. They argue that the comment requires manufacturers to show that the product was "incapable of being made safe," that it was "properly prepared and marketed," and that a "proper warning" was issued. *Amore*, 748 F. Supp. at 854.

70. The comment refers to "some products" which are incapable of being made safe. It states that these products are "especially common in the field of drugs." The post-*Brown* opinions note that when comment k states that certain products are not unreasonably dangerous, the comment explains "the same is true of *many* other drugs" (emphasis added) and "*many* new or experimental drugs." (emphasis added). The cases draw a negative inference from this wording that comment k was not intended to exclude *all* drugs from strict liability. *See, e.g.*, White v. Wyeth Laboratories, Inc., 40 Ohio St. 3d 390, 533 N.E. 2d 748 (1988). *See also* RESTATEMENT (SECOND) OF TORTS § 402A comment k (1965).

71. *See, e.g.*, Hill v. Searle Laboratories, 884 F.2d 1064 (8th Cir. 1989); *Amore*, 748 F. Supp. at 854.

72. *Amore*, 748 F. Supp. at 854 (citing 38 ALI Proc. 19, 90–98 (1961)).

73. REPORT OF COMMITTEE ON ESTABLISHMENT 29, 45 (1923), *reprinted in* THE AMERICAN LAW INSTITUTE—50TH ANNIVERSARY (1973) ("legislative enactment of the restatement as a code of law not desirable"); Wechsler, *The Course of The Restatements*, 55 ABA J. 147, 150 (1969) (Restatements are "a modest but essential aid in the improved analysis,

V. CANVASSING ALTERNATIVE LIABILITY RULES

Having examined the evolving and sometimes inconsistent law on drugs and vaccines, which is the closest analogy to biotech medical products, we find it useful to step back and consider costs and benefits of alternative liability rules. There are several possible approaches to the liability rules for biotech medical products. One is blanket strict liability. This rule would be harsher than the usual rule applied to drugs and vaccines and could be justified only by a claim that biotech medical products are more inherently dangerous and hold more net costs than traditionally produced drugs and vaccines. Yet, this claim has not been made.

The second is case-by-case analysis wherein the defendant must prove that the harm was unavoidable, that the product is socially valuable, and that there is no safer alternative. The third is a negligence-only rule for all biotech medical products. Here, we compare the second and third alternatives on the supposition that they will be the alternatives most seriously entertained.

A. The Case-by-Case Approach

The principal advantage of the case-by-case approach is that some injured persons recover from a non-negligent producer or seller. The problems, however, are numerous: (1) Invention is deterred by the added costs of possible strict liability. (2) Investment decisions are inefficient because the investor in innovation cannot know in advance what rule of law will apply to the outcome. (3) Judicial proceedings are long, complicated and expensive, and are likely to yield inconsistent results, causing a perception of illegitimacy of the process. (4) The substantive inquiry is not principled. It is a hybrid between ex ante and ex post considerations.

The substantive inquiry does not examine duty and breach but the social value of the product, the theoretical avoidability of unpredictable harm, and the rejection of a safer product even if one's own product was not known to be unsafe and might have appeared more innovative than an available alternative. Since knowledge of the rule of law is not expected to induce greater care, the inquiry is merely a tool used to locate an arbitrary line on one side of which injured persons recover from non-negligent sellers and on the other side of which they do not.

The weightiest disadvantage of the case-by-case approach is the chill it places on inventiveness (although less so than a pure strict liability

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clarification, growth and adaptation of the common law"); Perkins, *The Genesis and Goals of the ALI Corporate Governance Project*, 8 CARDOZO L. REV. 661, 684 (1987) ("No ALI Project has served to 'freeze' the law"). *See also* Grundberg v. Upjohn Co. 813 P.2d 89, 95 (Utah 1991).

approach). The court in *Toner* attempted to address this problem by stating that if shortages of drugs occur or new development is stifled one "would expect the Legislature to intervene to prevent the resulting health crisis."[74] But the possibility of legislative intervention at times of crisis cannot compensate for stifled innovation. Moreover, one cannot realistically expect legislatures to intervene or legislative solutions to be adequate in the case of every incipient health crisis. More importantly, in a regime that suppresses research, we may never know how to prevent health crises when they occur. We will never know what cures to what diseases would have been discovered. The new "penicillin" may never be invented. The research dollars will never have been committed.[75]

B. A Negligence-Only Rule through *Brown* or *Grundberg*,[76] or a Primary Recognition of the Limits of Strict Liability

A negligence-only rule for the design of biotech medical products will increase research, development, and production of these socially vital products, thus saving human suffering and human lives. Second, it will avoid the expense and waste of case-by-case determinations. Third, the rule will legitimize law and process because the rule is a principled one.

The disadvantage of this rule is that the victim will not be compensated by the non-negligent seller. Whether individuals who suffer personal injuries should have their medical expenses allayed (e.g., through national health insurance) is a remaining question. Here, we only suggest that the rule of compensation *from the seller* should be trumped when such a rule is likely to lead to more human suffering than a rule of no compensation from the seller.

C. The Illusive Appeal to the Alternative Design Test

Much has been written about product design in general and the resemblance of risk/utility tests to negligence tests, at least if analysis is not ex post. Moreover, many analysts have expressed concern that strict liability rules unduly impair incentives to invent. In view of potential costs of strict liability, the American Law Institute authorized a study on Enterprise Responsibility for Personal Injury. In their study, the reporters

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74. Toner v. Lederle Laboratories, 112 Idaho 328, 343, 732 P.2d 297, 312 (1987). *But cf.* L. KIRP & H. MAHER, THE POLITICS OF THE AIDS VACCINE OR HOW THE CALIFORNIA LEGISLATURE SEARCHED FOR THE MAGIC BULLET—AND WOUND UP SQUABBLING WITH THE TRIAL LAWYERS, THE BUDGET CUTTERS AND THE ALZHEIMER'S ESTABLISHMENT, (Institute of Governmental Studies, Univ. of Calif. at Berkeley, Working Paper No. 87–7, 1987).

75. *Cf.* Easterbrook, *The Limits of Antitrust*, 63 TEX. L. REV. 1 (1984); Jorde & Teece, *Innovation, Cooperation and Antitrust*, 4 HIGH TECH. L.J. 1 (1989). *See also supra* note 25.

76. Both *Brown* and *Grundberg* rely on comment k. Accordingly, they speak in terms of "immunity" from strict liability. A more open negligence rule would not start with strict liability as the main case, and freedom from strict liability would not need justification.

stated: "Because a producer is liable only if it balances risks and utilities incorrectly, the risk/utility test is not a true strict liability test, but rather looks much like legal negligence with a state of the art defense substituted for an explicit foreseeability requirement."[77] The Reporters propose the following substitute for the current risk-utility test:

> A product's design should be deemed defective if and only if there was a feasible alternative design which, consistent with the consumer's expected use of the product, would have avoided the particular injury, and if the costs of the alternative design are less than the costs of the injuries thereby avoidable.[78]

While at first blush the Reporters' suggestion might seem a reasonable compromise between the *Toner* case-by-case approach and a pure negligence-only rule, on a closer look the proposal incorporates some of the static elements of the *Toner* test and it would not provide the most enlightened principle for biotech products. Under the test, innovative change must be justified in view of what exists, rather than encouraged in view of what might be. The test ignores the fact that a new product may have appeared more promising than existing alternatives, and it may have promised positive spill-over benefits by opening new paths for innovation. If all creative people had to justify change, progress would be stopped in its tracks. It is impossible to optimize innovation by anchoring it to the status quo.[79] To foster research and design of new biotech medical products, biotech companies should not be required to prove that a biotech design is preferable to an existing conventional design.[80]

D. The Mechanics and Advantages of a Hospitable Negligence-Only Test

We prefer a negligence test that asks simply whether the biotech medical product "was properly prepared and accompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution."[81] Such a test

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77. 2 REPORTER'S STUDY TO THE AMERICAN LAW INSTITUTE, *supra* note 25, at 48.

78. *Id.* at 56.

79. The test also suffers from a peculiar mixture of ex post and ex ante analysis. The injury in suit is taken as a given although it may not have been foreseeable. If the product of alternative design would not foreseeably cause the same injury, the fact-finder would undoubtedly find that its use *would* have avoided the injury. Yet, ex ante, the alternative design may not have been safer. Moreover, the design in suit and the underlying technology for it may have held benefits beyond those promised by the alternative design.

80. *Compare* Traynor & Cunningham, *supra note* 14 at 178, 185–187 *with* O'Reilly, *Biotechnology Meets Products Liability: Problems Beyond the State of the Art*, 24 HOUS. L. REV. 451, 460–61, 477–78 (1987). *Cf.* Editorial, *Keep Medical Technology Healthy*, N.Y. Times, May 18, 1991, at 22, Col. 1.

81. Brown v. Superior Court, 44 Cal. 3d 1049, 1069, 751 P.2d 470, 483, 245 Cal. Rptr. 412, 424 (1988).

harmonizes with the standard negligence test articulated by the Restatement (Second) of Torts that "negligence is conduct which falls below the standard established by law for the protection of others against unreasonable risk of harm."[82]

The flexibility of the standard[83] is a virtue, because "unreasonable risk" is a concept well developed by the case law. Under such a standard, an unjustified departure from a manufacturer's design protocol, industry custom, or an FDA requirement would be negligent, as would a manufacturer's failure to provide adequate warnings. Under the same standard, bringing to the market an innovation that promises more benefit than harm would be non-negligent. A person might be injured and might claim and prove that the use of a different product would probably have avoided the harm, but this is a fortuity and would not be a basis for liability. Research and innovation beneficial to human health are more likely to flourish under the negligence-only standard than under either a strict liability regime or its complicated "alternative design," risk/utility, or other case-by-case variants.

To illustrate, let us imagine the case of a hypothetical biotech vaccine. Instead of using a killed virus or an attenuated live virus, a biotech vaccine manufacturer may attempt to replicate the virus by engineering only that portion of it that triggers the body's immune response. Only the portion of the virus that stimulates the immune system would be produced, not the infectious portion.[84] For this reason, the vaccine itself may present no risk or virtually no risk to the recipient.[85] The manufacturer may determine that the "subunit" vaccine should be accompanied by a substance commonly called an "adjuvant" that will enhance the immune response.[86] Conventional choices include

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82. RESTATEMENT (SECOND) OF TORTS § 282 (1965). *See also Brown*, at 283, 285, 289, 290, 291, 292, 293.

83. *See* W. KEETON, *supra* note 32, at 193 ("the application of this standard of reasonable conduct is as wide as all human behavior").

84. Traynor & Cunningham, *supra* note 14, at 161.

85. *Id.*

86. *See* R. HYDE & R. PATNODE, IMMUNOLOGY 65 (1987): "Enhancement of the immune response can be affected by increasing the rate at which the response occurs, elevating its magnitude, prolonging the response, or directing the response to a particular facet of the immune response. Substances capable of these actions may be specific or nonspecific potentiators. Nonspecific potentiators are called adjuvants. Adjuvants are substances that enhance the immunogenicity of molecules without altering their chemical composition. Adjuvants enhance immune response by their ability to increase the efficiency of macrophage processing of antigen, prolong the period of exposure to the antigen, and amplify the proliferation of immunologically committed lymphocytes." *See also* I. ROITT, ESSENTIAL IMMUNOLOGY 180–82 (6th ed. 1988); Tilton, *Vaccines Get Booster from High Technology*, CHEMICAL MARKETING REP., SR27 (Mar. 19, 1990).

The U.S. Patent and Trademark Office has recently issued a patent to Cambridge Biotech Corporation for an adjuvant that the company plans to use for its recombinant subunit vaccine against feline leukemia and in connection with preclinical studies to determine the feasibility of using the adjuvant in human vaccines against diseases like

Freund's adjuvant[87] and alum.[88] To increase potency and avoid known side effects of these adjuvants, the manufacturer may wish to instead create and use a biotech adjuvant.

Under a pure negligence-only rule, the manufacturer's choice of a biotech adjuvant would not need to be justified by comparison to the "alternative design" of Freund's adjuvant or alum or any other conventional product. The choice would be tested under the negligence standard of unreasonable risk, which always takes into account existing alternatives and prominently takes into account the manufacturer's care in following its design protocol, industry custom and applicable regulations, and the provision of adequate warnings. Significantly, the standard also takes into account the general and particular probable benefits of the innovative activity, especially the probable spill-over benefits to life and health.

VI. THE SOCIAL RESPONSIBILITY TO KNOW, LEARN, AND FORESEE

Biotechnology is imagined to hold mysterious risks.[89] If the benefits we expect from medical biotech products are much greater than the harms, liability and related rules should lean decisively on the side of facilitating non-negligent medical biotech development. At the same time, however, we are mindful of the unproud history of product after product from companies whose executives and spokespeople have refused to "know" of the harms their products cause long after the connections are, at first, suspicious, and later, barely contestable. Tobacco and asbestos are notorious examples.[90]

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malaria, herpes, certain forms of hepatitis, and even AIDS. N.Y. Times, Oct. 19, 1991, § 1, at 36, col. 5.

87. "Freund's adjuvant is a classic adjuvant that is an emulsion of paraffin or mineral oil (usually Bayol F) and water. Lanolin and arlocel A are used as emulsifying agents." *See* R. HYDE & R. PATNODE, *supra* note 86.

88. "Aluminum hydroxide and alum have a mechanism of action similar to Freund's adjuvant in retarding absorption of the antigen and thus prolonging exposure to antibody-forming tissues. They will also cause local inflammation, thus increasing mononuclear cell exposure." *Id.* at 66.

89. *See* S. NOVICK ET. AL., LAW OF ENVIRONMENTAL PROTECTION §§ 18–9 to 18–19 (1987).

90. *See The Effect of Cipollone: Has the Tobacco Industry Lost its Impenetrable Shield?* 23 GEORGIA L. REV. 763 (1989) (discussing Cipollone v. Liggett Group, 893 F.2d 541 (3d Cir. 1990), *cert. granted*, __ U.S. __, 111 S. Ct. 1386 (1991)).

See Nelson-Horchler, *Dodging the Liability Bullet*, INDUSTRY WEEK 30 (Apr. 6, 1987) (asbestos manufacturers were aware of the products' hazards as early as the 1930s, yet failed to provide workers with handling instructions or safety equipment, or to label the products as dangerous). *See also* Beshada v. Johns-Manville Prod. Corp., 90 N.J. 191, 447 A.2d 539 (1982); Hardy v. Johns-Manville Sales Corp., 681 F.2d 334 (5th Cir. 1982).

See Seltzer, *Punitive Damages in Mass Tort Litigation: Addressing the Problems of Fairness, Efficiency and Control*, 52 FORDHAM L. REV. 37, 51–55 (1983) (MER/29, used in the treatment of high cholesterol, was found to cause cataracts. Richardson-Merrell, the drug's

To be entitled to the respectful treatment we recommend, it would be incumbent upon the biotech companies to recognize their social responsibility. They should be held to high standards of quality assurance, including audits of raw material suppliers, testing and staff training. They should be constantly alert to receive and process information linking biotechnological methodologies to harms. They should be held to the highest obligation to prevent false and misleading denials, and to shun all cover-ups.[91] They should recognize their duty to investigate early warning signals, and to cause information to be published and disseminated, not bottled up. Product labeling and warnings should be monitored and updated carefully. Unbiased individuals should be in charge of analyzing all claimed linkages of biotech methodologies to harm. Before harm happens, medical biotech companies should examine and develop standards regarding what constitutes evidence of a meaningful causal linkage and what constitutes a warning signal. Before harm happens, the companies should formulate standards for identifying information that should be aired, and plans for disseminating and acting upon it. Such standards, plans and policies of forthrightness will enure not only to the benefit of the public,[92] but to the benefit of the biotech industry as well.[93]

Social responsibility also entails pricing at levels that are not exorbitant. Certain scarce drugs, including biotech drugs, sell for thousands of dollars per dose. In 1989 AZT, the only drug licensed to treat AIDS, cost each patient approximately $8,000 for "usual" yearly doses. Protesters claim that the AZT manufacturer is earning unconscionable profits by charging such a high price for the drug.[94]

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manufacturer, was found criminally liable for making false and fraudulent statements to the FDA regarding the drug's hazards. Richardson-Merrell was subsequently held liable for more than $200 million in damages in civil suits by injured persons.) *See also* Roginsky v. Richardson- Merrell, 378 F.2d 832 (2d Cir. 1967).

See Memo in Ray Case Warned of AIDS Link, United Press International, May 18, 1990, Tampa, Fl. (internal memorandum dated Dec. 1982 at blood products company reputedly recommended warning hemophiliacs of link between its products and acquired immune deficiency syndrome. No warning was issued until early 1984.) *See also* Ray v. Cutler Laboratories, 744 F. Supp. 1124 (M.D. Fla. 1990).

91. It bears noting that the trend in the law is to encourage and protect whistleblowers. *See, e.g.*, 5 U.S.C. § 2302(b)(8); 10 U.S.C. §§ 2409, 2409a; Cal. Lab. Code §§ 1102.5, 1103; Cal. Gov't Code § 19863.

92. *See* Lindell, *Biotech Firms Under the Microscope; Excess and Surplus Lines*, 91 BEST'S REVIEW—PROPERTY-CASUALTY INS. (Feb. 1991) ("Good manufacturing practices should go far beyond merely meeting FDA requirements for purity and consistency. They should include a meaningful commitment to responsible and legally correct actions in quality control, raw material supplier audits, product labelling, sales staff training and solicitation of post marketing surveillance.")

93. Not only will the firms command respect; they may benefit from assumption of the risk concepts and from inferences of no negligence.

94. Hilts, *Wave of Protests Developing on Profits From Aids Drug*, N.Y. Times, Sept. 16, 1989, at 1, col. 5.

Centoxin, a biotech drug used to treat septic infection, sells in the Netherlands and Great Britain at the equivalent of $3,800 a dose, and is expected to be priced in the same range when it reaches the U.S. market.[95]

In some cases the extraordinary price may reflect monopoly profits. Section 2 of the Sherman Antitrust Act prohibits monopolization.[96] The law against monopolization, however, is not a law against exorbitant profit-taking. It has been argued and judicially accepted that a monopoly price will simply draw new competition into the market, that in any event the courts are poor regulators of price, and that in the case of patents and intellectual property a higher than competitive price is a reward and inducement for innovation.[97]

Policymakers in European nations generally disagree. In the European Economic Community, for example, a dominant firm that charges a price far in excess of value thereby abuses its dominant position.[98] This principal is heavily criticized by American scholars and business people as excessive and counter-productive market intervention.[99] However, if U.S. firms fail to check their own excesses regarding products critical to life and health, they are likely to invite extensions of section 2 of the Sherman Act or direct price regulations.

The high price of scarce drugs is of course not all profits. Centocor, the patentee of Centoxin, which was the first commercially-available, genetically-engineered human monoclonal antibody, reports that it spent at least $250 million to develop the drug.[100] This extraordinary cost of development and production is a more intractable problem than excess profits. But the seller does not satisfy its social responsibility merely by proving that it spent $250 million to develop a desperately needed and wanted drug and that it must regain its expenses by charging thousands of dollars per dose. The challenge of society is to devise procedures and guidelines for determining who will get what critical drug and how society will pay for it. The developer of the drug and its core of scientists and business-people are among the most knowledgeable, involved individuals who can and must commit themselves to serious participation in the search for solutions.

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95. Winslow, *Dose of Reality: Costly Biotech Drugs Will Pose Hard Choices for U.S. Health Care*, Wall St. J., Nov. 5, 1991, at 1, col. 6.

96. 15 U.S.C. § 2 (1982).

97. Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 294 (2d Cir. 1979), *cert. denied*, 444 U.S. 1093 (1980).

98. *See, e.g.*, General Motors Continental N.V. v. Commission, [1975] E.C.R. 1367; Sirena v. Eda, [1971] E.C.R. 69 (decided under Treaty of Rome Establishing the European Community, March 25, 1957, Art. 86.)

99. *See, e.g.*, Kauper, *Whither Article 86? Observations on Excessive Prices and Refusals to Deal*, in FORDHAM CORPORATE LAW INSTITUTE (B. Hawk ed. 1989); EEC/US COMPETITION AND TRADE LAW, ch. 28 (1990).

100. *See* Winslow, *supra* note 95.

The market presence of extraordinarily costly biotech drugs will pose difficult questions in the 1990s.[101] By the year 2000, we must be able to look back on the decade and say: The availability of these drugs, and the distribution of their costs of development, production, and accidents, was as fair and legitimate as possible.

VII. CONCLUSION

In the third-quarter of this century, a socially-conscious America developed a panoply of legal principles that expanded the potential liabilities of producers in numerous ways. Most of this law is sound and commendable. Much of it promotes important incentives to act with due care and places accountability on powerful companies. It concurrently evolved to protect the rights of individuals and to correct for injustices.

However, some decisions expanded the law beyond its policy goals, and undercut important societal needs. Legal principles that undermine incentives to invent and bring to market life-saving medical products are in this category. In the tradition of seeking legal change at the margin, where change makes an important difference, we suggest a limit to strict and quasi-strict product liability rules where they intrude into the most critical incentives to invent. In this spirit, we suggest a negligence-only rule for biotechnologically produced medical products.

101. *See id.*

ARTICLE

REGULATION OF ALTERNATIVE OPERATOR SERVICES

BY FRANK P. DARR †

Table of Contents

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I. INTRODUCTION

Businesses, hotels, and airports often have large numbers of telephones but do not provide a direct connection to the national telephone network for each individual telephone. Instead, all calls from these telephones are routed through special equipment, known as a private branch exchange (PBX), which connects the call to the local telephone company. In addition, the PBX connects any calls that involve operator assistance, calling card numbers, and credit card numbers to an operator services company which then connects the call to a long distance carrier. While these operator services can be provided by traditional long distance companies such as AT&T, many businesses, hotels, and airports contract directly with Alternative Operator Services (AOS) companies to provide these services.[1]

Federal and state authorities have extensively regulated AOS and have ignored the competitive forces already working in the market. Unlike other long distance service alternatives, which have gained credibility with regulators, AOS companies have faced general hostility from utility regulators. In part, this reaction is understandable, because the introduction of AOS was marked by high rates, blocked calls and billing errors.[2] While the FCC initially took a measured response to AOS in the *Telecommunications Research and Action Center* (*TRAC*) decision,[3] state agencies have often attacked AOS with fervor.[4] This strict state regulation has been inconsistent with many states' generally positive

1. The distinction between AOS and operator services provided by AT&T and other traditional long distance companies may be less important than initially perceived. The Federal Communications Commission takes the position that the regulation of all interstate operator services is essentially the same. *Telephone Operator Services Protection Act of 1989: Hearings on H.R. 971 Before the Subcomm. on Telecommunications and Finance of the House Comm. on Energy and Commerce*, 101st Cong., 1st Sess. 52 (1989) [hereinafter *Hearings*] (testimony of Gerald Brock). Likewise, the Telephone Operator Services Consumer Act of 1990 does not distinguish between traditional and newer operator service providers. *See infra* text accompanying notes 114–16. Generally, however, traditional operator services are distinguished from AOS providers by the contractual relationship between the provider and the aggregator or end user. For a general description of alternative operator services, see *In re* Billing and Collection by Local Exchange Carriers for Uncertificated Operator Service Companies, 96 Pub. Util. Rep. 4th (PUR) 485, 487 (Ark. Pub. Serv. Comm'n 1988); *In re* Alternative Operator Servs., 97 Pub. Util. Rep. 4th (PUR) 161, 164–65 (N.C. Util. Comm'n 1988). *See infra* text accompanying notes 26–37.

2. *See infra* text accompanying notes 38–64.

3. Telecommunications Research and Action Center v. Central Corp. Int'l, 4 F.C.C. Rcd. 2157 (1989) [hereinafter TRAC]. The FCC eliminated blocking and required AOS company identification near telephones and before calls are connected. *See infra* text accompanying notes 105–12.

4. *See infra* text accompanying notes 136–53.

reaction to competition in the telephone market.[5] At the same time, Congress, consonant with the demands of state regulators,[6] pushed forward legislation to regulate AOS.[7] Faced with political pressure to increase regulation, the FCC initially announced a rule explicitly extending the *TRAC* decision to all AOS companies and added a few new wrinkles as well.[8] Despite the FCC's attempt to prevent legislation, in October 1990 Congress passed the Telephone Operator Consumer Services Improvement Act of 1990.[9] The Act sets out specific requirements

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5. United States v. American Tel. & Tel. Co., 552 F. Supp. 131 (D.D.C. 1982), *aff'd sub nom.* Maryland v. United States, 460 U.S. 1001 (1983) (order approving divestiture); Rates for Competitive Common Carrier Services and Facilities Authorizations Therefor 85 F.C.C.2d 1 (1980) (First Report and Order) [hereinafter Competitive Carrier Rulemaking] (limited regulation of nondominant carriers). Many states have passed statutes significantly broadening the approaches commissions may take in regulating competitive telephone services. *See, e.g.*, ARIZ. REV. STAT. ANN. § 40–281(E) (1985); COLO. REV. STAT. §§ 40–15–101 to –404 (1990); CONN. GEN. STAT. ANN. §§ 16–247f(b), 16–247i (West Supp. 1990); FLA. STAT. ANN. § 364.337 (West Supp. 1991); GA. CODE ANN. § 46–2–23 (Harrison Supp. 1989); IDAHO CODE §§ 62–601 to –622 (Supp. 1990); ILL. ANN. STAT. ch. 111 2/3, paras. 13–101 to –803 (Smith–Hurd 1988); IND. CODE ANN. §§ 8–1–2.6–1 to –8 (West Supp. 1990); IOWA CODE ANN. § 476.1 (West Supp. 1990); MICH. COMP. LAWS ANN. § 484.103a–f (West Supp. 1990); MINN. STAT. ANN. §§ 237.57–.711 (West Supp. 1991); MISS. CODE ANN. § 77–3–35 (Supp. 1990); MO. ANN. STAT. §§ 392.190–.530 (Vernon Supp. 1991); MONT. CODE ANN. §§ 69–3–801 to –824 (1989); NEV. REV. STAT. ANN. § 704.040 (Michie Supp. 1989); N.M. STAT. ANN. §§ 63–9A–1 to –20 (1989); N.D. CENT. CODE §§ 49–21–01 to –22 (Supp. 1989); OHIO REV. CODE ANN. §§ 4927.01 to .05 (Anderson Supp. 1989); OR. REV. STAT. §§ 757.810–.870 (1989); S.C. CODE ANN. § 58–9–230 (Law Co-op. Supp. 1990); S.D. CODIFIED LAWS ANN. §§ 49–31–1 to –4.3 (Supp. 1990); TEX. REV. CIV. STAT. ANN. art. 1446c (Vernon Supp. 1991); UTAH CODE ANN. §§ 54–8b–1 to –4 (1990 & Supp. 1990); VT. STAT. ANN. tit. 30, §§ 202c–d, 226a, 227a (Supp. 1989); WASH. REV. CODE ANN. §§ 80.36.300–.380 (West Supp. 1991); WIS. STAT. ANN. § 196.195 (West Supp. 1990).

6. National Ass'n of Reg. Util. Comm'rs, Resolution Recommending Guidelines for Agencies Considering Regulating Alternative Operator Services (July 27, 1988); National Ass'n of Reg. Util. Comm'rs, Resolution Regarding Additional Guidelines for Alternative Operator Services. (March 1, 1989).

7. *See, e.g.*, H.R. 971, 101st Cong., 1st Sess. (1989). As passed by the House of Representatives, the bill required an FCC rulemaking concerning AOS that included requirements for (1) the identification of AOS companies to end users; (2) disclosure of rates and methods of billing on request; (3) a ban on blocking; (4) installation or upgrading of equipment to permit open access to competing carriers; and (5) a cap on carrier rates for telephone credit card calls. *Id.* § 4(a). The bill also required that AOS companies file informational tariffs, ordered the FCC to review these tariffs for their reasonableness, and initiated a review of rates, quality, and compliance of AOS companies. *Id.* § 5. For the provisions of the bill as passed, *see infra* notes 113–35 and accompanying text.

8. Notice of Proposed Rule Making, Policies and Rules Concerning Operator Service Providers, F.C.C. Rel. No. 90–231, RM-6767 (July 17, 1990). *See infra* text accompanying notes 110–12.

9. 136 CONG. REC. H8744 (daily ed. Oct. 3, 1990). The act is codified as an amendment to Title II of the Communications Act of 1934, 48 STAT. 1064 (1934), codified at 47 U.S.C. §§ 151–609 (1982). Title II is amended by inserting section 226, and it contains the statutory provisions of the Act. 136 CONG. REC. H8744. Further references to the bill are to its codification.

for access and billing.[10] More importantly, it directs the FCC to investigate (and potentially set) rates of AOS providers.[11]

Indeed, it appears that the regulatory commissions are likely to maintain monopolies in operator services by either excluding competition or setting rates for the service at levels that will not be profitable. Yet, the rationale for asserting the full panoply of regulation is far from clear. The best argument for regulation is based on some sort of informational failure.[12] However, the available evidence indicates that most—if not all—of the regulation of AOS is inappropriate since normal market mechanisms should rectify the apparent concerns about rates and access.[13] By assisting customer choice rather than dictating it, the commissions could effect their regulatory goal of reasonable prices and protect against other unseemly practices.

Section II of this article reviews the history of telephone deregulation in general. Section III describes AOS and the problems that gave rise to the demand for regulation. Section IV discusses the alleged market failure associated with AOS and compares it with the rationales used to justify price and entry regulation. Section V considers the various forms of regulation adopted by the FCC and state commissions. Section VI then suggests a limited approach to the regulation of AOS that relies on effective enforcement of open access, as well as on the competitive forces already evident in the marketplace.

II. TELEPHONE DEREGULATION IN GENERAL

The emergent AOS market became possible as a result of the deregulation of two components of the telecommunications network. The FCC first directed its efforts at deregulating AT&T's monopoly control over equipment attached to the public phone system. In 1956, the Commission approved the attachment of a cup-like device that shielded conversation noise, in spite of a challenge by AT&T that the attachment threatened the integrity of the telephone system.[14] In the 1968 *Carterfone* case,[15] the FCC opened the door to real competitive entry in the equipment market by permitting the attachment of foreign electronic equipment (non-Bell owned) to the network. However, seven more years passed before the FCC approved a process for licensing attachments.[16]

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10. *See infra* text accompanying notes 120–27.
11. *See infra* text accompanying notes 128–35.
12. *See infra* text accompanying notes 65–95.
13. *See infra* text accompanying notes 96–103.
14. Hush-A-Phone Corp. v. United States, 238 F.2d 266 (D.C. Cir. 1956).
15. Use of the Carterfone Device in Message Toll Service, 13 F.C.C.2d 420 (1968), *aff'd on reconsideration*, 14 F.C.C.2d 571 (1968).
16. Interstate and Foreign Message Toll Telephone, First Report and Order, 56 F.C.C.2d 593 (1975), *modified on reconsideration*, 58 F.C.C.2d 716 (1976), Second Report and

The *Computer II* decision deregulated all equipment located on the customer's premises and allowed end users to seek out the most appropriate provider on an unbundled basis. In addition, the decision permitted some competitive activity on the part of AT&T through separate subsidiaries.[17]

Parallel with the decisions concerning equipment, the FCC, with prodding from the courts, opened the way for the introduction of competitive carriers in the interstate interexchange market. First, the FCC permitted creation of microwave facilities for private use in the *Above 890* docket.[18] It then approved point-to-point service between St. Louis and Chicago by MCI in 1969.[19] "This approval prompted a deluge of applications seeking authorization of similar microwave facilities."[20] The FCC responded with a rule that permitted the entry of carriers providing private line services.[21] Court action broadened the effect of the rule-making as MCI sought interstate common carrier service. The FCC initially sought to restrict the scope of the service by prohibiting MCI from offering two-way common carriage through its system.[22] The Court of Appeals reversed the Commission and later directed it to approve the tariff filing[23] authorizing the service.[24] Finally, the FCC approved the sale of competitive common carrier services in 1981.[25] Thus, by the end of 1981, the FCC had deregulated both components necessary to support AOS: equipment and transmission.

Order, 58 F.C.C.2d 736 (1976), *aff'd sub nom.* North Carolina Util. Comm'n v. FCC, 552 F.2d 1036 (4th Cir.), *cert. denied*, 434 U.S. 874 (1977).

17. Second Computer Inquiry, Final Decision, 77 F.C.C.2d 384 (1980), *modified on reconsideration*, 84 F.C.C.2d 50 (1980), *further modified on reconsideration*, 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. Cir. 1982), *cert. denied*, 461 U.S. 938 (1983).

18. Allocation of Frequencies in Bands Above 890 Mc., 27 F.C.C. 359 (1959), *modified on reconsideration*, 29 F.C.C. 825 (1960). As a result, a company with offices in two cities could connect their offices with a private phone system using microwave facilities.

19. Microwave Communications Inc., 18 F.C.C.2d 953 (1969).

20. Fowler, Halprin & Schlichting, *"Back to the Future": A Model for Telecommunications*, 38 FED. COMM. B.J. 145, 155 (1986).

21. Specialized Common Carrier Servs., First Report and Order, 29 F.C.C.2d 870 (1971), *aff'd on reconsideration*, 31 F.C.C.2d 1106 (1971), *aff'd sub nom.* Washington Util. Transp. Comm'n v. FCC, 513 F.2d 1142 (9th Cir. 1975), *cert. denied*, 423 U.S. 836 (1975).

22. *In re* MCI Telecommunications Corp., 57 F.C.C.2d 271 (1975) (Investigation into the Lawfulness of Tariff F.C.C. No. 1 insofar as it Purports to Offer Execunet Service), *rev'd sub nom.* MCI Telecomm. Corp. v. FCC, 561 F.2d 365 (D.C. Cir. 1977).

23. A tariff filing is an approved statement of rates for a service that must be available to all within the class of consumers covered by the filing. 47 U.S.C. § 203(a) (1988); 47 C.F.R. § 61.3(gg) (1989). *See* MCI Telecomm. Corp. v. FCC, 765 F.2d 1186 (D.C. Cir. 1985) (common carrier must file tariffs under 47 U.S.C. § 203).

24. MCI Telecomm. Corp. v. FCC, 580 F.2d 590 (D.C. Cir. 1978), *cert. denied sub nom.* United States Independent Tel. Ass'n v. MCI Telecomm. Corp., 439 U.S. 980 (1978).

25. *In re* Policy and Rules Concerning Rates for Competitive Common Carrier Servs. and Facilities Authorizations Therefor, 84 F.C.C.2d 445 (1981).

III. DEFINING ALTERNATIVE OPERATOR SERVICES

A. Technical Structure

A combination of technological and regulatory changes produced the AOS structure. The private branch exchange (PBX) provides the basic capacity to capture calls at the aggregator and route them to a particular operator. "A PBX is a small local telephone office—a private switching system located in an office, business complex, campus, government agency or apartment building."[26] The PBX connects a call with the local public exchange and provides the signaling to connect the call with a long distance carrier.[27] In the AOS arrangement, the PBX is programmed to direct all calls requesting operator assistance ("0" plus the desired phone number, or simply "0" for full operator assistance) to a particular AOS company.[28]

Once the call is initiated and routed by the PBX, its completion through an AOS system is relatively simple. The aggregator routes its operator-assisted calls[29] to the AOS company, usually over transmission facilities of other long distance carriers. The AOS operator provides the desired assistance and completes the call through additional rented long distance transmission facilities.[30] For example, an AOS call from a hotel in the Bronx, New York, to Columbus, Ohio starts when the traveler picks up his phone and dials 0 plus the number. The hotel's PBX routes the call to an AOS operator in Georgia over a long distance line. The AOS operator takes the billing information, such as the caller's calling card or credit card number, and routes the call to the Columbus destination. The AOS company then charges the call to the caller's credit card at the AOS company's rates. In effect, transmission of an operator assisted call is the completion of two resales, the first from the aggregator to the operator and the second from the operator to the call's destination.

B. Regulatory Structure

Under the regulated tariffs that existed before deregulation, the FCC permitted AT&T to return to hotels, hospitals, and similar large institutions a part of the service fee to cover the costs of providing each guest (or "end user") telephone service.[31] After deregulation, the FCC

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26. P. HUBER, THE GEODESIC NETWORK: 1987 REPORT ON COMPETITION IN THE TELEPHONE INDUSTRY at 2.5.

27. *Id.* at 2.6.

28. *In re* Alternative Operator Servs., 101 Pub. Util. Rep. 4th (PUR) 484, 490–91 (Ga. Pub. Serv. Comm'n 1988). *See infra* note 57.

29. Calls dialed 0 or 0 plus the desired number trigger operator assistance.

30. H.R. REP. NO. 213, 101st Cong., 1st Sess. 3 (1989).

31. Burkhart, *Alternative Operator Services: A New Dilemma for Regulators*, PUB. UTIL. FORT., Aug. 18, 1988, at 44.

suspended this practice and permitted aggregators to sell telephone services and directly add a surcharge to the customer's room bill. Some aggregators sought out contracts for this service from those companies willing to continue rebating a portion of the fees, rather than directly surcharging their guests. As the Tennessee commission sarcastically explained, "Into this market niche stepped the AOS companies, promising to pay the institutions large commissions on operator-assisted calls and offering them the convenience of hiding their surcharges among the pages of the ratepayer's next telephone bill."[32]

C. Economic Structure of the Industry

AOS is a relatively small portion of the total operator services market, despite the extensive state and federal interest. Currently, total revenues from all operator services are about $11 to $12 billion, but AOS companies have only five percent of the total, with the rest falling to AT&T and the local exchange monopolies.[33] This small share is then spread among at least thirty-five companies, primarily resellers of other companies' facilities, which provide some form of operator assistance.[34]

In addition to these resellers, the other large carriers, such as MCI and Sprint, which own their own transmission facilities, are entering the operator services field.[35] Furthermore, AT&T also has attempted to structure a service to compete with AOS by providing for five to thirty cent rebates for calls placed from an aggregator's premises.[36] This basic overview implies that the market is potentially competitive.[37]

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32. *In re* South Central Bell Tel. Co., 93 Pub. Util. Rep. 4th (PUR) 68, 71 (Tenn. Pub. Serv. Comm'n 1988).

33. Carnevale, *House Seeks Strict Rules for Phone Operator Firms*, Wall St. J., Sept. 26, 1989, at A12, col. 3; Sims, *Complaints Spur FCC Rules on High Cost Calls at Hotels*, N.Y. Times, Feb. 28, 1989, at A1, col. 5, and D14, col. 6.

34. *Hearings*, *supra* note 1, at 213 (statement of Mr. Berg) (70–75 companies); Burkhart, *supra* note 31, at 47 (35 companies); Sims, *supra* note 33, at D14, col. 5 (200 companies).

35. *Hearings*, *supra* note 1, at 134 (testimony of D. Thomas).

36. *In re* Revisions to AT&T Communications Tariff F.C.C. No.1, Hospitality Network Service, 3 F.C.C. Rcd. 975 (1988) (memorandum opinion and order).

37. Competitive Carrier Rulemaking, *supra* note 5, at 21. The FCC defined dominance within a market by "the number and size distribution of competing firms, the nature of barriers to entry, and the availability of reasonably substitutable services." AOS companies do not have the capacity to dominate since the number of competitors is significant and the service can be easily substituted. *See supra* text accompanying notes 33–36. Furthermore, reseller prices for service are constrained by dominant carrier rates if open access is available. In this regard, the rationale to deregulate is identical to that for other resellers. *See* Competitive Common Carrier Services and Facilities Authorizations, 84 F.C.C.2d 445, 494–95 (1981) (Further Notice of Proposed Rulemaking).

A similar argument can be made using "contestable markets" theory. Prices will be constrained if entry is free and exit is costless. Under these circumstances, the market is subject to hit and run entry whenever prices exceed competitive levels. Thus prices are always set at or very near competitive levels. Baumol, *Contestable Markets: An Uprising in the Theory of Industry Structure*, 72 AM. ECON. REV. 1 (1982). No market is perfectly

D. Regulatory Problems: Pricing and Access to Competition

The perceived regulatory problem was created by the division of the end user, usually transient,[38] from the service provider.[39] Unless modified by regulation, the AOS company generally contracts with an aggregator,[40] but bills the end user for providing operator-assisted calls.[41] Furthermore, to encourage aggregators to contract for an AOS service, the AOS company may offer the aggregators rebates of as much as twenty percent of the customer charge and also provide the aggregator with the option of an additional surcharge for each call.[42] The unusual nature of the service leads to several kinds of complaints and regulatory interests.

Repeated complaints[43] concerning AOS fall into several areas: problems with rates,[44] access to other local and interexchange carriers and operator service providers,[45] identification and billing practices,[46] and revenue losses due to improper use of interstate facilities for intrastate service.[47] A recent FCC audit indicates that many of these problems continue despite FCC and state regulatory action.[48]

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contestable (just as no market is perfectly competitive or monopolistic), but AOS presents an interesting analogy since there are few fixed costs or (except in those states that have enacted bans) barriers to entry.

38. *In re* Alternative Operator Servs., 101 Pub. Util. Rep. 4th (PUR) 484, 490 (Ga. Pub. Serv. Comm'n 1988).

39. *In re* Billing and Collection by Local Exchange Carriers for Uncertificated Alternative Operator Service Companies, 96 Pub. Util. Rep. 4th (PUR) 485, 487 (Ark. Pub. Serv. Comm'n 1988); *In re* Alternative Operator Servs., 97 Pub. Util. Rep. 4th (PUR) 161, 164–65 (N.C. Util. Comm'n 1988).

40. H.R. REP. NO. 213, *supra* note 30, at 3.

41. *Id.* The aggregator may also bill for some part of the call charges in the form of a user surcharge. *Id.*

42. *Id.*; Carnevale, *House Seeks Strict Rules for Phone Operator Firms*, Wall St. J., Sept. 26, 1989, at A12, col. 3.

43. The FCC has received more than 4000 complaints concerning AOS. S. REP. NO. 439, 101st Cong., 2d Sess. 3 (1990). The complaints appeared to peak in 1988 when the FCC received 2000. Sims, *supra* note 33, at D14, col. 4; Burgess, *"Operator Services" Told They Must Disclose Fees*, Wash. Post, Feb. 28, 1989, at A1, col. 2. Since the TRAC decision, the FCC has continued to receive 125–150 informal complaints a month. S. REP. NO. 439, *supra*, at 4.

44. *See infra* text accompanying notes 49–53.

45. *See infra* text accompanying notes 54–56.

46. *See infra* text accompanying notes 57–62.

47. *See infra* text accompanying notes 63–64.

48. FCC Public Notice No. 3418, FCC Interstate Operator Services Compliance Audit Findings (June 1, 1990). The auditors checked 971 telephones at 351 locations for compliance with federal requirements as stated in the TRAC decision. *See infra* text accompanying notes 105–109. Oral notification of the AOS provider occurred 87% of the time. Only 20 of the telephones fully complied with the written notification requirements. Also, a substantial amount of blocking continued to exist.

1. *RATES*

The most common complaint voiced against AOS is that the rates charged are too high.[49] Though the variance is apparently less dramatic in recent studies,[50] the difference between AT&T's charges and those of AOS companies was startling in some of the early complaints.[51] Additionally, rates were not very flexible. In one instance, a commission found that the rate proposed by the AOS company was higher than that of the dominant carrier even without any additional surcharge for the aggregator, and fell farther out of line because it did not provide for time-of-day discounts offered by dominant carriers.[52] Other than the FCC, most regulatory agencies found the rates to be abnormal and evidence of monopolistic behavior under the unusual conditions of AOS provision.[53]

2. *BLOCKING*

Blocking is a procedure by which the aggregator prevents the end user from accessing a carrier other than the one subscribed to by the aggregator.[54] The aggregator may limit the completion of calls to its carrier and block access to local or other interexchange carriers or operators, thus facilitating use of the AOS subscribed to by the aggregator.[55] Commissions have uniformly found blocking unreasonable.[56]

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49. *See generally In re* International Telecharge, Inc., 97 Pub. Util. Rep. 4th (PUR) 349, 359 (Mass. Dep't Pub. Util. 1988). For purposes of this paper and the appropriate analysis, one should probably look to the whole fee, since that is the economic signal that determines the end user's behavior under normal circumstances. The fee that the customer sees, however, is broken into a transmission charge, an operator charge, and a subscriber surcharge when permitted and contracted for by the aggregator. *Id.* at 351.

50. *See infra* text accompanying notes 101–103.

51. One reported complaint alleged that the rate charged by the AOS was ten times that of the comparable regulated carrier. Burgess, *FCC Says It Will Probe "Alternate" Phone Firms*, Wash. Post, Apr. 6, 1988, at A20, col. 3. Most reports suggested the rates were two to three times higher. *In re* South Cent. Bell Tel. Co., 93 Pub. Util. Rep. 4th (PUR) 68, 69 (Tenn. Pub. Serv. Comm'n 1988) (two times higher); *Hearings*, *supra* note 1, at 44 (testimony of S. Hewlett) (two to three times higher); Burgess, *supra* note 43, at A1, col. 2 (three times higher). *But see* Sims, *supra* note 33, at A1, col. 5 (rates four to five times higher than major long distance carriers). Rate concerns continue to constitute the largest portion of complaints filed with the FCC. Testimony before the Subcomm. on Communications of the Senate Comm. of Commerce, Science, and Transp. on Operator Services Providers, 1990 FCC LEXIS 828, *10 (Feb. 7, 1990)(LEXIS, Fedcom library, FCC file).

52. *In re* International Telecharge, Inc., 92 Pub. Util. Rep. 4th (PUR) 211, 212 (Ala. Pub. Serv. Comm'n 1988). The Indiana commission similarly found that the rates were substantially higher on credit card calls, which were the largest percentage of service offered by the AOS company. *In re* American Operator Serv., Inc., 102 Pub. Util. Rep. 4th (PUR) 336, 344 (Ind. Util. Reg. Comm'n 1989).

53. *See infra* text accompanying notes 141–43.

54. *In re* International Telecharge, Inc., 105 Pub. Util. Rep. 4th (PUR) 160, 168 (Ky. Pub. Serv. Comm'n 1989) (condition of certificate was to provide access to other carriers).

55. The Georgia commission found:

3. *IDENTIFICATION AND BILLING*

A third category of problems involved the failure of the AOS company to identify itself and to disclose its billing arrangements. First, end users often complained that they were not aware that an AOS company was carrying their calls.[57] Second, end users complained about slow billing or improper charges for uncompleted calls.[58] One study in Tennessee reportedly found that AOS companies improperly billed 40,000 calls during a six month period.[59] Third, end users complained about the threat of having their basic telephone service terminated for failure to pay improper bills levied through the local exchange carrier on behalf of the AOS company.[60]

4. *SPLASHING*

"Splashing" is the practice of billing calls from a point other than where a call is commenced. For example, a customer at a pay telephone in Nashville that presubscribed to an AOS provider may ask to be connected to an AT&T operator to call Memphis. The AOS operator located at the AOS operator center in Atlanta then transfers the caller to the nearest AT&T operator in Atlanta. Since AT&T is unaware of the origin of the call, it simply treats it as a call between Atlanta and Memphis. Therefore, the customer is charged for an Atlanta to Memphis

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It is not uncommon for traffic aggregators such as hotels, motels, hospitals and private pay phone operators to block access to any carrier other than their prescribed operator services carrier. The vast majority of institutions use a PBX (private branch exchange) to provide telecommunications service to their patrons. Under the traditional dialing arrangement, 9 is used to access the local exchange network and 8 is used to access the interexchange network. Thus, a call dialed 9–0 would be routed to the local exchange operator and a call dialed 8–0 would be routed to the interexchange carrier operator. However, it is not uncommon for institutions to block all 9–0 calls thereby blocking access to the local exchange operator. In addition, many institutions block access to any interexchange carrier other than the prescribed provider by blocking the carrier's access arrangements, be it "00", "10XXX" or "950–XXXX". Some AOS providers have the capability of connecting a customer to the carrier of his or her choice and others do not. Private pay telephones can also be configured to obtain similar blocking results.

In re Alternative Operator Servs., 101 Pub. Util. Rep. 4th (PUR) 484, 490–91 (Ga. Pub. Serv. Comm'n 1988).

56. *See infra* text accompanying notes 144–45.

57. *In re* Alternative Operator Servs., 101 Pub. Util. Rep. 4th (PUR) 484, 491 (Ga. Pub. Serv. Comm'n 1988).

58. *Id.*

59. *Hearings, supra* note 1, at 51, 53 (testimony of S. Hewlett).

60. The AOS provider contracts with the local exchange company to bill and collect for service by the latter's customers. Failure to pay a bill could result in termination of all phone service to the end user even if the end user disputed the AOS service or charges. *In re* South Central Bell Tel. Co., 93 Pub. Util. Rep. 4th (PUR) 68, 73 (Tenn. Pub. Serv. Comm'n 1988). The Tennessee commission sought to solve the problem by amending the billing and collection practices of the local exchange companies. Specifically, the commission prohibited billing on behalf of the AOS unless it demonstrated that it had an account with the billed party or limited the amount of charges to the highest intrastate or interstate tariffs for the same service. *Id.* at 74.

call even though the call originated in Nashville and terminated in Memphis.[61] Since calls are billed on the basis of distance,[62] the customer is overcharged for the call if the call is not properly monitored.

5. CONTRIBUTION TO LOCAL ACCESS

Lost local revenues for intrastate providers is a related problem associated with the use of interstate lines to connect the caller with the AOS provider. For example, a call from Cleveland to Columbus, Ohio, is an intrastate call. However, if the call is connected by an operator in Dallas, Texas, it appears to the network as the completion of two interstate calls, one from Cleveland to Dallas and a second from Dallas to Columbus. An intrastate call completed over an interstate line in this manner is treated as an interstate call[63] and diverts revenues to interstate carriers and away from the local exchange companies that possess intrastate toll monopoly. State commissions perceive the diversion as a threat to universal service since local rates might have to be increased to recover the lost toll revenue.[64]

IV. RATIONALE FOR AOS REGULATION: PERCEIVED MARKET FAILURE

The significant number and tone of the complaints, as well as the congressional reaction to them, suggested that regulation was likely. Nevertheless, none of the rationales usually justifying regulation provides a strong basis for imposing regulatory oversight over AOS.

A. Rationales for Regulation

In the traditional model of welfare economics, regulation is justified to correct market failures that lead to inefficiency.[65] First, an industry may be regulated so that its prices reflect the full costs, both internal and external, of its production. For example, regulation of polluting industries is designed to internalize the external costs imposed by pollution.[66] Second, direct price regulation is often used against monopolies that developed due to scale production factors or specific

61. H.R. REP. NO. 213, *supra* note 30, at 4.

62. C. PHILLIPS, THE REGULATION OF PUBLIC UTILITIES 481–84 (2d ed. 1988).

63. *In re* Alternative Operator Servs., 101 Pub. Util. Rep. 4th (PUR) 484, 492 (Ga. Pub. Serv. Comm'n 1988); *In re* International Telecharge, Inc., 95 Pub. Util. Rep. 4th (PUR) 421, 423–4 (Ky. Pub. Serv. Comm'n 1988).

64. *In re* Alternative Operator Servs., 101 Pub. Util. Rep. 4th (PUR) 484, 496 (Ga. Pub. Serv. Comm'n 1988); *In re* International Telecharge, Inc., 95 Pub. Util. Rep. 4th (PUR) 421, 423–24 (Ky. Pub. Serv. Comm'n 1988).

65. Aranson, *Theories of Economic Regulation: From Clarity to Confusion*, 6 J.L. & POL'Y 247, 249–50 (1990).

66. *Id.* at 250–52.

government decree. In the case of a natural monopoly, the government may intervene to prevent the monopolist's market power being used to raise prices above competitive levels.[67] Third, regulation may be used to reverse the effect of informational difficulties. For example, "[a] role for government may arise if workers remain ignorant of [a] risk to their health. . . . [G]overnment may exploit its coercive sanction and economies of scale in the collection, analysis, and dissemination of information to overcome this problem."[68]

The first and second rationales for regulation are not relevant to AOS. AOS does not create any external costs that would need to be internalized. In addition, both federal and state regulators recognize that AOS providers do not possess the type of market power that would generate traditional natural monopoly concerns.[69] Resellers, which include AOS providers, probably represent the most competitive segment of telecommunications transmission services.[70] Moreover, the number of

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67. *Id.* at 255–58.

68. *Id.* at 254.

69. The rationale for the FCC approach is contained in the Commission's determination that AOS companies are resellers and therefore nondominant carriers. TRAC, *supra* note 3, at 2158. In Competitive Carrier Rulemaking, *supra* note 5, at 10, the Commission divided the telecommunications world into dominant and nondominant carriers. Dominant carriers can exert market power in such a way as to extract supracompetitive profits and defeat entry by predatory pricing. *Id.* at 20–21. To determine dominance, the Commission suggested that several factors are relevant but placed special emphasis on the existence of bottleneck control of essential facilities. Under this definition of dominance, companies that leased lines from dominant carriers for resale to end users, generally known as resellers, were not dominant. The Commission justified its conclusion on the lack of entry barriers and the resellers' inability to raise or lower prices from competitive levels *Id.* at 29.

Having found resellers nondominant, the FCC then felt it could lower the degree of price and entry regulation in four areas. First, it eliminated the requirement for cost information to support tariff filings of nondominant carriers on the belief that the cost of filing outweighed the benefits to the customer. Second, the Commission shortened the notice periods for tariff changes to permit quicker response to the market. Third, the Commission revised the grounds for suspending tariffs to prevent the use of the regulatory process to impede competition. Fourth, it substantially revised the provisions for certification of carriers, amended the requirements for expansion of service, and eased the means for abandoning service by providing for a thirty-day notice if other alternatives are available (which by definition there must be). *Id.* at 33–49.

The Massachusetts commission determined that AOS companies were dominant but based its rationale upon the captive nature of the customer. *In re* International Telecharge, Inc., 97 Pub. Util. Rep. 4th (PUR) 349, 354–55 (Mass. Dep't Pub. Util. 1988). Thus the analysis urged here would apply even though some commissions may describe the service as "dominant."

70. Competitive Carrier Rulemaking, *supra* note 5, at 29 ("Given the low barriers to entry into these operations, resale carriers appear to be more subject to actual and potential competition than any other telecommunications industry."). *But see* P. HUBER, *supra* note 26, at 3.4 ("Resellers that add no independent value exist only at the pleasure of an imperfectly competitive market. Any carrier that depends on reselling AT&T services for much of its business will eventually be squeezed tightly as competition continues to drive AT&T prices toward cost.").

real and potential players in the AOS submarket indicates that this submarket should also be highly competitive.[71] Thus, if regulation is justified, it must be on the basis of informational failures in the existing market.

B. Defining the AOS Market Failure

A basic assumption of a competitive marketplace is the existence of sufficient information for the consumer to make an informed choice. However, choices about how much information is necessary are economically driven.[72] Information is a commodity and is costly to produce. For the consumer to be informed, she must incur search costs; likewise, the seller incurs costs to research, label, and advertise its products.[73] Thus, there is a limit to the amount of information that will be available to the consumer. "In well-functioning markets, one would expect to find as much information available as consumers are willing to pay for in order to lower the cost or to improve the quality of their choices."[74]

The fact that information is costly has significant implications. First, efficient markets may not operate on the basis of total information to all parties. Second, the consumer will not demand perfect information. The incentive to search for additional information is tied to the likelihood that additional information will lower costs successfully.[75] In turn, the likelihood of success depends on the dispersion of prices and the cost of the item being consumed; as each increases, the consumer will exert more effort to determine the best buy.[76] Third, "[a] seller who wishes to obtain continued patronage of those buyers who value the gains of search more highly or have lower costs of search must see to it that he is quoting relatively low prices."[77] This implication derives from the simple fact that those buyers are most likely to secure the most information to make a choice. Finally, inexperienced buyers will probably pay higher prices since their searches are not likely to be as complete as the searches of more experienced buyers.[78]

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71. *See supra* text accompanying notes 33–37. More needs to be done in the way of determining the extent of coverage available to various geographical areas to determine the real extent of the existing and potential competition. On the other hand, there appear to be few significant barriers to entering the market.

72. S. BREYER, REGULATION AND ITS REFORM 26 (1982). *See infra* notes 75–82 and accompanying text.

73. *Id.*

74. *Id.*

75. Stigler, *The Economics of Information*, 69 J. POL. ECON. 213, 214 (1961).

76. *Id.* at 215.

77. *Id.* at 218.

78. *Id.* at 218–19.

The information market, like other markets, may fail in one of several ways. First, the high initial cost of producing information may preclude its development if the benefits can be lost to free riding.[79] No one will produce information if its cost is high and the next party can use it with little or no cost. Second, sellers may provide misleading information if the costs of traditional forms of consumer remedies, such as litigation, are too high compared to possible benefits of enforcement.[80] For example, a consumer is not likely to sue to recover an overcharge for a single call since the expense of litigation is far more than the expected recovery. Third, the information the seller provides may not be easy for the consumer to evaluate.[81] Finally, there may be insufficient competition among sellers to provide information.[82] In each of these cases, regulation may benefit the consumer by providing information that otherwise would not exist, recasting information in a usable form, or creating a remedy that would otherwise be too expensive to pursue privately.

Both federal and state regulators recognize informational problems with AOS, and some of the rationales for regulation appear to be based on market failures such as the ones just described. Yet neither the details of the failures nor the mechanisms that sustain the failures are clear. For example, the FCC premised its decision to open access, but to avoid price regulation, on the belief that resellers could not exert market power due to low barriers to entry and significant real and potential competition.[83] Nonetheless, the FCC recognized that it had to "ensure that consumers are provided access to necessary information."[84] The Commission perceived that informational problems combined with lack of open access might prevent the operation of a competitive market.[85] Thus, the FCC focused its efforts on informing the consumer and assuring that the consumer could exercise his choice.[86] However, the FCC provided no explanation of how AOS companies maintained these informational barriers.

In contrast to the FCC's focus on informational barriers, state commissions have focused on structural inefficiencies that lead to higher prices. Some commissions concluded that the aggregator is not under any pressure to limit the prices charged to end users.[87] The aggregator will attempt to secure the highest amount it can from the AOS company either through surcharges or rebates. However, even if this argument is

79. S. BREYER, *supra* note 72, at 27.
80. *Id.*
81. *Id.* at 27–28.
82. *Id.* at 28.
83. TRAC, *supra* note 3, at 2158.
84. *Id.*
85. *Id.* at 2159.
86. *See infra* text accompanying notes 105–12.
87. *See, e.g., Hearings, supra* note 1, at 45 (testimony of S. Hewlett).

correct, it does not follow that regulation of AOS is appropriate. Since it is the aggregator that is sustaining higher prices, only the aggregator should be subject to direct price regulation under this theory. Moreover, the basic theory of aggregator market power is fundamentally flawed since aggregators themselves are reasonably competitive.[88]

Some state commissions have also argued that presubscription and blocking prevent customers from making a choice among potential carriers. The Georgia commission explained:

> [U]nlike the traditional interexchange telephone market, the customer in the AOS setting is the traffic aggregator and not the end user. It is the traffic aggregator . . . that makes the decision as to which interexchange carrier it will subscribe to. Therefore, the attribute of a free market, choice by the consumer among competing providers, is absent. This problem is exacerbated by the fact that many subscribers to AOS services block access to local exchange company operators and to other interexchange carriers.[89] Thus, the effects of choice are eliminated though there are literally hundreds of alternative providers for long distance service, of which a sizeable number provide operator services.[90]

However, this argument does not explain how the arrangement can be maintained if there is no informational failure. If the aggregator does not block calls, then nothing prevents the consumer from dialing around the presubscribed system. If blocking remains, informed consumers will not give any repeat business to an aggregator who engages in blocking. In the case of large hotel chains which rely on informed repeat customers, competitive pressures will force these hotels to stop engaging in blocking.

Finally, some commissions have advanced a more potent argument for regulation that focuses on the customer's inability to receive sufficient information from the carrier to make an informed choice.[91] Absent some sort of identification and explanation, the customer may not know who provides the long distance or operator services. Moreover, even if informed, the customer may not be able to use that information effectively due to blocking and high transaction costs resulting from the transient nature of customer usage. Since many aggregators, such as airports and hotels, will only be used once by an individual customer "the price charged by the AOS provider will not impact the customer's future choice."[92] This problem has been recognized by the Missouri commission:

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88. *See infra* text accompanying notes 96–103.

89. *In re* Alternative Operator Servs., 101 Pub. Util. Rep. 4th (PUR) 484, 491 (Ga. Pub. Serv. Comm'n 1988); *see also In re* International Telecharge, Inc., 105 Pub. Util. Rep. 4th (PUR) 160, 166 (Ky. Pub. Serv. Comm'n 1989).

90. *See supra* text accompanying notes 33–36.

91. *See supra* text accompanying notes 65–68.

92. *In re* Alternative Operator Servs., 101 Pub. Util. Rep. 4th (PUR) 484, 493 (Ga. Pub. Serv. Comm'n 1988).

> The end user is generally a transient customer for whom the usual telephone arrangements are, practically speaking, unavailable. He is the traveler at the airport, the guest at the hotel, the patient in the hospital, the driver at the truck stop, the soldier at the military base and the student at the university. Operator services from the provider of his choice may be entirely unavailable without traveling to another location. Traveling to another location might be difficult or impossible for some of these customers such as the hospital patient, the soldier and the air traveler.[93]

Thus, the rationale for fully regulating rates is premised on the lack of choice offered to the transient customer under these situations. In this sense, the commissions conclude that the customers are captive because of lack of information or high transactional costs. Once again, however, the argument fails to demonstrate why better choices would not emerge as customers become more experienced and demand better service from aggregators. Moreover, it does not explain why end users would remain ignorant.

The various arguments advanced by state commissions thus rest on some very odd assumptions. In an infrequent number of cases in which there is only one provider of the aggregator's service (for example, a city with one convenient airport), the end user is left without significant choices if blocking occurs. However, in the more general case, the state commissions assume that the customer will continue to use the same aggregator, despite available alternatives or the ability to dial around the AOS provider, even after the customer learns that he is being gouged by high prices. This assumption is simply not supported by the available evidence.[94] Moreover, even if "captive customers" do exist, this informational failure can be addressed by a relatively narrow regulatory response.[95]

C. The Myth of the Captive Customer

Aggregators undoubtedly possess some market power over transient end users since such users frequently face limited sources of products and services. A traveler in an airport pays a premium for a drink because of the restricted number of cocktail lounges. Likewise, a driver on an interstate highway may pay a premium for gasoline purchased near the highway. In each case, the seller has market power to extract extra profits because of its successful choice of location. However, price regulation is certainly not the solution to these common examples of

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93. *In re* American Operator Servs., Inc., 103 Pub. Util. Rep. 4th (PUR) 124, 130 (Mo. Pub. Serv. Comm'n 1989).

94. *See infra* text accompanying notes 96–103.

95. S. BREYER, *supra* note 72, at 34 ("[O]ne who believes that the primary problem is informational will tend to favor not classical regulation, but governmental efforts to provide more information.").

market power.[96] The appropriate solution for these sorts of problems is to open the market to other competitors. The high profits, if they exist, will draw new competitors to the field. The resulting competition eliminates supracompetitive pricing.

Moreover, the end user cannot be held captive for any significant time. First, the conception of the captive consumer is theoretically naive. It assumes that customers are a static, inattentive, and unresponsive lot. Yet, the very existence of complaints demonstrates that customers are attentive and responsive.[97] In fact, the complaints are evidence of the very processes one would expect to find when customers encounter new services. The process will not be seamless or painless. As with the introduction of competitive interexchange service,[98] there is a period in which the industry and the customers learn about each other.[99] While the level of information is low, there may be some excess profit taking. As end users become more knowledgeable, this informational failure will correct itself.

Second, the view that end users are captive is factually wrong. In practice, the aggregator already is under some pressure to lower rates where it faces consumer pressures. For example, major repeat customers, such as airlines at airports and corporate clients of hotels, have pressured aggregators to provide inexpensive, open phone service or face the loss of the customers' business.[100] The effect on prices should be universal since there is no evidence that the aggregator can effectively discriminate among its customers. Thus, both experienced and inexperienced customers should benefit.

Finally, the myth of the captive customer ignores the apparent tightening in prices that has occurred. The FCC in congressional hearings

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96. J. BONBRIGHT, A. DANIELSON & D. KAMERSCHEN, PRINCIPLES OF PUBLIC UTILITY RATES 29–30 (2d ed. 1988).

97. *See supra* note 43.

98. *Hearings, supra* note 1, at 49 (Statement of G. Brock).

99. *Id.* at 18–19 (Statement of Rep. W. Tauzin). One of the more common complaints was that the customer simply was not familiar with the available options. For example, the Georgia commission noted that customers were not yet conditioned to make the appropriate responses. *In re* Alternative Operator Servs., 101 Pub. Util. Rep. 4th (PUR) 484, 492 (Ga. Pub. Serv. Comm'n 1988). Others have noted a similar transition problem with the deregulation of customer premises equipment. Powers, *Public Interest Implications of Telecommunications Deregulation*, 16 POL'Y STUD. J. 146, 148 (1987). Time heals that sort of problem.

100. *See, e.g., Hearings, supra* note 1, at 12, 14–15 (statement of J. Cooper); *id.* at 90 (testimony of H. Berg); Burgess, *supra* note 51, at A20, col. 3. In Senate hearings, a representative for Sheraton Hotels testified it had terminated all AOS contracts based on the belief that AT&T provided higher quality service. The Sheraton representative went on to state that the incentives offered by the AOS companies were insufficient to outweigh Sheraton's interest in avoiding bad customer relations. *Telephone Operator Consumer Services Improvement Act of 1989: Hearings on S. 1643 and S. 1660 Before the Subcomm. on Communications of the Senate Comm. on Commerce, Science, and Transportation*, 101st Cong., 2d Sess. 251 (1990).

indicated that AOS prices generally were in a range between ten percent below to sixty percent above comparable AT&T rates.[101] Others have noted that rates in general are declining.[102] In effect, the available evidence supports the prediction that prices will continue to decrease.

These declining prices reflect several market forces which should drive the AOS market to price competitively. The apparent weak link, the aggregator who controls the transient end user, is subject to competitive pressures. If the aggregator is not responsive, the aggrieved customer will take his business elsewhere. If cost is a significant consideration, employers likewise may teach their employees how to bypass the overly expensive presubscribed AOS. This process is furthered by competitors, such as AT&T, who advertise ways end users can connect with its operators.[103] As a result, the aggregator will be unable to maintain high rates since they will lose repeat business from end users. These competitive pressures can overcome the ability to take advantage of the transient status of some end users and thereby eliminate the need for strict regulation.

V. REGULATORY RESPONSES TO AOS COMPLAINTS

Given the relatively poor justifications for regulation, the range of responses surveyed below is remarkable. The FCC has attempted to open the channels for effective customer choice, which would appear to be the most effective immediate and long term solution. Despite some early indications otherwise, Congress has also refrained substantially from imposing price regulation. In contrast, state action has ranged from open entry with price regulation to outright bans of AOS. The federal experiment in dual regulation of communications is problematic in this area.[104]

Recent experience continues to support the conclusion that aggregators are under substantial pressure. "The industry has experimented with different ways of billing customers," said Brian Kinsella, manager of governmental affairs for the Washington-based American Hotel and Motel Association. "Now the industry has said, 'We want to sell rooms; it's not worth aggravating a customer over a $2 phone charge.'" Hurdle, *Relief Is At Hand for Business Travelers and Companies Weary of Paying Outrageous Charges for Phone Calls Made From Hotel Rooms*, U.P.I., Sept. 1, 1991, BC cycle, Domestic News (Lexis, Nexis library, UPI file).

101. *Hearings, supra* note 1, at 21, 51–2 (testimony of G. Brock).

102. Burgess, *supra* note 43, at A1, col. 3. The same article attributes the price decline to state regulatory action as an alternative to competitive forces.

103. The author observed a print media campaign designed to advise end users to use the five digit AT&T access code to connect with its operators.

104. The Federal Communications Act of 1934 reserves to the states the right to regulate intrastate communications. 47 U.S.C. § 152(b) (1988). *See* Louisiana Pub. Serv. Comm'n v. FCC, 476 U.S. 355, 370–73 (1986). For a discussion of the curious development of federalism in communications law, see Haring and Levitz, *The Law and Economics of Federalism in Telecommunications*, 41 FED. COMM. L.J. 261 (1989).

A. The FCC's Initial Approach

As previously noted,[105] the FCC approached the problem as an informational failure and devised a response that is essentially consistent with that appraisal. In *TRAC*,[106] the FCC placed three requirements on an AOS provider. First, the AOS company must place certain information near any telephone presubscribed to them. This information must include the company's identity and a statement that its rates will be quoted upon request. Contracts with call aggregators must contain provisions to this effect.[107] Second, an AOS company must identify ("brand") itself before it connects a call. The company then must give a caller enough time before connecting the call to permit him to hang up or advise the operator to transfer the call to the customer's preferred carrier (such as AT&T, MCI, or Sprint).[108] Third, the FCC directed the elimination of blocking.[109]

In a subsequent rule-making order, the FCC proposed to extend the results of the *TRAC* decision to all carriers.[110] As expected, the rule-making would codify the branding and disclosure requirements as well as the prohibitions on call blocking.[111] In addition, the Commission sought to facilitate access to alternative carriers through improved notice to end users and the installation of equipment that would prevent call blocking.[112] There was no provision for monitoring rates in the proposed rule-making.

B. The Telephone Operator Services Improvement Act of 1990

In October, Congress redefined the debate by asserting authority over both operator services and aggregators in the Telephone Operator Services Improvement Act. Initially, it followed the lead of the FCC by directing AOS companies to provide open access and bill properly. In addition, the Act required aggregators to provide systems that permitted access to the end user's carrier of choice and outlawed the installation of equipment that failed to meet that standard. Most importantly, Congress reopened the issue of rate levels. The Act directed the FCC to accept informational tariffs, review them for their reasonableness, and open proceedings for setting rates if the market failed to control rate levels. Although the Act did not immediately endorse regulated rates for

105. *See supra* text accompanying notes 83–86.
106. 4 F.C.C. Rcd. 2157 (1989).
107. *Id.* at 2159.
108. *Id.*
109. *Id.*
110. Notice of Proposed Rule Making, Policies and Rules Concerning Operator Service Providers, F.C.C. Rel. No. 90-231, RM-6767, at 2 (July 17, 1990).
111. *Id.* at 3.
112. *Id.* at 4–5.

operator services,[113] it nonetheless retained some bite by threatening the imposition of some undefined form of rate-setting.

The Act covers a broad range of services. Operator service providers subject to the terms of the Act include "any common carrier that provides operator services or any other person determined by the [FCC] to be providing operator services."[114] "Operator services" is defined to include "any interstate telecommunications service initiated from an aggregator . . . [including] any automatic or live assistance to a consumer to arrange for billing or completion or both," other than calls automatically completed or those covered by the end user's prior subscription to a particular carrier.[115] Finally, an aggregator is defined as "any person that, in the ordinary course of its operations, makes telephones available to the public or to transient users of its premises, for interstate telephone calls using a provider of operator services."[116]

The Act then addresses each of the major areas of concern: identification, blocking, splashing, and rates. Initially, it requires operator service providers to brand their services. The provider must identify itself at the beginning of the connection, permit the user to terminate the call at no charge prior to connection, and disclose rates, collection processes, and the available complaint process upon request.[117] Additionally, the provider must identify itself again prior to completing the call.[118] In concert with the providers, the aggregators are directed to furnish information containing the name of the provider, the right to request rates and access to another carrier, and the right to direct complaints to the FCC's Common Carrier Bureau.[119]

Congress also attacked blocking by regulating the aggregators directly. The Act requires aggregators to provide connections with "800" and "950" calls to interstate carriers and prohibits them from discriminating in the rates charged for calls that bypass the aggregator's presubscribed provider.[120] Moreover, the Act requires aggregators to install equipment capable of meeting the new access standards within eighteen months after enactment.[121]

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113. The Senate Report concerning the Act emphasizes the role of informational difficulties in AOS. S. REP. NO. 439, *supra* note 43, at 9. *See supra* note 7 for a description of the more restrictive version passed by the House.

114. 47 U.S.C. § 226(a)(9).

115. *Id.* § 226(a)(7).

116. *Id.* § 226(a)(2).

117. *Id.* § 226(b)(1)(A)–(C).

118. *Id.* § 226(b)(2). These requirements will be suspended three years after enactment. *Id.*

119. *Id.* § 226(c)(1)(A).

120. *Id.* § 226(c)(1)(B)–(C).

121. *Id.* § 226(f). The Act does not specify when existing equipment must be converted; rather, it directs the FCC to initiate a proceeding to determine a reasonable

The Act directs providers to bill correctly but recognizes some of the limitations that exist due to unavailable technology. In those service areas that can provide for accurate call monitoring,[122] the Act prohibits a provider from billing for uncompleted calls.[123] Where equal access is not available, the provider may not knowingly bill for an uncompleted call.[124]

Congress also dictated specific procedures to be followed by providers to deal with the problem of splashing. Under the Act, "splashing" is

> the transfer of a telephone call from one provider of operator services to another such provider in such a manner that the subsequent provider is unable or unwilling to determine the location of the origination of the call and, because of such inability or unwillingness, is prevented from billing the call on the basis of such location.[125]

The Act directs the provider to avoid splashing unless the consumer requests the transfer, the consumer is informed that the rates may not reflect the charge from the originating point, and the consumer consents.[126] Furthermore, the provider may not bill a call that does not reflect its origination unless it has the consumer's prior consent to splash the call.[127]

These reforms are strengthened by the Act's threat of rate regulation. Within thirty days of enactment of the Act, AOS providers must file tariffs stating rates, terms and conditions of service, and surcharge levels.[128] The tariffs must contain an estimate of the amount of traffic associated with each tariffed service.[129] Any change in a tariff must be filed no later than the first day that the change is effective.[130] With this information in hand, the FCC is directed to review the tariffs to determine if they are just and reasonable.[131] If the FCC believes that the rates are unreasonable, it can order the AOS company to demonstrate the reasonableness of the rates or order the company to announce its rates at the beginning of each call.[132]

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time in which aggregators are to provide open access, providers are to have "800" or "950" access codes, or both. *Id.* § 226(e).

122. *See infra* text accompanying notes 168–71.

123. 47 U.S.C. § 226(b)(1)(F).

124. *Id.* § 226(b)(1)(G).

125. *Id.* § 226(a)(3).

126. *Id.* § 226(b)(1)(H).

127. *Id.* § 226(b)(1)(I).

128. *Id.* § 226(h)(1)(A).

129. *Id.*

130. *Id.*

131. *Id.* § 226(h)(2).

132. *Id.* The requirement to file tariffs sunsets after four years if the FCC determines that regulatory objectives of the Act are being met by the market and suspension will not disrupt the continued achievement of those goals. *Id.* § 226(h)(1)(B).

The Act also initiates additional monitoring of AOS. It directs the FCC to begin a proceeding within sixty days of enactment to monitor rates, check service quality, report on complaints, study the effects of surcharges on rates, and monitor compliance.[133] The FCC will then issue a series of reports to Congress based on the studies. The final report, due within 23 months of enactment, will control the rule-making procedures for establishing rate standards. Within 180 days after the final monitoring report, the FCC must complete a rule-making decision to establish "that rates and charges for operator services [are] just and reasonable. Such regulations shall include limitations on the amount of commissions or any other compensation given to aggregators by providers of operator service."[134] The rule-making decision is suspended, however, if the FCC determines in its final report that the market is functioning properly.[135]

As an overall approach, the Congressional solution primarily provides better information and access for the consumer while simultaneously threatening price regulation if AOS behavior does not respond accordingly.

C. State Restrictions: Bans

State regulation reflects an often strange divergence between perceived problems and solutions. Several states view AOS as evil incarnate and have either banned the service outright or imposed regulations tantamount to a ban. In initially banning AOS, the Alabama commission found that the service did not promote competition, did not provide any unique benefits, charged apparently excessive rates, and caused the local exchange companies to lose revenues.[136] The North Carolina commission followed a similar course and added its concern that AOS companies, based on their past performance, would tax the commission's limited regulatory resources to maintain compliance.[137]

In the same vein, several commissions permitted the introduction of AOS but restricted contracting with aggregators. The Missouri commission, for example, refused to permit the sale of operator services through aggregators and provided for highly structured, capped rates in

133. *Id.* § 226(h)(3)(A).
134. *Id.* § 226(h)(4)(A).
135. *Id.* § 226(h)(4)(B).
136. *In re* International Telecharge, Inc., 92 Pub. Util. Rep. 4th (PUR) 211, 213–14 (Ala. Pub. Serv. Comm'n 1988). The Alabama commission subsequently permitted one AOS company to operate in the state on an interim basis. OMOROGBE, THE EMERGENCE OF THE ALTERNATIVE OPERATOR SERVICE INDUSTRY AND ITS IMPLICATIONS FOR REGULATORS 23 (Working Paper presented at the Seventh NARUC Biennial Regulatory Information Conference, Columbus, Ohio, Sept. 5, 1990).
137. *In re* Alternative Operator Servs., 97 Pub. Util. Rep. 4th (PUR) 161, 168 (N.C. Util. Comm'n 1988).

sales to end users.[138] Similarly, the Tennessee commission ruled that the AOS company must establish a contractual relationship with the end user before billing for operator services.[139] The effect of each of these decisions was to eliminate the standard AOS arrangement.

D. State Restrictions: Price Caps and Open Access

More typically, state commissions have addressed AOS on two related levels. First, the commissions set rates by capping them to the dominant interstate or local carrier's rates. Second, they require the AOS company to guarantee the end user's access to the carrier of her choice. In effect, the commissions adopt a self-contradictory theory that says choice will regulate price through open access, but because choice alone does not work, the commissions will set prices.

1. *PRICE REGULATION*

The most common form of regulation is to cap the rates of the AOS company at the same level as the dominant carrier's rates.[140] Those commissions adopting rate caps must have explicitly or implicitly concluded that the rates of the dominant intrastate and interstate operators are reasonable.[141] Commissions have also combined price caps

138. *In re* American Operator Servs., Inc., 103 Pub. Util. Rep. 4th (PUR) 124, 131–35 (Mo. Pub. Serv. Comm'n 1989).

139. *In re* South Central Bell Tel. Co., 93 Pub. Util. Rep. 4th (PUR) 68, 72 (Tenn. Pub. Serv. Comm'n 1988).

140. *See, e.g., In re* Alternative Operator Servs., 101 Pub. Util. Rep. 4th (PUR) 484, 495 (Ga. Pub. Serv. Comm'n 1988); *In re* American Operator Servs., Inc., 102 Pub. Util. Rep. 4th (PUR) 336, 345 (Ind. Util. Reg. Comm'n 1989); *In re* International Telecharge, Inc., 105 Pub. Util. Rep. 4th (PUR) 160, 167 (Ky. Pub. Serv. Comm'n 1989); *In re* International Telecharge, Inc., 97 Pub. Util. Rep. 4th (PUR) 349, 356–57 (Mass. Dep't Pub. Util. 1988). The Florida commission attempted to establish a cap by ordering that revenues in excess of those charged by the dominant carrier be held subject to refund pending a hearing to determine if the provision of AOS was in the public interest. An appellate court held that the order was improperly promulgated. Florida Pub. Serv. Comm'n v. Central Corp., 551 So. 2d 568, 569 (Fla. Dist. Ct. App. 1989).

141. The Indiana commission offered the rationale that mirroring rates by the AOS companies would result in "predictability and reasonableness." *In re* American Operator Servs., Inc., 102 Pub. Util. Rep. 4th (PUR) 336, 345 (Ind. Util. Reg. Comm'n 1989). Similarly, based on rate cases with dominant carriers, the rates of Massachusetts traditional operator services were deemed just and reasonable on traditional rate-making principles and could be used as a surrogate by the AOS companies to avoid a full blown rate case. *In re* International Telecharge, Inc., 97 Pub. Util. Rep. 4th (PUR) 349, 356 (Mass. Dep't Pub. Util. 1988). The Massachusetts commission has followed the same approach in certifying several other carriers. *In re* Telesphere Network, Inc., 105 Pub. Util. Rep. 4th (PUR) 405 (Mass. Dep't Pub. Util. 1989); *In re* NYCom, Inc., 101 Pub. Util. Rep. 4th (PUR) 65 (Mass. Dep't Pub. Util. 1988); *In re* ACC Long Distance Corp., 101 Pub. Util. Rep. 4th (PUR) 506 (Mass. Dep't Pub. Util. 1988).

with restrictions on surcharges and the provision of time of day discounts.[142]

While some regulations do not technically cap rates, they do impose rate caps as a practical matter. For example, the Massachusetts commission concluded that an AOS company may charge rates up to the levels of the dominant carrier without undergoing full rate of return review. However, an AOS company desiring a higher rate must endure a full-blown rate case.[143] Since the small entrants are not likely to seek rate of return regulation and incur the costs that it entails, their rates are effectively capped.

2. *BLOCKING BANS AND CALL BRANDING*

In addition to setting rates, some commissions have imposed disclosure and open access requirements to promote better purchasing decisions on the part of consumers. Georgia, for example, capped rates that AOS companies might charge without suffering a rate review, but also required AOS providers to brand their services by identifying themselves to the end user, providing tent cards or stickers to identify the AOS company contracting with the aggregator, and providing rate disclosure on request.[144] To make the choice effective, the commission further directed that the AOS companies ensure, by contract with the aggregator or other arrangement, that the end user have access to the carrier of his choice.[145]

3. *OTHER STATE RESTRICTIONS*

Finally, state commissions have imposed a variety of additional operating requirements. Using a financial prod to enforce certification and tariff requirements, the Arkansas commission directed local exchange carriers to refuse billing and collection services to uncertificated AOS companies.[146] The Idaho commission directed AOS companies to discontinue splashing by ordering them to hand off calls to an

142. *In re* International Telecharge, Inc., 105 Pub. Util. Rep. 4th (PUR) 160, 166–67 (Ky. Pub. Serv. Comm'n 1989).

143. *In re* International Telecharge, Inc., 97 Pub. Util. Rep. 4th (PUR) 349, 356–57 (Mass. Dep't Pub. Util. 1988). The commission noted the expense and administrative burden of a rate case as a justification for the approach. *Id.* at 356.

144. *In re* Alternative Operator Servs., 101 Pub. Util. Rep. 4th (PUR) 484, 497 (Ga. Pub. Serv. Comm'n 1988); *see also In re* American Operator Servs., Inc., 102 Pub. Util. Rep. 4th (PUR) 336, 343-44 (Ind. Util. Reg. Comm'n 1989); *In re* International Telecharge, Inc., 105 Pub. Util. Rep. 4th (PUR) 160, 168–69 (Ky. Pub. Serv. Comm'n 1989).

145. *In re* Alternative Operator Servs., 101 Pub. Util. Rep. 4th (PUR) 484, 499–500 (Ga. Pub. Serv. Comm'n 1988).

146. *In re* Billing and Collection by Local Exchange Carriers for Uncertificated Alternative Operator Cos., 96 Pub. Util. Rep. 4th (PUR) 485, 491 (Ark. Pub. Serv. Comm'n 1988).

appropriate interexchange carrier, announce that calls might be splashed, or state that they could not complete calls as dialed.[147] The Idaho commission also prohibited local exchange companies from disconnecting customers for failure to pay AOS accounts.[148]

In addition, some commissions have sought to protect local exchanges from revenue losses. The Georgia commission directed that all local service pass through the local exchange operator.[149] Likewise, New Jersey required AOS providers to complete intrastate calls through the local exchange companies.[150] The commission further required direct access to the local exchange operator by dialing "0" and connection to the AOS provider by some other dialing code.[151] The requirement of direct connection thus routed all emergency calls through the local network.[152] Idaho, Indiana, and Kentucky have adopted similar requirements.[153]

VI. FREEING CAPTIVE CUSTOMERS AND OTHER MARKET MYTHS

Choosing among the various regulatory tools requires an accurate assessment of the market and its ability to correct apparent inefficiencies.[154] In the case of AOS, regulation cannot be justified on the basis of internalizing costs or containing natural monopoly since AOS imposes no external costs and is not a natural monopoly.[155] As a result, the only remaining justification for regulation is improving information flows and preserving customer choice. If effective choice is available and the information is relevant and understandable, the informed end user will force both the aggregator and the AOS company to price

147. *In re* Alternative Operator Servs., 95 Pub. Util. Rep. 4th (PUR) 411, 417–18 (Idaho Pub. Util. Comm'n 1988), *modified on other grounds*, 97 Pub. Util. Rep. 4th (PUR) 170 (Idaho Pub. Util. Comm'n 1988).

148. *Id.* at 419. The commission offered this cryptic comment on the refusal to permit disconnection: "AOS providers have other means to collect from telephone users." *Id.* It did not explain what those choices might be.

149. *In re* Alternative Operator Servs., 101 Pub. Util. Rep. 4th (PUR) 484, 498 (Ga. Pub. Serv. Comm'n 1988).

150. *In re* American Coin-Telephone, Inc., 91 Pub. Util. Rep. 4th (PUR) 103, 105 (N.J. Bd. Pub. Util. 1988).

151. *Id.* at 106.

152. *Id.* at 106–07.

153. *In re* Alternative Operator Servs., 95 Pub. Util. Rep. 4th (PUR) 411, 416 (Idaho Pub. Util. Comm'n 1988), *modified on other grounds*, 97 Pub. Util. Rep. 4th (PUR) 170 (Idaho Pub. Util. Comm'n 1988) (0– routed through local operators); *In re* American Operator Servs., Inc., 102 Pub. Util. Rep. 4th (PUR) 336, 345 (Ind. Util. Reg. Comm'n 1989); *In re* International Telecharge, Inc., 105 Pub. Util. Rep. 4th (PUR) 160, 169 (Ky. Pub. Serv. Comm'n 1989) (0– routed to local exchange operator; 0+ cannot be intercepted or blocked in equal access areas, but they can be intercepted in non-equal access areas).

154. S. BREYER, *supra* note 72, at 34.

155. *See supra* text accompanying notes 69–71.

competitively.[156] The former will fear the loss of business to other aggregators. The latter will set prices to attract both the end user directly and the aggregator who is sensitive to the end user's concerns and therefore generates high volumes of AOS calls. Once the problem is correctly defined, a regulatory approach stressing open access and providing the consumer with accurate information is much more appropriate than outright bans or rate setting and entry regulation.

A. Regulating AOS: The Appropriate Paradigm

1. *BANNING BLOCKING*

If sustainable, blocking poses an obvious barrier to the development of a competitive marketplace. In the first instance, the customer is prevented from exercising any choice in selecting an operator or carrier for her call. If the informed customer cannot exercise that choice, there is limited pressure on the AOS companies to charge competitive rates. The market mechanism is frustrated to the detriment of the end user.

However, as a practical matter, blocking may not be as significant a problem as feared by regulators. In the long run, someone will make unblocked service available, if there exists enough demand for it. Others will follow if unblocked service is significant to the choice of the end user. If it is not significant, an assumption that seems to be grossly at odds with that of every regulator, then regulating open access is wasted effort. No amount of open access would be relevant since the end user would not take advantage of it in any case.

Nonetheless, regulating open access may be justified in the shorter run. The eventual development of unblocked services does not help the end user who currently lacks the ability to connect with a desired carrier. Moreover, since the divestiture of AT&T, substantial regulatory and legislative effort has been expended to create a competitive telecommunications market and there is a certain amount of unfairness in not enabling end users to access that carefully created market.

In addition, technical limitations do not appear to be a significant obstacle to this form of regulation. While providing open access may be hampered by the limited capabilities of some aggregators' equipment,[157] and AT&T has voiced concerns about providing the number identification necessary for proper billing,[158] these technical limitations are not likely to be insurmountable or long-lived.[159]

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156. S. BREYER, *supra* note 72, at 164.

157. *In re* American Operator Servs., Inc., 103 Pub. Util. Rep. 4th (PUR) 124, 130 (Mo. Pub. Serv. Comm'n 1989).

158. *Id.*

159. *See infra* text accompanying notes 168–75.

2. *CUSTOMER INFORMATION*

In an effectively working market, competitive pressures would force the AOS provider to identify itself and disclose its rates on request. Both of these requirements are frequently a part of current state and federal regulation and are consistent with improving the AOS market.

Nevertheless, there does not appear to be any significant market failure that currently prevents the development of this information. Competitors have strong incentives to expose high priced providers. Customers learn about ways to bypass the expensive AOS system. Aggregators are pressured to provide accurate information or lose customers.[160] Taken together, real competitive pressures already exist and should facilitate the move to efficient pricing disclosure without the need for regulation.

Moreover, one particular aspect of informational regulation, posting rates either at telephones or in tariff filings, ironically appears inappropriate. If rates are competitively set, then the information on cards or tariffs could become quickly out of date and necessitate expensive substitutions.[161] Moreover, critics of regulation frequently point to posted rates as a source of non-competitive pricing.[162] "Since all price reductions are public, they can be quickly matched by competitors. This reduces the incentive to engage in price cutting."[163] Posting thus may lead to generally higher prices due to higher costs and lost incentives to cut rates.

B. Wrong Moves: Capping Rates

Price caps are inherently inefficient in light of strong evidence that economic forces can drive prices to reasonably competitive levels.[164] While many states use the rates charged by the traditional carriers to set AOS rates, this type of regulation presents several problems that undermine its rationale.[165] To the extent that the traditional carrier's rates are too high, then the use of the high rate encourages uneconomic

160. *See supra* text accompanying notes 96–103.

161. *In re* Alternative Operator Servs., 95 Pub. Util. Rep. 4th (PUR) 411, 415 (Idaho Pub. Util. Comm'n 1988), *modified on other grounds*, 97 Pub. Util. Rep. 4th (PUR) 170 (Idaho Pub. Util. Comm'n 1988).

162. Rates for Competitive Common Carrier Services and Facilities Authorizations Therefor, 84 F.C.C.2d 445, 454 (1980) (Further Notice of Proposed Rulemaking).

163. *Id.*

164. *See supra* text accompanying notes 102–103.

165. Massachusetts, for example, determined that an AOS provider was a dominant carrier and therefore subject to full rate regulation. However, the commission permitted the carrier to file tariffs that were no higher than those filed by New England Telephone and AT&T for similar services on the theory that the commission had already approved those rates as reasonable. *In re* International Telecharge, Inc., 97 Pub. Util. Rep. 4th (PUR) 349, 356 (Mass. Dept. Pub. Util. 1988).

development of competing services. Two alternative forms of waste are possible. First, as a strategic matter, the rate set by the commission makes it easier for firms to implicitly collude by simply matching the regulated rate. Regulation thus reduces the incentive of each AOS provider to engage in aggressive competition since the process used to set rates provides a simple and legal mechanism for AOS providers to achieve an implicit agreement on pricing. As a result, supracompetitive rates and returns can be maintained by several AOS providers at the expense of consumers and an efficient market. Second, the excessively high rates set by this type of regulation may cause excessive resources to be directed into AOS. When competitive forces eventually force prices downward, there are costs associated with the ultimate failure of the less efficient providers. In either situation, there is no apparent gain to society.

Nor is this type of regulation justified when the traditional carrier's rates are too low. This low price level will stifle competition among AOS providers by not providing sufficient remuneration to the new competitors. Moreover, the rate set for the traditional carrier may not reflect the true cost of providing operator services. Since the allocation of costs among different services provided by the traditional carrier is a difficult problem and subject to much discretion,[166] the traditional carrier can often shift costs generated by operator services to its monopoly local exchange business and use those costs to raise its regulated rates for monopoly services. As a practical matter, AOS providers face the possibility that operator rates charged by traditional carriers are being subsidized by revenues from their traditional monopoly services.[167] The cost ceiling imposed on the AOS competition thus unfairly excludes costs that the traditional carrier is incurring but recovering through other services. The resulting low rates set for operator services discourages sufficient entry by AOS providers to ensure a competitive marketplace. Any gains to consumers through the low rates charged by the traditional carrier are necessarily offset by increased rates for local exchange monopoly services.

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166. Peter Huber gives one of the more artful descriptions of the problem of cost allocation:

> Cost separation is a torture of a thousand cuts. A first cut divides costs between a LEC's regulated and unregulated businesses. A second, between interstate and intrastate services, and among the states themselves. Costs are then chopped and diced among dozens of different services—traffic-sensitive and non-traffic-sensitive, switched and special, intrastate and interstate, intraLATA and interLATA....
>
> What emerges from this regulatory Cuisinart is often interesting but always a surprise. Each slicing operation involves a measure of discretion. The discretionary judgments at the [sic] each tier of the dismemberment multiply. After four or five cuts, discretion has been raised to the fourth or fifth order. If there is 20 percent discretion as to just where each cost cut will be made, there is 250 percent discretion as to the size of each small piece that emerges.

P. HUBER, *supra* note 26, at 3.53 to 3.54.

167. Breyer, *Antitrust, Deregulation, and the Newly Liberated Marketplace*, 75 CALIF. L. REV. 1005, 1040–41 (1987).

C. Other Regulations and Enforcement

The remaining problems presented by AOS, such as billing and collection involving uncompleted calls, splashing, and the appropriate allocation of local to interstate calls, can be resolved by the installation of appropriate technology. The repeated problems associated with billing uncompleted calls should be eliminated by answer supervision, a technological advance that is available with the conversion to equal access.[168] The newer switches being installed by the Bell companies and the independent phone companies provide for answer supervision that "enables a carrier to ascertain the precise time between call placement and connection so as to distinguish between completed and uncompleted calls."[169] The FCC reported that ninety-three percent of all domestic lines should be connected to these switches by the end of 1989.[170] Although total conversion is impractical since the cost of such a change is relatively high compared to the probable benefits of universal call supervision,[171] on balance, the problem of improper billing should be substantially resolved by the conversion to equal access switching.

Splashing presents a more difficult technical problem. In 1989, the FCC ordered the AOS companies to stop call splashing to the extent that such action is technically possible with their current networks.[172] Additionally, the AOS providers were required to work with the Carrier Liaison Committee of the Exchange Carrier Standards Association to address the computer hardware and software problems associated with eliminating any other call splashing.[173] However, the resulting report of a task force established by the committee to address the problem was less comforting. The task force rejected several solutions because they required either high costs to install the necessary equipment or cooperation among competitors.[174] However, the task force did point to some technical and informational solutions that would eliminate most splashing. Primarily, the task force suggested the implementation of open access and consumer education.[175] The task force concluded that as

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168. *Hearings, supra* note 1, at 58 (testimony of G. Brock); Report on Billing for Unanswered Calls, *reprinted in Hearings, supra* note 1, at 61–63.

169. Report on Billing for Unanswered Calls, *reprinted in Hearings, supra* note 1, at 61 ("answer supervision enables a carrier to ascertain the precise time between call placement and connection as well as to distinguish between completed and uncompleted calls").

170. *Id.* at 61–62.

171. *Hearings, supra* note 1, at 58 (testimony of G. Brock).

172. TRAC, *supra* note 3, at 2159.

173. *Id.*

174. Task Force Report to the Federal Communications Commission Concerning "Call Splashing," FCC Docket No. CC 90–313 at 25 (June 1, 1989).

175. The task force summarized its conclusion:

> The task force recognized that call unblocking, while potentially difficult to fully implement, and the provision of consumer information as ordered by the FCC, coupled with consumer

the network becomes more open and understandable, problems of splashing will diminish.

The remaining problem of maintaining local revenues is not susceptible to an easy solution. The commission's first choice may be to protect the local monopoly and the income that operator services provides for the maintenance of universal service.[176] Its second choice may be to promote competition in the AOS market. A little political reality suggests which one of these interests will normally prevail. Local politicians do not get reelected when their decisions increase costs within their control which could be shifted to someone else. In the end, it is a primarily political choice for the state commissions to make. If they choose incorrectly, there will be losses to some part of the customer base.

Once the decision to regulate at some level is made, the practical problem of enforcement becomes more significant. For the system proposed here to work, there must be a significant credible threat that anticompetitive behavior will be costly and will offset the profits generated by that behavior. In the AOS market, enforcement may be problematic. As a recent FCC audit demonstrated,[177] rules without a substantial threat of enforcement may be meaningless to this market. Moreover, past practice suggests that AOS companies are risk takers. In Kentucky, for example, the commission detected one AOS company providing services while an application for a certificate to operate was pending.[178] Likewise, the North Carolina commission determined that thousands of dollars of overcharges were billed by uncertificated AOS

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education, would significantly contribute to the reduction of call splashing. In addition, call reorigination at the CPE and the establishment of billing and collection and billing validation agreements will further reduce splashing. However, these solutions may require varying lengths of time to implement and may not totally eliminate splashing due to other factors such as:

1) state regulatory requirements that callers be connected to preferred OSP [operator service provider] without having to redial, and

2) notwithstanding the waiver process, some blocking may continue to occur until technical solutions for prevention of toll fraud are implemented.

Id.

The Senate Report on AOS legislation takes a similar position.

The Committee beleives [sic] that the carrier identification and unblocking requirements contained in the bill as reported should resolve most of the problems with call splashing. As long as an aggregator has properly unblocked the telephone that the caller is using, there should be no need for the OSP to "splash" the call to the caller's desired carrier. The caller may simply hang up and dial the desired carrier's access code nubmer [sic].

S. REP. NO. 439, *supra* note 43, at 15.

176. *See supra* text accompanying notes 63–64.

177. *See supra* note 48.

178. *In re* International Telecharge, Inc., 95 Pub. Util. Rep. 4th (PUR) 421, 425 (Ky. Pub. Serv. Comm'n 1988).

companies.[179] The self-serving statements of the AOS companies may not satisfy many regulators that good performance will result.[180]

Recognizing the need for enforcement raises two issues. First, one must decide whether enforcement is public or private. In the case of AOS, the public enforcement mechanism is preferable. Individual claims are by definition small—usually the amount of overcharge for an operator assisted phone call—compared to the costs of private litigation. Thus, individuals are not likely to litigate these small claims. Yet, these small amounts could become quite large in the aggregate, as the Tennessee billing study suggests.[181] Collecting these interests through public enforcement then makes sense.[182]

Second, one must decide where resources will be spent. Again, one must attempt to balance the benefits and costs of various regulatory approaches. By definition, regulatory resources are limited. Limiting entry and closely regulating those entrants may prove cumbersome and expensive to the regulator. In contrast, providing information and keeping the system open may prove more cost efficient. "[W]hen regulators seek disclosure, they need not fine-tune standards quite so precisely. They themselves need less information from industry, there are fewer enforcement problems, there is less risk of anticompetitive harm, and there is greater probability of surviving judicial review."[183] Furthermore, to the extent that price and entry regulation does not appear necessary because open access and information can maintain competition, those regulatory resources may be directed toward enforcement.

VII. CONCLUSION

In summary, AOS is not an appropriate candidate for full-fledged price and entry regulation. The various theories of market failure do not account for high prices or poor service and do not justify regulatory intervention in the AOS market. Instead, competition offers an important and apparently real check on outrageous behavior. Nonetheless, regulators may want to maintain some control over the industry to assure themselves and the public that there is a source of continuing pressure for AOS to "live by the rules." Beyond that, regulation may prove more

179. *In re* Alternative Operator Servs., 97 Pub. Util. Rep. 4th (PUR) 161, 166–67 (N.C. Util. Comm'n 1988).

180. In response to criticism, several AOS companies have organized a trade group, the Operator Service Providers of America. The association has established general guidelines for pricing and service standards. *Hearings, supra* note 1, at 91–113 (statement of H. Berg).

181. *See supra* text accompanying note 59.

182. R. POSNER, ECONOMIC ANALYSIS OF THE LAW 344 (3d ed. 1986) ("if the injury to each victim is too small to make a lawsuit a paying proposition, there is an argument for direct regulation, provided the total injury is substantial in relation to the cost of prevention").

183. Breyer, *supra* note 167, at 580.

costly than necessary to meet the goals of just and reasonable prices and practices.

COMMENT

REGULATING INTERNATIONAL TRADE IN LAUNCH SERVICES

BY TIMOTHY A. BROOKS †

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I. INTRODUCTION

In the last half decade, the space transportation market has gone from a highly insular, government controlled and operated set of local monopolies to a fiercely competitive, multipartite international market. But because elements of the previous system still linger in the form of government launch providers, the market will never become freely competitive without an international regime to regulate trade in launch services. This Comment will discuss the development of the market and its present and future dynamics, and will then analyze several alternative regimes for its regulation.

II. DEVELOPMENT OF A COMPETITIVE LAUNCH SERVICES MARKET

A. Early Commercialization Efforts and Government Policy

In the early days of space exploration, space programs were conducted almost exclusively by the public sector with little involvement by the private sector.[1] The purposes of a space program were primarily national security and national prestige; economic benefits were difficult for anyone to capture.[2] There was little opportunity for commercial use of space as national defense establishments attempted to control leakage of vital technology.[3]

Gradually, commercial uses of space began to develop,[4] although space transportation remained an area of government monopoly. In the United States, the government proved inept at meeting the increasing demand. An overly politicized decisionmaking process led NASA to commit the bulk of its resources to the space shuttle, phasing out use of unmanned expendable launch vehicles (ELVs).[5] However, the shuttle proved not to be an economical launcher of commercial satellites.[6]

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1. In the United States, the National Aeronautics and Space Administration (NASA) determined the course of development and contracted with the private sector for particular engineering and construction needs. Corcoran & Beardsley, *The New Space Race*, SCI. AM., July 1990 at 72, 74.

2. Katz, *New Directions Needed in U.S. Space Policy*, in INTERNATIONAL SPACE POLICY: LEGAL, ECONOMIC, AND STRATEGIC OPTIONS FOR THE TWENTIETH CENTURY AND BEYOND 47, 47–48 (D. Papp & J. McIntyre eds. 1987) [hereinafter INTERNATIONAL SPACE POLICY].

3. Jones, *National Security, Technology Transfer Controls, and U.S. Space Policy*, in INTERNATIONAL SPACE POLICY, *supra* note 2, at 65, 66.

4. *See infra* notes 120–29, 140 and accompanying text.

5. *See generally*, Logsdon, *The Space Shuttle Program: A Policy Failure?*, 232 SCIENCE 1099, 1100–1101 (1986).

6. Original 1972 operating cost estimates for the shuttle were $10.4 million per flight, or $160 per pound put in orbit. *Id.* at 1102. Those estimates have been drastically revised. More recent estimates of the cost of a shuttle mission dedicated specifically to commercial satellite launching run as high as $350 million per flight. Corcoran & Beardsley, *supra* note 1, at 74. The price per launch charged by NASA's commercial competitors ranges from

Meanwhile, other countries, particularly in Europe, continued to develop ELV technology. The European consortium Arianespace entered the commercial market in 1980, and it soon became clear that NASA's monopoly on western commercial launches was broken.[7]

Beginning in the early 1980's there was some activity by companies interested in entering the commercial launch market.[8] In 1982 the Reagan Administration, as part of its general fervor for deregulation, began to encourage the commercialization and privatization of space transportation. On July 4, 1982, President Reagan unveiled his National Space Policy,[9] which anticipated private sector investment and involvement in the development of launch vehicles.[10] The National Security Council furthered this policy by issuing a comprehensive policy for ELV commercialization on May 16, 1983.[11] Nevertheless, companies were slow to invest in commercial launch services, perhaps because all other competitors were either governmental or government-owned.[12]

B. The Commercial Space Launch Act

The Administration continued to express its desire that commercial launch services be privatized,[13] and Congress acted on this policy in 1984

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the $50 million average of Arianespace, Comment, *Legal Aspects of the Commercialization of Space Transportation Systems*, 3 HIGH TECH. L.J. 99, 105 (1988), to the $125 million of Martin -Marietta, Kolcum, *Commercial Titan Launch Vehicle Places Two Communications Satellites in Orbit*, AVIATION WK. & SPACE TECH., Jan. 8, 1990, at 42-43. Foreign governmental launchers have been known to undercut commercial prices. *See infra* note 91. Even if NASA launches two satellites per shuttle flight, it will still have to justify the $50 million to $125 million premium per satellite by providing vastly superior service. If it cannot do so, it will have to recoup the shortfall by selling off ancillary services to the satellite launchers and other shuttle customers. Thus the shuttle cannot be competitive unless it charges rates below cost.

7. Corcoran & Beardsley, *supra* note 1, at 74–75.

8. *See infra* notes 46–65 and accompanying text.

9. Robinson & Meredith, *Domestic Commercialization of Space: The Current Political Atmosphere*, in 1 AMERICAN ENTERPRISE, THE LAW, AND THE COMMERCIAL USE OF SPACE 1, 4 (1986) [hereinafter AMERICAN ENTERPRISE]

10. *Id.*

11. Dula, *Private Sector Activities in Outer Space*, 19 INT'L LAW. 159, 183 (1985).

12. So long as government launchers are market leaders, pricing will not be indicative of costs, Hertzfeld, *Economic, Market, and Policy Issues of International Launch Vehicle Competition*, in INTERNATIONAL SPACE POLICY, *supra* note 2, at 203, 214, and commercial launchers will probably be forced to price at very low profitability in the short term in order to develop a capacity to compete in the long-term market.

13. One of the actions taken by the administration toward this end was the designation, by Executive Order 12465 on February 24, 1984, of the Department of Transportation as lead agency for the regulation of private ELV launching. The Department of Transportation then created the Office of Commercial Space Transportation to oversee its responsibilities. Robinson & Meredith, *supra* note 9, at 3.

with the Commercial Space Launch Act.[14] The purpose of the Act was to encourage entrepreneurial activity in launch services by providing for licensing requirements,[15] insurance requirements,[16] and the use of government property.[17] The Act also provides for the government to enter international negotiations to encourage fair competition in launch services.[18]

Although the Act originally left the details of the insurance requirement to the discretion of the Secretary of Transportation,[19] the 1988 Amendments set out comprehensive regulation of launch insurance.[20] The most important part of the insurance section limits the liability of the launcher to $500 million and requires that the launcher obtain an equal amount of insurance, or the maximum obtainable on the world market, whichever is less, for each launch.[21] As a condition of this minimum insurance requirement, the government is obligated to require all of its entities and all contractors and subcontractors associated with the launch to file cross-waivers of liability for amounts in excess of the level of insurance.[22] These provisions limiting the liability of commercial launchers could add greatly to the confidence of the industry by reducing the risk borne by each launcher, although this will depend on the cost of the insurance required by the Act.[23] Similar limits of liability have been used in the past to encourage the development of nuclear power and aviation.[24]

The 1988 Amendments to the Act also added provisions meant to encourage research and development. Section 10 of the 1988 Amendments requires NASA, in concert with representatives of the satellite and commercial launch industries, to develop a program to encourage research and development of advanced launch technologies with higher performance and lower costs.[25] This program would make these advances available to both government and commercial launch systems.

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14. Commercial Space Launch Act, Pub. L. No. 98–575, 98 Stat. 3055, *amended by* Commercial Space Launch Act Amendments of 1988, Pub. L. No. 100–657, 102 Stat. 3900 (codified as amended at 49 U.S.C. §§ 2601–2623 (1988)).

15. 49 U.S.C. §§ 2605–2613 (1988).

16. *Id.* § 2615.

17. *Id.* § 2614.

18. *Id. See infra* note 315 and accompanying text.

19. Commercial Space Launch Act, Pub. L. No. 98–575, § 16, 98 Stat. 3055 (1984).

20. *Id., as amended by* Commercial Space Launch Act Amendments of 1988, Pub. L. No. 100–657, § 5, 102 Stat. 3900, 3902 (codified as amended at 49 U.S.C. § 2615 (1988)).

21. 49 U.S.C. § 2615(a)(1)(A) (1988).

22. *Id.* § 2615(a)(1)(D).

23. *See infra* note 62 and accompanying text.

24. *See infra* notes 181–82 and accompanying text.

25. Commercial Space Launch Act Amendments of 1988, Pub. L. No. 100–657, § 10, 102 Stat. 3900, 3907 (1988).

The Act also provides that the government facilitate the use of excess capacity at government launch sites through sale or lease at fair market value.[26] For the use of launch services, the government is to charge only "direct costs," meaning those additional costs incurred solely because of the commercial launch.[27]

C. The Challenger Accident

While the enactment of the Commercial Space Launch Act has done much to encourage the growth of a commercial launch industry, another important development has been the change in United States space policy resulting from the loss of the Challenger space shuttle on January 28, 1986. The Challenger accident led NASA to redesign the space shuttle and reassess costs,[28] which in turn led the government to change its policy from active involvement in marketing launch services to removing itself from the commercial launch market.[29] This withdrawal of U.S. government competition has finally allowed private American ventures to develop.

III. COMPETITION IN LAUNCH SERVICES

As American commercial ventures have moved into the area of providing commercial launch services, a number of foreign ventures have done the same, and foreign governments have continued to develop their own launch systems. All must compete in the same market of users of launch services. The market is not a truly open one, since a great deal of business comes from government entities that are constrained in their choice of launchers. Many governments also limit private customers' use of foreign launchers. A segment of the market for international launch services is highly competitive; however, this segment cannot be adequately understood without analyzing the less competitive sectors of the market as well.

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26. 49 U.S.C. § 2614(a), (b) (1988).

27. *Id.* § 2614(b)(1). The Air Force's draft agreement for commercial use of government launch facilities was assaulted at House hearings by the commercial launch industry as overly burdensome. *State of the Commercial Launch Industry: Hearings Before the Subcomm. on Space Science and Applications of the House Comm. on Science, Space, and Technology*, 100th Cong., 1st Sess. (1987) [hereinafter *Hearings*]. The Air Force has since produced another draft of its agreement. Department of the Air Force, *Model Expendable Launch Vehicle Commercialization Agreement: Revision Two* (May 12, 1989). For a discussion of the original model agreement, see Comment, *supra* note 6, at 116.

28. *See* OFFICE OF TECH. ASSESSMENT, LAUNCH OPTIONS FOR THE FUTURE *x* (1988).

29. Comment, *supra* note 6, at 103.

A. Supply: The Domestic Launch Industry

The supply of launch services may be divided into two relevant sectors: domestic suppliers and foreign suppliers. The domestic sector is further subdivided into both public and private suppliers. For practical purposes, the purely public sector in the United States has ceased to operate, although NASA remains on the fringe of the market as a potential competitor should United States space policy change.[30] At least for the time being, responsibility for commercial launches has been passed to private launch providers.[31] The private sector will therefore be the primary area of concern of this Comment. The private sector is itself divided into two subsectors based on the size of the companies involved and the technology available to them. The first group is composed of large firms relying on old rocket technology developed in ICBM or NASA programs; the second is composed of small start-up corporations created to develop new technology specifically aimed at the commercial launch industry.[32]

1. *DEFENSE AND NASA CONTRACTORS*

The private commercial launch industry is still in its infancy in the United States.[33] The major American players, as yet, are the defense and NASA contractors that developed early rocket technology in the 1950's and continue to produce rockets for government use.[34] They are the only American companies presently able to lift payloads into geosynchronous transfer orbit (GTO),[35] a necessary prerequisite for competition in the most developed sector of launch service demand: the placement in orbit of large communications satellites. These contractors include General

30. The United States has not announced a policy with respect to providing commercial services of which only the space shuttle is capable, such as satellite recovery.

31. Kolcum, *Joint Atlas Centaur Mission Orbits FltSatCom Spacecraft*, AVIATION WK. & SPACE TECH., Oct. 2, 1989 at 23 (reporting launch of last government-commercial joint venture).

32. Reynolds & Merges, *Toward an Industrial Policy for Outer Space: Problems and Prospects of the Commercial Launch Industry*, 29 JURIMETRICS J. 7, 13 (1988).

33. The first successful commercial launch was the launch of a Delta from Cape Canaveral on August 27, 1989. Kolcum, *U.S. Reenters Commercial Launch Arena With Private Delta Mission*, AVIATION WK. & SPACE TECH., Sept. 4, 1989, at 24.

34. OFFICE OF TECH. ASSESSMENT, INTERNATIONAL COOPERATION & COMPETITION IN CIVILIAN SPACE ACTIVITIES 104–06. (1985).

35. Corcoran & Beardsley, *supra* note 1, at 74–75.

Dynamics with the Atlas launch vehicle,[36] McDonnell-Douglas with the Delta,[37] and Martin-Marietta with the Titan.[38]

Of the three launch systems, the Commercial Titan possesses an advantage of large payload capacity, which allows it to easily carry two satellites or carry single satellite payloads that are too large for other vehicles.[39] The development of the Titan IV vehicle for the United States Air Force[40] also gives Martin-Marietta tremendous economies of scale because the same production facilities can be used in the manufacture of the Commercial Titan. General Dynamics has developed a configuration which allows three smaller satellites to be launched into low earth orbit by a single Atlas,[41] which could give it a significant advantage in the small payload market.[42]

A challenge for domestic commercial launch firms will be to keep their launch technology up to date. Without any government contracts, the firms will have to initiate their own research and development to improve on the archaic systems presently in use.[43] Some effort is already under way with programs such as the Titan IV.[44] However, large American aerospace corporations have been criticized for not taking a more aggressive approach to financing leading-edge space commercialization efforts.[45] The need for entrepreneurial efforts, therefore, has been filled by smaller companies.

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36. The capacity of the Atlas to GTO is 2250 kg. Corcoran & Beardsley, *supra* note 1, at 75. The Atlas is an adequate competitor for single satellite launches, but is not large enough to handle double payloads. General Dynamics plans to produce Atlas rockets at the rate of eight per year through 1997, and has commitments to launch about half of them. Kolcum, *supra* note 31, at 23.

37. The payload capacity to GTO of the Delta II is 1800 kg, Corcoran & Beardsley, *supra* note 1, at 75, which might not be sufficient as demand in the 1990's shifts to larger satellites, *see* Dornheim, *Near-Term Launch Market Looks Bright, but Questions Remain on Future Prospects*, AVIATION WK. & SPACE TECH., Dec. 19, 1988, at 73. It has a fine record of success with 11 launches in 1990. *Laurels 1990*, AVIATION WK. & SPACE TECH., Jan. 7, 1991, at 11, 12.

38. The Commercial Titan has a payload capacity of 5625 kg to GTO, three times that of the Delta and more than twice that of the Atlas. Corcoran & Beardsley, *supra* note 1, at 75. Martin-Marietta has successfully launched two out of three Commercial Titans. Kolcum, *Intelsat F6 Orbited by Commercial Titan Will Ease Communications Congestion*, AVIATION WK. & SPACE TECH., July 2, 1990, at 25.

39. Kolcum, *supra* note 6, at 42, 43. The Titan's payload capacity to low Earth orbit (LEO) is 14,400 kg (17,700 kg for the Titan IV), Corcoran & Beardsley, *supra* note 1, at 75, which makes the Commercial Titan an attractive alternative to the space shuttle for lifting such large payloads as components of the space station, Kolcum, *supra* note 6, at 42–43.

40. The Air Force has given Martin-Marietta a firm commitment for 41 launches in the 1990's. Corcoran & Beardsley, *supra* note 1, at 75.

41. *Single Atlas to Launch Three Small Satellites*, AVIATION WK. & SPACE TECH., Mar. 26, 1990, at 24.

42. *See infra* notes 125–29 and accompanying text.

43. Reynolds & Merges, *supra* note 32, at 17.

44. R. Truly, SPACE SHUTTLE: THE JOURNEY CONTINUES 17 (1988).

45. *See* Asker, *Failure to Support Space Ventures Threatens U.S. Aerospace Industry*, AVIATION WK. & SPACE TECH., May 28, 1990, at 22.

2. *SMALL PAYLOAD LAUNCH SERVICES*

Presently in the United States there are a number of smaller ventures interested in the market for commercial launch services. Five are start-up efforts: E'Prime Aerospace Corp.,[46] Conatec, Inc.,[47] Space Services, Inc. (SSI),[48] American Rocket Company (Amroc),[49] and a joint venture between Orbital Sciences Corporation (OSC) and Hercules.[50] In addition to the start-ups, there is one established small payload launcher, LTV Aerospace, which developed the Scout launcher for the government.[51]

The start-up companies present a strong contrast to the major launch corporations. They are in many ways more innovative, building brand new rockets from the ground up, or using old technology in new ways.[52] OSC/Hercules, for example, has launched its Pegasus rocket from a B-52,[53] and Amroc has attempted a sea launch of its Dolphin rocket.[54] Despite the creativity of the start-ups, their market is limited because they cannot compete in the highly lucrative communications

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46. E'Prime is hoping to use Peacekeeper missiles as the basis for its launch system. Corcoran & Beardsley, *supra* note 1, at 82–84.

47. Conatec is offering suborbital launches of sounding rockets to carry microgravity experiments. *Hearings*, *supra* note 27, at 16 (statement of Eugene Kadar, President of Conatec).

48. SSI was the first small company to demonstrate its launch capabilities with a suborbital flight of its Conestoga rocket in 1982. Corcoran & Beardsley, *supra* note 1, at 82. SSI has not yet had a successful test flight of a booster capable of putting a payload into LEO.

49. Amroc, previously known as Starstruck, has had great difficulty in developing its own rocket. Dornheim, *Amroc Retains Key Personnel Despite Cutbacks After Pad Fire*, AVIATION WK. & SPACE TECH., Oct. 30, 1989, at 20. However, Amroc is continuing to develop its new Aquila booster. Marketing efforts are under way and Amroc anticipates testing Aquila within the next few years, with commercial launches to follow shortly. Telephone interview with James Bennett, President of the American Rocket Company (Apr. 15, 1991).

50. The company's Pegasus rocket has been launched twice from an airborne B–52. *Second Pegasus Launched Successfully; Small Satellites in Elliptical Orbit*, AVIATION WK. & SPACE TECH., July 22, 1991, at 24. For Pegasus to be commercially viable, OSC/Hercules must obtain a commercial aircraft since the B–52 is available only for governmental launches. Stavro, *Virginia Firm Uses a B–52 to Launch Satellites*, L.A. Times, Apr. 6, 1990, at D1, D7. Orbital Sciences has managed to capture one commercial payload already; Sweden has chosen Pegasus for its December 1992 launch of its 230 kg Freja satellite. *Sweden Reserves Space on Pegasus for Payload First Booked on Long March*, AVIATION WK. & SPACE TECH., Jan. 1, 1990, at 38 [hereinafter *Sweden Reserves Space*].

51. The Scout has a payload capacity of 215 kg to LEO. Corcoran & Beardsley, *supra* note 1, at 74. It had been launched 112 times through the end of 1988, with a 95.5% success rate. Scott, *Small-Payload Launch Companies Struggle to Define Their Market*, AVIATION WK. & SPACE TECH., Dec. 19, 1988, at 79, 82.

52. *See* Reynolds & Merges, *supra* note 32, at 17.

53. *See supra* note 50.

54. Sea launching, used for ballistic missiles, had never before been used to launch a rocket into space. Martin, *Space, Inc.*, SCI. DIG., March 1985, at 43, 49.

satellite market,[55] and they have few long-term purchase contracts.[56] They have had to compensate for this deficit with agressive marketing. OSC, for example, has retained Arianespace as its European marketing agent,[57] and has recently concluded a marketing agreement for Japan with Okura & Co., Ltd.[58] SSI submitted a proposal to the Department of Transportation to launch cremated human remains into space.[59] OSC has also made a public stock offering,[60] which should help give it an edge in an area where there is a dearth of capital.[61]

The small payload sector of the launch industry is enthusiastic, innovative, and quite capable of producing many useful, reasonably priced launchers. Small payload launchers are extremely vulnerable to launch failures, however. One failure could decimate the company's available capital, and even with reliable launchers, insurance rates could be too high for the smaller companies to afford.[62] Small payload launchers can be successful by emulating the large payload launchers' use of government contracts as the basis of their launch business.[63] They must also stress their abilities in areas in which they possess a cost advantage by encouraging the development of technologies that use lighter payloads, such as "lightsat" technology[64] and the use of reentry modules for microgravity experiments.[65]

B. Supply: Foreign Launch Services

Domestic providers of launch services face competition from a number of foreign suppliers. Even before the Challenger accident, foreign launchers were beginning to enter the international launch market. Governments have developed launch systems for a variety of reasons. France has tended to view its space program as essential to its national security, while Japan and Germany view their space programs as essential investments in leading edge technology.[66] Many developing countries also believe that an adequate space program will save money

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55. Reynolds & Merges, *supra* note 32, at 17. *See also* Kolcum, *supra* note 31.

56. Many of the small payload companies do, however, receive some form of government support. Scott, *supra* note 51, at 79.

57. *Sweden Reserves Space*, *supra* note 50, at 38.

58. *Pegasus Maker Readies Pacific Sales Push*, AVIATION WK. & SPACE TECH., Feb. 11, 1991, at 26.

59. OFFICE OF TECH. ASSESSMENT, *supra* note 34, at 121.

60. Asker, *Orbital Sciences Becomes First Commercial Space Firm to Go Public*, AVIATION WK. & SPACE TECH., Apr. 30, 1990, at 27.

61. Asker, *supra* note 45, at 23.

62. Asker, *Insurance Will Cost More, but Little Movement is Seen to U.S. Launchers*, AVIATION WK. & SPACE TECH., Mar. 5, 1990, at 21.

63. *See* Corcoran & Beardsley, *supra* note 1, at 84.

64. *See infra* note 128.

65. *See infra* note 127.

66. OFFICE OF TECH. ASSESSMENT, *supra* note 34, at 125.

by preventing exploitation by the developed world, making it well worth the actual investment of capital.[67]

The development of foreign space programs and their eventual entry into the commercial launch industry has had a profound effect on the shape of the market. From 1983 to 1985, foreign launchers provided only one-half to one shuttle equivalent per year to American users.[68] Since the Challenger accident, foreign launchers have capitalized on the U.S. standdown to develop the capability to supply six to ten shuttle equivalents per year through the rest of the 1990's.[69]

1. *EUROPE AND CANADA*

European space efforts resulted partly from dissatisfaction with NASA treatment of cooperative space ventures.[70] Indeed, the European Space Agency (ESA), in keeping with its criticism of NASA's failure to separate the commercial and research elements of its program,[71] transferred its launch services to the French corporation Arianespace in March 1980.[72] Since then, the ESA has continued to advocate that NASA return to a more research-oriented role.[73]

A variety of factors have made Arianespace a leader in the provision of commercial launch services.[74] Their launchers have been very reliable. Until a recent failure, Arianespace had successfully launched a total of seventeen rockets[75] and has since recovered to launch

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67. *See* Levine, *Commercialization of Space: Implications for U.S. Relations with Developing Countries*, in INTERNATIONAL SPACE POLICY *supra* note 2, at 119, 119–20.

68. CONGRESSIONAL BUDGET OFFICE, SETTING SPACE TRANSPORTATION POLICY FOR THE 1990'S 12 (1986).

69. *Id.* at 23. Original NASA estimates predicted that foreign launchers would capture only 25% of the total world market because of shuttle dominance. Due to the Challenger launch standdown, the figure is well over 50%, and the shuttle's share of commercial business is non-existent. *Id.*

70. *See* Johnson–Freese, *High Tech, High Cost: Reasons for Cooperation in Space?*, in INTERNATIONAL SPACE POLICY *supra* note 2, at 217, 221–25 (discussing U.S.–European cooperative space efforts).

71. *See id.* at 224. The criticism is at times quite vocal. Charles Bigot, the managing director of Arianespace described NASA's approach to clients as that of "a lord accepting peasants on his land." Corcoran & Beardsley, *supra* note 1, at 75.

72. OFFICE OF TECH. ASSESSMENT, *supra* note 34, at 111–16. Although still substantially owned by the various European national space agencies, *id.*, Arianespace has been run as an independent corporation, keeping the ESA out of the day-to-day administration of the launch business, Corcoran & Beardsley, *supra* note 1, at 74–75.

73. Johnson–Freese, *supra* note 70, at 224.

74. Arianespace launched its first commercial rocket, an Ariane 1, on May 23, 1984, OFFICE OF TECH. ASSESSMENT, *supra* note 34, at 110, giving NASA its first legitimate competitor. Arianespace now uses the Ariane 4, which is capable of carrying up to 4200 kg to GTO. Corcoran & Beardsley, *supra* note 1, at 75. The location of its Kouro, French Guiana facility near the equator gives Arianespace an advantage in lifting payloads into some orbits. CONGRESSIONAL BUDGET OFFICE, *supra* note 68, at 30–33.

75. Lenorovitz, *Inquiry Team Probes Cause of Ariane First-Stage Failure*, AVIATION WK. & SPACE TECH., Mar. 5, 1990, at 18, 19.

three more through mid-1991.[76] Even given the most recent launch failure, Arianespace is the clear market leader in launch services, with over half of all contracts for future launches.[77] To fortify its position, the company has concluded four "framework" agreements with European subcontractors for the production of 50 additional Ariane 4 launchers over the next eight years,[78] giving Arianespace the same economies of scale that American launchers achieve through government contracts. In addition, Arianespace has maintained a creative and aggressive marketing strategy, accepting equity rather than cash in some cases, and helping customers obtain insurance.[79] As a result of these advantages, Arianespace already commands more than half of the commercial launch market[80] and should remain a potent competitor throughout the low demand period of the 1990's.[81]

Because of the dominance of Arianespace, private efforts in Europe have lagged behind those in the United States. Orbital Transport-und-Raketen Aktiengesellschaft (Otrag) of Germany has been interested in commercial launching since the late 1970's, but has had difficulty finding a launch site.[82] The only other private corporations that have expressed interest in the commercial launch industry are Bristol Aerospace, Ltd. of Canada[83] and SovCan Star Satellite Communications, Inc., a joint venture between Canadian and Soviet corporations.[84]

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76. Lenorovitz, *Ariane V44 Mission Delayed For Third-Stage Modification*, AVIATION WK. & SPACE TECH., June 3, 1991, at 21.

77. *Arianespace Expects to Sign New Launch Contracts Despite V36 Launch Failure*, AVIATION WK. & SPACE TECH., Mar. 19, 1990, at 191 [hereinafter *New Launch Contracts*].

78. *Arianespace Racks up Launch Business: Ariane 5 Set for Launch in 1995* (advertiser sponsored market supplement), AVIATION WK. & SPACE TECH., Nov. 27, 1989, at S4.

79. Raclin, *Going to Work in Space: A Survey of Presently Available Launch Systems*, 1 AMERICAN ENTERPRISE, *supra* note 9, at 30, 47. Practices similar to these ultimately led Transpace Carriers, Inc. to pursue Section 301 relief based on allegations of two-tier pricing. *Id. See also infra* notes 261–65 and accompanying text.

80. *Ariane Will Broaden Launch Services to Counter Competition*, AVIATION WK. & SPACE TECH., Sept. 3, 1990, at 100.

81. Arianespace has such a strong international reputation among launch services customers that its February 22, 1990 failure did not impair any of its current contract negotiations. Arianespace concluded an important contract with Hughes Communications, Inc., one of the leaders in satellite production, immediately following the failure. *New Launch Contracts*, *supra* note 77, at 191. Recent Arianespace innovations include the development of a small payload module. Lenorovitz, *Commercial Flight Slots Offered for Auxiliary Payloads on Ariane*, AVIATION WK. & SPACE TECH., Feb 5, 1990, and the Ariane 5, which represents a 50% increase in capacity to GTO over its predecesor, the Ariane 4, R. TRULY, *supra* note 45, at 16. This development will also allow Arianespace to be more competitive with the Titan in the market for very large satellites. *See supra* notes 39–40 and accompanying text.

82. OFFICE OF TECH. ASSESSMENT, *supra* note 34, at 122.

83. Bristol had planned to develop a rocket capable of carrying 8000 pounds to LEO and 1700 pound to GTO by 1988. *Id.*

84. Hughes, *Soviet–Canadian Joint Venture to Design, Launch Satellites*, AVIATION WK. & SPACE TECH., Nov. 12, 1990, at 77, 79.

2. *JAPAN*

Japan's H-I launcher was developed from American Delta technology, and thus is burdened with a requirement that it not be used for commercial launches.[85] Japan is developing its H-II rocket from indigenous technology, however, so similar restrictions will not be placed on its use.[86] When the H-II is completed in 1993, the Japanese will likely become a major competitor in launch services.[87] Japan could be hindered by the limited availability of its launch facility, however, which can only be used for two 45-day periods every year.[88] Not only might this reduce Japan's ability to provide reliable, on-time launch services, but the development of the program as a whole could be slowed if any of the launch windows are wasted.

3. *CHINA*

The Chinese, who launched their first satellite in 1970,[89] have recently become involved in the commercial launch business as well. They are marketing launches to GTO on their Long March 3 and Long March 4 rockets[90] and have attracted several customers with their low prices.[91] These low prices are offset somewhat, however, because commercial launchers face additional preparation costs not incurred when launching from more advanced Western launch sites.[92] Although Chinese launches of American satellites are subject to strict export licensing requirements,[93] the Bush Administration recently approved

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85. OFFICE OF TECH. ASSESSMENT, *supra* note 34, at 120.

86. *Id.* The H-II will have the capability to lift a 2000 kg satellite to GTO, as compared with around 500 kg for the H-I. Swinbanks, *Engine Problems Shake Japan's Space Plans*, 340 NATURE 253 (1989).

87. Swinbanks, *supra* note 86, at 253. Recent problems with the engines of the H-II, have led to the delay of its first launch by a year. *Japanese Consider Further Changes in H-2 Booster's Rocket Engine*, AVIATION WK. & SPACE TECH., Oct. 15, 1990, at 30. Shortly after the H-II is ready, it will be complemented by reentry module currently under development. The module, which will allow an 800 kg payload to be exposed to up to seven days of microgravity before being returned to Earth, will give Japan an advantage in materials processing and with scientific customers. *Japan Reschedules H-1 Mission After Launch Pad Abort*, AVIATION WK. & SPACE TECH., Sept. 4, 1989, at 23.

88. Swinbanks, *First Setback for Japan*, 340 NATURE 493 (1989).

89. OFFICE OF TECH. ASSESSMENT, *supra* note 34, at 120.

90. The Long March 3 has a payload capacity of 1400 kg to GTO, and the Long March 4 a capacity of 2500 kg into sun synchronous orbit. Corcoran & Beardsley, *supra* note 1, at 75. As for reliability, the Chinese claim that the Long March family of boosters has produced only two failures in twenty-two launches, the last in January 1984. Proctor, *China Returns Salvaged Spacecraft to Orbit*, AVIATION WK. & SPACE TECH., Apr. 16, 1990, at 25.

91. The price for the April 7, 1990 launch by the Long March of the Asiasat 1 communications satellite was also approximately $30 million. Proctor, *supra* note 90, at 28. This price was probably introductory in nature.

92. *Id.* at 28.

93. *See infra* notes 272–314 and accompanying text.

licenses for three satellites. The Department of Transportation's Office of Commercial Space Transportation has expressed concern, however, that the pricing of Chinese launch services and the high number of launches violate a January 1989 agreement limiting China to nine commercial launches over the next six years and requiring pricing at market rates.[94] China can use its ever-expanding role in the launch market as an excellent way to generate foreign exchange, so long as America and other satellite producing countries allow export for launch in China.

4. *THE SOVIET UNION*

The Soviet Union is also interested in the ability of commercial launch opportunities to generate hard currency. The Soviets have launched several satellites for other governments[95] and have been interested in the commercial market since 1983.[96] The Soviets may find it difficult to sell launch services to commercial users from the United States; U.S. export control regulations pose an even greater barrier for the Soviets than for the Chinese.[97] Nevertheless, the Soviets are aggressively marketing the services of their Proton launcher and the other elements of their space program.[98]

The Soviets have a broad range of available launch vehicles,[99] and other than NASA, they are the only competitor capable of providing full-

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94. *Chinese Deal to Launch Arabsat Renews U.S. Concerns About Long March Pricing*, AVIATION WK. & SPACE TECH., Apr. 9, 1990, at 25 [hereinafter *Chinese Deal to Launch Arabsat*]. The Department of Transportation believes that the American commercial market cannot bear more than the nine allotted Chinese launches without crossing the "pain threshold." *Id. See also infra* note 265 and accompanying text.

95. As of 1989, the Soviets had launched a total of nine foreign satellites: four Indian, three French, and one each for Czechoslovakia and Bulgaria. GLAVKOSMOS, COMMERCIAL USES OF SPACE EXPLORATION 12 [author's pagination, actual pages not numbered] (1989) (Glavkosmos marketing brochure)

96. The Soviets first bid to provide commercial launch services for the launch of the Inmarsat communications satellite occurred in 1983. OFFICE OF TECH. ASSESSMENT, *supra* note 34, at 117.

97. This is because of the "China Green Line," discussed *infra* at note 297.

98. Already a German firm has taken advantage of Glavkosmos' low rates to launch the first of a series of five experiments on a Soviet Proton, and the Energetics Corporation of the U.S. has responded to flexible terms by Glavkosmos by concluding a $54 million agreement to carry up to eight Energetics experiments as secondary payloads on future Proton launches. Asker, *Glavkosmos Signs Energetics as First U.S. Launch Customer*, AVIATION WK. & SPACE TECH., Nov. 20, 1989, at 40.

99. In addition to the Proton, which is capable of launching 21,000 kg into LEO, and 2200 kg to GTO, the Soviets are also offering for commercial launches the Vostock booster (for sun-synchronous payloads up to 1840 kg), the Soyuz (for LEO payloads up to 6900 kg), the Molnia (to place payloads of up to 1800 kg into highly elliptical orbits), and the Tsiklon (4000 kg to LEO). GLAVKOSMOS, *supra* note 95, at 13–21. The Soviets also possess the largest available rocket, the Energia, which can launch up to 105 metric tons to LEO. Corcoran & Beardsley, *supra* note 1, at 74–75.

service space transportation.[100] Indeed, the first American company to receive an export license to use a Soviet launcher went to the Soviets precisely because of their ability to provide long-duration exposure to microgravity.[101] The Soviets have also shown innovation in developing portable commercial launchers.[102] However, to be truly successful in the international market, the Soviets will need to allow greater customer access to their production facilities so that customers can better analyze the quality of the launchers before entering into launch contracts.[103]

5. *BRAZIL AND INDIA*

For the time being, Brazil and India are only marginal players in commercial launch services and will probably remain so in the near future. India presently possesses the capability to launch satellites into orbit,[104] and Brazil anticipates the launch of its own rocket in 1992.[105] Although both countries have had recent difficulties that may make them hesitant to undertake the risks of commercial launching,[106] their ability to launch for themselves could lead them to avoid seeking commercial launch services on the open market.[107]

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100. The Energia arm of the Soviet space program is mounting a marketing campaign parallel to that of Glavkosmos. *Energia Group Offers Commercial Services*, AVIATION WK. & SPACE TECH., Sept. 18, 1989, at 28. Energia offers the use of the Mir space station, as well as Soyuz manned flights and long-duration missions. *Id.* Soviet advantages in this area include human monitoring and adjustment of experiments as they progress, as well as a four-day turnaround from when an experiment is delivered in Moscow until it is unpacked on the Mir station, which could be a tremendous advantage for less stable payloads. GLAVKOSMOS, *supra* note 95, at 30–37.

101. *See* Asker, *Crystal Experiments on Mir Signal Soviet Commercial Space Push*, AVIATION WK. & SPACE TECH., Apr. 2, 1990, at 28. The Soviets are building on their already formidable advantage in materials processing by adding a large new materials processing module to the Mir station. Covault, *Soviet Mir Cosmonauts Await Launch of Large Materials Processing Module*, AVIATION WK. & SPACE TECH., Apr. 23, 1990, at 27.

102. *Laser-for-Burger Swaps*, ECONOMIST, Mar. 3, 1990, at 78, 80. This type of launcher presents an interesting dilemma for regulating trade in launchers, since the launcher would be moving through international commerce as a good rather than as a service. *See generally infra* notes 204–70 and accompanying text.

103. The Soviets have already increased the vertical integration of information within their space program. Lenorovitz, *Soviet Space Program Reflects New Policies Initiated by Gorbachev*, AVIATION WK. & SPACE TECH., Dec. 18, 1989, at 52, 57. This openness will lead to better quality control and more comprehensive decision making. *Id.*

104. OFFICE OF TECH. ASSESSMENT, *supra* note 34, at 120.

105. Although Brazil had successfully launched 130 pounds aboard its Sonda III rocket to an altitude of 380 miles on a suborbital flight, *id.*, its program has progressed little since that time, Neto, *Brazil's Two-Thirds VLS Success*, 339 NATURE 329 (1989).

106. *See* Neto, *supra* note 105, at 329; Jayaraman, *Indian Launch Vehicle Grounded*, 340 NATURE 587 (1989).

107. Brazil has already shown this inclination, preferring to wait for the development of an indigenous launcher before launching its already completed Data Collection Satellite (SCD-1). Neto, *supra* note 105, at 329.

6. *OTHERS*

Most of the other countries that are developing rocket technology are doing so because of its military potential and are therefore concerned more with ballistic missiles, which need not be as powerful as rockets that attain low earth orbit.[108] Commercial programs, although internationally more respectable than military ones, will probably not be looked on with much favor by the major powers, especially since Iraq demonstrated the power even a rudimentary rocket program could provide.[109]

Other countries are attempting to enter the commercial launch market by providing launch sites. Australia has chosen to cooperate with the space powers by developing its own commercial spaceport at Cape York, Queensland,[110] and Mexico was the site of a recent launch for the Spaceport Florida Authority.[111]

C. Demand for Launch Services

Unlike the supply of launch services, which underwent a veritable explosion in the late 1980's and early 1990's, demand for launch services has remained static. This is a troubling development for the many companies attempting to enter the commercial market in the 1990's. Demand for launch services comes from two different sectors: public sector users and commercial users. Demand in these sectors is motivated by different factors. In order to analyze the commercial viability of

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108. In addition to Brazil and India, 13 developing or newly industrialized countries (Argentina, Egypt, Indonesia, Iraq, Israel, Libya, Mexico, Pakistan, Peru, the Philippines, South Africa, South Korea, and Taiwan) have rocket development programs driven by the desire to gain prestige through technological independence, and in many cases by the desire to improve national security. Karp, *The Commercialization of Space Technology and the Spread of Ballistic Missiles*, in INTERNATIONAL SPACE POLICY, *supra* note 2, at 179, 181.

109. *See* Smith, *Scud Propulsion Designs Help Patriot System Succeed*, AVIATION WK. & SPACE TECH., Jan. 28, 1991, at 28.

110. The spaceport will be available to all launchers. The Soviet Union is particularly interested in the Cape York program because it provides access to equatorial launching, which is less expensive. The Soviets were scheduled to begin launches in 1992, but the program ran into trouble when Australia was told by COCOM (the NATO Coordinating Committee on East-West trade policy) that any use of the facility by the Soviets might prevent its use by COCOM members, due to concerns over technology transfer. Ewing, *Queensland's Space Base Threatened*, 339 NATURE 650 (1989). The project depends a great deal on the accession of U.S. policymakers, as the denial of export licenses for either construction equipment or satellites could prove fatal to the project. Asker, *Australians Pitch Cape York Complex as Best Way to Ease Soviets into Launch Market*, AVIATION WK. & SPACE TECH., Apr. 9, 1990, at 25. There has been some progress: on August 22, 1990, President Bush authorized the State Department to allow an American company's satellites to be launched at Cape York. *President Authorizes U.S. Participation in Australian-USSR Space Launch Venture*, 7 Int'l Trade Rep. 1326 (Aug. 29, 1990) [hereinafter *President Authorizes U.S. Participation*].

111. *New Spaceport to Conduct First Launch from Mexico*, AVIATION WK. & SPACE TECH., June 3, 1991, at 21.

domestic and foreign launchers, it is necessary to understand the factors that drive competition in each area of demand.

1. *PUBLIC SECTOR USERS*

Public sector users of launch services include any users that are under government control and may thereby be compelled to use a governmental launch system.[112] Some of these are civilian users, such as national space agencies, weather services, research institutions and other government-supported scientific endeavors; others are national security users, such as defense departments, that have a variety of needs ranging from early warning, communications and spy satellites to space-based weapons programs.

Public sector users could account for as much as 75% of demand through at least the mid-1990's;[113] however, it is unlikely that private launchers will be able to capture a significant share of this market, even where private launching is more economically efficient. Although the cost of launching may enter into government calculations when developing a launch system,[114] once funds have been expended to bring a launch system to maturity, public sector users will usually be compelled to use the government system, regardless of cost.[115] The overwhelming importance of non-economic factors in the governmental sector of demand make price of much less concern. This is because a government will take into consideration the same concerns for national security and national prestige that motivated its desire to develop a launch program in the first place.[116]

Although public sector users may often be unable to use private launch systems, they can still have a beneficial effect on such systems. By limiting their consideration of non-economic factors to situations wherein those factors are pertinent, and by purchasing the remainder of their launch services from commercial providers, public sector users can increase demand for private launch services enough to make commercial launching feasible. With an assured level of demand from public sector

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112. This Comment includes in the public sector of demand only those countries that are able to provide their own launch services and thus avoid seeking launch services on the commercial launch market. The demand of those countries which do not possess launch capabilities are included in commercial demand.

113. OFFICE OF TECH. ASSESSMENT, *supra* note 34, at 122.

114. *See* Logsdon, *supra* note 5 (discussing the various considerations, including cost, in developing the space shuttle as the United States' primary launch vehicle).

115. Indeed, the United States pursued this policy of using governmental payloads to subsidize the commercial prices charged by NASA to maintain its market share in the face of competition from Arianespace. Logsdon & Williamson, *U.S. Access to Space*, SCI. AM., Mar. 1989, at 34, 35.

116. OFFICE OF TECH. ASSESSMENT, *supra* note 34, at 67. Maintaining a launch system regardless of its cost to the governmental users is also thought to be necessary to achieve technological synergies. Hertzfeld, *supra* note 12, at 206.

users, private launchers can then achieve economies of scale for the commercial sector. For American launchers, government business can be a tremendous boon, since the U.S. government spends a total of $33 billion per year on space.[117] This potential was partly realized by the increase in ELV business during the shuttle launch standdown that followed the Challenger accident.[118] Commercial launchers can also achieve economies of scale when the government purchases launch systems for its own use that are similar to those used by commercial launchers since this will reduce the cost of each booster.[119] Thus, so long as government does not invade the commercial launch market with its own subsidized launch systems, it can have a positive effect on commercial launchers.

2. *COMMERCIAL USERS*

Because private launchers cannot expect to capture much of the demand from public sector users, they must rely on the commercial sector for much of their business. Though presently small,[120] the commercial sector has much potential for future growth.

At present only the communications satellite market is fully mature and profitable.[121] This market was commercialized very early in its development, first with the American Comsat consortium, and later with Comsat's international successor, Intelsat.[122] Intelsat remains the most important international producer of communications satellites, but its satellites are very large, so that only those companies with the largest launchers are in a position to compete for Intelsat launches.[123] American satellite producers currently have a dominant share of the communications satellite market,[124] and thus provide the strongest customer base for American launchers.

Other markets, though presently less mature, may in the future play a significant role in generating commercial demand, particularly for

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117. *The Moon is Made of Gold*, in *The Uses of Heaven*, ECONOMIST, June 15, 1991, Supp. at 6.

118. *See, e.g., supra* note 40 (U.S. Air Force's contracts with Martin-Marietta).

119. CONGRESSIONAL BUDGET OFFICE, *supra* note 68, at 30–31. Similar savings are also expected for Arianespace, however. *See supra* note 78 and accompanying text.

120. Of the 136 satellites launched in 1989, only 16 were commercial. *International Space: Teaming Spurs New Growth* (advertiser sponsored market supplement), AVIATION WK. & SPACE TECH., Mar. 12, 1990, at S1 [hereinafter *International Space*].

121. Hertzfeld, *supra* note 13, at 208.

122. *See generally* Kwerel & Pitsch, *FCC Regulation of International Telecommunications Satellites and Cables*, in 2 AMERICAN ENTERPRISE, *supra* note 9, at 119, 119–41.

123. *Id.* at 122.

124. American companies produced nearly 70% of all communications satellites from 1980 to 1989, and are expected to continue with a market share of around 60% for 1990 to 1995. *Business as Usual*, in *The Uses of Heaven*, *supra* note 117 at 8.

smaller launch vehicles.[125] Among these nascent markets are remote sensing satellites,[126] materials processing,[127] and "lightsat" communications systems[128] such as Motorola's proposed Iridium communications network.[129]

D. Outlook for the Future

The commercial space launch industry is at a crucial phase in its development. The U.S. government has finally decided to encourage the development of the industry and to cease its own commercial launches. But commercial launchers are not necessarily any better off with the passing of NASA as a commercial competitor. Arianespace had already eclipsed NASA as the primary threat to commercial ventures by the late 1980's, when the commercial market first started to grow. Arianespace and the three major American launchers are presently fairly evenly matched,[130] but other countries are entering the market and could easily erode their market shares.

Over the short term, competition for launch services will be quite stiff. Projections of demand for launch services by all users prior to the Challenger accident were, for the most part, overly optimistic.[131] Much of

125. *See International Space*, *supra* note 120, at S10.

126. Though originally a governmental activity, remote sensing has begun commercialization with the privatization of Landsat and the development of the French SPOT system. *See generally* Henderson, *Private Sector Satellite Remote Sensing: Barriers to Commercialization*, in 2 AMERICAN ENTERPRISE, *supra* note 9, at 79. Other such systems are under development, Uhlir, *The Public International Law of Civilian Remote Sensing: An Overview*, in 2 AMERICAN ENTERPRISE, *supra* note 9, at 25, 65, but it remains to be seen how much additional demand this will create. The real potential for commercialization in remote sensing is in interpretation of data, rather than in the launching of new satellites. *The View from Nowhere*, in *The Uses of Heaven*, *supra* note 117, at 16, 18.

127. Experiments in materials processing can make use of short-term microgravity available from re-entry modules. Corcoran & Beardsley, *supra* note 1, at 85. OSC recently launched its first Prospector rocket, which though a failure was aimed specifically at providing microgravity for small companies and universities. *See Orbital Sciences Team Seeks Cause of Prospector Rocket Launch Failure*, AVIATION WK. & SPACE TECH., June 24, 1991, at 30. Materials processing still involves a great deal of government activity, OFFICE OF TECH. ASSESSMENT, *supra* note 34, at 419, but is becoming accessible at relatively low cost for small scale commercial applications. *Id.* at 340.

128. "Lightsat" systems use a large number of small satellites in low earth orbit, rather than one expensive satellite in geosynchronous orbit. *See International Space*, *supra* note 120, at S1.

129. *See* Klass, *Motorola's Iridium Satellite System Could Serve Aviation Market*, AVIATION WK. & SPACE TECH., June 3, 1991, at 80, 80–81.

130. Arianespace launched 30 satellites for American customers from 1980 to 1990, as compared to 27 launches for European customers by the three main American launchers. *The Moon is Made of Gold*, *supra* note 117, at 6. Of third market customers Arianespace launched 16 satellites as opposed to 11 launched by the Delta, Atlas and Titan. *Id.*

131. The official government projections for launch demand predicted huge increases in the late 1980's giving way to a steady high demand market in the 1990's. CONGRESSIONAL BUDGET OFFICE, *supra* note 68, at 7. Demand was measured in these projections in "shuttle equivalents" (50,000 pounds to LEO), with most commercial ELVs

this resulted from an overestimation of the performance of the space shuttle. As the program became more expensive, NASA continually downgraded its estimate of demand for shuttle services.[132] The backlog of launches created by recent failures has helped to keep demand constant over the past few years, but will eventually be cleared.

Over the long term, demand looks to be even softer than over the short term. Although the Challenger accident reduced short-term confidence in space launching, long-term demand should not be affected;[133] however, other factors could have an important impact on future demand. Improvements in technology have the potential to increase the life span of satellites[134] and reduce reliance on space-bound applications.[135] At present, launchers foresee commercial demand for satellite launches of around 20 to 25 launches in 1990 and 18 to 20 in future years,[136] though the Hughes Space and Communications Group places that number much lower, at around 10–12 per year.[137]

While demand for large-payload launch services diminishes, the supply of launchers will increase. Commercial providers will have the ability to perform slightly over 20 launches to GTO per year during the 1990's.[138] The Soviets and the Chinese can probably increase the availability of their launchers, if export controls on their use are relaxed.[139] Under Hughes' constrained scenario, competition could become fierce, and it is possible that some of the American commercial providers could be forced from the market by governmental providers with deeper pockets.

The future market for small-payload launchers is much harder to predict. The technologies demanding small-payload launch services are

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carrying between .25 and .7 shuttle equivalents. *Id.* at 6. From a total U.S. demand of 12 shuttle equivalents in the 1980's projections quickly rose to more than 30 in 1989, and then hovered around 30 throughout the 1990's. Commercial demand was put at between 5 and 9 shuttle equivalents per year through 2000. *Id.* at 7–9.

132. CONGRESSIONAL BUDGET OFFICE, *supra* note 68, at 10–11.

133. This is because government demand, which is not very price responsive, makes up such a large component of overall demand. Hertzfeld, *supra* note 12, at 214.

134. *See* Dornheim, *supra* note 37, at 76.

135. *See* Hertzfeld, *supra* note 12, at 209. Alternatives to launching new satellites are being considered even for such obviously space-bound applications as weather satellites. The Commerce Department is considering the use of existing European or Japanese weather satellites rather than launching a new one. Asker, *NOAA and Congress Ponder Backups for Troubled Weather Satellites*, AVIATION WK. & SPACE TECH., June 15, 1991, at 22, 22–23.

136. *International Space*, *supra* note 120, at S4. Arianespace has proffered similar estimates of demand in its "nominal" case of 15–19 launches per year and its "maximum" case of 18–24 per year. *New Launch Contracts*, *supra* note 77, at 191.

137. Dornheim, *supra* note 37, at 73.

138. CONGRESSIONAL BUDGET OFFICE, *supra* note 68, at 24.

139. *See supra* notes 89–103 and accompanying text; *infra* notes 272–314 and accompanying text.

not as well developed.[140] As a result, this segment of the market will be much more price sensitive. Any company that experiences more than one or two launch failures could easily fail.[141]

The effect of future developments in launch technology is also uncertain. At present ELVs are still the only way for commercial launchers to lift payloads into orbit, and no new technology is likely to supplant ELVs in the near future. However, innovation could lead to the development of alternative technologies, such as gun launchers,[142] which could capture a large portion of the small payload market if a workable system is developed. For large payloads, it is conceivable that the space shuttle or the proposed aerospace plane could become more economical for launches to low earth orbit, but this will happen only if full-scale commercial development is pursued. Other technologies are even further from availability.[143]

Given that the market for launch services is contracting, and that there are no presently viable alternatives to ELVs, competition between the various ELV launchers is certain to become more intense. New competitors are entering the market with below-cost pricing in order to gain market share.[144] Subsidization by foreign governments of their launch companies could easily damage the domestic commercial launch industry and threaten its viability. If the government does not take some action to safeguard the industry, America could lose an industry that is essential for the commercialization of space.

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140. *See supra* notes 46–65 and accompanying text. The remote sensing market is already fairly saturated with services available from the United States' Landsat, French SPOT, and Soviet Meteor, and many other countries are developing systems of their own. Uhlir, *supra* note 126, at 65. The potential of materials processing is very hard to predict. The time to develop technologies are quite long and many of the improvements developed in space are at least partially effective on Earth, reducing the need for further launches to microgravity. *See* Hertzfeld, *supra* note 12, at 209–11. In any event, materials processing is unlikely to blossom into a mature technology until the space station is completed, though the commercial use of the Soviet Mir station, *see supra* note 100, could give some corporations a head start. Although transmission from direct broadcasting satellites (DBS) is expected to increase, the actual number of satellites in use is expected to grow relatively slowly. Dornheim, *Mass Market for Satellites to Be Tested over Next Decade*, AVIATION WK. & SPACE TECH., Mar. 19, 1990, at 189.

141. As insurance costs become a greater part of the total cost of launching, low launch prices will not have the same inducement if a launcher is labelled as a bad insurance risk. *See supra* note 62 and accompanying text.

142. Henderson, *Sandia Researchers Test 'Coil Gun' for Use in Orbiting Small Payloads*, AVIATION WK. & SPACE TECH., May 7, 1990, at 88, 88–89.

143. The Air Force is currently developing its Advanced Launch System (ALS) that would carry heavy payloads into LEO for a cost of around $300 per pound. Logsdon & Williamson, *supra* note 115, at 40. It will in no event be developed before the beginning of the next century. *Id.* The ALS might make it possible to ferry satellites to the space station at very low cost and then launch them to geosynchronous orbit from from there. *Id.* If this proves feasible, the market for single payload launchers could evaporate.

144. *See supra* notes 79, 91, 94, and accompanying text.

IV. POSSIBLE GOVERNMENTAL RESPONSES

As competition in the commercial launch industry heats up, the U.S. government will be faced with a choice. Either it can seek to protect the domestic launch industry and ensure its survival, or it can reenter the commercial launch market to guarantee full access to space for American interests. Analysis will show that the latter alternative is unrealistic, and that the United States must take steps to preserve the domestic launch industry. Because the current market situation is competitive, the United States does not need to rush into a decision on regulating trade in launch services, but some international regime will be necessary as demand slackens and more suppliers come into the market. In this area it is important for the government to look at the entire market and arrive at a solution that addresses all the actors. It must consider the roles of governmental and private launchers, both domestic and international. It must also consider the needs of both public and private users, as well as a host of collateral concerns.

A. The Government's Role in Launch Services

Reentry by the government into the commercial launch market might, at first, seem like an attractive alternative to attempting to preserve the viability of private launchers. NASA could return to the launch business, or the government could form a "United States Space Transportation Company" with the government as a major or perhaps majority owner. The shuttle would be used for commercial missions in some cases, but the bulk of U.S. commercial launch business would continue to be carried by ELVs.[145] Space shuttles would have to be operated at higher capacity and additional orbiters might have to be constructed. Either direct NASA competition or a U.S. Space Transportation Company would enjoy the benefits of tremendous size and versatility of services from the availability of both the shuttle and ELVs,[146] as well as the ability to subsidize commercial launches with captive government launches that could be budgeted at higher cost.

There are a number of important drawbacks to such a scenario. First, it is unlikely that new shuttle capacity could be added at costs below the going market rate,[147] so the government would be forced to

145. *See* CONGRESSIONAL BUDGET OFFICE, *supra* note 68, at 45. The government itself uses the cost advantages of ELVs. Kolcum, *U.S. Maintains Busy Manifest of Manned, Unmanned Launches*, AVIATION WK. & SPACE TECH., Mar. 19, 1990, at 182, 184.

146. CONGRESSIONAL BUDGET OFFICE, *supra* note 68, at 48–49.

147. *See supra* note 6 and accompanying text. However, NASA could efficiently sell excess capacity on governmental shuttle missions since the capacity would otherwise be wasted. Covault, *Spacelab Flight Carries 2.5 Tons of Getaway Payloads*, AVIATION WK. & SPACE TECH., June 24, 1991, at 57. The Columbia recently carried several small payload "Getaway Specials" on its Spacelab mission. *Id.*

subsidize flights on the shuttle. Although this would work to the benefit of shuttle contractors, it would inefficiently take business away from profit-making ELV launchers and give it to a continually loss-generating program. The shuttle has proven to have many unique uses, but it is not the "space truck" it was originally intended to be. The cost of the orbiter and the human component involved in its launches require more preparation and care, which often lead to long delays.[148] But the political necessity of maintaining a manned space program would probably force continued over-reliance on the shuttle in spite of these costs.[149]

Regardless of the care involved, all launchers will at some point fail,[150] and the government needs commercial launchers as a backup for its own programs. A failure of an ELV can be an incredible loss—in the hundreds of million dollars—but the loss of a shuttle is catastrophic. Over-reliance on the shuttle also shuts down U.S. launch capabilities following a failure, as in 1986.[151] The existence of an alternative launcher would allow the government to continue launching important payloads during a shuttle launch standdown. Although the government could purchase ELVs for such an eventuality, it is possible that Congressional estimates of the number of ELVs needed, or the likelihood of shuttle failure, would prove overly optimistic. With launch services in the private sector, the government can be assured of an alternate launcher unimpeded by bureaucratic optimism. Moreover, shifting the costs of research and development of ELVs to the commercial providers would be more efficient and lead to the use of only those launchers that were economically feasible.[152]

Because of the inefficiency of government launch programs, it is clear that the U.S. government should not reenter the commercial launch industry. With the help of the changes in governmental policies since the Challenger accident, commercialization of launch services is already well underway, a development that should be encouraged. But even if the private sector can provide launch services more efficiently than the

148. *See* Kolcum, *NASA Due for Organizational Changes to Meet Aerospace Demands of 1990's*, AVIATION WK. & SPACE TECH., Dec. 24, 1990, at 52.

149. *Id.*

150. Even if the space shuttle remains 98% reliable, there is a 72% chance that at least one orbiter will be lost before assembly of the space station begins in 1995, according to the Office of Technology Assessment. Covault, *Panel Calls Shuttle Accident 'Likely' Unless Propulsion Systems Redesigned*, AVIATION WK. & SPACE TECH., Apr. 23, 1990, at 21.

151. The United States lost full access to space for nearly three years following the Challenger accident. Logsdon & Williamson, *supra* note 115, at 34.

152. *See generally* Cohen & Noll, *Government R&D Programs for Commercializing Space*, 76 AM. ECON. REV. 269 (1986). There are arguments that any commercial R&D by government is inefficient. Since members of Congress are interested in getting reelected, they are often motivated by a desire to see jobs produced in their districts before the next election, rather than by any interest in the long-term goals of the project. *Id.* at 270. Government programs also tend to be slower and more complicated, since they attempt to solve many problems with one program. *The Moon is Made of Gold*, *supra* note 117, at 6–7.

government, some governmental involvement at the regulatory level is needed to prevent hypercompetition and unfair trade practices by foreign launchers. Such efforts will undoubtedly increase costs to launch service users to the extent they successfully remove government subsidization of launching, but such a cost structure will lead to investment in space systems only when truly economical. The government has several options: industrial policy, implemented either through "targeting" the industry for special governmental treatment, or through the use of demand side pressure; cartelization of the market with other launch powers; the use of the current trade regulations; or inclusion of launch services under the proposed GATT services agreement. Not all options are compatible, nor are they mutually exclusive.

B. Industrial Policy

The formulation of a national industrial policy for launch services is one way to help the domestic launch industry compete.[153] Indeed, advocates of industrial policy portray it as the best alternative to protectionist use of the trade regulations.[154] To implement such a program would require extensive legislation, though not nearly as much as would be required for an industrial policy in other sectors of the economy.

Because of their importance as a threshold to space and their significance to technological development, launch services are the kind of strategic industry that is typically targeted for industrial policy. The commercial launch industry is already a part of the huge American defense establishment, for which the government has at least a de facto industrial policy.[155] As defense cuts begin to reduce the effectiveness of defense policy at helping American industry, the government can simply recast some of the defense programs as industrial competitiveness programs and allow them to continue unabated. Regardless of how these programs are characterized, there are a number of means through which the U.S. government can help the commercial launch industry: direct subsidies, the passthrough of benefits from government funded research, development of infrastructure, demand pressure, and other indirect benefits used to increase profitability.[156] The option of direct subsidies to launchers faced with unfair foreign competition can be immediately

153. *See* Reynolds & Merges, *supra* note 32, at 27.

154. *See, e.g.*, Reich, *Making Industrial Policy*, 60 FOREIGN AFF. 852 (1982).

155. Whereas industries with primarily commercial applications are generally ignored by the United States government, those related to national security have enjoyed strong support. *Id.* at 864–65.

156. Reynolds & Merges, *supra* note 32, at 27–28.

rejected. Such an approach could be extremely expensive for government and would likely make the launch industry more inefficient.[157]

One approach with potential to help commercial launchers is to allow private industry to ride on the coattails of governmental research. The commercial airline industry is one that has benefited greatly from such an organized policy of coordination between military and commercial research programs.[158] Instead of using direct subsidies, the United States cloaked its subsidies by allowing commercial aviation to pass the technology gained from government programs through to commercial development.[159] For example, Boeing was able to save markedly on its development costs by using technology from the government's KC-135 program to develop the 707 aircraft.[160] Indeed for aviation, the American policy of coordination between government and private industry seems to have worked much better than the policies of many other countries in which government directly financed most commercial aircraft development.[161] Another example is the development of the commercial satellite industry. NASA contributed mightily to the development of the communications satellite industry by providing the impetus for its development and later allowing Hughes to pass the technology through to its commercial satellites. Hughes is still dominant in the commercial satellite market.[162] A similar effort by NASA or another government agency could greatly benefit the commercial launch industry.[163]

Helping to build the infrastructure needed by industry is another form of industrial policy.[164] The commercial launch industry, however, can obtain only limited benefit from such a policy because the infrastructure for space services is already well established. The United States has two fully-developed launch sites,[165] which should be adequate

157. Reynolds, *Space Law in the 1990's: An Agenda for Research*, 31 JURIMETRICS J. 1, 8 (1990).

158. R. NELSON, HIGH-TECHNOLOGY POLICIES: A FIVE NATION COMPARISON 52 (1984).

159. *See id.* at 51.

160. Mowery & Rosenberg, *The Commercial Aircraft Industry*, in GOVERNMENT & TECHNICAL PROGRESS: A CROSS-INDUSTRY ANALYSIS 101, 131 (R. Nelson ed. 1982). Through this program, Boeing was transformed from an extremely minor player in commercial aviation before 1958 into the dominant international producer of commercial jet aircraft today. *Id.* at 111.

161. *See* R. NELSON, *supra* note 158, at 51–57.

162. Reynolds & Merges, *supra* note 32, at 35–36 n.92.

163. The Air Force's Advanced Launch System, *see supra* note 143, could fill this role quite nicely.

164. Such a policy has benefitted both the railroads, through the granting of rights of way, Reynolds & Merges, *supra* note 32, at 30, and the housing and automobile industries through the construction of the interstate highway system, Reich, *supra* note 154, at 880.

165. These are the Kennedy Space Center in Florida and Vandenberg Air Force Base in California. W. VON BRAUN, F. ORDWAY & D. DOOLING, SPACE TRAVEL: A HISTORY 242, 244 (4th ed. 1985).

given the expected flat or declining demand for launch services.[166] The government, thus, has little to do except assure that the environment for infrastructure improvement is good, and that commercial launchers have reasonable access to the available government facilities.[167] The government probably does not need to do much more to establish better public launch infrastructure,[168] as this would be a poor allocation of scarce resources.[169] Subsidies for the construction of private launch facilities are unnecessary because the Commercial Space Launch Act provides private launchers with access to government launch sites.[170] The combination of the expense of building new launch sites and the need for government oversight required by both the Liability Treaty[171] and the Commercial Space Launch Act[172] militates against the operation of a private spaceport.

Government demand-side pressure can also be very effective, as it was in the case of airline development. The Kelly Air Mail Act of 1925, for example, privatized air mail carriage and reduced airmail rates while keeping payments to air carriers constant, a subsidy that greatly increased the volume of mail travelling by air.[173] The government could easily initiate a similar policy with NASA and Defense Department demand.[174] In the area of demand-side pressure, the United States enjoys a huge advantage over other countries because public sector demand for

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166. *See supra* notes 131–37 and accompanying text.

167. The government has already taken action to standardize the availability of government launch sites with the Air Force's *Model Expendable Launch Vehicle Commercialization Agreement* (2d rev., May 12, 1989). *See supra* notes 26–27 and accompanying text. The most recent amendments to the Commercial Space Launch Act direct the Secretary of Transportation to encourage public–private partnerships in improving and expanding the space launch infrastructure. Pub. L. No. 101–611 § 117(e)(3), 104 Stat. 3188, 3203 (1990), 49 U.S.C.A. § 2604(a)(3) (West Supp. 1991).

168. *See* Hertzfeld, *supra* note 12, at 206.

169. Building new launch sites could easily run into the billions of dollars. *Hearings, supra* note 27, at 317. *Cf.* Kolcum, *Titan Launch Complexes Being Rebuilt to Meet Target Date for Mars Observer*, AVIATION WK. & SPACE TECH., Feb. 4, 1991, at 53 (renovation of a launch complex is a $300 million project).

170. *See supra* note 26 and accompanying text.

171. Convention on International Liability for Damage Caused by Space Objects, Mar. 29, 1972, 24 U.S.T. 2389, T.I.A.S. 7762.

172. 49 U.S.C. § 2613 (1988).

173. Mowery & Rosenberg, *supra* note 160, at 140–41. The McNary-Watres Act of 1930 helped airlines to purchase faster planes by rewarding carriers that used radios, multi-engine aircraft and other innovations. *Id.*

174. Space systems is one area of the military budget that has heretofore escaped major budget cuts, and the military is preparing to launch its next generation of surveillance satellites during the 1990's. Smith, *U.S. Military to Increase Reliance on Space Systems in Coming Decade*, AVIATION WK. & SPACE TECH., Mar. 19, 1990, at 187, 187–188. Since the Air Force is presently using only the Titan IV, however, the benefits of increased defense satellite usage might accrue only to Martin-Marietta. *See supra* notes 39–40 and accompanying text.

launch services is so large.[175] President Bush has already announced that launch of U.S. government satellites will be restricted to domestically manufactured vehicles unless specifically exempted by the President.[176] Given that the U.S. government accounts for 90% of U.S. demand and 40% of world demand for space products,[177] such a preference could be of great aid to the domestic launch industry. Demand-side pressure, though not an effective way to build infrastructure, is a relatively inexpensive way to increase the profitability of domestic launchers.

Profitability can also be increased by providing tax breaks or loans,[178] or by easing restrictions on industry.[179] One of the simplest means of easing restrictions on industry is by limiting liability. This approach has been used to encourage industry since the informal application of favorable tort treatment for railroads in the nineteenth century.[180] Later manifestations have been statutory, such as the Warsaw Convention,[181] and Section 4 of the Price-Anderson Act of 1957.[182] Section 16 of the Commercial Space Launch Act[183] is a good start at limiting the liability of commercial launchers, and should substantially ease the burdens on the industry. Antitrust exemption can also be beneficial,[184] as it was in the merger that produced McDonnell-Douglas in 1967.[185]

Despite its general aversion to governmental support of industry,[186] the Bush Administration has recently made some proposals to benefit

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175. *See supra* note 117 and accompanying text. A similar advantage allowed government demand to drive the American aircraft industry but not that of the Japanese. R. NELSON, *supra* note 158, at 57.

176. *Bush Issues Policy Directing Agencies to Focus on Commercial Space Industry*, 7 Int'l Trade Rep. (BNA) 1371 (Sept. 12, 1990) [hereinafter *Bush Issues Policy*].

177. Asker, *Demand for Space Products, Services Grows at Healthy Rate*, AVIATION WK. & SPACE TECH., May 28, 1990, at 51.

178. *See* Dula, *supra* note 11, at 186. For a discussion of the effects of the investment incentives of the Economic Recovery Act of 1981, see Thorning, *Investment Incentives: Do They Work?*, 31 TAX NOTES 515 (1986).

179. Efforts to increase profitability are generally framed as the removal of restrictions from the targeted industry, but these efforts do not necessarily lead to the savings being channeled into the improvement of profitability. Reich, *supra* note 154, at 857–59.

180. Reynolds & Merges, *supra* note 32, at 30–31.

181. Convention Relating to International Transportation by Air. October 12, 1929, 49 Stat. 3000, T.S. No. 876, 2 Bevans 983, 137 L.N.T.S. 11, *reprinted in* 49 U.S.C. § 1502 (1988) (international aviation).

182. 42 U.S.C. § 2210 (1988) (nuclear power accidents).

183. 49 U.S.C. § 2615 (1988). *See supra* note 22 and accompanying text.

184. For a discussion of the ability of antitrust exemptions to encourage innovation, see Jorde & Teece, *Innovation, Cooperation and Antitrust*, 4 HIGH TECH. L.J. 1 (1989).

185. Mowery & Rosenberg, *supra* note 160, at 113.

186. The Bush Administration recently sacked Craig Fields, the director of the Defense Advanced Research Projects Agency (DARPA), allegedly because he took an overly interventionist position on industrial policy and the role of government in United States technological development. His position reportedly ran afoul of the free market instincts

commercial space ventures. President Bush and congressional leaders have discussed such programs as federal "space bonds" and voluntary income tax checkoffs,[187] and the President has directed governmental agencies to "actively consider commercial space launch needs and factor them into their decisions."[188] State governments have also begun to coordinate space policy. Florida has organized the Aerospace States Association to coordinate state governmental efforts to support space technology.[189]

C. Cartelization

An alternative to domestic intervention into the commercial launch industry would be some form of international market cartelization. Such systems have been used in the past, notable examples being the United Nations Council on Trade and Development (UNCTAD) Convention on a Code of Conduct for Liner Conferences,[190] and airline capacity control agreements.[191] Indeed, the European Space Agency has expressed some interest in regulating prices,[192] and at least one proposal for controlling launch capacity has been made.[193]

The argument for capacity controls is that because so many launch providers are governments motivated by non-economic factors, some form of capacity controls is necessary to prevent a price war and "ruinous competition."[194] But capacity controls based on the airline and shipping

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of Budget Director Richard Darman and Chief Economic Adviser Michael Boskin. *Beheaded*, ECONOMIST, Apr. 28, 1990, at 27.

187. Asker, *Bush Lobbies Congressional Leaders for Support of U.S. Civil Space Efforts*, AVIATION WK. & SPACE TECH., May 7, 1990, at 31.

188. *Bush Issues Policy*, *supra* note 176, at 1371. Others have called for a cabinet level Department of Air and Space. *See* Engen, *New Air and Space Dept. Would Speed Progress Toward Meeting 21st Century Goals*, AVIATION WK. & SPACE TECH., Dec. 10, 1990, at 78, 78–79.

189. *Florida Leads Effort to Organize States with Stakes in Commercial Space*, AVIATION WK. & SPACE TECH., Sept. 17, 1990, at 41. In addition to Florida, representatives from the state governments of Alabama, California, Colorado, Hawaii and Virginia attended the Association's first meeting on July 31, 1990. *Id.* Other states, particularly Ohio, Texas, and Utah, have been invited to participate in future meetings. *Id.*

190. U.N. Reg. No. 22380, *reprinted in* 13 INT'L LEGAL MAT. 910–948 (1974) [hereinafter UNCTAD Code of Conduct]. As of December 1988, seventy-seven countries had signed, acceded to, or in some way approved of the Code of Conduct. These included the Soviet Union, the United Kingdom, Germany, India, and Brazil, but not the United States or Japan. UNITED NATIONS, MULTILATERAL TREATIES DEPOSITED WITH THE SECRETARY GENERAL (Status as of December 1988) (1989).

191. The International Air Transport Association (IATA) was set up as an "operators" conference similar to UNCTAD liner conferences. P. HAANAPPEL, PRICING AND CAPACITY DETERMINATION IN INTERNATIONAL AIR TRANSPORT: A LEGAL ANALYSIS 13–14, 18 (1984).

192. Raclin, *supra* note 79, at 52 n.83.

193. Jiefang, *Toward a Regulatory Regime for Competition in Space Transport*, in SPACE LAW: VIEWS OF THE FUTURE 57 (T. Zwaan ed. 1988).

194. *Id.*

models would be inappropriate because of important differences between those industries and the launch industry.[195] The most obvious difference is that launch providers, although suffering from high fixed costs, do not suffer from a problem of excess capacity. Because payloads are relatively small—one or two satellites at the most—filling a flight is much easier than filling a cargo ship or a commercial aircraft on scheduled service. Therefore, it is almost certain that every launch will be made at full cargo capacity. Even if the situations were more closely analogous, it is unclear how well capacity controls have worked in either the shipping industry or in aviation. The UNCTAD Code of Conduct has been criticized as "balkanizing" world trade in shipping by mandating national preferences,[196] and the wave of airline deregulation that shook the United States after 1978[197] appears to be imminent internationally.[198]

Analogies to primary product cartels, such as OPEC,[199] are also difficult. Although the service of launching is fungible, it is not a homogenous commodity like oil. The quality of service and its reliability can vary greatly. Under a system of capacity controls, certain commercial launch customers would therefore be relegated to inferior launch providers because the more reliable providers were fully booked. Governments would have to develop a system for yearly allocation of available satellites. A flat allocation based on current capabilities would be unable to respond to changing conditions, while a formula or ad hoc allocation could be exceedingly complex and politically charged. The cartel would have to make provisions for new members and for reallocating capacity within the cartel if a new launch power refused to join. Also, division of capacity between U.S. launchers would raise considerable antitrust concerns.[200]

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195. Once launchers begin carrying cargo and passengers to particular points in space, rather than simply into orbit, the analogy might be closer. Countries might want to impose capacity controls on service to their space stations and lunar bases to assure full utilization of capacity. *Id.* at 60–62. Even this scenario is a long way off, however, since it assumes low marginal costs and excess cargo capacity. At least with regard to lunar bases, capacity controls might be in violation of the Outer Space Treaty. Multilateral Treaty on the Exploration and Use of Outer Space, Jan. 27, 1967, 18 U.S.T. 2410, T.I.A.S. 6347, 610 U.N.T.S. 205. Article XII requires that "all stations . . . on the moon and other celestial bodies shall be open to representatives of other States Parties to the Treaty on a basis of reciprocity." *Id.* at 2418. Since the Treaty is widely accepted, this could prove a major barrier to capacity controls on lunar service.

196. The Code of Conduct could virtually eliminate international competition with its national preferences. *See* Kanuk, *The UNCTAD Code of Conduct for Liner Conferences: Trade Milestone or Millstone—Time Will Soon Tell*, 6 Nw. J. INT'L L. & BUS. 357, 358 (1984).

197. P. HAANAPPEL, *supra* note 191, at 50–56.

198. *Id. at* 57–60.

199. For a discussion of the structure and operation of OPEC, see Comment, *OPEC as a Legal Entity*, 3 FORDHAM INT'L L. FORUM 91 (1979–80).

200. In order to implement airline capacity controls, the Civil Aeronautics Board waived applicability of the antitrust laws. P. HAANAPPEL, *supra* note 191, at 83. The launch industry would require similar intervention.

Economically, cartels are difficult to sustain. Cartels can only exist if there are no good substitutes for the product, reasonable size of membership is maintained, administrative costs are low, and there is a low risk of defection and new entry.[201] There are certainly high barriers to entry into the launch industry, since governments can control who uses space, but membership in the cartel would have to include all the present and potential space powers to prevent cheating. It is also unclear whether demand for launch services is sufficiently inelastic to prevent the substitution of satellite alternatives, such as undersea cable. The administrative costs of cartels can be quite high, and the protected market can lead members to become less efficient.[202] This could be particularly problematic for launch services, since some members of the cartel would be governments, which are motivated by a host of political and other non-economic factors that could further hinder attempts at efficiency. If a cartel is only partially successful, the result can be the hypercompetitive market it was formed to prevent.[203]

D. Use of Existing Trade Regulations

Rather than intervene directly into the commercial launch market through either industrial policy or cartelization, the government could take the approach of using regulations—either national, international or both—to aid the commercial launch industry. The unilateral use of existing U.S. trade regulations would require the least legislative change and could probably be carried out entirely by the Administration. But the unilateral nature of the use of the U.S. trade laws could increase tension between the United States and other launch providers. Trade regulations that could be brought to bear on launch services include countervailing duty and anti-dumping laws, powers granted to the United States Trade Representative (USTR), and export controls.

1. *COUNTERVAILING DUTIES AND ANTIDUMPING MEASURES*

Although countervailing duties and antidumping measures are a primary way to combat unfair trade practices, both are aimed at the importation of goods into the United States. Countervailing duties are

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201. McGee, *Ocean Freight Rate Conferences and the American Merchant Marine*, 27 U. CHI. L. REV. 191, 197 (1960).

202. *Id.* at 199, 201.

203. If the cartel experiences enough success to maintain monopoly profits long enough for other parties to realize their value, there will be new entrants into the market. These new competitors will eventually cause the collapse of the cartel, and there will be even more competitors, with even more excess capacity, than before the cartel was formed. *Id.* at 202.

authorized by Section 303 of the Tariff Act of 1930.[204] If the U.S. International Trade Commission (ITC) finds that "any country . . . shall pay or bestow, directly or indirectly, any bounty or grant upon the manufacture or production or export, of any article or merchandise manufactured or produced in such country,"[205] it is to apply a countervailing duty equal to the "net amount of such bounty or grant."[206] However, imports produced in countries party to the General Agreement on Tariffs and Trade (GATT) Subsidies Code[207] are covered by Section 701(a) of the Act[208] rather than by Section 303.[209] Section 701 adds an injury requirement[210] to the basic rule of Section 303, and uses the term "subsidy" rather than "bounty or grant."[211] Subsidies are countervailable if they are aimed primarily at the export market,[212] or if they are "domestic" subsidies that provide a specific benefit to the producer.[213] Although the statute provides no specific rules for determining the amount of a subsidy,[214] the general rule is that the subsidy is equal to the cost advantage of the government-provided services over obtaining them on the open market.[215] Countervailing duty investigations may be instigated by the ITC[216] or by private petition.[217]

Antidumping law is also aimed at unfairly priced imports. Section 731 of the Tariff Act[218] provides relief against goods priced at "less than fair value,"[219] so it applies more to individual producers than do countervailing duties. Antidumping investigations may be initiated by the International Trade Administration (ITA)[220] or by private petition

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204. 19 U.S.C. § 1303 (1988).
205. *Id.* § 1303(a)(1) (1988).
206. *Id.*
207. Agreement on Interpretation and Application of Articles VI, XVI, and XXIII of the General Agreement on Tariffs and Trade, *opened for signature* June 30, 1979, GATT Basic Instruments and Selected Documents 58–83 (26th Supp. 1980) [hereinafter Subsidies Code].
208. 19 U.S.C. § 1671 (1988).
209. *Id.* § 1303(a)(1).
210. *Id.* § 1671(a)(2).
211. *Id.* § 1671(a)(1)."Subsidy" is defined by 19 U.S.C. § 1677(5), and is intended to have the same meaning as "bounty or grant."
212. *Id.* § 1677(5)(A)(i). These subsidies are listed in an annex to the Subsidies Code, *supra* note 207, Annex(a), at 80, but can be difficult to classify in practice. Sykes, *Countervailing Duty Law: An Economic Perspective*, 89 COLUM. L. REV 199, 203 (1989).
213. 19 U.S.C. § 1677(5)(A)(ii) (1988). Specific benefits are those provided to the producer alone rather than to the general public. Sykes, *supra* note 212, at 204.
214. Ipsco, Inc. v. United States, 899 F.2d 1192, 1195–96 (Fed. Cir. 1990). The court found that the ITC is often inconsistent in figuring the amounts of subsidies. *Id.* at 1197.
215. *See* Sykes, *supra* note 212, at 205.
216. 19 U.S.C. § 1671a(a) (1988).
217. *Id.* § 1671a(b).
218. *Id.* § 1673.
219. *Id.* § 1673(1).
220. *Id.* § 1673a(a).

through the ITC.[221] As do the countervailing duty laws, Section 731 has a material injury requirement,[222] and lists numerous factors to be considered in the determination of injury.[223] Section 731 also applies only to "merchandise."[224] The limitation to "merchandise" is consistent with GATT coverage of antidùmping, which allows antidumping measures only against dumped "products."[225] Services traditionally have not been covered by international and domestic antidumping regulations.[226] In addition to the trade laws, those injured by dumping may rely on Section 801 of the Antidumping Act of 1916,[227] which is part of the antitrust laws and provides for both criminal penalties and private suits.[228] The coverage of the 1916 Act is also limited to "articles" imported into the United States.[229]

At present, services do not fall within the technical coverage of domestic countervailing duty[230] and antidumping laws.[231] However, efforts are being made at both national and international levels to bring services within the coverage of antidumping regulations.[232] The developing GATT services agreement could provide some protection against dumping of services,[233] although the United States professes to

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221. *Id.* § 1673a(b).

222. *Id.* § 1673(2).

223. *Id.* § 1677(7)(B), (C). One factor that could be important for the commercial launch industry is the potential injury to the industry's ability to develop derivative technology, *id.* § 1677(7)(C)(iii)(IV), since many of the country's future space plans depend on development of technology by existing NASA contractors.

224. *Id.* § 1673.

225. General Agreement on Tariffs and Trade, Oct. 30, 1947, art. VI, 61 Stat. 5, 11, 58, T.I.A.S. No. 1700, 55 U.N.T.S. 187, 258.

226. Zerby, Ellsworth & Schmitt, *Dumping of Non-Factor Services: Some Implications of Recent Experiences with Controlled-Economy Shipping*, 4 NW. J. INT'L L. & BUS. 37, 38–39 (1982).

227. 15 U.S.C. § 72 (1988).

228. *Id.* The 1916 Act also allows the President to prohibit the import of the offending item. 15 U.S.C. § 75 (1988). For a discussion of the Antidumping Act of 1916, see Sidak, *A Framework for Administering the 1916 Antidumping Act: Lessons from Antitrust Economics*, 18 STAN. J. INT'L L. 337 (1982).

229. 15 U.S.C. § 72 (1988).

230. Currently countervailing duties may be imposed only on "any article or merchandise." 19 U.S.C. § 1303(a)(1) (1988). *See supra* note 205 and accompanying text.

231. 19 U.S.C. § 1673 (1988). *See supra* note 224 and accompanying text.

232. The European Community's GATT services proposal addresses the issue of dumping of services. Hindley, *Services*, in COMPLETING THE URUGUAY ROUND: A RESULTS-ORIENTED APPROACH TO THE GATT TRADE NEGOTIATIONS 130, 136 n.3. (J. Schott ed. 1990). One sector of services in which dumping has already been examined is that of shipping. Zerby, Ellsworth & Schmitt, *supra* note 226, at 51–56. More recently, there have been allegations of dumping by foreign providers on the U.S. market. *U.S. Supports Cross Retaliation Concept in GATT Services Talks, USTR Official Says*, 7 Int'l Trade Rep. (BNA) 1111, 1111 (July 18, 1990) [hereinafter *U.S. Supports Cross Retaliation*].

233. *U.S. Supports Cross Retaliation*, *supra* note 232, at 1111–12.

prefer modification of domestic antidumping law as the best way to expand coverage to include services.[234]

Although technical changes could with some difficulty bring services under the coverage of the countervailing duty and antidumping laws,[235] there are serious doctrinal obstacles to doing so. Because foreign launch services are provided outside the United States, beyond the traditional jurisdiction of the United States, application of U.S. trade laws would require use of effects jurisdiction. The United States supports this doctrine for the purpose of enforcing its antitrust laws,[236] but other countries have strongly criticized this approach.[237] Even in the area of antitrust,[238] the effects doctrine has been limited to acts that affect imports into the United States, or to acts involving export trade or commerce that affects U.S. exporters.[239] Application to launch services would therefore

234. *Id.* However, Deputy Assistant Secretary of Commerce for Services Linda Powers told the House Task Force on the International Competitiveness of U.S. Financial Institutions that although the United States is concerned with services dumping and is considering modifying domestic antidumping law, it must do so cautiously since the U.S. could stand to lose a great deal from foreign retaliatory measures against U.S. services. *Id.*

235. Adding the word "services" to the definitions in 19 U.S.C. §§ 1303(a)(1), 1671(a)(1), & 1673, and 15 U.S.C. § 72, and corresponding modifications to include "service providers" would not be enough. Because services can be "exported" by the service provider going to the customer or by the customer coming to the service provider, the definition of "export" would be crucial.

236. The effects doctrine was first enunciated in the field of antitrust law by Judge Learned Hand in United States v. Aluminum Co. of Am., 148 F.2d 416 (1945). The Supreme Court has since indicated its approval of the effects doctrine. Continental Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 704 (1962) ("[a] conspiracy to monopolize or restrain the domestic or foreign commerce of the United States is not outside the reach of the Sherman Act just because part of the conduct complained of occurs in foreign countries" (citations omitted)). It has since been codified as Section 7 of the Sherman Act by the Foreign Trade Antitrust Improvements Act of 1982, Pub. L. 97-290, Title IV § 402, 96 Stat. 1246 (codified as amended at 15 U.S.C. § 6a (1988)). Standards governing when to apply the effects doctrine were set out in Timberlane Lumber Co. v. Bank of Am., 749 F.2d 1378 (9th Cir. 1984), *cert. denied*, 472 U.S. 1032 (1985).

237. The European Court of Justice declined to rely on the effects doctrine in striking down North American and Scandanavian pulpwood cartels under European Community competition laws. A. Ahlström Osakeyhtiö v. Comm'n, Case 89/85, 1988 Common Mkt. Rep. (CCH) ¶ 14,491 at 18,612 (1988). This was despite strong argument by the Advocate General that the effects doctrine be adopted. *Id.* at 18,623. At the national level, the United Kingdom has gone so far as to prohibit its courts from assisting in the adjudication of any case or the enforcement of any judgment that infringes on its sovereignty. Protection of Trading Interests Act, 1982, ch. 11, §§ 4–6, *reprinted in* 21 INT'L LEGAL MAT. 834 (1982). For an exchange of diplomatic notes between the United States and the United Kingdom on the subject of antitrust jurisdiction, *see* 21 INT'L LEGAL MAT. 840–50 (1980). For a discussion of other countries' blocking laws in response to the effects doctrine, *see* Cira, *The Challenge of Foreign Laws to Block American Antitrust Actions*, 18 STAN. J. INT'L L. 247, 248–60 (1982).

238. The development of antitrust and antidumping law shares some parallels. Zerby, Ellsworth & Schmitt, *supra* note 226, at 42–43.

239. 15 U.S.C. § 6a (1988).

require a significant extension of the effects doctrine since it is unclear whether launch services providers would be considered exporters.[240]

The doctrine of foreign sovereign immunity and the act of state doctrine are of much less concern. Each of these doctrines contains an exception for commercial activity undertaken by the foreign government.[241] Any commercial launching by launchers owned by foreign governments is clearly commercial activity if sold on the international market to public and private users of many nationalities.[242]

Application of countervailing duty and antidumping law to services is complicated by the difficulty of enforcement. In the commercial launch market, as with other service markets, it is the customer or the factors of production that moves across national borders,[243] so the service never actually "enters" the United States.[244] One way to circumvent this problem would be to apply a special tax to the export of satellites from the United States for foreign launch.[245] Where there is elasticity of import supply, countervailing duties will tend to injure domestic consumers because it is they who will pay the duty entirely out of their consumer surplus.[246] For less elastic markets the amount of the duty paid by

240. There is very little case law on this subject. *See* McGlinchy v. Shell Chemical Co., 845 F.2d 802, 814–15 (9th Cir. 1988) (sales agents who provided services for chemical company in Southeast Asia were not "exporters" for purposes of § 6a(1)(B)). *But see In re* Insurance Antitrust Litigation, 723 F. Supp. 464, 486 (N.D. Cal. 1989) (applying effects doctrine to find that foreign reinsurers were importers of reinsurance services for purposes of § 6a(1)(A)), *rev'd on other grounds*, 938 F.2d 919 (9th Cir. 1991). No cases have addressed whether U.S. service providers that provide services within the United States are exporters under section 6a(1)(B).

241. Section 1605(a)(2) of the Foreign Sovereign Immunities Act states that no foreign state will be immune from U.S. jurisdiction in an action based on commercial activity. 28 U.S.C. § 1605(a)(2). Commercial activity is defined by type, rather than by purpose. *Id.* § 1603(d). Activities typically carried out for profit are usually considered commercial if performed by a government. Comment, *Two Faces of the Trader: Guidelines for Distinguishing Between Governmental and Commercial Acts Under the Foreign Sovereign Immunities Act of 1976*, 23 TEX. INT'L L.J. 465, 469–70 (1988).

There is strong evidence for a commercial exception to the act of state doctrine. A plurality of the Supreme Court has suggested that the act of state doctrine should not be extended to commercial activities in light of the current restrictive approach to sovereign immunity. Alfred Dunhill of London, Inc. v. Republic of Cuba, 425 U.S. 682, 695 (1976). *See also* Northrop Corp. v. McDonnell Douglas Corp., 705 F.2d 1030, 1048 n.25 (9th Cir. 1983); Hunt v. Mobil Oil Corp., 550 F.2d 68, 73 (2d Cir. 1977); Leigh & Sabbatino, *Silver Anniversary and the Restatement: No Cause for Celebration*, 24 INT'L L. 1, 12–14 (1990).

242. Launches by a governmental launcher for its own government would not always be commercial activity, since the profit motive will not usually be present. This Comment does not take the position that governments should be regulated when providing launch services for themselves.

243. Hindley, *supra* note 232, at 130–131.

244. Zerby, Ellsworth & Schmitt, *supra* note 226, at 38 n.8.

245. Comment, *supra* note 6, at 146. In this regard launch services are different from most services, for which the only possible trade regulation is through the use of non-tariff barriers. Hindley, *supra* note 232, at 133.

246. Sykes, *supra* note 212, at 220.

consumers and by foreign producers will vary.[247] Economists view countervailing and antidumping duties as a "second best" alternative to be used only if the economic and political costs of displacement of workers and reallocation of resources are too high.[248] This is not the case in the commercial launch industry since the satellite makers provide a powerful political counterweight to domestic launchers.

Given the practical difficulties in implementing antidumping measures and countervailing duties, along with their questionable economic effects, the Administration should be very careful in implementing them in the area of services. Furthermore, the radical change in policy that would be required to implement the trade laws extraterritorially could cause an enormous international protest.[249]

2. *RELIEF FROM UNFAIR TRADE PRACTICES*

Two alternatives to countervailing duty and antidumping laws are Section 301 of the Trade Act of 1974,[250] and Section 337 of the Tariff Act of 1930,[251] each of which can be used to combat unfair trade practices. Section 301 is designed to give the USTR sweeping powers to combat unfair trade practices by foreign governments and specifically provides remedies for unfair trade in services.[252] It is not limited to imports, but applies to any unjusticiable injury to U.S. commerce.[253] Section 301's definition of what constitutes unfair trade practices is very broad. It provides generally that the USTR may impose sanctions against countries that have denied U.S. rights under any trade agreement,[254] or have unfairly restricted U.S. trade.[255] This combination of objective and subjective factors gives the USTR great latitude in finding violations. Especially powerful are the "Super 301" provisions, which provide the USTR with a laundry list of violations including barriers to entry, inadequate intellectual property protection, excessive government tolerance of antitrust violations, export targeting, and unfair labor practices,[256] as well as closed service sectors.[257]

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247. *See id.* In these cases, which are more common than perfect elasticity, the benefits to the economy as a whole, and to domestic consumers, are very hard to quantify. *Id.* The ability of a firm receiving a subsidy to shift the effect of a countervailing duty will depend on the market power of that seller and on the monopsony power of the imposing country's consumers. *See id.* at 223.

248. *See id.* at 236.

249. *See supra* note 234.

250. 19 U.S.C. § 2411 (1988).

251. *Id.* § 1337.

252. *Id.* § 2411(c)(1)(B).

253. *Id.* § 2411(a)(1)(B)(ii).

254. *Id.* § 2411(a)(1)(A).

255. *Id.* § 2411(a)(1)(B)(ii).

256. *Id.* § 2411(d)(3)(B).

257. *Id.* § 2411(c)(1)(B).

The remedies available to the USTR are also broad.[258] Section 302 allows private parties to petition the USTR,[259] or the USTR may initiate an action herself.[260] Because of the potential for international controversy in a Section 301 investigation, the government might want to wait for a private petition before pursuing an investigation of unfair trade practices in the launch services market. Reliance on private party petitions would leave assessment of the various market factors to the petitioner and would serve to keep the government relatively neutral in the investigation. An appearance of neutrality will be especially important for countries with which the United States is trying to negotiate trade agreements. It is highly probable that the importance of launch services to national security and technological development would cause offending countries to refuse to make any concessions.

Private parties in the launch services industry have already attempted to petition for redress under Section 301. In 1984, Transpace Carriers, Inc., one of the several small companies trying to get a foothold in the launch industry, filed a petition pursuant to Section 301 with the Commerce Department.[261] Transpace alleged that the European firm Arianespace was engaged in two-tiered pricing and asked for relief.[262] President Reagan rejected the petition, however, because at the time NASA was also providing launch services at below cost.[263] Since the time of the Transpace petition, efforts of the USTR in applying "Super 301" measures in the space services industry have met with some success in regard to Japan, which has tentatively agreed to make its government procurement of satellites more open to foreign businesses.[264] The sole

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258. Section 301(b) allows the USTR to withdraw trade concessions, impose new restrictions, and obtain new agreements from offending countries. *Id.* § 2411(c)(1)(A)–(C).

259. The USTR must determine whether to act on a private petition within 45 days. *Id.* § 2412(a)(2). If she decides not to act, she must "inform the petitioner of the reasons therefor." *Id.* § 2412(a)(3).

260. *Id.* § 2412(b).

261. Raclin, *supra* note 79, at 50–52.

262. Determination Under Section 301 of the Trade Act of 1974 (memorandum for the United States Trade Representative), 50 Fed. Reg. 29631–32 (1985).

263. The President stated that many of Arianespace's alleged violations were also practiced by the United States. Since up to this time only governments had been involved in providing launch services, the President reasoned that the trade laws should not be used to judge the validity of government programs to encourage the use of space. He went on to say that there was little difference between the American and European markets for launch services. For the most part, both were captive markets of the government launcher, since the overall majority of demand for launch services was governmental. The only difference was that in the United States there was a growing private buyers' market. Furthermore, given the lack of a private sellers' market, there was no harm in governments offering discounts to establish themselves in the commercial market, since this was an economically acceptable practice. *Id.*

264. *U.S., Japan Reach Tentative Pact to Open Japan's Public Sector Satellite Markets*, 7 Int'l Trade Rep. (BNA) 460 (Apr. 4, 1990).

private party petition in the area of launch services filed since the Transpace petition is currently inactive.[265]

Section 337 of the Tariff Act of 1930[266] also provides relief against unfair trade practices in broad terms similar to those of Section 301. It directs the ITC in response to private petition[267] to conduct investigations of unfair trade practices other than those requiring antidumping penalties or countervailing duties,[268] and to exclude the importation of offending articles.[269] Section 337 applies only to "articles,"[270] and also imposes an injury requirement.[271] Because of these limitations, it is of little use to the commercial launch industry.

3. *EXPORT CONTROLS*

Export controls do not directly address the launch industry,[272] as none of the rockets or launch services is actually exported from the United States. Rather, export controls affect the export of satellites for launch elsewhere, and can therefore be used to keep satellites within the United States, where the satellite owners would have no choice but to use domestic launchers. Because the United States is the dominant producer of satellites,[273] this approach could be very effective. Indeed, Congress has already attempted to use export controls to protect the domestic launch industry.[274]

The export of most satellites is covered by the Arms Export Control Act (AECA)[275] and the accompanying International Traffic in Arms

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265. The petition of the National Space Society was lodged in protest of Chinese violations of the 1989 space launch agreement between the United States and China. *President Authorizes U.S. Participation, supra* note 110, at 1326–27. *See also supra* note 94 and accompanying text.

266. 19 U.S.C. § 1337 (1988).

267. *Id.* § 1337(b)(1).

268. *Id.* § 1337(b)(3).

269. *Id.* § 1337(d).

270. *Id.* § 1337(a)(1).

271. *Id.* § 1337(a)(1)(A).

272. Although the federal government requires domestic launchers to obtain a launch license for domestic launches licensed under the Commercial Space Launch Act, 49 U.S.C. § 2605 (1988), export licenses are no longer required. *Id.* § 2620 (1988). The Department of Transportation is to issue terms for review of launch license applications, 14 C.F.R. §§ 400–415 (1990), but is free to allow national security concerns to be used as a justification for a denial of a launch license. *Id.* § 411.7(a) (1990).

273. *See supra* note 124 and accompanying text.

274. Pub. L. No. 101–162, § 610, 103 Stat. 988, 1038 (1989) (prohibiting the use of Commerce Department funds to approve export licenses for launch in China or the Soviet Union). President Bush was able to avoid the scope of this statute in approving the launch AsiaSat on the Long March rocket, *see supra* note 91 and accompanying text, through the use of a substantial national interest exception. Kuckelman, *Regulation of Exports for Commercial Space Launches Outside the United States*, 38 FED. B. NEWS & J. 135, 138 (1991).

275. 22 U.S.C. §§ 2751–2796 (1988). For an in depth discussion of the AECA as it applies to satellite exporters, *see* Kuckelman, *supra* note 274.

Regulations (ITAR).[276] The manufacture or export of items included on the ITAR Munitions List must be registered with the Office for Defense Trade Control (ODTC).[277] Most satellites are included within the coverage of the Munitions List because they qualify as "inherently military."[278] The export of items on the Munitions List is prohibited to certain countries,[279] and export licenses are required for export to all other countries.[280] Applications for export licenses under AECA are reviewed by the Department of Defense, as well as other interested agencies,[281] and occasionally by the Coordinating Committee on Multilateral Export Controls (COCOM).[282]

Since commercial communications satellites are specifically excluded from AECA coverage, their export must be analyzed under the Export Administration Act of 1979 (EAA).[283] Section 4 of the Act establishes several types of licenses,[284] and authorizes the Secretary of Commerce to compile a control list.[285] An export may be prohibited for reasons of national security,[286] foreign policy,[287] or short domestic supply.[288] The Secretary may not prohibit export of items on national security or foreign policy grounds if those items are readily available

276. 22 C.F.R. §§ 120–130 (1991).

277. 22 U.S.C. § 2778 (1988).

278. 22 C.F.R. §§ 120.3, 121.1(b) (1991). Non-military communications satellites are not included on the Munitions List, and therefore could fall under the coverage of the EAA and the COCOM Core list. *Id.*

279. 22 C.F.R. § 126.1 (1991). Included under the arms embargoes are most Communist countries, as well as those recently freed from Communist rule. Of possible launch providers, the prohibition includes the Soviet Union, but not China. *Id.* However, exceptions can be granted. *Id.* § 126.3.

280. *Id.* §§ 123.1 (unclassified defense articles), 125.2 (unclassified technical data), 125.3 (classified technical data and defense articles). Both defense articles and technical data are relevant to the export of satellites, since exporters will need to export the satellite and provide satellite mating and preparation services at the site of the launch. Kuckelman, *supra* note 274, at 136, 137. Proposals to sell significant military equipment on the Munitions List in excess of $14 million (which includes most satellites) for use by the military of a non-COCOM government (except Iceland) also requires prior notification of the Office of Munitions Control. 22 C.F.R. § 126.8 (1991).

281. Kuckelman, *supra* note 274, at 136. Although review is based on a list of objective factors, it is done on a case by case basis and can easily be made subjective by the world peace and foreign policy exceptions. *Id.* at 137. Recently, particularly with regard to the launch of the AsiaSat in China, *see supra* note 91 and accompanying text, it appears that the Administration has added the consideration of the effect of the license on trade. Kuckelman, *supra* note 274, at 137–38. Such a calculus involves both the relation of the agreement to existing trade agreements, and the effect on the specific parties seeking to export. *Id.*

282. For a discussion of COCOM, see *infra* notes 295–99 and accompanying text.

283. 50 U.S.C. §§ 2401–2406 (1988).

284. *Id.* § 2403(a).

285. *Id.* §§ 2403(b), 2404(c), 2405(*l*).

286. *Id.* § 2404.

287. *Id.* § 2405.

288. *Id.* § 2406.

outside the United States.[289] Short supply controls are not limited by foreign availability, but currently only include strategic resources.[290] Under the EAA, countries are divided into seven different groups on which different export requirements are imposed.[291] Strategic items not on the Munitions List are included in the Commodity Control List (CCL),[292] which is divided into ten commodity groups.[293] Items are classified according to the technical designations within the control list.[294] Satellites are not specifically enumerated in the CCL, but satellite components could easily fall into one of the many technical categories contained therein, so the applicability of the EAA to a particular satellite would depend upon whether its components were included in the list.

Using these regulations, as well as those mandated by COCOM,[295] the government has the potential to control the market availability of foreign launch services. The main purpose of COCOM is, or was, to control export of strategic items to the (former) Communist Bloc.[296] China is given special "green line" treatment.[297] There is a general license permitting exports of certain items to COCOM members,[298] but satellites are not specifically listed, so their export even to COCOM members is probably controlled by EAA.[299]

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289. *Id.* §§ 2403(c), 2404(f), 2405(h).

290. *Id.* § 2406.

291. Japan and Europe are included in the relatively liberal Group V, as is China (with restrictions), but the Soviet Union is included in the more strict Group Y. 15 C.F.R. § 770, Supp. 1 (1991).

292. *Id.* §§ 799.1(a), 799.1, Supp. 1 (1991).

293. *Id.* § 799.1(b).

294. *Id.* §§ 799.1(f), 799.1, Supp. 1 (1991).

295. COCOM is a voluntary organization that has no formal treaty or organization. Decisions on export controls are made unanimously on issues such as inclusion of items on its control list and granting of individual exceptions. COCOM also tries to coordinate enforcement efforts. COCOM includes the United States, Belgium, Canada, Denmark, France, Germany, Greece, Italy, Japan, Luxembourg, the Netherlands, Norway, Portugal, Turkey, and the United Kingdom. In the U.S., the Department of Commerce is responsible for enforcing COCOM regulations. Comment, *Curbing Illegal Transfers of Foreign-Developed Critical High Technology from CoCom Nations to the Soviet Union: An Analysis of the Toshiba–Kongsberg Incident*, 12 B.C. INT'L & COMP. L. REV. 181, 201–02 (1989). The rules and procedures of COCOM are confidential, so specific information about COCOM is very scarce. Hunt, *COCOM and Other International Cooperation in Export Control*, in COPING WITH U.S. EXPORT CONTROLS 1991 97, 104–05 (Practising Law Institute 1991). There is no official publication of COCOM core lists, which serve only as guidelines for the regulations of the member states. *Id.* at 106.

296. Hunt, *supra* note 295, at 106.

297. This constitutes a group of exceptions to the general COCOM guidelines which results in a significantly more liberal export regime with regard to China. *Id.* at 109.

298. 15 C.F.R. § 771.25 (1991).

299. It is possible this could change soon. A recent report prepared by an influential panel recommends that existing controls on trade with COCOM nations be significantly reduced. National Academy of Science, National Academy of Engineering, & Institute of Medicine, *Findings and Recommendations from Executive Summary of Report, "Finding*

Recently, however, U.S. export control policy has changed somewhat. President Bush has called for "higher fences around fewer goods."[300] Certain telecommunication items will be included in the liberalization, but it is unclear whether the lowered restrictions will apply to satellites. Also included in the liberalization is "green line" treatment for the Soviet Union and Eastern Europe, similar to that accorded China.[301] Under green lining, COCOM imposes a level of technology below which case by case export licenses are not needed.

This liberalization of export controls will be accomplished by compiling a new COCOM Core List with accompanying changes in national regulations. An abbreviated Core List was approved by COCOM on May 23, 1991, and is to take effect by September 1, 1991.[302] The recently released fact sheet on the new Core List does not mention the degree to which satellites are covered,[303] but an earlier U.S. proposal for the "core list" significantly decontrolled some types of rocket engines and "spacecraft", a generic term which should include satellites.[304] Because the new list will be more specific than the previous list as to what items are controlled,[305] it is possible that it could result in the exclusion of satellites if they are not specifically listed as controlled items. Although the new list may be successful in "building higher fences around fewer items,"[306] many in industry are disappointed that the decontrols are not more significant.[307]

Since even the new export control laws might prevent export of satellites from the United States, the United States could use export controls as an instrument to protect domestic launchers,[308] as Congress did with regard to China and the Soviet Union in 1990.[309] However, the American satellite industry is as important as the launch industry,[310] and

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Common Ground: U.S. Export Controls in a Changed Global Environment," reprinted in 8 Int'l Trade Rep. (BNA) 218, 221 (Feb. 6, 1991).

300. Pine, *U.S. Offers to Ease High-Tech Trade*, L.A. Times, May 3, 1990, at A1.

301. *Id.* at A9.

302. *U.S., COCOM Allies Agree on New "Core List" of Controlled Exports, Industry Disappointed*, 8 Int'l Trade Rep. (BNA) 800 (May 29, 1991) [hereinafter *U.S., COCOM Allies Agree*].

303. White House Fact Sheet on Core List of Controlled Exports by Industry Sector, Agreed upon by Coordinating Committee for Multilateral Export Controls (COCOM) in Paris May 24, 1991, *reprinted in* 8 Int'l Trade Rep. (BNA) 839 (May 29, 1991).

304. Fact Sheet on U.S. Core List Proposal to COCOM, *reprinted in* 7 Int'l Trade Rep. (BNA) 1526, 1527 (Oct. 3, 1990).

305. Lenorovitz, *Cocom Eases Restrictions on Export of High-Tech Equipment to Eastern Bloc*, AVIATION WK. & SPACE TECH., June 10, 1991, at 73.

306. *Id.*

307. *U.S., COCOM Allies Agree, supra* note 302, at 800–801.

308. However, predatory use of export control regulations would violate the spirit of Section 9 of the Commercial Space Launch Act Amendments of 1988. *See infra* note 315.

309. *See supra* note 274.

310. *See supra* note 124 and accompanying text.

to compete internationally satellite makers believe they must have access to all available launchers.[311] Export controls should therefore be applied as loosely as possible without allowing sensitive technology to be transferred to undesirable countries. On-site monitoring of major launch sites by COCOM or American export control officials can assure that no leakage occurs.[312] Controls should be used only to assure compliance with existing trade agreements.[313] This approach appears to have been reasonably successful in recent dealings with China[314] and might be the only way to influence the launch practices of recalcitrant countries.

E. GATT Services

The conclusion of some multilateral agreement on trade in launch services would be the most comprehensive way to regulate these services and prevent unfair competition by foreign launchers. Section 9 of the 1988 Amendments to the Commercial Space Launch Act instructs the President to conclude bilateral trade agreements in launch services with other space powers.[315] The United States has already concluded such an agreement with China,[316] and negotiations with the European Space Agency, Japan, and the Soviet Union are planned.[317] A series of bilateral agreements with the major launch powers could do much to assure a competitive commercial launch industry.

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311. Hughes has strongly advocated such an open access policy. Asker, *U.S. Approval of Satellite Launches by China Not the End of Sanctions*, AVIATION WK. & SPACE TECH., Jan. 1, 1990, at 40. This is particularly important for countries far from the Equator, such as the Soviet Union, which is seeking to use Australia's Cape York facility. *See supra* note 110.

312. Hughes' export license to allow the recent launch of its satellites in China was conditioned on just this kind of arrangement. One dozen Hughes and military guards stood watch over the satellites during their stay in China to assure that U.S. regulations on technology transfer were not violated. Proctor, *supra* note 90, at 28. Since satellites are practically unrecoverable once in orbit, this type of monitoring would be sufficient to protect the technology and prevent its adverse use, so long as manipulation of controlled technology could not be achieved from a ground station.

313. Kuckelman, *supra* note 274, at 138.

314. *Id.* at 137–38.

315. Section 9 of the 1988 Amendments states:

> It is the sense of the Congress that the United States should explore ways and means of developing a dialogue with appropriate foreign government representatives to seek the development of guidelines for access to launch services by satellite builders and users in a manner that assures the conduct of reasonable and fair international competition in commercial space activities.

Pub. L. No. 100–657, § 9, 102 Stat. 3900, 3906 (1988). This position should eventually lead to a U.S. position on trade in launch services; however, the government has yet to enunciate a program for international negotiations on launch services.

316. *Chinese Deal to Launch Arabsat*, *supra* note 94, at 25.

317. Kuckelman, *supra* note 274, at 135.

Because launch services have a relatively low priority in most countries' international trade policies,[318] a more comprehensive way to achieve international agreement on launch services and other low priority trade issues is to consolidate them in the GATT services negotiations currently under way in the Uruguay Round. This will allow the inclusion in the agreement of developing countries that do not presently have viable launch industries. Such countries would probably be hesitant to negotiate an agreement aimed specifically at launch services.

The GATT services negotiations have been underway since 1986, and were scheduled to conclude by the end of 1990.[319] The talks collapsed in December 1990, but have since resumed.[320] The talks are expected to continue through 1992,[321] though they could conclude sooner.[322] President Bush has asked Congress to extend authorization of "fast-track" approval for GATT through June 1, 1993.[323] This renews the possibility of achieving some success in services.[324]

There is also the possibility that some smaller version of the General Agreement on Trade in Services (GATS),[325] will be concluded among

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318. There are indications that this is changing. The United States, for example, has given trade negotiations regarding the space industry increased priority. *See Bush Issues Policy, supra* note 176, at 1371.

319. *GATT Brief: Centre Stage for Services?*, ECONOMIST, May 5, 1990, at 88 [hereinafter *GATT Brief*].

320. *President Bush Set to Ask Congress to Extend 'Fast-Track' Authority as GATT Talks Resume*, 8 Int'l Trade Rep. (BNA) 295 (Feb. 27, 1991).

321. *Uruguay Round Negotiation back on Track as Participants Agree to Tackle Farm Trade*, 8 Int'l Trade Rep. (BNA) 294 (Feb. 27, 1991).

322. *USTR Hills 'Delighted' EC Now Prepared to Negotiate, but EC Sees No Breakthrough*, 8 Int'l Trade Rep. (BNA) 881, 882 (June 12, 1991). GATT delegates were to hold a result-oriented "work program" during June and July 1991 in an attempt to speed negotiations. *GATT Director General Unveils Work Plan For Uruguay Round over Next Two Months*, 8 Int'l Trade Rep. (BNA) 897 (June 12, 1991).

323. *President As Expected, Requests Extension of 'Fast-Track' Trade Authority Until 1993*, 8 Int'l Trade Rep. (BNA) 340 (Mar. 6, 1991) [hereinafter *President Requests Extension*]. Under "fast-track" approval, Congress cannot amend the agreement, rather it can only vote "yes" or "no." *Id.* Although there is heavy opposition in Congress to extending "fast track" and the President predicts a "tough fight," *Rep. Dorgan Introduces Resolution Opposing President's Bid for Fast-Track Extension*, 8 Int'l Trade Rep. (BNA) 342 (Mar. 6, 1991), it is supported by some key members of Congress. *President Requests Extension, supra* at 340.

324. There is reason for optimism about the chances for a services agreement unless the entire Uruguay Round collapses. Hindley, *supra* note 232, at 130. The ultimate success of the Uruguay Round as a whole probably depends on the granting of fast-track authority by the U.S. Congress, *EC Ministers Say Uruguay Round Progress Must Wait Until U.S. Fast-Track Decision*, 8 Int'l Trade Rep. (BNA) 576 (Apr. 17, 1991), and some compromise by the European Community on agriculture. *USTR Hills Opposes Setting New Deadline in GATT Talks Until EC Moves on Agriculture*, 8 Int'l Trade Rep. (BNA) 600 (Apr. 24, 1991).

325. The GATS negotiations, though part of the Uruguay Round, have been formally separated from the GATT framework. Negotiators are to report through the Trade Negotiations Committee (TNC), rather than to the Group of Negotiations on Goods. Randhawa, *Punta del Este and After: Negotiations on Trade in Services and the Uruguay Round*, J. WORLD TRADE L., Aug. 1987, 163, 164.

thirty to forty countries even if an agreement including the over one-hundred members of GATT fails.[326] Whether such a limited agreement would be of benefit to the launch industry is uncertain, however. An agreement limited to the developed country members of the Organization of Economic Cooperation and Development (OECD)[327] would include the major launch competitors—Europe, Japan, and the United States—but would leave out marginal competitors such as the Soviet Union and China. As these countries begin to increase their presence in the commercial launch market, other competitors will need some forum in which to address the competitive practices of these launchers. Since these countries are seeking membership in GATT,[328] they may be more easily coerced into joining GATS as well, thereby achieving greater coverage of world services.[329] To assure the inclusion of other launchers not involved in the GATS negotiations, the United States should insist that membership in GATT be conditioned on GATS membership as well.

It is still too early in the restarted round to predict what kind of agreement will be produced, but the most comprehensive proposal to date is the U.S. proposal,[330] which adopts several of the cornerstones of GATT as the basis for the services agreement. Article 8 of the proposal provides for national treatment of service providers, except to the extent "necessary for prudential, fiduciary, or health and safety reasons."[331] Article 7 applies national treatment to licensing, requiring that licensing

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326. *GATT Brief, supra* note 319, at 88–89.

327. The OECD's main purpose is to encourage economic cooperation among its members, which include Germany, Belgium, Austria, Canada, Denmark, Spain, the United States, France, Greece, Ireland, Iceland, Italy, Luxembourg, Norway, the Netherlands, Portugal, the United Kingdom, Sweden, Switzerland, Turkey, Australia, Finland, Japan, and New Zealand. The binding force of OECD agreements comes more from political pressure than from a formal obligation under international law. Audretsch, *Supervision in the EEC, OECD, and Benelux—A Difference in Degree, but Also in Kind?*, 36 INT'L & COMP. L.Q. 838, 844–49 (1987).

328. *Soviet Union Access to Antidumping Committee Another Step Toward Full Membership in GATT*, 8 Int'l Trade Rep. (BNA) 696 (May 8, 1991); *GATT Rejects New Chinese Membership Bid, Requests More Data on Trade Liberalization*, 7 Int'l Trade Rep. (BNA) 1477, (Sept. 26, 1990).

329. This is a general concern shared by all services industries. An OECD agreement would exclude newly industrialized countries (NICs), which are providers of some important services. American companies in these areas, such as Bechtel and other members of the Coalition of Services Industries (CSI), are adamant in their belief that a services agreement must include all GATT members. *Yeutter Reaffirms U.S. Desire to Reach Accord at Uruguay Round Midterm Review in December*, 5 Int'l Trade Rep. (BNA) 1002, 1003 (July 13, 1988).

330. Office of U.S. Trade Representative, U.S. Proposal for a General Agreement on Trade in Services and U.S. Submission to GATT Negotiators on Agricultural Reform, *reprinted in* 6 Int'l Trade Rep. (BNA) 1391 (Oct. 25, 1989) [hereinafter U.S. Services Proposal].

331. *Id.*, Art. 8.2.1, at 1392. Even this exception to national treatment is limited to situations in which it is "equivalent in effect to the treatment accorded by the Party to its own persons in like circumstances." *Id.*, Art. 8.2.2, at 1392.

and certification be based on competence,[332] and that it not be used to discriminate against foreign providers.[333] Another GATT cornerstone, general non-discrimination, is also required by the U.S. proposal, giving the agreement an analogue to "most favored nation" (MFN) status.[334] For the commercial launch industry, MFN status or national treatment is achieved by allowing satellite owners to export their satellites to the launchers of their choice. The basics of implementing such a policy are therefore much less complicated than for other service sectors. This simplicity will be undercut if states are allowed to use the health and safety exception[335] too freely, particularly if it were to be used to justify the imposition of export controls by the United States.

Although the proposal allows for the maintenance of existing domestic regulations,[336] it requires "transparency," a term of art meaning that regulation of covered industries, be it judicial, legislative, or administrative, be promptly published, and that in all review of foreign services, the foreign provider be kept apprised of the status of its case or application.[337] The proposal also provides for a standing committee on services[338] and for dispute resolution procedures.[339]

The American GATS proposal would include many services, but allows for the exclusion of some sectors. Rather than allow countries to include specific industries within the GATS framework, the U.S. proposal

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332. *Id.*, Art. 7.1, at 1392.

333. *Id.*, Art. 7.2, at 1392.

334. *Id.*, Art. 9, at 1392. National treatment puts foreign service providers on an equal footing with domestic providers, whereas most favored nation status allows for discrimination against foreign service providers so long as all foreign providers are treated the same. The European Community's most recent services proposal, which is in many ways similar to the U.S. proposal, places more emphasis on "national" treatment as an important element of the GATS agreement. *EC, in Effort to Speed up Talks, Submits Draft Agreement on Trade in Services at GATT*, 7 Int'l Trade Rep. (BNA) 893, 893 (June 20, 1990) [hereinafter *EC Submits Draft Agreement*].

335. *See supra* note 331 and accompanying text.

336. U.S. Services Proposal, *supra* note 330, Art. 11, at 1392. The proposal further requires that all future regulation be in accord with GATS. *Id.* The liberalization of existing regulations is likely to be the province of future GATS negotiating rounds, in much the same way as they are presently negotiated under GATT. *GATT Brief, supra* note 319, at 88.

337. U.S. Services Proposal, *supra* note 330, Art. 12, at 1392. In addition to transparency of regulations, GATS might also involve attempts to harmonize various national regulations over time. Hindley, *supra* note 232, at 133–134.

338. U.S. Services Proposal, *supra* note 330, Art. 18, at 1394.

339. *Id.*, Art. 19, at 1934. Recently the Office of the U.S. Trade Representative has indicated that it desires cross-retaliation provisions in GATS to go beyond more formal dispute resolution procedures. *U.S. Supports Cross-Retaliation, supra* note 232, at 1111. Cross-retaliation procedures set standards which allow signatories to impose retaliatory tariffs or other barriers when another signatory commits violations of the Agreement. *Id.* It is unclear from the text of the U.S. proposal whether cross-retaliation will be extended only for violations in services trade, or whether there will be cross-retaliation between goods and services sectors. Hindley, *supra* note 232, at 142.

requires an "opt out" approach, in which every excluded industry must be specifically included in an annex for each signatory.[340] Whether launch services would be included in the coverage of GATS or be opted out remains to be seen. The United States has expressed its desire to include telecommunications under a separate annex,[341] and launch services are the kind of strategic industry many countries might be inclined to exclude. Article 16.1 of the U.S. Services Proposal[342] allows countries to exclude services when necessary for national security. Other countries have also expressed concerns over GATS coverage of industries vital to national security, cultural independence, or technological development.[343] The U.S. proposal also allows exceptions for government procurement,[344] and allows countries to limit government aid to domestic services providers.[345] Both of these provisions have the potential to be problematic for U.S. commercial launchers should foreign governments abuse the government procurement and subsidization exceptions, but they could also be helpful if governments take a managed approach.

The European Community (EC) also presented general counter-proposals meant to challenge areas of weakness in the U.S. draft. The main thrust of the EC proposal is to define services in very broad terms in order to prevent the exclusion of transportation and telecommunications implied by the U.S. proposal.[346] The European proposal has important

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340. U.S. Services Proposal, *supra* note 330, Art. 2.2, at 1391. Each service will be discussed on a sector-by-sector basis, with each country making its own decision whether or not to opt out for a particular sector. *U.S. Presents "Bold" Proposal Before GATT Services Meeting, USTR Hills Tells Reporters*, 6 Int'l Trade Rep. (BNA) 1368, 1369 (Oct. 25, 1989) [hereinafter *U.S. Presents "Bold" Proposal*]. Fifteen sector negotiating groups have already been formed and asked to submit drafts. *U.S. to Present Services Proposal at GATT Next Month, Administration Officials Say*, 6 Int'l Trade Rep. (BNA) 1153 (Sept. 13, 1989) [hereinafter *U.S. to Present Services Proposal*]. If a country believed that another country had excluded too many sectors from GATS coverage, it could withhold benefits from the offender through a "non-application" clause. *U.S. Presents "Bold" Proposal, supra*, at 1369. The U.S. remains adamant in its support for this kind of reciprocal agreement. *U.S. Insists on Right to Withhold MFN as Part of Broader GATT Services Accord*, 8 Int'l Trade Rep. (BNA) 317 (Feb. 27, 1991). American negotiators hope that such a scheme will not lead to a "cafeteria plan" agreement, in which every country is allowed to pick and choose which services to include and which countries to grant reciprocity, but even a cafeteria plan agreement is preferable to no agreement on services. *U.S. to Present Services Proposal, supra*, at 1153.

341. *U.S. Presents "Bold" Proposal, supra* note 340, at 1368.

342. U.S. Services Proposal, *supra* note 330, Art. 16.1, at 1393.

343. Nayyar, *Some Reflections on the Uruguay Round and Trade in Services*, J. WORLD TRADE L., Oct. 1988, 35, 46–47.

344. U.S. Services Proposal, *supra* note 330, Art. 8.3, at 1392.

345. *Id.*, Art. 8.4, at 1392.

346. The EC proposal provides for all services to be brought within GATS without any opportunity to exclude strategic industries. *TNC Opens 'Make-or-Break' Session with some Progress Seen in Agriculture Discussions*, 7 Int'l Trade Rep. (BNA) 1141 (July 25, 1990). The proposal also allows for cross border flows of both service providers and costumers. *EC*

implications for the commercial launch industry because it is a sector that would likely be excluded from the agreement if either telecommunications or transportation were excluded. The breadth of the European proposal is also important in that it binds the EC to include launch services in GATS, something they might otherwise be disinclined to do given Arianespace's reliance on government support. The main drawback of the EC proposal is that it provides for a "relative reciprocity" approach, which allows a country to withhold benefits of GATS to countries it believes have not entered into the same level of commitment as the withholding state.[347] This approach could lead to differences of treatment within GATS, and possibly to squabbles between countries alleging discrimination.

Initially, most countries reacted favorably to the U.S. proposal, including the Group of Ten, ten developing countries led by India and Brazil.[348] Along with other developing countries, the Group of Ten had earlier insisted on the inclusion of labor flows in services, and relative reciprocity for developing countries.[349] Although developing countries are abandoning their previously recalcitrant positions on some issues,[350] and accepting, with some modifications, the U.S. proposal's exception for balance of payment reasons,[351] they are still lobbying for a more territorial approach to services than the U.S. and EC proposals.[352] These differences do not have a significant impact on the area of launch services, however, because they involve the movement of consumers, an area on which all sides agree.[353] The issue of the movement of service providers and factors of production is more contentious.

GATS is by no means a panacea for the launch industry or the services sector in general. Many stumbling blocks remain, such as the

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Submits Draft Agreement, *supra* note 334, at 893. Lately, however, the EC has wavered on its insistence that all services be included. It intimated that it would accept the exclusion of shipping from GATS, although other transportation services still appear to be part of its proposal. *EC Now Prepared to Exclude Shipping from New GATT Agreement, EC Official Says*, 8 Int'l Trade Rep. (BNA) 47, 47–48 (Jan. 9, 1991).

347. Hindley, *supra* note 232, at 136–137 n.3.

348. Nayyar, *supra* note 343, at 35. India gave an official assessment of the U.S. proposal, and gave its conditional support so long as the interests of developing countries were ultimately recognized. Brazil, Yugoslavia, and Tanzania all expressed their concurrence with the Indian delegation's assessment. *U.S. Presents "Bold" Proposal*, *supra* note 340, at 1369.

349. *Australian GATT Plan Draws Positive Reaction but Objections Raised to Mexican Proposal*, 5 Int'l Trade Rep. (BNA) 1067 (July 27, 1988). *See also* Nayyar, *supra* note 343, at 40–41.

350. *GATT Brief*, *supra* note 319, at 88–89.

351. U.S. Services Proposal, *supra* note 330, Art. 15, at 1393.

352. The less developed countries would allow free international flows of service customers, but would be more restrictive in allowing foreign service providers to establish themselves within their countries. Hindley, *supra* note 232, at 139.

353. Both Brazil and Cameroon, in the two major proposals of developing countries, provide for cross-border flows of consumers. *Id.*

treatment of financial services,[354] professional services,[355] cultural industries,[356] and existing international regimes in telecommunications and transportation.[357] Furthermore, GATS breaks new ground in international regulation of trade since regulation of services requires regulation of providers rather than of goods.[358] This is an ambitious incursion for international law, which has traditionally kept out of the internal affairs of nation states. The most important contribution that GATS could make is to provide a framework for regulating trade in services through which further progress in launch services could be achieved.

V. CONCLUSION

Given the present successes of the domestic launch industry, a non-interventionist approach would probably be of most benefit to the industry. The United States has the strongest aerospace industry in the world, as demonstrated by American dominance in commercial aviation, and it is likely that both American satellite producers and launch providers will benefit greatly from free trade in launch services. Attempts to give one industry an international advantage could cause corresponding harm to the other.

The government would also benefit from non-intervention. Because of budget cuts, extensive expenditures for the launch industry are impractical. Moreover, the general governmental trend over the last decade has been one of deregulation domestically, and of championing trade liberalization internationally. In order to maintain its image as an

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354. Applying liberal trade policies to financial services may not benefit countries concerned with debt management. *Participants in Uruguay Round of Talks Generally Agree Services Pact is Needed*, 6 Int'l Trade Rep. (BNA) 1227, 1227–1228 (Sept. 27, 1989).

355. The licensing of doctors, lawyers, architects, and other professionals can be very controversial, since every country has its own concepts of professional competence and responsibility, which often outweigh purely economic considerations. The World Union of Professions (UMPL) contends that the professions conflict with market forces and would be greatly hurt by deregulation. *World Professions Union Calls for Special Treatment in GATT Negotiations on Services*, 6 Int'l Trade Rep. (BNA) 1355 (Oct. 18, 1989).

356. *U.S. to Present Services Proposal, supra* note 340, at 1153.

357. The International Telecommunications Union (ITU) currently controls much of the regulation of international telecommunications, Nayyar, *supra* note 343, at 41, and might resist a GATS incursion into its regulatory realm. The transportation industry is also governed by several agreements, such as the UNCTAD Code of Conduct for Liner Conferences for shipping and the IATA for aviation. *Id. See supra* notes 190–91 and accompanying text. *See also EC Proposes Rules for Negotiating Liberalization of Trade in Services*, 6 Int'l Trade Rep. (BNA) 989 (July 26, 1989); *U.S. Presents "Bold" Proposal, supra* note 340, at 1369.

358. Randhawa, *supra* note 325, at 170. Because producers of services are involved, the collateral concerns of labor flows and investment would also be affected by a services agreement. *See* Nayyar, *supra* note 343, at 37. *See also* Hindley, *supra* note 232, at 131–135. Setbacks in either of these areas could slow progress in services trade as well.

advocate of free trade, the Administration will need to abstain from saber-rattling with the U.S. trade laws.[359] The government cannot sit idly by, however. Some measures are needed to safeguard the competitiveness of domestic commercial launchers.

Present U.S. trade regulations do not adequately address the problems inherent in services trade, let alone those of the launch industry. Those provisions that do touch on unfair service practices, such as "Super 301," do so only in the context of a more general, broad-based pattern of unfair trade practices. The remedies imposed by "Super 301" are retaliatory rather than conciliatory, and can potentially tarnish the United States' reputation as a free trader.[360] The United States should therefore rely on private petitioners to uncover unfair trading practices,[361] and should act against foreign practices only when both the commercial launch industry and the government are in agreement about the unfair nature of the foreign practice at issue. Although efforts at brinksmanship have thus far been relatively successful, at least with regard to recent improvements in U.S.–Japan trade policy,[362] they lead to bilateral solutions, which invariably leave important players out of the picture.

Liberalization of export controls should also continue. Because American industry is on both sides of the launch transaction, restraints on the free movement of satellites can only hurt domestic launchers and satellite producers.[363] Most launching states have stated that they respect the proprietary nature of the technology involved, and will make no attempts to expropriate it. Safeguards for foreign launches can be accomplished at a minimal additional cost, considering the high basic cost of each launch.

Other governmental measures, such as export targeting, require increased expenditure, and could lead to inefficiency. Indeed, a highly competitive policy of export targeting could cost the government huge amounts of money, with the benefits accruing mostly to foreign satellite users.[364] American industrial policy efforts in this area should instead concentrate on policies that are likely to benefit domestic launchers without harming domestic satellite producers. The United States has for many years had a de facto industrial policy with regard to the defense industry.[365] Although some budget cuts are unavoidable, the

359. *See supra* notes 204–71 and accompanying text.
360. *See supra* notes 258–60 and accompanying text.
361. Now that NASA is no longer active in the commercial launch industry, a future 301 petition might not suffer the same fate as the 1984 Transpace petition. *See supra* notes 261–63 and accompanying text.
362. *See supra* note 264 and accompanying text.
363. *See supra* notes 272–314 and accompanying text.
364. *See supra* note 157 and accompanying text.
365. *See supra* note 155 and accompanying text.

government should attempt to transfer some of the savings from defense programs into modest civilian programs.

The subsidies need not be direct, however. A simple change in defense and civilian space policy to use a greater number of ELVs should give the commercial launch industry the economies of scale necessary to compete effectively. The Defense Department will be needing increased satellite capabilities as earth-based forces are reduced. Any procurement program should be aimed at allowing commercial launchers to develop economies of scale.[366] This is the type of industrial policy that has worked best for the United States in the past. NASA can also contribute, albeit on a smaller scale, by reevaluating its manned mission policy. Such a reevaluation would give ELVs increased government business and reduce the possibility of another tragic shuttle accident.

A policy of non-intervention will not be successful if the United States cannot convince other nations to go along. A recent statement by USTR Carla Hills reflects this thinking: "There's a concern at home that our market is open and that the rest of the world is closed, and there's no enthusiasm for freezing the issue this way in the Uruguay Round."[367] This is especially true in the area of launch services.

Some international regime is needed to prevent predatory behavior by foreign, government-financed launchers. A cartel arrangement would be hard to administer and would lead to difficulties in both international and domestic allocation of capacity,[368] and it would run counter to a policy of non-interventionism. Liberalizing world trade in services through the GATS negotiations is a far better alternative. This would allow American competitive advantages to be fully exploited and would reward only those firms that could compete effectively. It would also provide some modicum of international oversight to the commercial launch industry, and provide the United States with a means of redress against unfair foreign competition.[369] A free trade regime, coupled with governmental awareness of the needs of the commercial launch industry, is all the industry needs.

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366. *See supra* notes 173–77 and accompanying text.

367. *Hills Calls U.S. Textiles Position Flexible, Hints at Possible Break in Agriculture Talks*, 7 Int'l Trade Rep. (BNA) 1427, 1428 (Sept. 19, 1990)

368. *See supra* notes 190–203 and accompanying text.

369. *See supra* notes 330–47 and accompanying text.

reward only those firms that could compete effectively. It would also provide some modicum of international oversight to the commercial launch industry, and provide the United States with a means of redress against unfair foreign competition.[369] A free trade regime, coupled with governmental awareness of the needs of the commercial launch industry, is all the industry needs.

369. *See supra* notes 330–47 and accompanying text.

COMMENT

PROTEIN PATENTS AND THE DOCTRINE OF EQUIVALENTS: LIMITS ON THE EXPANSION OF PATENT RIGHTS

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I. INTRODUCTION

A little over a decade ago, the Supreme Court in *Diamond v. Chakrabarty*[1] held that inventions involving living organisms altered by man were entitled to patent law protection. The Court's interpretation of of the breadth of section 101 of the Patent Act[2] provided the nascent biotechnology industry with precisely the type of stimulus necessary to launch and drive a furious and exciting period of development. The phenomenal volume of patent application filings which followed the Court's holding, as well as the vigorous enforcement postures assumed by biotechnology firms over the past decade, illustrate the importance biotechnology companies place on patent protection. The industry's reactions to *Chakrabarty* also demonstrate the capacity of an effective patent system to drive innovation and development, as well as encourage investment.[3]

Developers of blockbuster drugs, such as erythropoeitin, tissue plasminogen activator, and factor VIII:c, are now beginning to realize the rewards made possible through the exercise of effective patent rights. For example, the recent holding of the Federal Circuit in *Amgen, Inc., v. Chugai Pharmaceutical Co.*[4] had the effect of giving Amgen exclusive rights to the recombinant manufacture and sale of the anemia drug erythropoeitin in the United States. In response to this holding, Amgen's stock jumped nearly 20% overnight while the stock of Genetics Institute, a co-defendant in the case, declined by nearly a third. The events surrounding the *Amgen* decision demonstrate the value of strong and enforceable patent rights, as well as the importance of adequately and effectively defining rights to the products of biotechnology through patents.[5]

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1. Diamond v. Chakrabarty, 447 U.S. 303 (1980).

2. 35 U.S.C. § 101 (1988).

3. In the research-intensive biotechnology industry, patents serve three essential functions. First, patents help inventors protect the long term commitments required for investigation and development of unknown, and unproven areas of biochemistry and molecular biology. Second, patents provide the sponsors of such efforts a means for protecting their often substantial investments. Finally, the active scientific community gains immeasurably by the early disclosure of both important and incremental scientific advances. For start-up biotechnology ventures and established pharmaceutical firms alike, these functions of the patent system have proven to be not only desirable, but essential. *See* The Report of the President's Commission on the Patent System, November 17, 1966. *See generally* R. CHOATE, W. FRANCIS & R. COLLINS, PATENT LAW 70–75 (1987).

4. 927 F.2d 1200 (Fed. Cir. 1991). The holding invalidated certain patent claims to naturally derived erythropoeitin held by Genetics Institute due to deficiencies under 35 U.S.C. § 112, and affirmed the validity of most of Amgen's host cell and native sequence DNA patent claims.

5. Just 4 days before the Federal Circuit handed down its decision in *Amgen*, one biotechnology stock analyst had even gone to the point of classifying Amgen stock as "sell," Amgen stock rose $12 per share the day after the decision was made public. *See* Fisher, *Still More Growth in Biotechnology?*, N.Y. Times, March 1, 1991, at 8.

Effective enforcement of one's patent rights depends on the underlying patent application, the patent claims, and the prosecution history. Inadequacies in any of these three elements can effectively negate the patent as a viable safeguards of investments in time, money, and research. Of the three elements, the claims are the most important for purposes of assessing the scope of enforceable rights possessed by a patentee. Inadequacies in the claim scope are thus immediately thrust to the forefront, and can become a serious stumbling block for the patentee attempting to enforce its rights. In view of the important role claims play in the interpretation and effective use of patent rights, this paper will focus on how claims function to protect inventions in the field of biotechnology, and in particular, will explore the options available to the patentee once the literal scope of the patent claims to a new and useful genetically engineered-protein proves inadequate.

Consider a situation where a broad, yet poorly drawn patent claim is invalidated due to formalistic deficiencies, leaving the patentee with a scope of protection not much broader than the actual species of protein developed.[6] When this occurs, or when the patentee holds an original claim so limited, the patentee finds itself exposed to the threats of competitors who can easily make insignificant changes and escape the literal scope of the claims.[7] To permit a third party to easily evade the literal scope of a protein patent claim, and exploit the often significant efforts and costs incurred by a patentee in identifying, isolating, and effectively producing a protein, seems unjust. Yet, the Federal Circuit has emphasized that the function of the claims are to measure the enforceable scope of patent protection and that this function must be preserved in order to ensure that patents continue to stimulate further innovation.[8] A

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6. Reference is made here to claim 7 of the Amgen patent. The claim literally encompassed DNA which encoded any form or derivative of erythropoeitin which had a structure similar enough to the native structure so as to allow possession of the same biological activity as native erythropoeitin. The lower court's holding of invalidity of this claim due to lack of enablement was affirmed by the Federal Circuit, albeit through a different rationale. The suite of patent claims Amgen retained was thus limited to DNA which encoded, and host cells which expressed native sequence erythropoeitin, a scope of protection significantly less than that afforded by the original patent. *Amgen*, 927 F.2d at 1212–13.

7. Literal infringement only occurs when an accused device possesses all the limitations found in a claim. Thus, literal enforcement of a protein sequence claim provides the patentee with an extremely narrow enforceable scope of protection; namely, to the precise amino acid sequence listed in the claim or possessed by the protein.

8. As the Federal Circuit noted in Perkin-Elmer Corp. v. Westinghouse Electric Corp., 822 F.2d 1528, 1532 (Fed. Cir. 1984),

> Though the doctrine of equivalents is designed to do equity, and to relieve an inventor from a semantic strait jacket when equity requires, it is not designed to permit wholesale redrafting of a claim to cover non-equivalent devices, i.e., to permit a claim expansion that would encompass more than an insubstantial change.

Recently, the Federal Circuit again emphasized that the right of the public to "design around" the claims of a patent is an inherent, and absolutely essential element of the

court presented with this type of dilemma of resolving the relative rights of the patentee and the alleged infringer must act within an equitable framework.

The doctrine of equivalents[9] provides such an equitable framework.[10] It seems appropriate that a patentee holding unduly narrowed patent claims to a protein should be able to bypass the restrictions imposed by the literal scope of patent claims in extraordinary situations to protect him from "the unscrupulous copyist" who makes "unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law."[11] Indeed, the analysis of this issue by the Federal Circuit in its opinion in *Hormone*

United States patent system. In Slimfold Mfg. Co., Inc., v. Kinkead Indus., Inc., 932 F.2d. 1453, 1457 (Fed. Cir. 1991), the court held:

> Intentional "designing around" the claims of a patent is not by itself a wrong which must be compensated by invocation of the doctrine of equivalents. Designing around patents is, in fact, one of the ways in which the patent system works to the advantage of the public in promoting progress in the useful arts, its constitutional purpose. Inherent in our claim-based patent system is also the principle that the protected invention is what the claims say it is, and thus that infringement can be avoided by avoiding the language of the claims.

9. Under the doctrine of equivalents, a device infringes "if it performs substantially the same function in substantially the same way, to obtain substantially the same result." Graver Tank & Mfg. Co., v. Linde Air Prods. Co., 339 U.S. 605, 608 (1950), *reh'g denied*, 340 U.S. 845 (1950). The doctrine is founded on the theory that "if two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form or shape." *Id.*

10. The Federal Circuit has repeatedly stressed that there is an equitable basis for the doctrine, and that this basis must be considered when applying the doctrine of equivalents. *See, e.g.*, Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 870 (Fed. Cir. 1985) ("The doctrine [of equivalents] has been 'judicially devised to do equity' in situations where there is no literal infringement but liability is nevertheless appropriate to prevent what is in essence a pirating of the patentee's invention."). The rationale of the doctrine was perhaps best stated in Texas Instruments, Inc., v. I.T.C.:

> The doctrine of equivalents, ubiquitous since its origin in Winans v. Denmead, 56 U.S. (15 How.) 330 (1853), exists solely for the equitable purpose of "prevent[ing] an infringer from stealing the benefit of an invention." Graver Tank, 339 U.S. at 608. To achieve this purpose, equivalency is judicially determined by reviewing the content of the patent, the prior art, and the accused device, and essentially redefining the scope of the claims. This constitutes a deviation from the need of the public to know the precise legal limits of patent protection without recourse to judicial ruling. For the occasional pioneering invention, devoid of significant prior art—as in the case before us—whose boundaries probe the policy behind the law, there are no immutable rules. We caution that the incentive to innovation that flows from "inventing around" an adversely held patent must be preserved. To the extent that the doctrine of equivalents represents an exception to the requirement that the claims define the metes and bounds of the patent protection, we hearken to the wisdom of the Court in *Graver Tank*, that the purpose of the rule is "to temper unsparing logic" and thus to serve the greater interest of justice.

805 F.2d 1558, 1583 (Fed. Cir. 1986).

A good overview of the equitable origin of the doctrine of equivalents is found in H. WEGNER, EQUITABLE EQUIVALENTS: WEIGHING THE EQUITIES TO DETERMINE PATENT INFRINGEMENT IN BIOTECHNOLOGY AND OTHER EMERGING TECHNOLOGIES (1991).

11. *Graver Tank*, 339 U.S. at 607.

Research Foundation v. Genentech[12] indicates that the *equitable* doctrine of equivalents does have a role to play in enforcement of protein claims.

Application of the doctrine to actions for infringement of protein patent claims must be approached carefully by the court when it weighs the equities of the case before it. For example, few would hesitate to label a "conservative" amino acid substitution[13] in a polypeptide sequence of a complex, patented protein, which was implemented for the sole purpose of escaping the literal scope of a patent claim, as anything but an "unimportant and insubstantial" modification.[14] Allowing the patentee to expand the enforceable scope of protection of a patent claim without restriction, however, seems inequitable to later parties who do not derive their work from that of the patentee, especially where a modified protein is superior to the earlier, patented protein.[15] A third, often overlooked

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12. 904 F.2d 1558 (Fed. Cir. 1990). The Federal Circuit reversed the lower court's holding on summary judgment that statements of the inventor created a prosecution history estoppel and barred the application of the doctrine of equivalents, and remanded the case to ascertain whether the statements, in fact, did create an estoppel. *Id* at 1569. In the course of doing this the court referred to the equitable nature and origin of the doctrine of equivalents. *Id.* at 1564.

13. A "conservative" amino acid substitution is one which does not affect the structure or function of a polypeptide. Most often, a conservative change is limited to a substitution in the amino acid sequence of a single amino acid which shares the physico-chemical attributes of the amino acid which is replaced. Such a change escapes literal infringement of a patent claim to the native sequence protein simply because the changed protein is now chemically distinct from the native sequence protein. For example, a claim limited to a protein which includes the sequence "X–Gly–Ser–Glu–Y" would not be infringed by a protein having the sequence "X–Gly–Ser–Asp–Y" as the latter protein is a distinct chemical entity from the claimed protein. For those readers unfamiliar with protein technology, a brief summary is provided *infra* p. 113.

14. As the Supreme Court stated in the seminal case on the doctrine of equivalents, "[t]o permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing." *Graver Tank*, 339 U.S. at 607.

15. The Federal Circuit, in its opinion in Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565 (Fed. Cir. 1991), left open the question of whether patent rights from a claim based upon purification from natural sources would dominate later claims to a slightly different recombinant version of the same protein. The direct question of construction of the naturally derived protein claim to incorporate the process by which it was produced was avoided due to inconsistent legal arguments presented by Genentech. The related question of whether the "reverse doctrine of equivalents" should apply to limit the enforceable scope of a claim which could be construed to literally read upon the later product was remanded to the district court, pursuant to a reversal of a summary judgment finding of no infringement. *Id.* at 1580–81. As to this point, the court stated:

> Genentech asserts that the specific activities and purity that are obtainable by recombinant technology exceed those available by the Scripps process; an assertion disputed by Scripps, but which if found to be correct could provide—depending on the specific facts of similarities and differences—sufficient ground for invoking the reverse doctrine.

Id. at 1581.

Later in the decision, the court addressed the question raised by Scripps as to whether a claim to a protein phrased in product-by-process format could resort to the doctrine of equivalents to support a finding of infringement against a substantially identical form of

factor should also be taken into account: namely, the dubious societal value of an overly expansive doctrine of equivalents.[16] When courts allow the doctrine of equivalents to serve as an easily invoked and loosely applied adjunct to literal infringement, they create a risk of muddying the already murky waters of protein patent claim interpretation.

These equitable considerations have been the primary focus of doctrine of equivalents analysis since its inception. The mechanics of doctrine of equivalents analysis, however, have been refined substantially in recent years. This is largely attributable to the creation of the Court of Appeals for the Federal Circuit.[17] For example, a patentee in today's court who seeks to use the doctrine of equivalents now faces not only the burden of proving actual equivalence, but also the burden of proving that the expanded scope of protection sought will not ensnare the prior art in existence at the time of the patent grant. This second burden has, until recently, been largely ignored, or left for either the court or the defendant to the infringement action to raise. Last year, the Federal Circuit, in *Wilson Sporting Goods, Inc. v. David Geoffrey Associates*,[18] explained this new burden of proof and indicated the proper role that the doctrine of equivalents should have in the enforcement of patent claims.[19] As protein technology matures and the emphasis of innovation shifts from newly discovered proteins to modified and "improved" variants, the doctrine of equivalents will play an increasingly important role in the enforcement of protein patents. This paper attempts to provide the reader with a perspective on some of the issues facing a patentee contemplating such use of the doctrine of equivalents.

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the protein produced using recombinant techniques. *Id.* at 1583–84. Here the issue was whether the naturally derived factor VIII:C protein, phrased in the product-by-process claim format could reach the recombinantly derived factor VIII:C protein produced by Genentech. In remanding the case to the district court for assessment of the claim of infringement of the product-by-process claims, the court held that

> [i]n determining patentability we construe the product as not limited by the process stated in the claims. Since claims must be construed the same way for validity and for infringement, the correct reading of product-by-process claims is that they are not limited to product prepared by the process set forth in the claims.

Id. at 1583. Instead, the court held that the product claims must be construed for purposes of infringement pursuant to standards applicable to regular product claims not possessing process limitations. *Id.*

16. Indeed, one may question whether a pro-innovation patent policy is actually served at all by provision of an expansive doctrine of equivalents. Such a policy can create confusion as to patent rights, both for the patentee and for parties pursuing products outside the literal scope of a patentee's claims. It may also render a reward far in excess of the original contribution of the patentee through a process wholly removed from the arguably balanced patentability analysis conducted by the Patent and Trademark Office. Uncertainty over the basic question of infringement may even serve to discourage investment and research. *See* Merges & Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990).

17. Federal Courts Improvement Act of 1982, 28 U.S.C. § 1295 (1988).

18. 904 F.2d 677 (Fed. Cir. 1990), *cert. denied*, 111 S. Ct 537 (1990).

19. *See infra* note 58 for discussion.

II. OVERVIEW OF PROTEIN TECHNOLOGY

The initial goal of many biotechnology companies during the 1980's was the exploitation of a known, pharmaceutically important protein. This goal seemed both attractive and attainable due to the advances in genetic engineering which were being taking place. For example, through the exercise of relatively straight forward laboratory procedures, a researcher could transform the genetic makeup of a host cell thereby inducing that cell to produce a desired protein. This process of exploiting nature's own resources could thus be used to simultaneously solve the problems of purity and quantity which prevented earlier exploitation of the protein through conventional purification technology.

This initial objective and accomplishment of many biotechnology firms pales in comparison to the potential of applied protein engineering. The ability of a protein engineer to dissect and reassemble segments of biologically active proteins to arrive at completely new and useful proteins holds incredible potential.[20] Native proteins thus may become "building blocks" for an entirely new generation of protein entities. With these technological advances, new legal questions have arisen. In the context of defining patent rights, the most important question is what impact will the grant of initial patents covering native proteins have on the patenting and production of these "third generation" products?

A. Fundamental Principles and Terms of the Art

Some proteins are commercially interesting compounds because they possess a desirable biological activity. Examples of such proteins are tissue plasminogen activator (t-PA), which breaks down blood clots, and erythropoeitin (EPO), which stimulates the production of red blood cells. The relationship between a protein's biological activity and its structure, however, is rarely, if ever completely understood. However, it is this relationship between structure and function which is most critical for the predictive use of protein structure information to engineer new protein analogs which retain or introduce desired biological functions of known proteins.

A brief overview of the fundamentals of protein structure and function may be helpful at this point. Proteins are complex macromolecular chemical structures, composed of one or more polypeptide chains. Each polypeptide is made up of a linear sequence of amino acid residues covalently attached to each other through peptide

20. For example, using recombinant techniques, a protein engineer can assemble a hybrid protein having the regions of an antibody which give the antibody its unique specificity, and the cell killing potential of a highly lethal toxin, yielding a safe "magic bullet" that can selectively find and kill cancer cells. *See, e.g.*, Merz, *Fine-tuned and Loaded, Monoclonals Treat Cancer*, 256 J. A.M.A. 1406, 1412 (1986).

bonds.[21] This linear amino acid sequence is termed the primary structure of a protein. There are only 20 commonly occurring amino acids. However, this small number is sufficient to yield an enormous number of possible polypeptide sequences.[22] These polypeptide sequences possess a dramatic range of physico-chemical properties, which impart an almost incomprehensible range of possible protein structures and biological activities.

Each amino acid residue in a protein sequence plays a different role in defining the overall structure of a protein, depending on the nature of the side chain group which is attached to the central or alpha carbon. The chemical nature of the side chain group defines whether the amino acid residue will impart a hydrophilic ("water loving") or hydrophobic ("water hating") effect upon the region of the polypeptide chain in which the residue is located.[23] The localized effect of different interactions between adjacent amino acid side chains, in combination with the restricted rotational flexibility of the basic polypeptide chain,[24] gives rise to a limited number of energetically favored localized conformations. These conformations are termed the secondary structure of the protein.[25]

The secondary structure plays an important role in how the protein assumes its overall three dimensional conformation, termed the tertiary structure of the protein. A protein has a quaternary structure if more than one polypeptide chain contributes to its conformation. Individual polypeptide chains can assume, in theory, a tremendously large number of possible overall conformations.[26] In nature they typically assume only

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21. The peptide bond is represented as follows: R(NH)(CO)CHX–R, where R represents strings of amino acids, and X represents the side chain group of the central amino acid depicted.

22. Depending upon the length of the polypeptide chain, an incredibly large number of possible distinct or unique polypeptide entities can be imagined. For example, a polypeptide chain having 100 sequential amino acid residues can give rise, in theory, to 20^{100} possible sequences.

23. Residues having a nonpolar, uncharged side group impart hydrophobic effects (e.g. Ala, Val, Leu, Ile, Pro, Met, Phe, Trp). Residues which are polar and either charged or uncharged impart hydrophilic effects (e.g. Gly, Ser, Thr, Cys, Tyr, Asp, Glu, Asn, Gln, Lys, Arg, His). *See* LEHNINGER, BIOCHEMISTRY 100–03 (1982).

24. The peptide bond has a "double bond-like" character, forcing it to adopt a planar conformation. The combined effect of this "rigid" structure and the interactions between the side chains attached to the alpha-carbon has a significant influence upon the secondary structure of the peptide region. *See id.* at 150–52.

25. Early studies focused on two predominant conformations for secondary structures: the alpha helix and the ß–pleated sheet. The former resembles a repeating spring-like or twisted rope-like coil structure, while the latter is an extended or "stretched" conformation. *See id.* at 151–56. Due to more complex molecular modeling systems and increased information from X-ray diffraction studies, additional conformations, such as tight turns, small loops, and random coils, have been deduced, and more accurate estimates of the regional conformations of proteins can therefore be made.

26. The hypothetical 100 residue polypeptide could assume 10^{100} "energetically reasonable" conformations. T. CREIGHTON, PROTEINS 135 (1984).

a few preferred, or native conformations. These conformations are normally the most stable, or lowest energy, forms of the protein, taking into account all the possible interactions between different regions or domains of the protein[27] and between the protein and its local environment. Typically, the preferred conformations are the ones in which a protein exhibits its biological activity. For the protein chemist, attempting to "engineer" a novel, biologically active form of a protein, conformations therefore become extremely important.

B. Understanding the Importance of Protein Conformations

As noted earlier, biologically active proteins are often extremely complex chemical structures. This complexity is due primarily to the way proteins change or adopt conformations in response to different physiological conditions.[28] These conformations are influenced by a bewildering array of interrelated forces, each having a variable degree of impact on the overall conformation of the protein. More than anything else, the extremely complex interrelationship between structure, conformation, and biological activity renders protein "engineering" an inherently unpredictable and imprecise discipline. While a complete summary of all the possible forces which influence a protein's conformational dynamics is beyond the scope of this paper, one can get a feel for the difficulty associated with the prediction of such conformations by recognizing the major factors which influence protein conformations.

The primary structure of a protein is the most direct influence on the overall conformation and activity of a protein, simply because it serves to define the various secondary, tertiary, and quaternary structures possessed by a protein. The primary structure of a protein is also the one structure protein engineers have which can be directly measured, which will remain static, and which must be used to base conclusions and make predictions. Thus, the amino acid sequence of the protein often becomes the primary focus when studying a protein's conformational dynamics and their effects upon biological activity and function.

Regions of secondary structures, on the other hand, play a dynamic role in defining which of the many possible conformations the protein will assume at any one time. First, different regions of secondary

27. Regions or domains as used here means those identifiable stretches of amino acids having distinct secondary structures.

28. Most biologically active proteins have three-dimensional conformations which are "globular," meaning their conformations are composed of many secondary structures. On the other hand, structural proteins which make up things like muscle and hair are "ordered" structures in the sense that they have identifiable, repeating, and predictable conformations. A globular protein does not have a fixed and readily predictable structure. Instead, these proteins are loosely ordered and frequently shift between many different overall conformations.

structures can interact with each other. For example, hydrophobic regions will often associate in pockets within the protein because less energy is required for them to interact with each other than to interact with the aqueous environment.[29] Conversely, hydrophilic regions are readily soluble in an aqueous environment and tend to reside on the outer regions of the protein which are exposed to the aqueous environment. The combined effect of these region-to-region interactions plays a large role in defining the predominant tertiary conformation of the protein, and therefore, its overall three-dimensional conformation.

Where a protein is actually a complex of several distinct polypeptide chains, interactions analogous to intra-chain interactions occur. Instead of two regions from a single polypeptide interacting with each other, regions in distinct polypeptides interact. There is a much greater range of variability in the overall conformations possible in these types of interactions because the involved regions are not necessarily constrained by being on the same chain.

If the sole source of influence for conformational changes in a protein were its amino acid sequence, predictions of protein conformations would still remain complex and largely empirical. This, however, is not the case. Many factors other than the amino acid sequence of the protein serve to influence and change its conformations. First, the physical environment in which the protein exists has a large effect on what conformations it will adopt. For example, placing a protein in a nonaqueous environment often destroys the biological function of the protein because drastic changes occur in the conformation of the protein. Changing the nature of the aqueous environment can cause this effect as well. For example, a substantial change in the pH or ionic strength of a solution containing a protein can destroy biological function as effectively as placing the protein in a non-aqueous environment. Less severe changes often occur naturally in the aqueous environment found in living cells. Such changes are often responsible for

29. Hydrophilicity and hydrophobicity are very important factors used by protein engineers to predict protein conformations, often through use of a concept of a "localized environment" for a protein region. This term is often used to describe the nature of a particular region of the protein under study. For example, if a region of the protein has a high concentration of hydrophilic amino acid residues, the protein engineer will normally consider the localized environment of that region to be hydrophilic. This information is useful to the protein engineer because, instead of having to actually calculate the effect of the interactions of each amino acid residue in that region, the engineer can make a rough estimate that this hydrophilic region will be on the exterior of the protein, where the protein interacts with its aqueous environment. Likewise, a stretch of amino acid residues which are predominantly hydrophobic will be expected to adopt a conformation which shields these residues from the protein's aqueous environment. Hydrophobic regions of the protein therefore are likely to be found in the interior region of the protein.

changes in levels of biological function or activity, and typically occur in response to a cellular stimulus.[30]

The interactions between different regions of proteins discussed above have all been in the context of non-covalent interactions. Keep in mind, however, that different regions of a single polypeptide, as well as distinct polypeptides, can associate through covalent bonds as well. The most common association is the disulfide bond which forms between the side chains of two cysteine amino acids. A covalent association can greatly restrict the range of possible protein conformations for either a single polypeptide or a complex of multiple polypeptide chains, as it is a much stronger interaction than a non-covalent interaction.

There are also non-covalent, non-polypeptide, and non-environmental interactions which influence protein activity. The biological activity of many proteins often depends upon whether the protein has complexed with a co-factor, such as a metal ion. The most well-known example of such a protein is hemoglobin. If the iron co-factor of hemoglobin is removed, the ability of the protein to carry out its oxygen-transporting "biological function" is greatly diminished. This derives from the inability of the protein to adopt or retain certain conformations necessary to bind or release oxygen. Other ways of influencing the protein activity derive from post-translational modifications of the polypeptide backbone of the protein.[31] Here, certain amino acid residues in the protein are altered either directly or by covalent attachment of other compounds, such as sugar residues.[32] Often, these modifications contribute to the stability of a particular biologically active conformation.

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30. For example, a cell may change its internal environment in response to a hormone binding to a cellular receptor. This change in environment can then induce a protein to adopt a particular conformation which renders the protein either active or inactive.

31. The term "post-translational modification" includes all processing done by the cell after a cell assembles the protein from free amino acids and the information stored in the DNA which codes for the particular amino acid sequence. After it has "translated" the genetic information into a polypeptide sequence, the cell will often chemically modify the translated polypeptide product to yield the mature, fully functional form of the protein. Examples of amino acid residues which result from such modifications include hydroxy-proline (from proline), and gamma-carboxyglutamic acid (from glutamic acid residues). Other types of post-translational modifications do not change the structure of the amino acid side chain group, but simply attach additional functional groups to the side chains, such as sugar residues or lipids.

32. Strings of sugar residues attached to a particular amino acid side chain are termed "glycosylation." Glycosylation can affect biological activity without directly influencing protein conformation For example, glycosylation in erythropoeitin serves to enhance retention of the protein in mammals, without significantly affecting the biological activity of the protein. Without the glycosylation, erythropoeitin is cleared rapidly from the bloodstream. Yet the unglycosylated protein shows nearly full biological activity when measured in *in vitro* biological assays.

A final factor bears mention. Changes made to one region of a protein will often affect other regions which then alter the tertiary structure of the protein. This introduces another level of complexity in the overall picture of interchain and environmental factors that can influence a protein's conformation. Predictions based upon a certain factor may require that other factors be held "constant." This can significantly diminish the accuracy of a protein model to the "real world" protein.

In short, a protein is subjected to a bewildering array of different factors—interdependent to some degree—which have the capability to alter and change its conformation. Yet it is the overall structure of the protein, or a specific region of the protein that is essential to the native biological activity of the protein.[33] For example, one region of a protein might play a role in associating the protein to a particular type of cellular receptor, while another region might act as a receptor for a different protein, or act to catalyze a particular reaction.[34] Correlating the activity of a protein with the structure of a region of the protein is one of the most difficult questions facing the protein engineer. Elucidation of this relationship between amino acid sequence, conformation, and function thus becomes the essential prerequisite for *predictive* use of amino acid sequence data. This relationship, which has been termed the "second genetic code,"[35] remains an elusive target.

C. What Is "Protein Engineering"?

The complexity of factors which affect protein conformation and biological activity illustrates why "engineering" a new or even modified form of a protein seems like an incomprehensibly complex task. Luckily, this is not the case. Even a cursory look at the accomplishments in the past decade in the realm of "protein engineering" shows that goals set in this area are not only possible, but attainable. Furthermore, with the

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33. It is not uncommon for a single amino acid change to significantly affect the structure and activity of a particular protein. In the context of measuring the impact of substitutions of amino acid residues in conserved regions of enzymes, workers have reported decreases in the rate of catalysis ranging from a factor of 2 to a factor of more than 25,000. Leatherbarrow & Fersht, *Protein Engineering*, 1 PROTEIN ENGINEERING 7, 9 (1986). *See also* Cordonnier, Montagnier & Emerman, *Single Amino-Acid Changes in HIV Envelope Protein Affect Viral Tropism and Receptor Binding*, 340 NATURE 571 (1989) (changing of single residue in the envelope protein of HIV affects receptor binding capacity).

34. A good example of a well-characterized protein which has several distinct domains is t-PA. This protein has one region which catalyzes the degradation of polymeric fibrin, otherwise known as blood clots. A different region plays a role in binding to the fibrin clot.

35. "The ultimate solution to the 'protein folding problem' will be the elucidation of the 'second genetic code' relating the amino acid sequence of a protein to its secondary, tertiary, and quaternary structures." Creighton, *Protein Structures* (Book Review), 247 SCIENCE 1351 (1990).

improvements in available computing power, and the almost constant increase in the understanding of protein conformational dynamics, protein engineers are now able to predict confidently the effects of often significant structural modifications to proteins.

"Protein engineering" is a term which can have several meanings, depending upon who is asked. Generally speaking, protein engineering encompasses a range of activities whose goal is the creation of novel, non-naturally occurring protein structures. This may be accomplished by altering existing polypeptide sequences, combining segments or regions of different proteins, or by designing polypeptide sequences *de novo*. A 1986 commentary is still useful in providing additional structure to this field of technology by defining four classes of "protein engineering."[36] The first class of engineering work is based upon relationships which can be deduced from primary sequence information and then applied to different systems. Examples include short peptide sequences having functional significance irrespective of the regions flanking the sequence, and changes which can be made in particular residues of a peptide which are based upon knowledge of the chemical nature of the residue side chain.[37] The second class identified includes experiments which correlate the results of random mutations with empirical observations, but do not require specific knowledge of "fundamental structure-function relationships." The type of work falling into this class includes screening and selection procedures based on random mutations of a known sequence. The third class encompasses work done to elucidate and quantify fundamental relationships between structure and function, typically in the context of measurement of changes resulting from specific changes in sequences, and studies of homologous protein sequences from different species.[38] This class of work is currently viewed as being the most common form of "protein engineering." Finally, a fourth class, considered to be "true" protein engineering includes "those experiments in which a protein of improved features is confidently synthesized from a design based on well-understood structure-function relationships."[39]

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36. Wetzel, *What Is Protein Engineering?*, 1 PROTEIN ENGINEERING 3, 3–4 (1986).

37. The specific example cited was changing a residue susceptible to oxidation, such as methionine or cysteine, to an oxidatively resistant analog. This gives the modified protein an improved "shelf life" when compared to the native protein simply by removing the portion of the protein which makes the native protein susceptible to degradation.

38. A common example of this class is where a single residue is varied to assess the "tolerance" to change of that site in the primary structure. Typically this will involve production of a range of mutants varying only at the preselected residue. The activity of these species will then be measured as one means for assessing the tolerance of the site to change. This is a common procedure for enzymes, which typically interact with substrates through specific residues.

39. The number of examples of "true" protein engineering continues to grow. Highly publicized members of this group include the single chain and "chimeric" antibodies, and the Genetics Institute t-PA construct.

While certain instances of success in this last category are known, it is safe to say that this stage of protein engineering is not commonplace.[40]

Advances in recombinant DNA technology during the 1980's facilitated the dramatic increase in our understanding of how proteins adopt and assume conformations. This tool allowed protein engineers to make specific changes in the primary sequence of a protein to test hypothetical models in "real world" terms in a very short time frame. This, in turn, enabled protein engineers to assess the impact of changes made to the primary sequence of a protein and then use this knowledge to make further predictions. Through this iterative process of modification and measurement, protein engineers gained the ability to deduce some preliminary, albeit generalized, conclusions regarding structure-function relationships between primary sequence data and conformational dynamics. Analyzing this empirical data led to some fairly well accepted theories as to the interchangability of certain chemically similar amino acids, and more importantly, defined relationships which could be used to predict the general nature of conformations for wholly *de novo* polypeptide structures.[41]

The advances in understanding through this period have also led to certain basic conclusions. One very important conclusion, for purposes of assessing both factual and legal equivalence among modified but closely related forms of a protein, is that minor, conservative changes in protein

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40. Recent work in the area of "single chain antibodies" arguably falls into this "fourth class." These entities are designed using a complex computer-based modeling program which takes two fragments of existing antibody chains, and then "engineers" a linking region to join the two fragments in a way which retains the conformations of the native antibody binding region so as to retain the original antigen-binding function.

41. The following summary illustrates the "state of the art" of the effects of genetic mutations on protein structure and conformation:

> Despite the difficulty of partitioning mutational effects between the folded and unfolded states, several general conclusions are emerging:
>
> 1. The role of each amino acid depends on its structural context. Sensitivity to severe destabilizing substitutions is correlated with features of the folded state, implying that interactions in this state are often dominant. With the exception of charged residues, most amino acids that make critical interactions are rigid or buried in the folded structure.
>
> 2. Many different types of interactions—including disulfide bonds, hydrophobic forces, hydrogen bonds, electrostatic interactions, and dispersion forces—make quantitatively comparable contributions to stability.
>
> 3. Specific interactions of each type make a wide range of stabilizing contributions. The observed range of contributions is not adequately described by the behavior of the simple chemical model systems traditionally used to evaluate the strengths of noncovalent interactions. Model systems generally do not account for the unique environments of each residue in the folded and unfolded states or for the entropy changes associated with forming specific interactions.
>
> 4. Many amino acid substitutions do not have large effects on stability. Proteins tolerate substitutions because (a) some substitutions preserve critical interactions, (b) some interactions apparently do not make large contributions to stability, and (c) protein structures adjust to compensate for changes in sequence. The impact of an amino acid substitution is a combination of its intrinsic effects on the folded and unfolded states and the relative abilities of the two states to relax in response to the change. Relaxations minimize destabilizing effects.

Alber, *Mutational Effects on Protein Stability*, 58 ANN. REV. BIOCHEM. 765, 766 (1989).

sequences effected through either random mutations or site directed mutagenesis no longer can be treated as an inherently unpredictable feat. The thrust of several recent articles tends to minimize the impact of such conservative changes, concluding that a large number of conservative amino acid changes can be made without significant effects on the overall conformation and activity of the protein, as compared to the naturally occurring or wild type protein.[42] As advances in recombinant technology, molecular modeling, and protein chemistry continue, the unraveling of the second genetic code may someday be possible. Until then, anyone venturing into the world of predictive protein engineering must recognize not only the inherent unpredictability associated with such efforts, but also that such unpredictability does not necessarily represent an insurmountable barrier to a "protein engineer" even at this early stage in the industry.

III. THE DOCTRINE OF EQUIVALENTS

The 1980's were a period of extensive scientific development for biotechnology in which a substantial advance in patent-rights interpretation took place. Leading this advance was the Court of Appeals for the Federal Circuit.[43] In a number of published opinions, this court addressed the question of the equitable nature of patent rights arising from expansion of these rights under the doctrine of equivalents. A brief summary of the current state of the doctrine may serve to place the question of expansion of the enforceable protection of protein patent rights clearly in focus.

A. A Current Overview of the Requirements for Use of the Doctrine of Equivalents

The doctrine of equivalents is a mechanism for a patentee to establish infringement of the patent rights. However, the doctrine is not the first issue a patentee faces in an action to prove infringement of patent rights. Only where there is no literal infringement of one or more of the patent claims does the question of through equivalents arise..[44] The issue of equivalence is a question of fact reviewed under the clearly erroneous

42. *See, e.g.*, Bowie, Reidhaar-Olson, Lim & Sauer, *Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions*, 247 SCIENCE 1306 (1990).

43. *See* Kastriner, *The Revival of Confidence in the Patent System*, 73 J. PAT. OFF. SOC'Y 5, 8 (1991) (CAFC has brought about uniformity and certainty in interpretation of the patent laws, and has significantly enhanced the economic power of patents). For an extensive study of the impact of the Federal Circuit on modern patent litigation, see Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1 (1989).

44. The doctrine of equivalents comes into play only when actual literal infringement is not present. Hughes Aircraft Co. v. United States, 717 F.2d 1351 (Fed. Cir. 1983).

standard.[45] The patentee, in this context, must show that the allegedly infringing 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."[46] Satisfaction of each of the three prongs of this test for equivalence is a condition precedent to any further analysis under the doctrine of equivalence. Meeting this burden in the context of protein claims is itself a complex process which will not be addressed in this paper.[47]

Once the factual burden of proving equivalence has been met by the patentee, two questions of law can intervene to preclude extension of the patentee's patent rights.[48] Both involve the prior art in existence at the time of the patent grant.

> First, the doctrine will not extend to an infringing device within the public domain, i.e., found in the prior art at the time the patent issued; second, prosecution history estoppel will not allow the patentee to recapture through equivalence certain coverage given up during prosecution.[49]

Prosecution history estoppel, the second intervening question of law, is commonly raised as an affirmative defense by an alleged infringer in order to prevent a finding of infringement after equivalence has been established.[50] The success this defense depends upon the claim amendments and representations made by the patentee to the Patent

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45. Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 610 (1950), *reh'g denied*, 340 U.S. 845 (1950).

46. Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 934 (Fed. Cir. 1987) (en banc), *cert. denied*, 485 U.S. 961, (1988), *cert. denied*, 485 U.S. 1009 (1988). The oft-quoted language adopted by the Supreme Court in Sanitary Refrigerator v. Winters follows:

> [G]enerally speaking, one device is an infringement of another "if it performs substantially the same function in substantially the same way to obtain the same result. . . . Authorities concur that the substantial equivalent of a thing, in the sense of the patent law, is the same as the thing itself; so that if two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form, or shape."

280 U.S. 30, 42 (1929) (quoting Machine Co. v. Murphy, 97 U.S. 120, 125 (1878)).

47. Functional equivalence of proteins is a complex issue. A protein having a substantially changed structure may not function in the same manner as the native protein in terms of yielding a similar biological function. Some "functions" of the protein may be retained, while others may be lost. Does the doctrine require complete equivalence, or equivalence as to the activity of interest? These, and many other questions await a thorough analysis.

48. The application of the reverse doctrine of equivalents acting to limit a patentee's claims to a novel and nonobvious protein is a related issue which will not be addressed at this point. This doctrine awaits further development once the comments of the Federal Circuit in *Scripps Clinic* have been absorbed. *See supra* note 15. The specific question of whether the reverse doctrine of equivalents will intervene to preclude enforcement of a claim based upon isolation and purification of a naturally occurring protein against a recombinantly produced version of the protein remains to be substantively addressed.

49. Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 870 (Fed. Cir. 1985).

50. Estoppel is an affirmative defense. *See* Fed. R. Civ. P. 52(a).

Office during prosecution of the patent application.[51] Needless to say, this is a very fact-dependent issue. However, there is an intervening question of law that has not been thoroughly considered by the courts: the degree to which the prior art may preclude a finding of equivalence.

B. The Second Burden of Proof: Patentable Hypothetical Claims

Wilson Sporting Goods Co. v. David Geoffrey & Associates[52] is the first appellate decision in a half century to directly address the role of the prior art as a limit on the expansion of patent rights through the doctrine of equivalents. The Federal Circuit started its analysis in this case by reiterating the proper role of the prior art in a doctrine of equivalents analysis.

> The doctrine of equivalents exists to prevent fraud on a patent, *not* to give a patentee something which he could not have lawfully obtained from the PTO had he tried. Thus, since prior art always limits what an inventor could have claimed, it limits the range of permissible equivalents of a claim.[53]

This statement is consistent with the well-accepted view that the doctrine of equivalents "will not be used to extend a patent claim to cover a device in the public domain, i.e. found in the prior art applicable to the patent."[54] The holding in *Wilson Sporting Goods* departs from recent decisions by actually requiring the *patentee* to establish as part of his case-in-chief that the proposed scope of enforcement, cast broadly enough to

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51. Prosecution history estoppel is an essential, recurring concept in the application of the doctrine equivalents. The Supreme Court has held that "[w]hatever may be the appropriate scope and application of the doctrine of equivalents, where a claim is allowed without a restrictive amendment, it has long been settled that recourse may not be had to that doctrine to recapture claims which the patentee has surrendered by amendment." Exhibit Supply Co. v. Ace Patents Corp., 315 U.S. 126, 136 (1942).

The Federal Circuit also has recognized that "file wrapper estoppel" is a limit on the expansion of patent rights through the doctrine of equivalents. In Hughes Aircraft Co. v. United States, 717 F.2d 1351, 1363, the Court cited with approval the following text from Autogiro Co. of Am. v. United States, 384 F.2d 391, 400–01, (Ct. Cl. 1967):

> The doctrine of equivalence [sic] is subservient to file wrapper estoppel. It may not include within its range anything that would vitiate limitations expressed before the Patent Office. Thus a patent that has been severely limited to avoid the prior art will only have a small range between it and the point beyond which it violates file wrapper estoppel.

In Coleco Indus. v. I.T.C., 573 F.2d 1247, 1257 (C.C.P.A. 1978), the predecessor court to the Federal Circuit pointed out that estoppel can derive from representations made to the Patent Office as well as through actual amendments to the claims. "A patentee having argued a narrow construction for his claims before the Patent and Trademark Office (PTO) should be precluded from arguing a broader construction for the purposes of infringement." Note that prosecution history estoppel is not simply limited to estoppel created by actual amendments to the claims, but also can be based upon arguments made by the patentee to the PTO in order to obtain the patent.

52. 904 F.2d 677 (Fed. Cir. 1990), *cert. denied*, 111 S. Ct. 537 (1990).

53. *Id.* at 684 (citation omitted).

54. Ryco v. Ag-Bag Corp., 857 F.2d 1418, 1426 (Fed. Cir. 1988).

cover an accused product, does not also ensnare subject matter in the public domain.[55]

Before *Wilson Sporting Goods*, prior art most commonly intervened to block the expansion of patent rights through the doctrine of equivalents as prosecution history estoppel[56] raised by the alleged infringer in response to the assertion of infringement through equivalence. As such, the patentee did not have an explicit burden of proving that a finding of equivalence would ensnare the propr art as well. Thus, in one sense, *Wilson Sporting Goods* serves as a signal that the Federal Circuit intends to clarify the doctrine to reflect more accurately its equitable foundations, simply by requiring a higher standard of proof from the patentee seeking to use the doctrine to his advantage.[57]

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55. *Wilson Sporting Goods* is also significant in the context of clarifying what actually occurs when a patent is held to be infringed under the doctrine of equivalents. The Federal Circuit in this holding emphasized that the actual claims of the patent are not affected by an expansion of patent rights through the doctrine of equivalents.

> To say that the doctrine of equivalents extends or enlarges the claims is a contradiction in terms. The claims—i.e. the scope of patent protection as defined by the claims—remains the same and application of the doctrine expands the right to exclude "equivalents" of what is claimed.
>
> The doctrine of equivalents, by definition, involves going beyond any permissible interpretation of the claim language; i.e. it involves determining whether the accused product is "equivalent" to what is described by the claim language.

Wilson Sporting Goods, 904 F.2d at 684.

In view of this clarification, one should be careful to avoid use of the term "expanded claims" to describe the expanded scope of enforceable protection that occurs via a showing of equivalence to the claimed invention. Reference by the author to "expanded claims" in this paper is limited to those instances where this language was used in a cited decision.

56. For a substantive discussion of prosecution history estoppel, also referred to as "file wrapper estoppel," *see* D. CHISUM, PATENTS § 18.02[3] (1990). As indicated therein, the leading modern Supreme Court holding on the role and application of prosecution history estoppel is Exhibit Supply Co. v. Ace Patents Corp., 315 U.S. 126 (1942). *Exhibit Supply* sets forth the basic rule that narrowing of claims by a patent applicant during prosecution, if done to overcome a rejection based upon prior art, acts as a disclaimer of the subject matter so excised from the claim. If a patent applicant disagrees with the rejection, and wishes to preserve the full scope of protection sought in the claims, the proper course is appeal of the rejection.

57. The practical effect of *Wilson Sporting Goods* is that the patentee must now shoulder the burden of proving that a hypothetical claim covering the alleged equivalents would have been patentable over the prior art. 904 F.2d at 685. This is in addition to establishing the actual equivalence of the claimed invention and the accused product. 904 F.2d at 683. If the patentee fails to meet both of these burdens, then the accused infringer need not resort to any specific defenses, such as prosecution history estoppel.

While not addressed by the panel in the *Wilson Sporting Goods* decision, one would presume that the patentee would have to establish a prima facie case that the hypothetical claim would be novel and nonobvious over the prior art of record in the file wrapper, i.e. prior art which was considered by the patent examiner during the prosecution of the patent in question. The accused infringer, however, should be entitled to supplement the file wrapper with any additional prior art pertinent to the patentability of the hypothetical claim, and presûmably the patentee would be required to disclose any prior art not contained in the file wrapper that would be equally pertinent. The patentee's burden of establishing a prima facie case of patentability of the hypothetical claim and, specifically,

Placing a greater burden on the patentee also emphasizes the fact that the doctrine of equivalents is not simply an adjunct to a charge of literal infringement. Instead, it shifts the role of the prior art from primarily a defensive mechanism used to escape patent infringement to an active element necessary to establish a valid and enforceable right. The patentee must show that the prior art in existence at the time of the patent grant was insufficient to preclude a claim for the desired scope of protection. Furthermore, casting the issue as one where the patentee, rather than an accused infringer, must bear the bulk of the burden in order to stake a valid right to the accused product solidly grounds the doctrine of equivalents in an equitable framework.

1. *THE ROLE OF THE PRIOR ART AS A BARRIER TO "BROADENED" PATENT RIGHTS BEFORE WILSON SPORTING GOODS*

Outside the context of prosecution history estoppel, it is fair to say that prior to *Wilson Sporting Goods* there were only a handful of cases in which the issue of prior art acted as a limitation on the expansion of patent rights through the doctrine of equivalents.[58] The vast majority of references to the role of the prior art in the doctrine of equivalents analysis have been in the form of a brief, passing references in dicta to the general proposition that a patentee could not "expand his claims" to cover subject matter in the public domain.[59] This historical result may be caused by the lack of a consistent manner for interpreting prior art in the context of "broadened claims," or from the almost automatic use of prosecution history estoppel by accused infringers to thwart a patent right expansion. In any case, a summary of these past decisions helps us

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novelty and nonobviousness should therefore be based on the prior art uncovered from these three sources.

58. *See, e.g.*, Thomas & Betts Corp. v. Litton Sys., 720 F.2d 1572 (Fed. Cir. 1983); Carman v. Wahl, 724 F.2d 932 (Fed. Cir. 1983); Claude Neon Lights v. E. Machlett & Son, 36 F.2d 574 (2d Cir. 1929).

59. *See, e.g.*, Senmed, Inc. v. Richard Allan Medical Indus., 888 F.2d 815, 821 (Fed. Cir. 1989) (court noted that limitations in a claim cannot be given range of equivalents so wide as to cause the claim to encompass prior art, but precluded holding infringement through equivalence under theory of prosecution history estoppel); Tandon v. I.T.C., 831 F.2d 1017, 1026 (Fed. Cir. 1987) (after noting that claims may not be enlarged by equivalents to encompass the teachings of prior art, court precluded holding of infringement under doctrine of equivalents due to arguments made by patentee to procure patent from the Patent and Trademark Office); Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 870 (1985) (doctrine of equivalents will not permit extension to reach infringing device in the public domain, and a finding of infringement through the doctrine of equivalents can be blocked by prosecution history estoppel); Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 900 (Fed. Cir. 1984) (if equivalence is determined, infringement will be found unless prosecution history estoppel applies or if "the equivalent device is within the public domain, i.e. found in the prior art").

understand the clarification supplied by the Federal Circuit in this area through the *Wilson Sporting Goods* holding.

Prior art intervenes most effectively to block an attempted expansion of patent rights when the alleged infringer can show that the patentee actually took a position regarding the prior art during prosecution which is inconsistent with a position necessary to support expansion of the enforceable scope of the patent claims.[60] If the court is forced to delve into prior art not addressed in the prosecution, the court must consider the question of patentability of the "expanded claim" without the benefit of previous considerations of the prior art by the Patent Office or by the patentee. In addition, in the context of prosecution history estoppel, the accused infringer has traditionally borne the burden of proof in showing that the patentee did in fact forfeit the subject matter now alleged to be within the equitable enforcement rights of the issued patent claims.[61] Requiring the accused infringer to raise prosecution history estoppel as an affirmative defense relieves the court of answering the sometimes difficult question of whether the "expanded claim" would have been patentable over the prior art at the time of the patent grant.

Nevertheless, a few instances exist wherein equivalence was shown, the affirmative defense of prosecution history estoppel was not raised, and prior art actually played a role in the outcome of the case. For example, the rationale from the holding in *Claude Neon Lights v. Machlett & Son*,[62] authored by Judge Learned Hand early in this century is echoed in the opinion of the Federal Circuit in *Wilson Sporting Goods*. In *Claude Neon Lights*, the patentee attempted to expand his scope of enforceable protection to reach an electrode having an overall size which was clearly outside the literal scope of the patent claims.[63] Judge Hand concluded that to reach the accused electrode, the patentee's claim would have had to have been modified to remove the one element which rendered it patentable over the prior art.[64] He then pointed out that it was the patentee's burden to establish that such a construction could be made in order to define an "expanded claim" which would both reach the accused device and which would be patentable over the prior art.[65] As he stated, "even though we were to agree that [the accused electrode was an equivalent], we should still be faced with the question whether the added

60. *See, e.g.*, Coleco Indus. v. I.T.C., 573 F.2d 1247, 1258 (C.C.P.A. 1978).

61. Note that the issue of estoppel arises only after equivalence has been established: "Assuming the three-pronged test establishes equivalency between the claims and the infringing device, the extent to which the doctrine is utilized by a court to benefit the patentee is measured by estoppels arising from the prosecution history." *Id.* at 1257–58.

62. 36 F.2d 574.

63. *Id.* at 575.

64. *Id.* at 578.

65. *Id.*

matter so included involved invention. The plaintiff has the burden of proof on that issue and has not carried it."[66]

Perhaps the most recent case presenting an analysis similar to the *Wilson Sporting Goods* framework is *Thomas & Betts Corp. v. Litton Systems*.[67] In this case, the patentee asserted that a single strut electrical connector produced by Litton Systems infringed its claimed double strut connector.[68] Litton had modified its original parallel double strut connector design in response to an action for infringement by T & B, and had represented to its licensee that the change would not be detrimental to the function of the connector.[69] The district court held that the difference between the claimed invention and the accused connector precluded a finding of literal infringement.[70] The court then refused to permit extension of the scope of the patent claims to cover the accused device through the doctrine of equivalents, despite having concluded that the accused device was an equivalent to the device defined by the claims.[71] The court pointed out that the claimed connector, construed "sufficiently broadly" to encompass the accused connector, would have been obvious to the person of ordinary skill in view of the prior art at the time of the patent grant.[72]

In reversing the holding of obviousness of the "expanded claim," the Federal Circuit stressed that the "subject matter as a whole" must be found to have been obvious in view of the prior art.[73] The subject matter as a whole was defined by the subject matter encompassed within the "broadened" claim. The Court also emphasized that even though the patented invention did not enjoy status as a "pioneer", it was still entitled to a defined, albeit narrower, range of equivalents.[74] As the court stated,

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66. *Id.*

67. 720 F.2d 1572 (Fed. Cir 1983). The court emphasized that the validity of the actual claims in the patent was not to be questioned when assessing the patentability of the subject matter defined by the scope of equivalents: "[A]lthough the effect of the prior art on the scope of the claims in suit is to be considered, our approach should not be a 'camouflaged or back-handed attack' on the validity of the . . . patent." *Id.* at 1580.

68. *Id.* at 1573.

69. *Id.*

70. *Id.* at 1574.

71. *Id.*

72. *Id.*

73. *Id.* at 1581 (quoting 35 U.S.C. § 103).

74. *Id.* The stature of the invention is often relied upon by courts and others in determining the appropriate scope of equivalents to which the patentee is entitled. For example, Chisum identifies three categories for classifying ranges of equivalents; "pioneers, entitled to a broad range of equivalents; marked improvements, entitled to a substantial range of equivalents; and narrow improvements, entitled to limited or no range of equivalents." D. CHISUM, *supra* note 56, § 18.04[2] (citations omitted). This view is not new. The Supreme Court, for instance, identified the distinction between "pioneering" and lesser inventions in a number of early decisions. *See* Continental Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405, 415 (1908) (not only pioneer patents are entitled to invoke doctrine, but range of equivalents depends on degree of invention);

"while a pioneer invention is entitled to a broad application of the doctrine of equivalents, an invention representing only a modest advance over the prior art is given a more restricted (narrower range) application of the doctrine."[75] The critical element, then, was defining the range of equivalents to reach the accused infringing product while remaining valid over the prior art. Considering the invention based upon the "expanded claim" as a whole, the court concluded it would not have been obvious to a person of ordinary skill in the art.[76]

Similarly, *Carmen Industries v. Wahl*[77] involved a question of equivalence between two devices which promoted the flow of agricultural solids that have poor flow characteristics through the use of a vibrating device attached to the base of a hopper or storage bin.[78] The invention, as defined by the claims, required that the device have "material-receiving members" which were *concave*.[79] The district court held that although the accused device, which had a *conical* material-receiving member, did not fall within the literal scope of the claims, it was nevertheless a legal equivalent of the claimed device.[80] It then conducted an exhaustive analysis and held that the "proposed construction of the claims under the doctrine of equivalents" satisfied the requirements of patentability over the prior art.[81] The Federal Circuit upheld the lower court's finding that equivalence had been demonstrated, and agreed with

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Cimiotti Unhairing Co. v. American Fur Refining Co., 198 U.S. 399, 407 (1905) (greater liberality permitted when invention is of a pioneer character than when it is simply an improvement); Westinghouse v. Boyden Power Brake Co., 170 U.S. 537, 561–62 (1898) (claims to pioneering inventions entitled to more liberal construction).

The Federal Circuit has also recognized such a "sliding scale" of ranges of equivalents. *See, e.g., Texas Instruments*, 805 F.2d at 1563 ("It has long been recognized that the range of permissible equivalents depends upon the extent and nature of the invention, and may be more generously interpreted for a basic invention than for a less dramatic technological advance.").

In the post-*Wilson Sporting Goods* setting, however, the question of whether an invention is pioneering or incremental may serve a much reduced role. By requiring the patentee to compare the proposed "hypothetical claim" to the prior art, the court will be given an opportunity to assess exactly how significant an advance the patented invention actually was. If there is no prior art even close to the hypothetical claim, then there will be a "de facto" pioneering stature assigned to the patented invention. If, on the other hand, there is an abundance of prior art surrounding the hypothetical claim, forcing the patentee to restrict its scope so as to be closer to the actual patent claims, the invention will assume the "incremental" rather than pioneering status. What significance, if any, remains of the pioneering status label after *Wilson Sporting Goods* is yet to be determined.

75. Thomas & Betts, 720 F.2d at 1580.
76. *Id.* at 1582.
77. 724 F.2d 932 (Fed. Cir. 1983).
78. *Id.* at 934.
79. *Id.*
80. *Id.* at 936.
81. *Id.*

the district court that "in spite of the broadening effect of the doctrine of equivalents," the claims remained patentable over the prior art.[82]

Finally, in *Ryco v. Ag-Bag Corp.*,[83] the Federal Circuit upheld a lower court's determination of infringement through equivalence of two agricultural bagging machines.[84] The court rejected the assertions of Ryco that the lower court had improperly "extended the scope" of the claimed bagger so as to encompass a prior art bagger.[85] In so holding, the court compared the *accused product* to the prior art bagger and found that the accused product functioned more like the claimed bagger than the prior art baggers.[86] The court concluded that "Ryco had substituted an equivalent of the required element of the claim thereby appropriating the benefits of the invention while technically escaping the claim language."[87] The court's framing of the issue in this case was specifically rejected in *Wilson Sporting Goods*. Nonetheless, the central issue underlying the decision clearly was, in fact, whether the prior art should preclude the "expansion of the claims" to cover the accused device.

2. *THE "HYPOTHETICAL CLAIM" PRIOR ART TEST FROM WILSON SPORTING GOODS*

The analysis presented in *Wilson Sporting Goods* provides a general framework in which to assess the impact of prior art upon a doctrine of equivalents patent right expansion. The Federal Circuit instructs us to "visualize a hypothetical claim" which would be broad enough in scope to *literally* read upon or cover the accused product.[88] It is this hypothetical claim that is to be compared against the prior art at the time of the patent grant.[89] If the hypothetical claim could have been allowed by the Patent Office in view of the prior art, then prior art is not a bar to the expansion of the claim to cover the accused device. If the hypothetical claim would not have been patentable over the prior art at the time of the

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82. *Id.* at 942.
83. 857 F.2d 1418 (Fed. Cir. 1988).
84. *Id.* at 1420.
85. *Id.* at 1426.
86. *Id.*
87. *Id.*
88. 904 F.2d 677, 684 (Fed. Cir. 1990), *cert. denied*, 111 S. Ct. 537 (1990).
89. *Id.* Constructing hypothetical claims in relatively predictable technologies, such as golf ball design should not present a significant conceptual hurdle. Constructing hypothetical claims in areas such as protein chemistry, on the other hand, represents an excursion into complexity. For example, to reach a protein in which a competitor has changed one amino acid residue with no discernible effect, the patentee could phrase the claim as "a polypeptide sufficiently similar to sequence XYZ so as to retain biological activity W." Alternatively, the claim can be constructed to read "A protein having sequence AxBC," where x denotes a markush group of the actual amino acid residue and the residue replaced by the accused party. The discussion of hypothetical claim constructions presented *infra* pp. 130-133, addresses this issue in depth.

patent grant, then it is improper to permit the patentee to enforce that scope of protection in an infringement suit through the doctrine of equivalents. Even if the accused product is a factual "equivalent" of the claimed invention, there can be no infringement if the "hypothetical claim" would ensnare subject matter in the public domain at the time of the patent grant.

As noted earlier, *Wilson Sporting Goods* is significant because it shifts the burden of proving that the "hypothetical claim" would have been patentable *at the time of the patent grant.* As the Federal Circuit noted, "the patent owner has always borne the burden of proving infringement."[90] Essentially, this burden requires the patentee to establish that the hypothetical claim would have been found patentable by the Patent Office over the prior art *had the hypothetical claim originally been presented.* Prior art, as noted earlier, should include all prior art in existence at the time of the patent grant, whether it was cited during prosecution, or whether it is provided by the accused infringer to show that the hypothetical claim would not have been patentable.[91] In predictable or established technologies, proving that a hypothetical claim would have been patentable at the time of its application should not present a significant problem for the patentee. It is in the less predictable, or even unpredictable areas, such as protein chemistry and molecular biology, that the patentability of a "hypothetical claim" will prove to be a significant burden.

3. *THE "HYPOTHETICAL CLAIM" TEST APPLIED*

The hypothetical claim test from *Wilson Sporting Goods* is designed to provide a consistent, understandable mechanism for courts to use in assessing whether a desired scope of enforceable protection would be permissible in view of the prior art. As the court stated, "[v]iewing the issue in this manner allows use of traditional patentability rules and permits a more precise analysis than determining whether an *accused product* (which has no claim limitations on which to focus) would have been obvious in view of the prior art."[92] This test is applied for the sole purpose of assessing the patentability of a hypothetical claim over the prior art in existence at the time of the patent grant.[93] The court assessing

90. *Wilson Sporting Goods*, 904 F.2d at 685. *See also* Claude Neon Lights, 36 F.2d at 580.

91. *See supra* note 58.

92. *Wilson Sporting Goods*, 904 F.2d at 684 (emphasis in original).

93. *Id.* Despite the clear language presented in *Wilson Sporting Goods*, some commentators have questioned whether the requirements of 35 U.S.C. § 112 must be met pursuant to the proof of patentability of a proposed hypothetical claim. *See*, Parker, *Doctrine of Equivalents Analysis After Wilson Sporting Goods: The Hypothetical Claim Hydra*, 18 A.I.P.L.A. Q.J. 262 (1991). Delving into this question ignores the basic purpose of the test; namely to provide a consistent framework for assessing the significance of prior art against a scope of protection which the patentee does not actually have, but instead is

this argument must therefore conduct a "quasi-examination" of the hypothetical claim to assess its patentability over the prior art.[94]

The first post-*Wilson* appellate decision to apply this "hypothetical claim" analysis did so in an almost cursory fashion. In *Insta-Foam Products v. Universal Foam Systems*,[95] the Federal Circuit did not require the hypothetical claim test to be satisfied by the patentee, but did use the analysis to reject the accused infringer's contention that the proposed expansion of protection should be precluded because of the prior art.[96] Then, in *Hormone Research Foundation v. Genentech*,[97] the Federal Circuit instructed the district court, on remand, to use the *Wilson Sporting Goods* framework if it found that prosecution history estoppel would not preclude a finding of equivalence.[98] Again, the court failed to explicitly require the patentee to show that the proposed expanded scope of protection would have been patentable over the prior art as part of its basic proof.

Finally, in *Key Manufacturing Group v. Microdot, Inc.*,[99] the Federal Circuit revisited and clarified the "hypothetical claim" approach of *Wilson Sporting Goods*.[100] First, the court pointed out that the use of the

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seeking through equity. *See, e.g., Wilson Sporting Goods*, 904 F.2d at 684. Whether the party is entitled to an expansion of patent rights based upon the contribution to the advancement in technology is addressed through the question of factual equivalence in the first stage of the doctrine of equivalents analysis.

94. Judge Rich, shortly after the *Wilson Sporting Goods* opinion, discussed the role of the prior art in limiting expansion of patent rights through the doctrine of equivalents as follows:

> Several recent opinions in the Federal Circuit have stated that there are two limitations on the application of the doctrine of equivalents. *First*, claims cannot be construed so broadly under the doctrine that they *would be invalid in view of the prior art. Second*, claims cannot be so construed as to recapture what was given up during prosecution of the application for patent in order to obtain allowance of the claim, which is known as *"file wrapper estoppel."*
>
> The first exception or limitation is simply a special application of the general rule that a claim cannot be construed so broadly that it will read on or be obvious in view of the prior art. If that construction be given it, then it covers subject matter which is unpatentable under the statute. What it amounts to is that the court has to consider the validity of the claim in the form in which the patentee wishes to have it construed by application of the doctrine. All prior art known by the time of trial must be considered, not merely that cited by the examiner.

Rich, *Extent of Protection and Interpretation of Claims—American Perspectives*, 21 INT'L REV. INDUS. PROP. & COPYRIGHT L. 497, 507 (1990).

95. 906 F.2d 698 (Fed. Cir. 1990).

96. *Id.* at 704. The Federal Circuit, after reiterating the role of the prior art in a doctrine of equivalents analysis, held

> [t]hat truism, however, is of no avail to Universal because, in the terminology of *Wilson*, the hypothetical claim drawn to encompass Universal's gun would not have been unpatentable under 35 U.S.C. § 103 in view of the Johnson patent. The latter would not have motivated one of ordinary skill in the art to employ an external rather than internal biasing means.

Id. This somewhat cursory assessment of obviousness of the hypothetical claim was made without explanation beyond what is cited here.

97. 904 F.2d 1558 (Fed. Cir. 1990).

98. *Id.* at 1569

99. 925 F.2d 1444 (Fed. Cir. 1991).

100. *Id.* at 1449.

hypothetical claim analysis was not a mandatory procedure, but was instead a way to "help define the limits imposed by prior art on the range of equivalents."[101] The second point made by the court was that the patentability assessment was not intended to rise to the level of a "full blown patentability analysis."[102] Instead, the court seemed to imply that the hypothetical claim framework was more like a screening procedure to measure a proposed scope of enforceability against the prior art in existence at the time of the patent grant. The court then applied such a screening test and found that a hypothetical claim sufficiently broad to reach the Microdot's product would have been obvious over the prior art.[103] Accordingly, the court reversed the lower court's finding of infringement through equivalents.[104]

The process of clarifying of the "hypothetical claim" test for prior art continued in the holding of *Jurgens v. McKasy*.[105] In that case, the plaintiffs had sued for and obtained a finding of infringement through equivalence of a wind sock duck decoy.[106] The findings of the jury were not challenged at trial by the defendants. This allowed the Federal Circuit to review the question of infringement through equivalents essentially as a question of law.[107] First, the panel classified the "hypothetical claim" question as being one of law with factual underpinnings, citing the holdings of *Loctite* and *Wilson Sporting Goods*.[108] The panel then constructed a "hypothetical patent claim—similar to the asserted claim but broad enough to literally cover the accused products" and tested "whether that claim would have been patentable in view of the prior art."[109] The court found that such a claim was identical to the existing patent claims, except for the removal of limitations on the arrangement of the elements of the windsock which had originally placed the accused product outside of the literal scope of the claims.[110] The court then turned to a conclusion of the jury that a certain element in the prior art which showed this arrangement of elements was not relevant to the patented windsock because the cited disclosure was not analogous art. This finding, the court held, justified its conclusion that the "hypothetical claim" in question would not have been rendered unpatentable by the

101. *Id.*
102. *Id.*
103. *Id.*
104. *Id.*
105. 927 F.2d 1552 (Fed. Cir. 1991).
106. *Id.* at 1555.
107. The failure of the defendants to challenge the jury's finding of factual equivalence led to a summary disposal of this aspect of the defendant's appeal on review, leaving only the legal question of equivalence for the court. *Id.* at 1561.
108. *Id.*
109. *Id.*
110. *Id.*

prior art.[111] Therefore, the court affirmed the legal conclusion of infringement through equivalence.[112]

The posture of the Federal Circuit in these post-*Wilson Sporting Goods* decisions tends to downplay the prospect of the hypothetical claim test becoming an unmanageable and threatening burden for patentees. While the court does classify the question of patentability of the hypothetical claim over the prior art as one of law, it appears that the court will look to the conclusions of the fact finder to assess the significance of the prior art. The hypothetical claim test should not force courts to take the place of the Patent and Trademark Office, conducting *de novo* examinations of proposed claims and assessing their patentability in view of all the statutory patent guidelines. Nor is it likely that the test will require extensive excursions into prior art, assessing in detail the significance of individual disclosures. As Judge Rich pointed out, this test is merely a means for assessing the significance of the prior art using an analysis with which the courts are familiar: the questions of novelty and nonobviousness.[113]

IV. APPLYING THE HYPOTHETICAL CLAIM TEST TO PROTEIN PATENTS

The progress of the prior art at the time the patent application was filed is critical to a hypothetical claim analysis. First, since the effect of the prior art upon expanded patent rights is to be measured at the time of

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111. *Id.* at 1561–62.

112. *Id.* at 1562.

113. *See supra* note 95. A fear that this hypothetical claim framework lessens the presumption of validity that is attached to issued patents seems unfounded as well. Parker, *supra* note 94, at 276. The text of *Wilson Sporting Goods* provides several reminders that any assessment under the doctrine of equivalents necessarily involves going outside of the patentee's actual claims. The merits of a hypothetical claim outside the context of measuring and assessing the prior art are irrelevant, simply because they are not actual claims. As the court emphasizes, "[t]he doctrine of equivalents, by definition, involves going beyond any permissible interpretation of claim language." Wilson Sporting Goods Co. v. David Geoffrey & Assocs., 904 F.2d 677, 684 (Fed. Cir. 1990), *cert. denied*, 111 S. Ct. 537 (1990). Conclusions reached concerning the patentability of a hypothetical claim over the prior art have no effect and no bearing on the question of validity of the actual claims. "Wilson's claims remain valid whether or not Wilson persuades us that it is entitled to the range of equivalents sought here." *Id.* at 685.

Many practical questions regarding implementation of the hypothetical claim test, however, remain to be elucidated. For example, although the patentee is to shoulder the burden of proving that the proposed scope of protection would have been patentable over the prior art, it is unclear what sort of burden will be imposed on the patentee to search and provide prior art beyond what was considered in the original prosecution. Even more perplexing is any expectation of the court that a patentee will adopt a detailed theory as to such a claim's patentability which differs in any form from that already present in the prosecution history for the original claims. Thus, patentees may approach this burden of proof by adopting a simple pro forma statement of patentability based upon the rationale used in the prosecution history.

the patent grant, the patentee must ascertain what the prior art would have meant to the person of ordinary skill at that time.[114] Second, whether a novel species of protein encompassed by a hypothetical claim would have been obvious to the ordinary worker rather than "obvious to try"[115] will depend upon factors such as whether the primary structure was known, or whether any structure-function relationships had been elucidated. The successful application of this "hypothetical claim" approach requires the patentee to first identify the prior art in existence at the time the patent application was filed; second, to ascertain the level of skill of the ordinary worker at that time; and finally, to demonstrate that the prior art would neither have anticipated, nor would have made obvious, the protein species defined by the hypothetical claim.

A. A Typical Evolution of Prior Art Following Protein Discovery

A very general summary of a typical progression that is observed once a novel protein or activity has been identified may be set out as follows.

1. Stage One: the protein is isolated and purified from natural sources;
   a) Unique biological activity is discovered in purified extract and assigned to an identifiable protein species;

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114. "[T]he doctrine will not extend to an an infringing device within the public domain, i.e., found in the prior art *at the time the patent issued.*" Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 870 (Fed. Cir. 1985) (emphasis added). This statement, taken literally, is at odds with the requirement that patentability be assessed at the time the patent was applied for, rather than at the time of its examination and issuance. In proving patentability of the hypothetical claim, it must follow that one must assess the state of the art, and ascertain the level of skill at the time the patent application was filed. The notorious backlog in biotechnology related patent applications at the Patent & Trademark Office has created a situation where one cannot realistically equate the level of skill at the time of application with that at the time of issuance of the patent (e.g. an application filed in 1984 may not have issued until 1990). Where technology is rapidly maturing, as in protein chemistry, such 3 to 5 year delays can have a significant impact on interpretations of the "ordinary level of skill in the art." As the Federal Circuit stated, it is essential that

> the decisionmaker forget what he or she has been taught at trial about the claimed invention and cast the mind back to the time the invention was made . . . to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art.

W.L. Gore & Assocs., v. Garlock, Inc., 721 F.2d 1540, 1553 (Fed.Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

It should be kept in mind that the accused infringer has a potentially critical role in ensuring that all relevant prior art is before the court before it attempts to assess the patentability of a hypothetical claim. Since the hypothetical claim analysis involves the comparison of subject matter beyond what was considered by the patent examiner during prosecution, there is a grave potential for prior art not in the file wrapper to play a significant role in determining the patentability of the hypothetical claim. *See supra* note 58.

115. For a discussion of the "obvious to try" doctrine, see *infra* note 132.

b) Protein is purified using conventional techniques to an essentially homogeneous level;
c) Primary structure is partially identified (e.g. N-terminal amino acid sequence elucidated), presence of post-translational modifications are detected.

2. Stage Two: the primary structure of the protein is elucidated and the protein is expressed by recombinant techniques;
   a) Gene coding for the protein is ascertained through the use of DNA probes; full sequence for the protein is predicted;
   b) Protein is expressed recombinantly so it possesses biological function, full sequence of protein is verified.
3. Stage Three: novel protein sequences are designed and expressed;
   a) Site-directed mutagenesis is used to identify amino acid residues essential to proper structure and function of the protein, elucidation of secondary sequence;
   b) Molecular modeling, x-ray crystallography, and genetic mutational studies used to elucidate sequence-structure-function relationships;
   c) Non-naturally occurring species of peptides and proteins designed and expressed based upon knowledge of sequence-structure-function relationships of the isolated protein.[116]

The purpose behind outlining this generalized progression in the art is to focus the reader's attention on a situation which is somewhat unusual when considering the impact of prior art upon a particular claimed protein. Until *de novo* protein engineering is possible, the protein engineer must first identify and isolate a protein from natural sources before expressing a wild type protein in recombinant form and producing non-naturally occurring forms of a protein. In other words, a person of

116. A final stage which is not realistically included in this paper is *de novo* protein synthesis not based upon known sequences. Four years ago, the following summary represented a fair estimate of the state of the art: Designing proteins *de novo* is the Holy Grail of the protein engineer. The greatest challenge of all is to create a functional enzyme or protein—properly folded—from first principles. And the obstacles are staggering. To date, it is still not possible to predict the tertiary structure of a protein from its amino acid sequence—unless that sequence is very homologous to some other protein whose X-ray crystallographic structure is already known. Van Brunt, *Protein Architecture: Designing from the Ground up*, 4 BIO/TECHNOLOGY 277 (1986).

At this time, *de novo* protein design and synthesis remains at a rudimentary stage, concentrating more on the successful prediction of protein conformations rather than on an attempt to predict biological function associated with different conceptual conformations. Advances in computing power, increased amounts of structural data, and instances of success all have led to incremental advances, yet by no means can one say that the "Holy Grail" is within reach. *See also* DeGrado, Wasserman & Lear, *Protein Design, a Minimalist Approach*, 243 SCIENCE 622–28 (1989) (hereinafter DeGrado).

ordinary skill in the protein engineering art cannot at this time adapt existing knowledge of protein structure and function to produce a completely new protein entity. The overall "machinery" of discovery, isolation, purification, and characterization available to the skilled worker are of little help in "inventing" a previously unknown protein. Until the naturally occurring species is discovered and characterized at least to a partial degree, the later stages of invention are simply not possible.

Again, this summary is not intended to cover every possible situation; instead it presents a general progression that usually follows the discovery of a new protein. Likewise, an attempt to identify and address every possible interaction between the prior art and a hypothetical protein claim would be both futile and incomplete. Rather than attempt to categorize and predict the outcomes of all such potential interactions, this paper focuses on a few key points that need to be considered when construing the effect prior art has on hypothetical "expanded" claims.

B. A Purified Protein Patent Has a "Quasi-Pioneering" Stature

A patentee holding a claim based upon isolation and purification of a protein from "natural" sources is not likely to encounter problems from the prior art when seeking to expand patent rights through the doctrine of equivalents. Generally speaking, the discovery of a new protein has a "pioneering stature" because, unlike new compounds produced through chemical synthesis, a newly discovered protein having a novel activity or "function" could not have been "predicted" or even contemplated prior to its actual discovery. At most, the prior art at the time of the patent grant will have disclosed the protein in an unpurified, or less purified state.[117] Also, this sort of absence of "significant" prior art is often viewed by the courts as an important factor when assessing whether or not an invention should be classified as "pioneering."[118] Yet, the successful identification and isolation of a new species of protein does not typically rise to the level of a truly pioneering invention when measured in terms of the conventional procedures used to identify, isolate, produce and purify, proteins.[119] In this respect, the "pioneering" aspect of a new

117. The presumption underlying this conclusion is that an increased purity led to the finding of patentability of the protein claim. If the prior art teaches a protein having the same level of purity and activity, it should not be possible to obtain a claim to a protein lacking some qualifying parameters drawn to purity or activity. Typically, when a protein is expressed by a recombinant host, routine procedures permit recovery of high purity protein.

118. For example, in Texas Instruments v. I.T.C., the Federal Circuit found persuasive the absence of "significant" prior art in holding the electronic hand-held calculator of T.I. to be a "pioneering" invention. 805 F.2d 1558, 1572 (Fed. Cir. 1986).

119. The Federal Circuit in Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir. 1991), provided a good example for this "quasi-pioneering" characterization.

protein discovery stems from the inherent unpredictability of the discovery itself.

Prior art insufficient to have made "obvious" or to have "anticipated" the *actually* claimed protein at the time of the patent grant is also not likely to be construed to render a hypothetical claim to a protein unpatentable, at least where the levels of purity are equal.[120] As the court reminds us in *Wilson Sporting Goods*, the pertinent question is "whether that hypothetical claim could have been allowed by the PTO over the prior art."[121] The patentee in this situation must show that a hypothetical claim can be written which encompasses the accused protein without ensnaring *less purified*, naturally derived protein compositions. This burden is not expected to be formidable. Accordingly, a newly discovered and isolated protein species can have a pioneering nature at least with respect to the limiting impact of the prior art.

C. Hypothetical Claims Based Upon Patented Native Sequence Recombinant Proteins

A patentee holding a claim to a native sequence protein produced through recombinant procedures is in a situation analogous to the patentee with a claim based upon purified protein work. In such a scenario, it is likely that the protein engineer had to solve some problems prior to successfully expressing a fully functional native sequence protein by recombinant means. It is the resolution of these problems, not the superiority of the recombinant product over existing prior art, that will persuade the examiner to allow the claim. As such, the prior art the patent applicant must distinguish is not "significant" in the sense that it was not sufficient to bar the allowance of a claim to a protein having the same sequence expressed through recombinant means. This same prior art will not be capable of precluding expansion of patent rights to subsequent efforts (e.g. non-native sequence proteins). Since patentability will often be based on the expression of the recombinant gene rather than the protein itself, the prior art should not bar hypothetical claims to

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There the court found that Amgen had achieved a simultaneous conception and reduction to practice through the successful characterization and subsequent expression of the erythropoeitin protein. *Id.* at 1205. It noted that even though the procedures used by Amgen had been commonly used and known prior to their application to the erythropoeitin problem, there was a level of uncertainty and unpredictability associated with the successful application of these techniques to yield erythropoeitin. *Id.* at 1208–09.

120. Whether the target of the "expanded claims" is a recombinant version of the protein having a primary structure identical to or distinct from that of the native protein is irrelevant as these species represent later stages of invention that would not have been possible absent the actual discovery and characterization of the new protein. In assessing such hypothetically claimed proteins, keep in mind that the recombinant version will have a purity and activity typically at least as high as the protein teachings which served as the basis for the patent.

121. *Wilson Sporting Goods*, 904 F.2d at 684.

recombinant expression of non-native sequence proteins.[122] Any other result would raise questions as to the validity of the patented protein claim itself.

D. Limitations of the Prior Art Arise for "Mutant" Proteins

The first stage at which the prior art will realistically act to limit expansion of patent rights occurs where the patentee holds a claim to a non-naturally occurring species derived from a known protein.[123] Here, the patentee's claimed species is likely to have a different primary structure than the species of protein found in nature, or will differ through the absence or modification of the post-translational chemical modifications possessed by the naturally occurring species. In both situations, the patentee is likely to have obtained protection for a species of protein because of a material distinction in the protein as compared to the way the protein is found in nature, or as it is produced through conventional recombinant techniques. The material distinction is assumed to have provided the basis for the finding that the mutant protein species itself was patentable over the prior art. For simplicity, this analysis will focus on the scenario in which only the primary structure of the protein has been altered.

1. *PRACTICAL PROBLEMS IN CONSTRUCTION AND PROOF OF PATENTABILITY OF HYPOTHETICAL MUTANT PROTEIN CLAIMS*

The patentee faces the practical problem of *constructing* a hypothetical claim which reads upon both the patented protein and the accused protein, but which does not ensnare the naturally occurring species of the protein. How this claim is constructed will directly influence the outcome of the "hypothetical claim" approach. If the hypothetical claim is patentable over the prior art, the prior art will not limit the expansion of patent rights sought by the patentee.

How the patentee will actually structure the hypothetical claim is highly dependent upon the relationship between the patented and accused species of proteins. Two important factors to consider when assessing both the patented species and the accused species include the extent of change of the primary structure (e.g., single residue changed, removal of portion of the sequence, addition of non-native sequence) and

122. The target of the expansion of patent rights will normally represent a stage of invention at or beyond that which the patented protein represents.

123. For the sake of simplicity, a protein which has been modified so as to be different from the protein as it is found in nature will be called a "mutant." Also, a basic assumption that the prior art discloses the full length primary structure of the protein has been made for the purposes of this discussion.

the introduction of any novel functions into the mutated species (e.g., diminished or enhanced biological function or activity as compared to native species, additional activities not possessed by native species). In this context, the hypothetical claim will have to vary in its use of structural and functional terms so as to ensure that the proposed "literal scope" reaches both the patented and the accused species. Where the accused species has a substantially altered primary sequence relative to the patented sequence, as well as to the native sequence, a function-oriented hypothetical claim may be necessary to reach it. However, because the use of function-oriented terms in a claim tends to increase the number of prior art species falling within its "literal" scope, the hypothetical claim is less likely to be patentable.

(a) A "Hypothetical Markush Group" Claim

A hypothetical claim theoretically could be cast as a simple markush group consisting of the accused mutant and the claimed mutant. Here, the focus of the "hypothetical" claimed mutant is, of course, *directly* on the accused species. It follows then, that if the accused species differs significantly from the native sequence, or changes the activity or stability of the protein, it will likely be found patentable over the art at the time of the patent grant. This is because the first species of the markush type claim has already been held to have been patentable.[124] In essence, the burden facing the patentee in this approach will be to establish that the accused mutant protein would have been patentable over the art at the time of the patent grant.

The markush-type approach is problematic because it falls back on the type of comparison that the Federal Circuit specifically instructs us *not* to adopt in construing the effect of the prior art. The court in *Wilson Sporting Goods* was critical of earlier judicial opinions which compared the accused product to the prior art in assessing whether the prior art would serve to prevent expansion of patent rights through a finding of equivalence. Such a comparison negates the benefit envisioned through the hypothetical claim approach. "Viewing the issue [as a hypothetical broadened claim] allows use of traditional patentability rules and permits a more precise analysis than determining whether an accused product (which has no claim limitations on which to focus) would have been obvious in view of the prior art."[125] There is an obvious risk then that a simple markush group will be held to improperly focus on the accused species of protein.

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124. The court indicated in *Wilson Sporting Goods* that the validity of the actual claims was not at issue when considering the patentability of the hypothetical claim during a doctrine of equivalents analysis. 904 F.2d at 684.

125. *Id.*

(b) Broad "Function-Oriented" Hypothetical Claims

At the other extreme is the hypothetical claim cast in predominantly functional terms. Use of functional terms without structural limits presents two problems. First, the patentee may not be able to even *identify* the range of species falling within a predominantly functional hypothetical claim. For example, if a claim simply reads "a protein having function Z of protein X where at least one residue has been changed, deleted, or added in the native sequence of protein X," ascertaining which species actually do retain the function Z will prove to be a practically impossible task.[126] Second, the absence of enough qualifying structural elements will result in a claim that literally encompasses an enormous number of species of new sequences. The risk in this scenario is that one or more species falling within the literal scope of the hypothetical claim will be found to have been unpatentable over the prior art, thereby negating the proposed expansion of patent rights.

At this point in time, there is insufficient guidance from the courts to ascertain which of the various approaches is proper. From the perspective of the patentee seeking to establish that a hypothetical claim would have been patentable, obviously the markush group approach simplifies the task. In any case, an understanding of the issues of patentability facing the patentee is essential.

2. PATENTABILITY ISSUES

Once the hypothetical claim has been defined by the patentee, it must be shown to have been patentable over the prior art at the time of the patent grant. In practice this burden will boil down to the question of whether the mutated protein would have been obvious in view of the prior art. This conclusion stems from the simple recognition that if the hypothetical claim is drawn to reach species actually disclosed in prior art prior to the filing of the patentee's application, the hypothetical claim would have been unpatentable due to anticipation. Also note that in this type of scenario, where the patentee holds a patent to a mutant species, it is very likely that the native sequence species was fully disclosed at the time of the patent grant.

Assessing obviousness of a novel protein sequence is not a simple exercise, and is highly fact dependent. Some common issues, however,

126. This problem is illustrated well by the Federal Circuit's affirmance of the finding of invalidity due to a lack of enablement in Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir. 1991). The district court found that over 3,600 different EPO analogs can be made by substituting at only a single amino acid position, and over a million different analogs can be made by substituting three amino acids. After five years of experimentation, the court noted, "Amgen is still unable to specify which analogs have the biological properties set forth in claim 7." *Id.* at 1213.

can be identified.[127] First, if the change introduced affects the activity or function of the protein in a positive or desirable manner, an argument focusing on the inability to accurately predict such a change should be persuasive in establishing nonobviousness of the change. Likewise, if the primary structure of the native protein is significantly altered (e.g., large domains or regions removed), unpredictability of the effects of that change should fall into the same category of nonobvious modifications. If, on the other hand, the change is a "conservative" change, or if the change is one which has been routinely successful in analogous protein systems, the burden of establishing that such a species was nonobvious may be difficult to meet, especially in view of the recent revival of structural obviousness.[128] The burden facing the patentee requires recognition of which of the two situations is present, and how to best cast the claim in the context of the former, rather than the latter.

(a) Conservatively Changed Mutants as Structurally Obvious Homologs or Analogs

By the mid-1980's, advances in DNA techniques, particularly site directed-mutagenesis, enabled the average worker in this field to confidently produce a wide range of closely homologous species of proteins based upon a fully characterized primary structure of a known protein.[129] In a relatively short time frame, the typical investigator would have been able to ascertain which amino acid substitutions could be tolerated at a preselected site in the native sequence.[130] Producing a mutant having the same activity and overall conformation as the native protein but which differed through one or more conservative changes in the primary structure could arguably have been accomplished with nothing more than routine amounts of experimentation.

An assessment of the "obviousness" of such a species is of course debatable,[131] but in view of the fact that the result of the change imparted

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127. It is likely that the prior art showed recombinant expression of the native sequence protein at the time of the patent grant. This is because elucidation of the protein's primary structure is a necessary prerequisite to both recombinant expression of the native sequence and the non-native mutants. Furthermore, the typical progression in research is to successfully express the native sequence before attempting to create novel mutants derived from that native sequence.

128. *See In re* Dillon, 919 F.2d 688 (Fed. Cir. 1990) (en banc).

129. In fact, a common use of site directed mutagenesis is to ascertain structural information about the protein by assessing the sensitivity of the native sequence at particular residues to changes. *See* Bowie, *supra* note 42, at 1306 (proteins are surprisingly tolerant of amino acid substitutions); DeGrado, *supra* note 117, at 622 (site-directed mutagenesis is standard technique for determining which residues in a protein are essential for folding or function).

130. *See, e.g.*, Leatherbarrow & Fersht, *supra* note 33, at 8.

131. Invariably, a debate over whether such a mutant would have been "obvious to try" rather than obvious will arise. The patentee wishing to pursue this line of reasoning

no new activities or properties to the protein, that the method used to impart the change was well known and within the ordinary level of skill in this art, and that in the course of study of the protein, such species would be produced, it is hard to justify a conclusion that a nominally changed protein would have been nonobvious.

The source of this view is the notion of "structural obviousness" based upon similarities of one chemical species to a homolog or analog of that species. The relationship between conservatively substituted species of a known polypeptide sequence and the sequence from which they derive justifies treating these species as "homologs" in the context of assessing the patentability of each species. It may be helpful to consider the "structural obviousness" standard a first screen for the different species encompassed by the hypothetical claim. In light of the recent decision of the Federal Circuit sitting en banc in *In re Dillon*,[132] structural obviousness is by no means a dormant or out-of-date concept. In *Dillon*, the Federal Circuit summarized the concept of structural obviousness as follows:

> In brief, the cases establish that if an examiner considers that he has found prior art close enough to the claimed invention to give one skilled in the relevant chemical art the motivation to make close relatives (homologs, analogs, isomers, etc.) of the prior art compound(s), then there arises what has been called a presumption of obviousness or a prima facie case of obviousness. . . . The burden then shifts to the applicant, who then can present arguments and/or data to show that what appears to be obvious, is not in fact that, when the invention is looked at as a whole. . . . The cases of *Hass* and *Henze* established the rule that, unless an applicant showed that the prior art compound lacked the property or advantage asserted for the claimed compound, the presumption of unpatentability was not overcome.[133]

In essence, the structural obviousness standard requires that "to be patentable, novel members of a homologous series of (chemical) compounds must possess some nonobvious or unexpected beneficial properties not possessed by a homologous compound disclosed in the prior art."[134] What satisfies this "unexpected beneficial property" requirement varies depending on the facts of the situation. The predecessor court to the Federal Circuit noted, however, that

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in the context of a broad hypothetical claim, however, will not be able to rely upon the benefits of the particular changes made by the patentee or the accused infringer in bolstering such an assertion. *See In re* O'Farrell, 853 F.2d 894 (Fed. Cir. 1988) (holding that unpredictability in the field does not automatically relegate any effort of the ordinary worker to the "obvious to try," rather than obvious standard).

132. 919 F.2d at 692 (reaffirming that structural similarity between claimed and prior art subject matter creates a prima facie case of obviousness where the prior art gives reason or motivation to make the claimed compositions).

133. *Id. at* 696 (citations omitted).

134. *In re* Hass, 141 F.2d 127, 129 (C.C.P.A. 1944).

> [p]atentability is not resolved conclusively even where unexpected or nonobvious beneficial properties are established to exist in novel members of a homologous series over prior art members, as the circumstances of the case may require a consideration of other factors. A mere difference in degree is not the marked superiority which ordinarily will remove the unpatentability of adjacent homologs of old substances. The reason for the rule is that the characteristics normally possessed by members of a homologous series are principally the same, and vary but gradually from member to member. Chemists knowing the properties of one member of a series would in general know what to expect in adjacent members.[135]

Biological activity of the compound in question, or its homologs, is often a controversial "unexpected beneficial property," at least to the degree that the species to which it is being compared as an analog lacks the particular activity or function. In one context, the courts have viewed the possession of a particular biological activity as being an expected property of the homolog.[136] When, however, a new or modified activity is induced or first identified in the homolog, the courts have been reluctant to sustain a prima facie obvious holding.[137] The possession of a *patentably distinct* biological function seems to take the new species out of the realm of "structurally obvious" homologs or analogs.

(b) Unpredictability and Unexpected Results: The Foil of Structural Obviousness

The presence of unexpected results, or unpredictability in the art is a complementary issue to "structural obviousness" for homologs. In the context of changing specific amino acid sites in polypeptide sequences to achieve a specific result, this argument may carry some weight.[138] This conclusion is based upon three assumptions; first, that the prior art at the time of the patent grant most likely did not disclose information

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135. *In re* Henze, 181 F.2d 196, 201 (C.C.P.A. 1950) (citations omitted).

136. *See, e.g., In re* Merck, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (claimed drug was obvious in light of structurally similar prior art drug with similar antidepressant properties); *In re* Wood, 582 F.2d 638, 644 (C.C.P.A. 1978) (structural similarity would have led one skilled in the art to expect anti-microbial properties of prior art compound to appear in claimed compound); *In re* Mod, 408 F.2d 1055, 1059 (C.C.P.A. 1969) (anti-microbial activity discovered in claimed compound insufficient to distinguish it from structurally similar prior art compound having other properties in common with it).

137. *See, e.g., In re* Schechter, 205 F.2d 185, 191 (C.C.P.A. 1953) (claimed synthetic analogs possessing commercial advantages over natural insecticides were not obvious).

138. *See* Leatherbarrow & Fersch, *supra* note 33, at 8 ("It is clear, however, that in the absence of structural data on a protein, interpretation of the effects of sequence alteration is often at best difficult and at worst impossible."). In the same issue of PROTEIN ENGINEERING, Wetzel states in the context of discussing applications of deduced primary sequence relationships: "Of course, while the effect of such a 'primary sequence element' on a particular property (target site, stability, etc.) may be predictable, the effect of the element on the active conformation of the protein is unpredictable; for example, one may succeed in making an inactive, oxidatively stable mutant." Wetzel, *supra* note 36, at 3.

concerning the relationship between structure and function of the protein; second, that there is an absence of motivation to make the specific change that was made in the accused mutant species; and finally, that there is some non-trivial impact arising from the specific change made. A persuasive argument can be made that while production of the specific mutant species might have been within the abilities of the ordinary worker, the prior art failed to teach that the particular species having the *novel functional characteristics* of the new species could be produced. The result of this unpredictability element, then, is that production of the species would have been merely "obvious to try," rather than obvious.[139]

The "obvious to try" argument generally focuses on the absence of any suggestion in the prior art to produce the exact species contemplated. In essence, the argument serves to counter a conclusion of obviousness for particular inventions in which unusual or unpredictable factors were significant, even though actual reduction to practice of the invention may have required only routine efforts of the ordinary worker in the art. The argument that the invention would have been obvious is thus rejected because it improperly relies on hindsight in evaluating the contribution of the invention.[140] The patentee must be careful in using this type of an argument to support a bare contention that the hypothetically claimed species would have been patentable over the prior art simply because the modification would have been "unpredictable" in its effect without further justification. Recent decisions of the Federal Circuit have emphasized that a certain degree of unpredictability in the art does not automatically render production of any species in that technology merely

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139. The Federal Circuit addressed the issue of the "obvious to try" standard in the context of expression of a particular protein in bacterial cells in *In re* O'Farrell, 853 F.2d 894 (Fed. Cir. 1988). The court pointed out that this argument does not apply to every attempt in an art which has a certain level of unpredictability. Instead, the court identified two basic types of "obvious to try" situations:

> The admonition that "obvious to try" is not the standard under §103 has been directed mainly at two kinds of error. In some cases, what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. . . . In others, what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.

Id. at 903.

In the context of a specific mutation made to produce a mutant having some desirable and novel characteristic, the argument that it would have been at best obvious to try to make the mutant is persuasive. This is so because it fits into the analysis that (a) general procedures were known in the art that could produce the mutant, but (b) there was no specific direction available to produce the "successful result" (e.g., the new mutant having the unique activity or function). A detailed discussion of the "obvious to try" doctrine is outside the scope of this paper.

140. *See In re* Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988); Hybritech Inc. v. Monoclonal Antibodies, 802 F.2d 1367, 1380 (Fed. Cir. 1986).

"obvious to try" rather than actually obvious.[141] Instead, the patentee should focus an "obvious to try" argument on the elements present in the hypothetical claim, and on the impact these structural elements have on any novel functions or activities derived from the change.[142] Resort to this argument, therefore, requires a specific, rather than generalized, argument that the result obtained is significant.

V. CONCLUSION

The limiting effect of the prior art on expansion of protein patent rights through the doctrine of equivalents, as embodied by the new "hypothetical claim" test, will not present an insurmountable burden for a patentee holding an early protein patent.[143] This "second burden of proof" should prove to be minimal where, as is typical for most early "purified protein" and recombinant native sequence protein patents, the patentee obtained the patent due to the absence of a significant amount of prior art. The "quasi-pioneering" stature that these early patents enjoy serves to relieve the patentee of a potentially difficult burden.

As protein engineering technology matures, the burden of proving that a new protein mutant as embodied by a "hypothetical claim" is not only a structural and functional equivalent to the assertedly infringing protein, but also that the prior art should not be construed to hold that "hypothetically claimed" protein unpatentable, will become significant. This burden will be especially significant when the patentee holds a patent limited to a specific, non-naturally occurring protein sequence, and there has been substantial activity in the prior art. As discussed at length above, even constructing an appropriate hypothetical claim in such situations will be a difficult task, especially in view of the complex interplay between structural obviousness and "obvious to try" theories for efforts undertaken in the realm of protein engineering.

This summary is not intended to suggest that holders of early protein patents will not face substantial barriers to expanding protein patent rights through the doctrine of equivalents. The burden of proof created by *Wilson Sporting Goods* arises only after factual equivalence between the claimed protein and the accused species has been established by the patentee. Proof of factual equivalence between a naturally

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141. *See In re* O'Farrell, 853 F.2d at 903, (possibility of unexpected results provides objective basis for showing invention is nonobvious); *In re* Merck, 800 F.2d at 1097 (obviousness requires only a reasonable expectation that the beneficial result will be achieved).

142. For example, improved resistance to oxidation, increased retention time in the host after administration, omission of a particular functional domain, decreased activity relative to the native species, or additional functional properties.

143. The Federal Circuit applied the hypothetical claim test almost as an afterthought in Instafoam Prods. v. Universal Foam Sys., 906 F.2d 698, 704 (Fed. Cir. 1990).

occurring protein and an even moderately altered derivative is the most significant burden for the patentee to bear in an infringement through equivalence proceeding because of the inherent complexities of protein conformation and function. As the protein engineering field matures, patentees holding such protein patents, or seeking to expand patent rights to novel protein derivatives, will begin to find that the combined effect of these two burdens of proof will be formidable. This burden, however, will help ensure that the doctrine of equivalents will retain the role it was designed to serve: namely, as a means for preventing, through equity, the "piracy" of an applicant's patented invention.

SYMPOSIUM REPORT

BIOTECHNOLOGY LAW

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INTRODUCTION

On November 8 and 9, 1990, the American Law Institute–American Bar Association Committee on Continuing Education presented a symposium on Biotechnology Law which was cosponsored by California Continuing Education of the Bar. The following are short summaries of the speeches presented at that conference.

BIOTECH 91: A CHANGING ENVIRONMENT

Mr. G. Steven Burrill
Ernst & Young
San Francisco, CA

Biotechnology began in the 1970s as an industry dominated by geographic areas noted for their academic resources and populated by academics, rather than business people. Today, there are approximately 1100 biotechnology companies in the United States, one third of which are located in the San Francisco Bay Area. While most companies have fewer than fifty employees, a few companies dominate the industry. The largest nine percent of biotechnology companies employ 55% of those working in the industry and generate almost all of the sales revenue.

With the decline of ready capital from initial public offerings, strategic alliances have become an important source of financing. Bringing even a single pharmaceutical product to market requires approximately $200 million, thus precluding independent projects by small and mid-sized companies. Strategic alliances with foreign companies can provide access to both capital and foreign markets.

Uncertainty in the FDA's regulatory approval process has also hurt the entire industry and presents substantial problems for marketing products in the United States. The FDA has moved toward using outside panels for advice which often become sidetracked from the main issues of safety and efficacy.

In addition, the backlog on patent litigation has led to a decreased focus on patent protection. Instead, cross-licensing is fast becoming an increasingly popular mechanism for protecting products and settling disputes.

Finally, although regulatory hurdles are increasing for health-care related products and the capital market for new companies is fairly weak, the industry remains reasonably healthy, generating about $100 billion by the end of the century. The new reality for biotechnology consists of increasing consolidation, efforts at regulatory approval and reimbursements, and changes in government policy.

PRODUCT LIABILITY CONSIDERATIONS

Professor Eleanor Fox
New York University School of Law
New York, NY

Mr. Michael Traynor, Esquire
Cooley Godward Castro Huddleson & Tatum
San Francisco, CA

In *Brown v. Superior Court,* the California Supreme Court held that strict liability does not apply to manufacturers of consumer drugs. In reaching its decision, the court looked to comment K of the Restatement of Torts which applies a negligence standard to products that are unavoidably unsafe. The court rejected a case-by-case approach and instead articulated a blanket rule that prescription drugs are not subject to strict liability for design defects.

The *Brown* negligence rule has not gained whole-hearted acceptance around the country. Some courts have explicitly rejected *Brown,* while others have made compliance with FDA regulations a defense only against punitive damages.

While strict liability provided an efficient mechanism for compensating accident victims whereby companies internalized the cost of such social insurance, changing market conditions have made strict liability unworkable. Given the high costs of insurance, strict liability could stifle important research. Comment K attempts to address this problem by applying a negligence-only standard to products that are essential for human health and need to reach the commercial market quickly.

The core problem behind the strict product liability debate is the cost of medical innovation. The courts should draw from other disciplines, such as antitrust, where difficult issues have been resolved to allow for significant invention. In addition, the courts must distinguish between the negligence and insurance aspects of the law. The twin goals of deterrence and compensation must be kept distinct. Finally, the rules must be designed to maximize human life and health. Therefore, the Restatement should be amended in §402a to read "products for human life or health are presumptively not dangerous without proof of negligence." Compliance with regulatory guidelines should provide a liberal defense, and punitive damages should be awarded cautiously. Judges should also be bolder in finding that there is insufficient evidence to send the case to a jury.

THIRD PARTY REIMBURSEMENT FOR GOODS AND SERVICES

Mr. Wayne Roe
President
Health Technology Associates
Washington, DC

Biotechnology companies must focus on payment planning as much as seven years before marketing their product. This consideration is

especially important if the product involves high clinical visibility, high unit costs, an institutional setting, injection or infusion of the drug, or significant payer market exposure. For most products, insurance companies will pay the lion's share of the costs. However, the presence of any of these factors should trigger an initial evaluation of third party payment.

Previously, insurers paid for any drug with FDA approval. Today, the situation is less clear. To avoid diminishing market penetration, biotechnology companies must be more aggressive. Since the insurance company is the target market, companies must segment the payer market, using information from sources such as the National Hospital Discharge survey.

An example would be a drug that had two possible applications, one for breast cancer and one for prostate cancer. The company would need to consider different patient groups. Breast cancer victims would largely be insured through groups like Blue Cross, while prostate cancer victims are more likely to be on Medicare, which will not reimburse for self-administered drugs. Thus, dosage and method of administration can both have implications for payment.

PATENT STRATEGY FOR BIOTECHNOLOGY PRODUCTS

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The term "patent policy" is often associated with the selection of foreign countries in which to file counterpart applications to a patent application originally filed in the United States. However, when properly understood, the subject is far broader, encompassing a number of considerations. These include: (1) obtaining patent protection, (2) exploiting issued patents, (3) enforcing patents, and (4) selecting products based on patent considerations.

Obtaining Patent Protection:

Should an inventor seek patent protection at all? In most cases, the answer is yes, although several situations can militate against patent protection and in favor of trade secret protection. For example, patents for manufacturing processes are difficult to enforce because the process may be practiced behind closed doors where infringement cannot be readily detected. Some inventions are likely to become obsolete well before the patent term expires due to the rapid evolution of the particular technology. In some countries, local law may require mandatory

licensing of patents for certain kinds of inventions or may not provide meaningful protection of patents.

There are two schools of thought as to when a biotechnology patent application should be filed. The first counsels the inventor to file early and often in order to obtain the earliest possible filing dates, even at the expense of narrow claims. The second maintains that it is better to defer filing until the best data is available to support the strongest and broadest claims.

Exploitation:

Patents are exploited by means of manufacture and sale of covered products, through licensing transactions, joint ventures, and a variety of other techniques. The selection of the right technique for a particular situation involves the consideration of several factors, including the resources of the patent holder to fully develop and commercialize the invention, the breadth of the patent, and the size and location of potential markets. The feasibility of using patent litigation to prevent others from practicing the patented invention is also an important consideration in this decision.

Enforcement:

The formation in the early 1980s of the Court of Appeals for the Federal Circuit, to which all appeals of patent decisions must now go, has increased the likelihood that patents will be upheld. Despite this, the size of the market for biotechnological products has led large, well-established companies to bring declaratory judgment actions challenging patents issued to small, new biotechnology companies. Patent litigation is very expensive and can consume significant personnel time. For this reason, biotechnology companies must be careful in deciding whether to take an aggressive posture with respect to their patents, lest they attract this kind of litigation.

Product Selection:

The likelihood that a patent will actually issue, the enforceability of that patent, as well as the size and location of important markets each play a role in deciding whether to pursue a particular biotechnology product opportunity. Often these decisions must be made with insufficient information about whether other necessary technology can be developed, whether competing inventors will obtain superior patent coverage, or whether the products for which regulatory approvals are ultimately obtained will correspond to the patents which eventually issue.

RELEASES TO THE ENVIRONMENT

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The National Wildlife Federation has a special biotechnology division which is concerned with possible dangers presented by emerging technologies, particularly those presented by synthetic chemicals.

In the past, scientists had always been limited to engineering traits that could be modified through breeding. Now, biotechnology has become extremely powerful, enabling scientists to take genes and transfer them across taxonomic barriers.

So far, there have been over 100 approved releases of genetically engineered organisms in the United States, including transgenic plants such as alfalfa, corn, cantaloupe, and walnut trees. Certain microbes such as Rhizobium have also been field-tested.

The main players are large chemical companies and, to a lesser extent, universities. From the perspective of the National Wildlife Federation, there are three types of risks. The first is a direct risk that the organism released into the environment will have a harmful effect. Fish that have been engineered to be more tolerant of colder waters might be a good example. These newly tolerant fish might inhabit waters not previously available to them, thus displacing the original inhabitants and upsetting the ecosystem. A similar problem might result from putting pest-tolerant genes into plants that have nearby relatives that are themselves weeds. The resistant gene might be transferred to the relative, creating a more invasive weed that would be difficult to control.

Secondary effects can also create problems. Crops designed for herbicide resistance may have an effect on patterns of herbicide use. Increasing the use of herbicides may have serious collateral consequences.

Finally, there are serious ethical risks as in the use of technology to create pollution-resistant organisms. Even if such organisms are made completely safe, it is arguable that resources should not be expended to adapt organisms to polluted areas and instead devoted to eliminating the pollution itself.

Who will pay for releases to the environment that cause damage must also be determined. Liability insurance is currently unavailable for such damage. Moreover, many releases will likely be made by smaller companies who will not have the resources to pay for the damage they cause.

Assigning damages will be complicated by the difficulty in tracing a particular problem to a particular corporation. One solution might be to require molecular signatures on individual genes to allow source identification.

The case of Tryptophan, which is the first candidate for a biotechnology products liability suit, may address these issues. Tryptophan is a common, naturally occurring amino acid. Preparations of this amino acid made by one company caused 27 deaths. While the reasons for the disaster are unclear, there is a disturbing implication that genetic engineering may have caused otherwise pure preparations to become lethal. Given the potential for this kind of damage, the government must take a leadership position to safeguard the technology, the industry, and the public health.

OWNERSHIP OF BIOLOGICAL MATERIALS (THE MOORE CASE)

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John Moore v. Regents of the University of California, 51 Cal. 3d 120 (1990):

In August 1976, John Moore came to the U.C.L.A. Medical Center with a rare form of leukemia. His spleen was removed as part of the treatment, and he returned for follow-up visits from October 1976 to September 1983. The doctor treating Moore requested that his research assistant obtain a tissue sample from the spleen before it was destroyed in order to culture a cell line. At that time, the first of three discoveries was made. While it had been thought that this particular type of leukemia only infected B-cells, it was found that Moore's T-cells were infected. The cell line was then found to produce larger than usual quantities of lymphokines—small proteins that trigger certain immune system reactions. Finally, the researchers discovered that the cell line was infected by a retrovirus, HTLV-2. At that time, only three such viruses were known; namely, the AIDS virus, a virus that caused another form of leukemia, and Moore's virus. In April 1983, the University asked Moore for permission to draw blood for further research.

In August 1979, the University filed a patent application on the cell line, as required by statute to maintain federal funding. In September 1984, Moore filed suit against the University alleging conversion of property and failure to obtain informed consent. Moore sought monetary

damages and a declaratory judgment of his rights in the results of the research. While the trial court dismissed the conversion claim on the theory that a person does not have a property right in removed tissue, the appellate court reversed. Since conversion is a strict liability tort, this appellate ruling would have had a broad impact on university research since researchers would be responsible for investigating the source of the tissue and obtaining consent for their research.

However, the California Supreme Court reversed the appellate court decision and held that no property interest exists in excised tissue. In the absence of common law or statutory support, the court concluded that a conversion claim should not be allowed in view of society's interest in the advancement of science, the exposure of third parties to the "lottery of litigation" due to the strict liability aspects of conversion, and the adequate protection provided by the requirement of informed consent. The Supreme Court left Mr. Moore with a remedy, however, because it noted that the requirement of informed consent is not met unless the physician discloses all research and financial interests in the patient's tissue while discussing the patient's treatment options. The extent of Mr. Moore's potential damages for the University's failure to obtain informed consent remains unclear.

IMPLICATIONS OF THE HUMAN GENOME PROJECT

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The Human Genome Project is a research effort being undertaken by the Department of Energy, National Institute of Health, and the Howard Hughes Institute, each of whom are funding their own initiatives. The program at NIH, headed by Dr. James Watson, is aimed at mapping all the human chromosomes at different levels of resolution by different dates. From the perspective of a lawyer, three major problems appear with the project; namely, the creepiness problem, the prediction problem, and the creation problem.

The creepiness problem involves the perception that there are certain types of knowledge that mankind should not have. This concern implies that research projects should have scientific and moral justifications as well as novelty value. In addition, researchers must be open about their procedures and findings. Nonetheless, the creepiness problem is not of paramount importance; such concerns were overcome in the context of heart transplants some years ago.

The prediction problem is more serious, however. As knowledge of the genetic code increases, it will be possible to tell someone that they will

die in a certain number of years from a genetic disorder, such as Huntington's Chorea, even though they have not yet had any symptoms of the disease. This prediction ability raises additional issues for insurers and health care finance in general. In the case of individually underwritten insurance, insurance companies may deny coverage to those who test positive for a genetic disorder. Even if insurers are forbidden from considering the genetic information, anyone who discovers they have the disease will rush to get insurance coverage, which will dramatically raise the cost of insurance for everyone. For employer-provided insurance, employers will have an incentive to discriminate against those likely to become ill. Beyond the cost of enforcement, anti-discrimination legislation may be insufficient because it tends towards overinclusion in some areas and underinclusion in others. Moreover, such legislation may simply encourage employers to stop health-care coverage altogether. National health insurance, however, could provide some answers to the insurance aspects of the prediction problem.

Finally, the creation problem raises several ethical concerns regarding the ability to select genetically superior and inferior individuals. The risk of an explicit government mandated eugenics program seems small since it is unlikely to win political support and it is almost certainly unconstitutional under *Skinner v. Oklahoma.* However, a more insidious problem is presented by denying medical coverage to children born with certain screenable defects, thus creating a *de facto* genetic selection process. In theory, this implicit eugenics program should be relatively easy to eliminate through regulation. Finally, additional ethical problems are created by parents who might want to use this technology to select a child who not only lacks genetic disorders but also possess certain positive characteristics.

TRANSGENICS: MONSTERS, MADNESS, OR MONEY? TECHNICAL AND ETHICAL ISSUES SURROUNDING ANIMAL BIOTECHNOLOGY

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Three types of issues are associated with the genetic manipulation of animals through "genetic engineering."

Patent issues

While it is clear that laboratory animals can be patented (the "Harvard mouse"), agricultural livestock have not yet been patented, and

issues related to offspring and royalty payments have not yet been clarified.

Ethical issues

Criticisms of genetically-altered animals, especially those with foreign genes, are based on the notion of unnatural species-tampering, "playing God," and concerns over ecological effects of accidental or intentional release into the environment. In addition, some animal welfare rights activists have argued that such alterations are inherently cruel. However, the Office of Technology Assessment has not found these to be compelling arguments.

Scientific issues

Transgenic sheep, goats, mice, fish, and other vertebrate animals have been created, and other species will soon follow. The current alteration technique is still inefficient because only a few animals in each cohort actually incorporate and express the new genes, but rapid improvements can be expected soon.

SELECTION AND USE OF EXPERTS

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Expert witnesses in biotechnology product liability cases must be selected and utilized with great care and precision. In-house experts can prove invaluable by providing reliable assistance and education to the attorney. This is within the potential protection of the attorney-client privilege. In-house experts can also help select and prepare testifying witnesses. Consulting experts can provide a more detached and objective source of information, though protection of their reports from discovery poses a problem. Nevertheless, the testifying expert is indispensable to introduce supporting materials and objectively discuss the ultimate issues. Moreover, testifying experts can introduce favorable material at trial which is ordinarily inadmissible as hearsay. Thus, a testifying expert can introduce data, literature, and even opinions of other experts provided they form a basis of the testifying expert's opinion.

In biotechnology cases, counsel may best employ experts in the applicable scientific or medical fields, such as epidemiology, product regulation, warning communications, and damages. However, counsel must temper selection of testifying experts with consideration of their qualifications and the potential for impeachment. In general, counsel

should consider the expert's credentials, specific experience with the subject matter at issue, availability, location, appearance, ability to communicate, and any prior testimony or writings.

TRIER OF FACT: JURY VS. JUDGE

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A trial lawyer's presentation is directed to either a judge or a jury. Of these two, the judge is sophisticated, will read the materials, and will remain attentive throughout the trial. The jury is twelve unknown people whose response to the same case is highly variable. Therefore, the trial lawyer's presentation must be responsive to whether the audience is a judge or a jury.

A judge may communicate to the lawyer whenever he does not understand, but a jury must usually remain silent. If the jurors become confused, they will lose interest. The judge has no such luxury. Thus, the lawyer usually prefers that a judge try the case. However, in patent trials, decision by jury is the rule rather than the exception.

Time, or the lack of it, is the foremost factor requiring simplification of complex technological issues. In the past, judges have not had time for complex technical issues. A judge will not permit juries to sit for a lengthy period in civil suits involving high technology. Furthermore, judges often split the court's days between high-technology trials and criminal cases. Therefore, time constraints strongly influence trial presentation.

A judge wants to hear the detailed development of a case before arriving at a conclusion and is not easily swayed by audio-visual presentations. However, since the jury has no written documents available to it during trial, the lawyer must make briefs and other important written documents available to the jury by videotape, overhead projections, and charts. These also help to retain the jurors' attention. One effective way for a lawyer to communicate a favorable view point is through a "day-in-the-life-of . . ." re-enactment videotape. Using visual aids, a lawyer can convey to the jury within days or even hours the same point that would have taken weeks to describe step by step.

Because jurors tend to remember visually, a lawyer can display photos of the witnesses during closing argument so that the jurors can understand the summary of the testimonies in light of their recollection of the witnesses.

In addition to using audio-visual techniques to simplify evidence it is essential to determine what evidence is important. Here, an experienced trial lawyer's instinct should ultimately take precedence over the advice of an outside committee of analysts pouring over polls.

A lawyer must not succumb to the temptation of utilizing every tool available. Jurors inundated with audio-visual effects may become so fascinated with the technical wizardry that they may lose focus of the technical issues presented. Therefore jury presentations should be visual, understandable, and brief.

An essential difference between judge and jury is their knowledge of the law. The judge knows the law and the arguments. The jury only knows the facts but not how they apply to the law until instructions are given after closing arguments. The lawyer must present the facts so as to lead the jury to arrive at a favorable conclusion without them knowing what the law is along the way.

Therefore, a lawyer's trial presentation plan should be considered at the earliest pleading with attention to the issues and their proof at trial. Later decisions should be based on this previously established architecture. Witnesses must be presented in testimonial sequence consistent with the scenario developed in the opening statements.

In response to the inadequate presentation of evidence at high technology trials, a federal commission plans to issue a training manual for judges on technical matters. However, with proper presentation technique, lawyers can more effectively persuade not only the judge but also the jury.

AVOIDING PITFALLS IN PHARMACEUTICAL LICENSING

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In the field of biopharmaceuticals, the enormous risk involved in bringing a new product to market encourages creative commercial and financial arrangements between companies to share both the risks and the rewards. The negotiators of these cooperative deals typically have little experience in bringing a molecular drug to market. Therefore, unaware of the pitfalls common to biopharmaceutical licensing, the negotiators conclude deals that ignore problems which often are resolved through litigation.

Several problems exist in the structuring and implementation of a joint effort to bring a biologic to market. The cause of these problems stems from the fact that the FDA looks at biologics differently than pharmaceutical drugs due to the independent centers which evaluate

biologics and drugs. Negotiators usually understand pharmaceuticals, but few are familiar with biologics, resulting in numerous pitfalls when dealing with biologics.

A joint effort typically involves a small start-up company and an established pharmaceutical giant. The start-up wants a small share of the market in order to gain a foothold in the industry. The established pharmaceutical company wants new products with marketing rights while leaving the risks with the developer. Despite this inherent tension, both firms share a common interest in knowing whether the biologics or drug department of the FDA will regulate this particular product. The answer should be obtained before beginning negotiations because this information substantially changes the structure of the deal.

The first question this information raises is: who is going to sell the drug? If the biologics center of FDA regulates, only the license holder can sell, unlike the case with drugs. In order to obtain the market rights by holding the license for the biologic, the licensee must also manufacture the biologic. Thus, the manufacturing rights for biologics are crucial and should not be split or given away easily. Furthermore, biologics in general require the entire manufacturing process from top to bottom to be in control of the license holder. Often, pharmaceutical companies want to participate in manufacturing due to increased efficiency and tax shelters, but this participation may cause enormous problems in obtaining FDA approval of biologics.

A second question is: who will share the risks? Risks are involved in developing the biologic through clinicals and in upscaling the product to commercial form before the biologic can be validated for licensing. The development house, usually the start-up, should develop the biologic for clinical trials. The FDA considers a biologic to be a different product depending on where it is produced. Therefore, the method of upscaling from clinicals to large-scale production by transferring the manufacturing location from developer to pharmaceutical company may alter FDA approval, although this would not happen with drugs. A change in FDA approval would delay the time in getting the product to market as well as increase the costs.

In clinical development, who is responsible? What is the standard of effort required? In this industry, time is money. Suppose manufacturing and marketing were divided separately between the start-up and established company, respectively. Marketing always wants to get the product out quickly, so it insists on the right to control the clinical trial. Who bears product liability for off-label promotion if the marketer chooses a narrow usage on the label to get the product out without performing clinicals on off-label uses?

After clinical trials, who is responsible for obtaining FDA approval? What is the standard of effort? What if the opportunity is fumbled away in that party's hands?

After FDA approval, who has the responsibility of bringing the biologic onto the market? How is this affected by the splitting of rights? What if the start-up depends on the biologic for its livelihood, but the large company decides that this product is now low priority, five years into the deal?

In all of these cases, the parties need to determine who has responsibility, what it is, how to measure it, and what to do if one party is dissatisfied with it. When one party inevitably becomes dissatisfied with the other party, should their dispute be settled by mediation, arbitration, or litigation?

Currently, alternative dispute resolution is popular in corporate America. Unfortunately, no well-developed, routinized, highly defined course of dealing exists in this area. Thus, every contract where an alternative dispute resolution mechanism arises provides an opportunity for new litigation because every single contract is subject to challenge and must be interpreted.

Therefore, alternative dispute resolution techniques must be approached with caution. For example, even if an arbitration clause is included in a contract, California courts retain jurisdiction and can enter interlocutory injunctive relief pending arbitration, notwithstanding the jurisdiction of the arbitrators. Certain federal circuits agree. The Third circuit, for example, held that notwithstanding the Federal Arbitration Act or express statutes against judicial intervention, the court retains jurisdiction to enter injunctive relief on the merits of the arbitrative dispute. Therefore, one can simultaneously litigate and arbitrate the same matter.

Litigation is superior to arbitration when an adversary's purpose is not to enlighten and clarify, but rather to misdirect, especially in complex technological areas alien to the common sense of judge and jurors? Litigation allows a collection of jurors' minds, not just one person, to arrive at a result. Among arbitrators, there exists little patience for rules of procedure, rules of evidence, and the devices established over the past several hundred years to eliminate unsubstantiated, extraneous, and misdirected allegations, smears, and innuendoes which have no place in the proper resolution of a dispute. If one desires an effective and rigid application of the law, litigation provides the best route.

SCIENCE IN THE COURTROOM

The Honorable William W. Schwarzer
Director

Federal Judicial Center
Washington, DC

With the advent of high-tech issues in the courtroom, it is important to prepare judges for cases involving science and technology. Judges cannot be sent back to school, but there are ways to teach judges about scientific issues so that justice can be better served in the court system.

The critical issue for the judge is to distinguish between a working hypothesis and a scientific fact. However, this is easier said than done.

Consider the following case. One of the leading aerospace engineers in the field testified that by concentrating on the result of the flip of a coin, one can cause one side to come up more frequently than the other. His experiments showed that in 750,000 trials, heads came up more often, at a rate which had odds of 1 to 5000 if occurring by chance. Is this fact or a working hypothesis? Is there a scientific basis?

Consider another example. Before the polio virus was discovered, experiments showed that the occurrence of polio increased with the amount of Coca-Cola consumed, both of which increased during the summertime. Is this fact or working hypothesis?

The distinction between fact and working hypothesis is a useful analytical device to help judges focus on technological problems in the courtroom. This distinction also brings up a question to consider: what is the responsibility of the judge?

Traditionally, any expert with minimum qualifications can express an opinion. What to do with the opinion is left to the jury. It is frightening to think of all the complex questions on the frontier of science which go to a jury. The jury, however, is limited to what a reasonable jury would find based on the evidence. The role of the judge, then, is to determine what evidence the jury is allowed to consider.

Many judges abdicate this responsibility when confronted with complex scientific problems. Judges, however, should not let evidence go to the jury unless it is founded on an acceptable scientific basis and on valid scientific methodology properly applied. An expert's qualifications must be relevant to the specific scientific question at issue. In addition, the expert must have relied on material that would have been reasonably relied on by other experts in that field.

How can judges be expected to make such determinations when the amount of scientific knowledge is doubling every five years? Judges rarely study science and therefore become intimidated, allowing the jury to decide scientific questions.

First, judges need to realize their function. Their purpose is to resolve legal disputes within a legal structure using rules of burden of proof, not to decide whether specific scientific propositions are true or

false. The basic rule for a judge to administer is that the proponent of a proposition has the burden of proof.

Judges must understand a scientific proposition for it to fit into a legal framework. A judge cannot depend on the adversarial process to determine the truth. Experts and patent lawyers often forget how to communicate with lay people. They do not realize that the most effective tool in high-tech cases is not argument but rather enlightenment. Patent lawyers tend to speak in counterproductive scientific jargon. They should speak in plain English and translate complexity into simple language.

Judges, on their part, must play a more active role. They need to ask questions to make an opinion comprehensible in order for them to apply the distinction between a working hypothesis and scientific fact. The fact that other judges accepted an opinion does not mean that the present judge should do the same. Precedent has little influence in this field because technology changes rapidly and enormously over a short period of time.

In addition, judges must not be afraid to look ignorant. The greatest crime a judge can commit is to fail to ask the elementary questions necessary for the judge to understand the essence of the technological issue. Judges need the courage, self-confidence, and interest to ask hard questions and not take anything for granted. Things are not always as they seem.

Judges must also find out why experts disagree. Different assumptions, approaches or value systems may need to be exposed in order to get at the heart of the matter. A court-appointed expert should not be emphasized because no expert is neutral; each comes in with individual assumptions, approaches and values. Therefore, a court-appointed expert will not suddenly make the case comprehensible. However, the court expert does have the limited role of asking the right questions so as to assist the judge in understanding the matter more fully.

One method to improve understanding is for the judge to hold a tutorial prior to the trial where opposing counsel explain to the judge and jury the basics of the science relevant to the contested issue.

Judges should not assume that science always supplies the answers. In fact, science is the search for answers, not an answer in itself. Judges must fit scientific thinking into the legal framework, where scientific language tends to confuse the legal outcome. The bottom line is that lawyers have an obligation to be helpful to the judge in clarifying the truth, not simply to act as confrontational advocates.

ORPHAN DRUG PERSPECTIVE

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In 1980, Congress received complaints about known therapies that were unavailable in the United States and which had to be imported illegally to be obtained. A subsequent survey of the pharmaceutical industry found that at that time there existed 134 known therapies, most of which were not approved, for small diseased populations.

Why did no company seek FDA approval for these therapies? One reason is that the small size of the patient population combined with the huge costs of obtaining FDA approval made companies unwilling to invest in the therapies. In addition, the small size of the patient population rendered it difficult to obtain enough test patients for the clinical trials required for FDA approval. Furthermore, many of the therapies were difficult to patent because they were either old therapies or simply unpatentable.

In response, Congress enacted the Orphan Drug Act of 1983 which provided four incentives for companies to develop these therapies and to seek FDA approval:

(1) a hefty tax credit
(2) written guidance on clinical data provided by the FDA
(3) market exclusivity
(4) a modest grant program for non-profit research.

The tax credit turned out to be an ineffective incentive; only $100,000 per year has been claimed by the entire industry since the inception of the Orphan Drug Act. The second incentive failed because the FDA does not in fact respond to requests for guidance, contrary to the provision of the Act. Market exclusivity is the most important incentive to have arisen from this act.

Companies qualify for market exclusivity if:

(1) the disease in question afflicts less than 200,000 people in the United States; or
(2) the disease in question afflicts over 200,000 people in the United States but the company has no reasonable expectation of recovering costs from sales in the United States.

The first part of the test can be satisfied by any information on the disease, demographics, or population, whether published or unpublished. If applying under the first test, the population must be under 200,000 at the time the company seeks designation under the Orphan Drug Act. Later increases in the patient population will not affect

eligibility for market exclusivity. In contrast, the hurdle of the second part of the test is so difficult to overcome that no company has yet attempted to satisfy it.

This market exclusivity may be limited by proposed legislation requiring the sponsor to project the size of the population in three years and giving the FDA authorization to remove market exclusivity at any time during the seven years granted. These propositions were vetoed in 1990 but will be the focus of Congressional action in the near future.

Assuming market exclusivity is granted, what does it provide? Market exclusivity allows seven years of patent life protection. During that time, no other company can manufacture or market the same drug for the same application. However a different drug for the same application or the same drug for a different application is allowed. In determining whether two drugs are the same, the FDA, in the example of small molecules, looks at the active chemical structure.

Market exclusivity is not granted if the holder of FDA approval consents to approval of a third party or if the FDA determines that the sponsor cannot provide adequate quantities to the patient population. Neither of these conditions have yet been invoked. In addition, the proposed legislation would have two companies share exclusivity if they simultaneously develop the drug.

In conclusion, the Orphan Drug Act has been remarkably successful, standing as one of the most effective public health policy initiatives in the past several decades. This act resulted in the approval of over 40 orphan drugs and the testing of over 150 more in clinicals. Market exclusivity is the reason for the act's success because exclusivity provides the certainty of patent rights, allowing businesses to make decisions.

PATENT LAW PERSPECTIVE

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An important patent issue facing biotechnology companies is whether claims for proteins isolated by recombinant techniques infringe claims for proteins isolated by other methods. In *Scripps Clinic v. Genentech,* the court found that although Scripps isolated a protein by natural techniques, it was entitled to a claim which covered the protein "whether derived through its disclosed process or any other process achieving the same result." Because Genentech's recombinant protein is structurally and functionally the same as the natural versions,

Genentech's protein infringes Scripps' patent claim. In *Amgen v. Chugai,* the same result was reached with respect to human EPO.

Under the doctrine of equivalents, the court will find infringement, even in the absence of literal infringement, if the accused product is a "rip-off" of the patented invention. Nonetheless, in *Genentech v. Wellcome,* the court found that minor modifications to a protein which change its nature but preserve the same functions were sufficient to avoid infringing a composition claim. In a dispute over Pituitary Growth Hormone, the appellate court was unwilling to rule whether a claim for a recombinant protein would infringe on a composition claim for a naturally purified protein, when the primary sequences of the two proteins differed.

The courts have ruled that a protein created by recombinant methods infringes on the patent rights of a protein isolated by natural methods. These cases have not been argued on the public policy ground that these results are unfair to biotechnology companies, who have spent more time and money to find, in most cases, the only practical method to make the protein. Instead, the courts have focused on narrow, legal patent arguments regarding interpretation of claims, rather than on the purpose of patents. This result, unfortunately, may have a "chilling effect" throughout the biotechnology industry and retard research.

TECHNOLOGY TRANSFER ACT

Mr. Joseph P. Allen
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Office of Technology Commercialization
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Washington, DC

The Japanese use "study teams" to acquire knowledge of state of the art research in the United States simply by inquiring at research sites. This knowledge is then used to narrowly focus Japanese research on developing cutting edge commercial applications.

In contrast, government policies in the United States had historically discouraged the development of commercial technologies funded by the 70 billion federal dollars spent annually on research. The requirement that all results derived therefrom remain in the public domain created a disincentive to private industry to make the large investments necessary to commercialize a breakthrough in basic research. By the late 1970s, the United States Government had licensed only 4% of its 28,000 patents for commercial development.

In 1980, Congress restructured the system, allowing university ownership of the patent rights resulting from federally funded research. Upon licensing, royalties remain with the university and a percentage

goes to the individual inventor. Incentive to the researcher or inventor is necessary to compensate for the publish-or-perish pressures for early publication that also destroy the chances for international patents. These changes spawned the biotech industry, first at Stanford University, with the inventions of Boyer and Cohen and later at other major research universities.

Under current law, companies can share research costs with universities and negotiate exclusive rights to patent or field of use licenses. This year, there are 500 such public/private agreements. University run laboratories were added to the system in 1984, and federally owned laboratories followed with the 1986 Federal Technology Transfer Act. In 1989, Congress authorized withholding of some information under the Freedom of Information Act for up to five years.

Universities are balancing their public mission to contribute to the scientific dialogue with their commercial interests under the new technology transfer system. However, concerns that the universities will be "bought out" by the private sector,, were raised at the 1990 hearings on researcher conflicts of interest. The financial disclosure guidelines developed at those hearings are problematic for research not involving clinical trials or public health.

Finally, further progress can be made by lowering the remaining legal barriers to federal employees owning software copyrights, and by creating a database for industry that details federal research subjects and their status. The Office of Technology Transfer is moving away from eliminating legal barriers and toward encouraging industry participation in the new system. The new stage may include direct consulting with industry to determine which basic research should be funded.

PATENT HARMONIZATION

Mr. Harold C. Wegner, Esquire
Wegner, Cantor, Mueller & Player
Washington, DC

Procedural Aspects

Existing patent harmonization at the Bureau of PCT has produced several procedural advantages. For example, foreign patent filing decisions may be deferred for 30 months. While there are obvious reasons for filing a patent application as soon as possible after the "concrete embodiment" stage (filing early insures priority rights and blocks other parties from obtaining claims that may interfere with research), there are also situations where delayed filing may be advantageous under foreign laws. The 30 month deferral provides

flexibility in relation to these issues. Another procedural advantage is the low patent-search per year ratio that an examiner performs. Furthermore, the procedures are economical due to credits given by the European Patent Office.

The Rationale for United States Involvement in Harmonization

The United States formerly had the distinction of having the best patent system in the world; however, this is no longer the case. The current international system, derived from a model set of principles for substantive patent law, improves upon the American system. The United States can gain two benefits from harmonization: a grace period, and better protection for claiming in Japan. The benefits that will result from joining harmonization outweigh negative factors, such as a restrictive filing date.

TRIPS

TRIPS (Trade Related Aspects of Intellectual Property) is one of the elements of the Uruguay Round of the GATT. Two elements of TRIPS pertinent to the patent field are minimum standards and the United States' continued involvement in the harmonization process.

BOOKS SUMMARY

LAW, DECISION-MAKING, AND MICROCOMPUTERS: CROSS-NATIONAL PERSPECTIVES. Edited by *Stuart S. Nagel.* Greenwood Press, Inc., 1991. Pp. 376. $65.00 cloth.

Practicing attorneys often need to perform risk analysis when studying various litigation strategies. Policy-makers frequently need to decide among competing legislative choices. This book surveys the use of computers and computer programs in studying the costs and benefits of using different strategic alternatives before and during trial. It begins with articles discussing how software can be used to assist attorneys and lawmakers in the decision-making process. The remaining articles focus on the development of using computers in academic research and legal education.

FORENSIC DNA TECHNOLOGY. Edited by *Mark A. Farley & James J. Harrington.* Lewis Publishers, Inc., 1991. Pp. 250. $69.95 cloth.

In criminal cases, forensic DNA tests that compare the genetic patterns of a suspect or victim with the body tissues, blood, or semen found at the scene of a crime have gradually gained acceptance in the courtroom. This book discusses the scientific and legal issues related to the implementation of DNA technology in the criminal justice system. The main focus of the book discusses the underlying theory and historical development of "genetic fingerprinting" and the possibility of error in the interpretation of the results of DNA prints. The last three articles in this book examine existing guidelines for the use of this technology in determining the admissibility and weight of such evidence at trial.

PATENT ALTERNATIVE DISPUTE RESOLUTION HANDBOOK. By *Tom Arnold.* Clark Boardman Callaghan, 1991. Pp. 180. $85.00 paper.

Due to the problems of escalating costs and prolonged delays associated with patent litigation, the author argues that clients are more likely to benefit from settling their disputes through alternative dispute resolutions, rather than through standard court proceedings. This handbook presents and evaluates the multitude of options available outside the judicial system. These options include formal binding arbitration, informal non-binding arbitration, a summary jury trial, and moderated settlement conferences. Finally, the book also outlines current legal issues, rules, and strategies surrounding the arbitration of patent disputes.

LEGAL ISSUES IN BIOTECHNOLOGY AND HUMAN REPRODUCTION: ARTIFICIAL CONCEPTION AND MODERN GENETICS. By *Warren Freedman*. Greenwood Press Inc., 1991. Pp. 240. $55.00 cloth.

Numerous legal and moral issues arise in the wake of new reproductive technologies such as artificial insemination, cryo-preservation, in-vitro fertilization and surrogate motherhood. While surveying the developments of these new technologies, Warren Freedman presents his views on the rights and responsibilities of individuals, families, and society in the face of these new developments. The book also reviews statutes, case law, and policies surrounding these modern ethical questions.

LEGAL RELATIONSHIPS BETWEEN TRANSNATIONAL CORPORATIONS AND HOST STATES. By *P. Ebow Bondzi-Simpson*. Greenwood Press, Inc., 1990. Pp. 240. $49.95 cloth.

Complex legal issues involving consumer protection, transfer of technology, copyright infringement, and environmental protection frequently arise when transnational corporations invest in the host countries in which they operate. These questions are difficult to resolve without some form of international regulation. Instead of just revisiting the controversies surrounding the legal relationships between multinational corporations and host countries, the author uses the draft of the *United Nations Code of Conduct of Transnational Corporations* as an example to help resolve the conflicting economic interests. Furthermore, the book discusses the possible roles of various international organizations in providing guidelines for host countries to regulate foreign investment and setting standards of conduct for multinational corporations.

LEGISLATIVE UPDATE †

Legislative Update is a comprehensive survey of important federal and state legislation related to high technology that has been passed in 1990. The survey consists of abbreviated summaries of new laws grouped under appropriate topic headings.

Where several states have passed similar legislation, the state summaries are preceded by a brief introduction setting forth common provisions.

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† The *High Technology Law Journal* wishes to thank Information for Public Affairs of Sacramento, California for providing us with access to their comprehensive computerized database of state legislation.

GOVERNMENT PROMOTION OF HIGH TECHNOLOGY DEVELOPMENT

Government Programs

The following acts are designed to promote high technology development.

FEDERAL

State Energy Efficiency Programs Improvement Act of 1990, Pub. L. No. 101-440, § 4(b), 104 Stat. 1006, 1008-09 (codified as amended at 42 U.S.C. § 6322 (1991)).

Among its many provisions, this act provides for federal funding of state programs to assist small and start-up businesses in the energy technology area. The assistance is to include providing information about energy technology production techniques and maintaining a data base of available energy technology experts.

CALIFORNIA

Act approved September 22, 1990, ch. 1230, 1990 Cal. Stat. ____ (codified at CAL. GOV'T CODE §§ 15399.30 to 15399.37 and as amended at CAL. GOV'T CODE § 15325 (West 1991)).

This act provides for the development of a broad strategic plan for future technological development in California. Elements of the plan include the following:

(a) providing technical assistance to the private sector in the use of established technologies;

(b) better educating the private sector and the public in general on technological matters;

(c) attaining greater access to global markets;

(d) stimulating new company formation and creating new jobs;

(e) encouraging high technology industries to focus less on national security and more on commercially orientated programs; and

(f) balancing technological progress with environmental needs.

COLORADO

Act approved April 9, 1990, ch. 177, 1990 Colo. Sess. Laws 1238 (codified at COLO. REV. STAT. §§ 24-48-101 to 24-48-105 and as amended at COLO. REV. STAT. § 2-3-1203 (1991)).

This act was passed to advance the objectives of the Colorado space initiative. The initiative's goal is to establish Colorado as an internationally recognized center of space-related industry. To

encourage progress toward this goal, the act creates the Colorado Space Advisory Council and the position of the Colorado Space Advocate.

FLORIDA

Act approved July 3, 1990, ch. 90-325, 1990 Fla. Laws 2635 (codified as amended at FLA. STAT. § 229.8053 (1991)).

This act permits the Florida High Technology and Industry Council to create a not-for-profit corporation to support the state's high technology industry. The corporation would coordinate and assist high technology-related activities of other state agencies and assist small disadvantaged manufacturers in obtaining high technology contracts.

HAWAII

Act approved June 8, 1990, ch. 106, 1990 Haw. Sess. Laws 184 (codified as amended at HAW. REV. STAT. §§ 206M-1 to 206M-20 (1991)).

This act establishes a state software service center in order to create a viable, nationally competitive software industry in Hawaii. The center's duties include monitoring the software industry to identify infrastructure and industry deficiencies, organizing partnerships between software companies, academia, and the state government, and producing a plan to establish a center for excellence in software development in Hawaii. The act also provides that the state government give preference to software developed in Hawaii when purchasing.

Act approved June 8, 1990, ch. 110, 1990 Haw. Sess. Laws 194 (codified as amended at HAW. REV. STAT. §§ 211F-1 to 211F-46 (1991)).

This act creates the Hawaii Strategic Development Corporation to stimulate and augment private investment in small businesses, including those involved in high technology. The powers and functions of the corporation include establishing a seed capital assistance program, a venture capital program, and a capital access program. The corporation may also assist small businesses by providing technical, managerial, and marketing advice.

NEW YORK

International Trade and Industrial Competitiveness Act of 1990, ch. 291, 1990 N.Y. Laws ____ (codified at N.Y. ECON. DEV. LAW §§ 224, 225; N.Y. PUB. AUTH. LAW § 3102-a and as amended at N.Y. AGRIC & MKTS. LAW § 16; N.Y. ECON DEV. LAW §§ 220 to 223; N.Y. PUB AUTH. LAW §§ 3102, 3102-d (McKinney 1991)).

The purpose of this act is to fortify New York's competitive position in the world economy. Among its provisions, the act creates the industrial technology extension service, a network of regional state organizations, which is to assist businesses in researching, evaluating, and implementing technology productivity improvements.

SOUTH CAROLINA

Act approved June 11, 1990, No. 581, 1990 S.C. Acts 2468 (codified as amended at S.C. CODE ANN. §§ 13-17-30, 13-17-90 (Law Co-Op. 1991)).

This act authorizes a state agency to establish and operate research, computer, and technology related projects. Such projects are to be designed to strengthen the state's high technology industries.

Education

COLORADO

K-12 Mathematics, Science, and Technology Improvement Act of 1990, ch. 151, 1990 Colo. Sess. Laws 1133 (codified at COLO. REV. STAT. §§ 22-81-101 to 22-81-104 and as amended at COLO. REV. STAT. §§ 24-30-903, 24-30-1801 to 24-30-1803 (1991)).

This act calls for the development of a strategic plan for improving K-12 mathematics, science, and technology education in the state through the use of telecommunications networks and facilities.

Taxation

CALIFORNIA

Act approved September 30, 1990, ch. 1618, 1990 Cal. Stat. ____ (codified as amended at CAL. REV. & TAX CODE § 24357.8 (West 1991)).

This act extends through 1993 a charitable deduction for donations of scientific property used for instructional purposes at institutions of higher education.

WASHINGTON

Act approved March 28, 1990, ch. 255, 1990 Wash. Laws 1443.

In order to develop a uniform statewide property tax treatment of computer software, this act provides for a thorough study of such taxation. Pending completion of the study, the act restricts the authority of counties to either change the assessment of previously assessed software items or to assess new software items.

WEST VIRGINIA

Act approved March 9, 1990, ch. 37, 1990 W. Va. Acts 405 (codified as amended at W. VA. CODE § 5E-1-4 (1991)).

This act adds computer software development to the list of qualified activities for which tax credits are extended for venture capital financing.

GOVERNMENT USE OF HIGH TECHNOLOGY

Telecommuting

These acts establish telecommuting programs whereby state and municipal workers can forego commuting to work, instead remaining at home to perform their duties via computer terminals. Legislators hope that programs such as these can improve traffic conditions and decrease auto pollution.

CALIFORNIA

Act approved September 26, 1990, ch. 1389, 1990 Cal. Stat. ____ (codified as CAL. GOV'T CODE §§ 14200 to 14203 (West 1991)).

This act authorizes all state agencies and commissions to adopt telecommuting programs.

FLORIDA

State Employee Telecommuting Act, ch. 90-291, 1990 Fla. Laws 2316 (codified as FLA STAT. §§ 110.171 to 110.174 (1990)).

This act authorizes state agencies to implement pilot voluntary telecommuting programs for all state employees.

VIRGINIA

H.D.J. Res. 77, 1990 Va. Acts 2271.

This resolution requires a state commission to study the benefits of telecommuting trial programs in California and other states for possible future use in Virginia.

Telecommunications Hiring Systems

NEW JERSEY

Act approved July 9, 1990, ch. 59, 1990 N.J. Laws ____ (codified at N.J. REV. STAT. §§ 32:23-105.1 to 32:23-105.3 (West 1991)).

This act requires the waterfront and airport commission to establish a telecommunications hiring system through which longshoremen and checkers may be hired without ever appearing in person.

Teleconferencing

TENNESSEE

Act approved April 5, 1990, ch. 815, 1990 Tenn. Pub. Acts 332 (codified at TENN. CODE ANN. § 8-44-108 (Supp. 1991)).

This act allows members of state agencies and commissions, upon declaration of necessity, to participate in meetings via electronics or other communications through which all members may simultaneously hear and speak to each other during the meeting. All members participating in this manner shall be deemed present for voting and quorum requirements.

WISCONSIN

Act approved April 23, 1990, Act 308, 1989 Wis. Laws 1422 (codified as amended at WIS. STAT. §§ 180.37, 181.24, 185.32, 186.07, 186.22, 215.50, 215.70, 221.08, 221.21, 611.51 (West 1990)).

This act authorizes the board of directors of a corporation to permit any or all directors to participate in any meeting through any means of communication so long as all participants may simultaneously hear and speak to each other, the communication is immediately transmitted, and each participant is able to send messages immediately to other participants. Each person participating in this manner shall be deemed present at the meeting.

Use of Two-Way Television in Criminal Proceedings

The following acts allow defendants and witnesses to appear in certain specified criminal proceedings via two-way television.

CALIFORNIA

Act approved July 25, 1990, ch. 427, 1990 Cal. Stat. ____ (codified as amended at CAL. PENAL CODE § 977.2 (West 1991)).

This act authorizes any California county to participate in the state's already existing pilot project permitting the use of two-way television in arraignments for misdemeanor and felony charges.

Act approved September 23, 1990, ch. 1271, 1990 Cal. Stat. ____ (codified as amended at CAL. PENAL CODE § 977.2 (West 1991)).

This act provides that a judge may accept a defendant's plea of guilty or no contest via two-way television during arraignment proceedings.

LOUISIANA

Act approved July 6, 1990, No. 593, 1990 La. Acts 1320 (codified as amended at LA. CODE CRIM PROC. ANN. arts. 551, 553, 831 to 833 (West 1991)).

This act allows criminal defendants to appear during arraignment proceedings via two-way television. While the act disfavors use of this technology in felony cases, it nonetheless permits it when authorized by local rules.

NEW YORK

Act approved July 30, 1990, ch. 894, 1990 N.Y. Laws ____ (codified at N.Y. CRIM. PROC. LAW §§ 182.10 to 182.40 (McKinney 1991)).

This act authorizes courts to allow defendants to appear via two-way television at proceedings other than hearings and trials. Electronic appearances may not be used to enter a plea of guilty to a felony or a plea of not responsible by reason of mental disease. Nor can electronic appearance be used when incarceration will result from a guilty plea in misdemeanor cases.

WASHINGTON

Act approved March 23, 1990, ch. 150, 1990 Wash. Laws 978 (codified at WASH. REV. CODE ANN § 9A.44.150 (Supp. 1991)).

This act allows child victims of sexual assault to testify in court via closed-circuit television. Prior to allowing such testimony, the court must make specific findings regarding the strength of the state's case, the trauma to the victim, and the defendant's constitutional rights.

Use of Telecommunications Technology in Law Enforcement

INDIANA

Act approved March 20, 1990, P.L. 161-1990, § 2, 1990 Ind. Acts 2161, 2162-63 (codified at IND. CODE § 35-33-5-8 (1991)).

This act allows a judge to issue a warrant based upon sworn testimony received via telephone, radio, or facsimile.

MICHIGAN

Act approved March 29, 1990, No. 41, 1990 Mich. Pub. Acts ____ (codified as amended at MICH. COMP. LAWS § 764.1 (1991)).

This act authorizes the use of electronically transmitted arrest warrants.

Act approved March 29, 1990, No. 43, 1990 Mich. Pub. Acts ____ (codified as amended at MICH. COMP. LAWS § 780.651 (1991)).

This act authorizes police to apply for and receive search warrants via electronic communications devices.

Act approved March 29, 1990, No. 44, 1990 Mich. Pub. Acts ____ (codified as amended at MICH. COMP. LAWS § 600.1440 (1991)).

This act provides for the use of oaths or affirmations administered before a justice, judge, or district court magistrate via electronic or electromagnetic means.

Electronic Transmission of Documents

The following acts authorize certain documents to be delivered to the state electronically.

ARIZONA

Act approved April 11, 1990, ch. 44, 1990 Ariz. Sess. Laws 144 (codified at ARIZ. REV. STAT. ANN § 10-131 (1990)).

This act provides that corporations and associations may deliver documents to the state via facsimile transmissions.

CALIFORNIA

Act approved September 19, 1990, ch. 1110, 1990 Cal. Stat. ____ (codified at CAL. INS. CODE§§ 12960 to 12965 (West 1990)).

This act provides that insurers and government agencies regulating insurers may make certain required filings with the government electronically.

KANSAS

Act approved April 23, 1990, ch. 85, 1990 Kan. Sess. Laws 623 (codified as amended at KAN. STAT. ANN. §§ 17-2718, 17-7503, 17-7505 (1990)).

This act provides that corporate filings with the state may be made via facsimile transmissions provided that the original document is filed within seven days after its facsimile filing date.

MARYLAND

Act approved April 24, 1990, ch. 131, 1990 Md. Laws 592 (codified as amended at MD. CORPS. & ASS'N CODE ANN. § 1-201 (1990)).

This act provides that corporate charters and limited partnership documents may be filed with the state via facsimile transmissions.

Act approved May 2, 1990, ch. 392, 1990 Md. Laws 1310 (codified as amended at MD. STATE GOV'T CODE ANN. § 7-213 (1990)).

This act provides that documents may be submitted for publication in the state register electronically.

Electronic Preservation of Documents

The following acts authorize the electronic preservation of certain state records and make other provisions regarding the electronic preservation of documents by the state.

CALIFORNIA

Act approved September 26, 1990, ch. 1380, 1990 Cal. Stat. ____ (codified at CAL. GOV'T CODE §§ 11773 to 11775 (West 1990)).

This act requires each state agency to develop a disaster recovery plan regarding information technology to minimize the impact a disaster might have on state government computer operations.

NEW HAMPSHIRE

Act approved April 28, 1990, No. 183, 1990 N.H. Laws 280 (codified as amended at N.H. REV. STAT. ANN. § 478:5 (1990)).

This act provides that those who register deeds and other documents may do so on an optical disk.

NEW YORK

Act approved July 18, 1990, ch. 561, 1990 N.Y. Laws ____ (codified as amended at N.Y. EXEC LAW §§ 93, 96, 96-a; N.Y. LIEN LAW§§ 240 to 242; N.Y. U.C.C. LAW §§ 9-403 to 9-407 (1990)).

This act provides that records in the custody of the Department of State may be stored electronically.

OKLAHOMA

Act approved April 9, 1990, ch. 50, 1990 Okla. Sess. Laws 86 (codified as amended at OKLA. STAT. tit. 11, § 22-132 (1990)).

This act provides that any municipality may store records on optical disk.

Computer Databases and Networks

The following acts establish various computer databases and networks.

CALIFORNIA

Act approved September 11, 1990, ch. 795, 1990 Cal. Stat. ____ (codified at CAL. HEALTH & SAFETY CODE§ 11983.22 and as amended at CAL HEALTH & SAFETY CODE§§ 11755, 11815.5, 11818.5, 11983.2, 11983.21 (West 1991)).

This act establishes a centralized alcohol and drug abuse data system to obtain information on state drug treatment and law enforcement activities.

COLORADO

Act approved June 7, 1990, ch. 196, 1990 Colo. Sess. Laws 1304 (codified at COLO. REV. STAT. §§ 24-90-301 to 24-90-303 and as amended at COLO. REV. STAT. § 24-90-105 (1991)).

This act declares that public access to information is of utmost importance and that access to computer information should be equal, regardless of place of residence or economic status. The act thus establishes a publicly accessible state computer information network linking a number of existing library networks and provides for public access throughout the state.

INDIANA

Act approved March 27, 1990, P.L. 37-1990, § 3, 1990 Ind. Acts 1262, 1263-64 (codified at IND. CODE §§ 20-12-34.5-1 to 20-12-34.5-6 (1991)).

This act establishes a database of DNA population statistics to include information concerning allele frequency and demographics generated by state laboratories conducting DNA analyses.

KANSAS

Act approved April 6, 1990, ch. 266, 1990 Kan. Sess. Laws 1565 (codified at KAN. STAT. ANN. §§ 74-9301 to 74-9309 (Supp. 1990).

This act creates a state information network to allow the public electronic access to information generated by the state. An agency is established to explore ways to increase information in, and expand public access to, the state network.

KENTUCKY

Act approved March 16, 1990, ch. 66, 1990 Ky. Acts 143 (codified at KY. REV. STAT. ANN. §§ 7. 510 to 7.520 (Michie Supp. 1990)).

This act establishes a legislative electronic information system to provide public access to state statutes and regulations and to information on pending bills and resolutions.

MICHIGAN

Act approved June 20, 1990, No. 112, 1990 Mich. Pub. Acts ____ (codified at MICH. COMP. LAWS § 211.42a (1991)).

This act allows local tax collecting entities to use computerized databases as tax rolls.

MINNESOTA

Act approved May 3, 1990, ch. 583, § 11, 1990 Minn. Laws 2198, 2205-06.

This act provides for a study of the feasibility and cost of establishing a statewide domestic abuse database which would include parties' names, arrests made, and release conditions.

TENNESSEE

Act approved April 5, 1990, ch. 775, 1990 Tenn. Pub. Acts 265 (codified at TENN. CODE ANN. § 4-3-2011 (1991)).

This act establishes a centralized database of organ and tissue donors to provide continuous information to donor service agencies.

VIRGINIA

Act approved March 7, 1990, ch. 103, 1990 Va. Acts 181 (codified as amended at VA. CODE ANN. § 32.1-122.02 (1991)).

This act requires a state health board to make recommendations concerning statewide data collection systems for health care manpower and for state mortality and morbidity rates.

Electronic Voting

HAWAII

Act approved June 19, 1990, ch. 174, 1990 Haw. Sess. Laws 359.

This act authorizes an advisory committee to investigate and select a new, completely electronic voting system to replace the state's current voting system.

WEST VIRGINIA

Act approved March 10, 1990, ch. 80, 1990 W. Va. Acts 679 (codified as amended at scattered sections of W. VA. CODE §§ 3-4A-2 to 3-4A-25 (West 1991)).

This act sets forth the requirements for operating electronic voting facilities. The act requires all essential elements of voting (including secrecy, correct tabulation, and the ability to change one's vote before submitting the ballot) to be present in electronically conducted elections. The act also establishes technical requirements of ballot appearance and certain administrative procedures.

GOVERNMENT REGULATION OF HIGH TECHNOLOGY ACTIVITIES

Computer Crime

CALIFORNIA

Act approved March 13, 1990, ch. 22, 1990 Cal. Stat. ____ (codified as amended at CAL. PENAL CODE § 502.01 (West 1991)).

This act resolves a conflict in prior law relating to probation guidelines for certain computer crimes. It repeals probation guidelines that provided (a) that persons convicted of certain computer crimes could be granted probation for *up to three years* and (b) that the court could prohibit employment where the convict would have access to computers not operated by his or her

employer. The probation guidelines left intact are more severe. They require a probation period of *not less than three years* and prohibit employment involving computer use unless a court finds that such employment would pose no risk to the public.

MAINE

Act approved February 23, 1990, ch. 620, 1989 Me. Laws 1633 (codified at ME. REV. STAT. ANN. tit. 17-A, §§ 431 to 433 (1991)).

This act finds the unauthorized access of a computer resource to be a criminal invasion of computer privacy. It declares the invasion to be aggravated when the perpetrator copies computer information, damages computer resources, or introduces a virus into a computer system.

Telecommunications and Cable Television Theft

The following acts prohibit the fraudulent obtainment of various telecommunications and cable television services.

COLORADO

Act approved April 3, 1990, ch. 131, 1990 Colo. Sess. Laws 993 (codified at COLO. REV. STAT § 18-9-309.5 and as amended at COLO. REV. STAT. § 18-9-309 (1991)).

This act criminalizes the unauthorized use of or damage to telecommunications equipment. It criminalizes the fraudulent obtainment of telecommunication services by means including, but not limited to, improper use of credit cards or the tampering with telecommunications equipment. The act provides for the forfeiture of property used in violation of its provisions and provides for injunctive relief against such violators.

MINNESOTA

Act Approved April 24, 1990, ch. 494, 1990 Minn. Laws 1233 (codified at MINN. STAT. §§ 237.73, 609.892, 609.893 and as amended at MINN STAT. §§ 609.531, 609.87 (1991)).

This act criminalizes the fraudulent obtainment of telecommunication and information services with the intent to evade lawful charges. It makes it a felony to facilitate such telecommunications fraud. The act provides for injunctive relief and forfeitures of telecommunication devices used for fraudulent purposes.

SOUTH DAKOTA

Act approved February 28, 1990, ch. 169, 1990 S.D. Laws 212 (codified as amended at S.D. CODIFIED LAWS ANN. §§ 22-44-2, 22-44-4 (1991)).

This act increases the penalty for knowingly manufacturing, selling, or distributing equipment intended for use in the theft of cable television services.

WASHINGTON

Act approved March 6, 1990, ch. 11, 1990 Wash. Laws 125 (codified as amended at WASH. REV. CODE §§ 9.26A.090, 9.45.240 (1991)).

This act criminalizes the fraudulent obtainment of telephone, telegraph, and telecommunications services through tampering with electronic devices or through computer trespass. Injunctive relief is provided.

Cable Television Access

WISCONSIN

Act approved March 23, 1990, Act 143, 1989 Wis. Laws 1057 (codified at WIS. STAT. § 66.085 (1991)).

This law prohibits owners or managers of multi-unit dwellings, including condominiums, from preventing or interfering with cable television service to residents. Cable operators are held responsible for any building repairs required because of the installation of cable service in multi-unit dwellings.

Use of Paging Devices on School Property

These acts are designed to curb drug trafficking by prohibiting student use of paging devices on public school property. However, school authorities may, in their discretion, allow student use of such devices.

ILLINOIS

Act approved September 10, 1990, P.A. 86-1391, 1990 Ill. Laws 2957 (codified at ILL. REV. STAT ch. 122, ¶¶ 10-20.28, 34-18.14 and as amended at ILL. REV. STAT ch. 56 1/2, ¶ 1401.1 (1991)).

In addition to prohibiting the use of cellular telecommunication devices on school property, this act also makes it a felony to knowingly use such devices in the trafficking of controlled substances.

KENTUCKY

Act approved March 19, 1990, ch. 87, 1990 Ky. Acts 176 (codified at KY. REV. STAT. ANN. § 158.165 (Michie Supp. 1990)).

This act provides an exception to the prohibition on student use of paging devices for students who are members of a voluntary fire fighting or emergency medical organization.

RHODE ISLAND

Act approved July 12, 1991, ch. 475, 1990 R.I. Pub. Laws ____ (codified at R. I. GEN. LAWS § 16-21.2-11 (1991).

WISCONSIN

Act approved January 19, 1990, Act 121, § 13, 1989 Wis. Laws 984, 988 (codified at WIS. STAT. § 118.258 (1991)).

Telecommunications Regulation

FEDERAL

Federal Communications Commission Authorization Act of 1990, Pub. L. No. 101-396, § 9, 104 Stat. 848, 850-51 (codified at 47 U.S.C. § 333 (1991)).

This act prohibits the willful or malicious interference with the radio communications of any station either licensed under federal law or operated by the federal government.

Telephone Operator Consumer Services Improvement Act of 1990, Pub. L. No. 101-435, 104 Stat. 986 (codified at 47 U.S.C. § 226 (1991)).

This act was passed in response to criticisms concerning the operator services industry. Congress has found that consumers using public pay phones often have no meaningful choice of long distance carrier because aggregators of telephone services (such as hotels, restaurants, and airports) contract with specific providers of operator service, blocking access to alternative providers. Congress has also found that consumers are often deceived about the identity of the company providing operator service and the rates being charged and that consumers lack information on how to complain about such unfair treatment.

This act requires providers of operator services to fully disclose their identity, the rates being charged, and the procedures by which consumer complaints will be handled. Aggregators of telephone services are required to provide notice to consumers of the identity

of the company providing operator service and of the consumer's right to choose their own long distance carrier. Aggregators must ensure that access to other carriers is not blocked.

Business and Trade Regulation

CALIFORNIA

Act approved September 22, 1990, ch. 1226, 1990 Cal. Stat. ____ (codified as amended at CAL. BUS. & PROF. CODE§§ 6731, 6731.1, 8726 (West 1991)).

This act modifies the definitions of civil engineering and land surveying to include the creation, preparation, or modification of electronic or computerized data in the performance of certain enumerated activities. Persons in the business of engaging in such activities are thus now required to obtain a state license.

Automatic Phone Dialing Machines

The following acts generally prohibit the use of automatic phone dialing machines and/or recorded telephone solicitations. Most provide an exception where the solicitee has a pre-existing business relationship with the solicitor. Some allow the use of such devices during set time periods. Individual differences among the various acts are set forth in detail below.

CALIFORNIA

Act approved September 30, 1990, ch. 1641, 1990 Cal. Stat. ____ (codified as amended at CAL. CIV. CODE§ 1770 (West 1991)).

This act prohibits using recorded telephone solicitations without first obtaining the solicitee's consent, unless the solicitee has a pre-existing business relationship with the solicitor.

FLORIDA

Act approved June 22, 1990, ch. 90-143, 1990 Fla. Laws 635 (codified as amended at FLA. STAT. § 501.059 (1991)).

This act prohibits the use of automatic phone dialing machines to send recorded messages for commercial solicitation purposes.

MAINE

Act approved April 3, 1990, ch. 775, 1989 Me. Laws 1842 (codified at ME. REV. STAT. ANN. tit. 10, § 1498 (1991)).

This act prohibits the use of automatic phone dialing machines to make commercial solicitation calls to emergency telephone numbers, cellular and paging phones, or any unlisted or unpublished telephone numbers. Otherwise, such machines may be used for commercial solicitation purposes on weekdays between the hours of 9 AM to 5 PM or when the solicitee has a pre-existing business relationship with the solicitor. Persons intending to use automatic phone dialing machines must register with the secretary of state.

MARYLAND

Act approved May 29, 1990, ch. 607, 1990 Md. Laws 2647 (codified as amended at MD. ANN. CODEart. 78, § 55C (1991)).

This act prohibits the use of automatic phone dialing machines and prerecorded messages without the solicitee's consent unless a pre-existing business relationship is present. Senders of prerecorded messages are required to terminate the message within ten seconds after recipient has terminated the call. This act does not apply to government agencies using automatic phone dialing machines for emergency purposes.

TENNESSEE

Consumer Telemarketing Protection Act of 1990, ch. 874, 1990 Tenn. Pub. Acts 437 (codified at TENN. CODE ANN. §§ 47-18-1501 to 47-18-1510 (Supp. 1991)).

This act prohibits the use of automatic phone dialing machines for commercial solicitation purposes except when prior consent is given. Moreover, before playing a recorded message, a live operator must obtain the solicitee's consent. Such machines must disconnect from the telephone line within ten seconds if the recipient refuses consent or terminates the call. Such machines may not be used between the hours of 9 PM and 8 AM and may not be used to place calls to emergency telephone numbers or randomly selected numbers. The act also prohibits the use of automatic phone dialing machines to solicit business for telephone access lines ("976" and "900" numbers). Finally, persons intending to use such machines must obtain a permit.

UTAH

Act approved March 7, 1990, ch. 33, 1990 Utah Laws 166 (codified at UTAH CODE ANN. §§ 13-25-1 to 13-25-5 and as amended at UTAH CODE ANN. § 63-55-213 (1991)).

This act requires persons using automatic phone dialing machines for commercial solicitation purposes to register with the state unless the machines are used solely to contact solicitees who have a pre-existing business relationship with the solicitor. Such devices may not be used between the hours of 8 PM and 9 AM and may not be used to place calls to emergency telephone numbers or randomly selected numbers. Recorded messages must identify the business initiating the call and provide a summary of the call's purpose. The telephone line of recipient must be disconnected within 30 seconds of when recipient terminates the call.

Unsolicited Facsimiles

With minor variations, the following acts prohibit the sending of unsolicited commercial advertising material via a fax machine except when the solicitee has a pre-existing business relationship with the solicitor. This exception does not apply where the recipient has notified the sender that he or she does not wish to receive such solicitations. These acts generally prescribe penalties for violations and provide for civil damages and injunctive relief against violators.

GEORGIA

Act approved March 22, 1990, H.B. 1181, 1990 Ga. Laws 252 (codified at GA. CODE ANN. § 46-5-25 (1991)).

MAINE

Act approved March 30, 1990, ch. 758, 1989 Me. Laws 1818 (codified at ME. REV. STAT. ANN. tit. 10, § 1496 (1991)).

This act expressly includes material seeking charitable contributions in the prohibition against the sending of unsolicited advertising material via fax machine.

MICHIGAN

Act approved March 30, 1990, No. 48, 1990 Mich. Pub. Acts ____ (codified at MICH COMP. LAWS §§ 445.1771 to 445.1776 (1991)).

This act has no "pre-existing business relationship" exception.

OKLAHOMA

Act approved May 2, 1990, ch. 169, 1990 Okla. Sess. Laws 496 (codified at OKLA. STAT. tit. 21, §§ 1862, 1863 (1991)).

TENNESSEE

Unsolicited Telefacsimile Advertising Act, ch. 877, 1990 Tenn. Pub. Acts 443 (codified at TENN. CODE ANN. §§ 47-18-1601 to 47-18-1604 (Supp. 1991)).

VIRGINIA

Act approved March 24, 1990, ch. 246, 1990 Va. Acts 339 (codified as amended at VA. CODE ANN. § 8.01-40.2 (1991)).

This act adds a provision for seeking civil damages and injunctive relief to prior law that already prohibited the sending of unsolicited commercial advertising via fax machine.

WASHINGTON

Act approved March 27, 1990, ch. 221, 1990 Wash. Laws 1242 (codified at WASH. REV. CODE ANN § 80.36.540 (1991)).

WEST VIRGINIA

Act approved March 26, 1990, ch. 47, 1990 W. Va. Acts 507 (codified at W. VA. CODE § 46A-2-139 and as amended at W. VA. CODE § 46A-1-102 (1991)).

This act prohibits the sending of unsolicited commercial advertising material via fax machine to recipients who have previously notified the sender that they wish not to receive such material.

PRIVACY

Electronic Monitoring of House Arrests

These acts authorize the use of electronic devices to monitor criminal defendants' compliance with house arrest requirements. Such devices record information about the defendants' presence in the house. Generally these acts establish guidelines for the use of such devices, requiring them to be minimally intrusive and requiring the consent of the participant and other residents in the home before they may be used.

ILLINOIS

Electronic Home Detention Law, P.A. 86-1281, 1990 Ill. Laws 2231 (codified at ILL. REV. STAT ch. 38, ¶¶ 1005-8A-1 to 1005-8A-5 and as amended at ILL. REV. STAT ch. 37, ¶ 805-24; ch. 38, ¶¶ 110-10, 1003-14-2, 1005-6-3, 1005-7-1 (1991)).

NEBRASKA

Act approved February 7, 1990, LB 399, 1990 Neb. Laws 187 (codified as amended at NEB. REV. STAT. § 47-401 (1991)).

This act authorizes the use of electronic surveillance systems to monitor house arrests but provides no guidelines for their use.

SOUTH CAROLINA

Home Detention Act, No. 594, 1990 S.C. Acts 2509 (codified at S.C. CODE ANN. §§ 24-13-1510 to 24-13-1590 (Law Co-op 1991)).

Expectation of Privacy in Telecommunications Transmissions

The following acts address whether there is an expectation of privacy in telecommunications transmissions, despite the possibility of interception by third parties.

CALIFORNIA

Act approved September 10, 1990, ch. 696, 1990 Cal. Stat. ____ (codified at CAL. PENAL CODE § 632.6 and as amended at CAL. PENAL CODE §§ 632, 633, 633.5, 634, 635 (West 1991)).

Existing law makes it a crime to intercept cellular telephone transmissions. This act makes it a crime to intercept cordless telephone communications as well.

CONNECTICUT

Act approved June 12, 1990, P.A. 90-305, 1990 Conn. Acts 1022 (Reg. Sess.)(codified at CONN. GEN STAT. ANN. § 52-570d (West 1991)).

This act prohibits the recording of private telephone communications without prior notification to all parties. Such notification may include the use of an automatic tone warning device while the recording equipment is in use. Exceptions are provided for law enforcement and public safety officials in the lawful performance of their duties, recipients of extortion threats or other unlawful requests, and officers of the Federal Communications Commission who record conversations for broadcast over the air.

ILLINOIS

Act approved August 29, 1990, P.A. 86-1206, 1990 Ill. Laws 1876 (codified as amended at ILL. REV. STAT ch. 38, ¶ 108B-1 (1991)).

This act declares that persons using a cordless telephone or a cellular communication device have a reasonable expectation of privacy in their communications.

MINNESOTA

Act approved April 16, 1990, ch. 455, 1990 Minn. Laws 952 (codified as amended at MINN. STAT. §§ 626A.01, 626A.02 (1991)).

This act provides that it is not unlawful to inadvertently intercept a cordless telephone communication.

Police Interception of Telecommunications Transmissions

INDIANA

Act approved March 20, 1990, P.L. 161-1990, § 3, 1990 Ind. Acts 2161, 2163-76 (codified at IND. CODE §§ 35-33.5-1-1 to 35-33.5-5-6 (1991)).

This act establishes procedures that police must follow to intercept telephonic or telegraphic communications. It strictly limits the admissibility of evidence obtained through wiretapping and the manner by which authority to wiretap may be obtained. The act requires that a warrant be obtained to establish electronic surveillance and limits surveillance to 14 days absent a judicial extension.

PENNSYLVANIA

Act approved February 2, 1990, P.L. 1990-3, 1990 Pa. Laws ____ (codified as amended at 18 PA. CONS. STAT. § 5708 (1991)).

This act authorizes the use of wiretapping to investigate crimes involving the selling of infant children.

Telecommunications Harassment

OKLAHOMA

Act Approved April 16, 1990, ch. 73, 1990 Okla. Sess. Laws 231 (codified as amended at OKLA. STAT. tit. 21, § 850 (1991)).

This act prohibits the malicious intimidation of minorities through the transmission of telephone or electronic messages. Immunity is granted to entities installing telephone or electronic

message equipment unless the entity has actual knowledge that such equipment is being used in violation of this section.

Facsimile Number Directories

CALIFORNIA

Act approved September 17, 1990, ch. 973, 1990 Cal. Stat. ____ (codified at CAL. BUS. & PROF. CODE§ 22600 and CAL. PUB. UTIL CODE § 728.4 (West 1991)).

This act requires owner consent before his or her facsimile machine number may be included in a commercial directory.

INTELLECTUAL PROPERTY

Applicability of Federal Law

FEDERAL

Copyright Remedy Clarification Act, Pub. L. No. 101-553, 104 Stat. 2749 (1990) (codified at 17 U.S.C. § 511 and as amended at 17 U.S.C. §§ 501, 910, 911 (1991)).

This act clarifies existing law by providing that states are subject to suit in federal court for copyright infringement, thereby expressly abrogating the states' Eleventh Amendment immunity from copyright infringement actions. Under the act, all remedies for infringement against a private person are likewise available against states.

Act approved November 15, 1990, Pub. L. No. 101-580, 104 Stat. 2863 (codified at 35 U.S.C. § 105 (1991)).

This act provides that inventions made, used, or sold in space on a United States space object or component will be considered made, used, or sold within the United States. If the space object belongs to another country, the invention will be deemed as made within the Untied States if an international agreement between the two countries so provides.

Government Ownership of Copyrights

FLORIDA

Act approved July 2 1990, ch. 90-237, 1990 Fla. Laws 1769 (codified at FLA. STAT. § 119.083 (1991)).

This act authorizes certain governmental agencies to obtain copyrights for data processing software created by the agencies. It provides that an agency which obtains a copyright for data processing may enforce its rights and sell or license the copyright subject to certain restrictions.

State Public Records Acts

State public records acts generally require that government records be accessible to the public unless there is a state need for maintaining their confidentiality. The following acts are designed to protect the confidentiality of intellectual property owned by the state from the effect of such public records acts.

ALASKA

Act approved May 15, 1990, ch. 55, 1990 Alaska Sess. Laws ____ (codified at ALASKA STAT. § 14.40.453 (1991)).

This act provides that the state public records act does not apply to intellectual property or proprietary information received by the University of Alaska until the information is released, copyrighted, or patented. An exception is provided for descriptions of projects, the names of researchers, and the amount and source of funding.

KENTUCKY

Res. approved April 10, 1990, ch. 430, 1990 Ky. Acts 983.

This resolution creates a task force to study the effect that advances in computer technology and data management have had on the state public records act. The task force is to consider amending the state public records act to balance public need for access to public records against public agencies' need for confidentiality.

Regulation of Invention Promotion Services

KANSAS

Act approved April 12, 1990, ch. 181, 1990 Kan. Sess. Laws 1091 (codified at KAN. STAT. ANN §§ 50-666 to 50-668 (Supp. 1990)).

This act requires "invention promoters" to make certain disclosures in their contracts with inventors. Invention promoters are persons who develop and promote inventions on behalf of inventors. The required disclosures include (a) the fees to be charged, (b) whether or not prototypes will be made or sold, and (c) whether the invention promoter evaluates the technical or commercial feasibility of the invention. In addition, a mandatory clause must be inserted in the contract explaining the consequences of assigning interests in the invention, the importance of consulting an attorney, and the effect the contract may have on patent rights.

Noncompetitive Agreements

LOUISIANA

Act approved June 29, 1990, No. 137, 1990 La. Acts 458 (codified as amended at LA. REV. STAT. ANN § 23:921 (West 1991)).

This act legalizes employment agreements which preclude ex-employees from working on any computer program that competes with any confidential computer program owned by their former employer and to which the employee had direct access during employment.

Trade Secrets

CALIFORNIA

Act approved June 18, 1990, ch. 149, 1990 Cal. Stat. ____ (codified at CAL. EVID. CODE§§ 1061, 1062 (West 1991)).

This act creates a privilege protecting trade secrets during criminal proceedings. Courts are authorized to issue protective orders when the privilege is invoked by an owner of a trade secret. It also provides for closing to the public such portions of criminal proceedings as are necessary to prevent the disclosure of trade secrets.

Uniform Trade Secrets Act

The following acts adopt the Uniform Trade Secrets Act ("U.T.S.A."), which authorizes injunctive relief and damages for the misappropriation of trade secrets. The U.T.S.A. authorizes attorney's fees when a misappropriation claim is made in bad faith or a motion to terminate an injunction is made or resisted in bad faith. Both attorney's fees and exemplary damages are authorized when willful and malicious misappropriation is found. In civil actions under the act, the court is charged with preserving the secrecy of alleged trade secrets by reasonable means. There are minor variations among the various enactments.

ARIZONA

Uniform Trade Secrets Act, ch. 37, 1990 Ariz. Sess. Laws ____ (codified at ARIZ. REV. STAT. ANN §§ 44-401 to 44-407 (1991)).

GEORGIA

Georgia Trade Secrets Act of 1990, H.B. 1449, 1990 Ga. Laws 1560 (codified at GA. CODE ANN §§ 10-1-761 to 10-1-767 and as amended at GA. CODE ANN § 10-1-760 (1991)).

IOWA

Uniform Trade Secrets Act, ch. 1201, 1990 Iowa Acts 288 (codified at IOWA CODE §§ 550.1 to 550.8 (1991)).

KENTUCKY

Uniform Trade Secrets Act, ch. 300, 1990 Ky. Acts 608 (codified at KY. REV. STAT. ANN. §§ 365.880 to 365.900 (Michie Supp. 1990)).

MISSISSIPPI

Mississippi Uniform Trade Secrets Act, ch. 442, §§ 1 to 10, 1990 Miss. Laws 294 (codified at MISS. CODE ANN. §§ 75-26-1 to 75-26-19 (1991)).

PUBLIC HEALTH AND MEDICINE

Surrogate Parentage Contracts

MICHIGAN

Act approved July 23, 1990, No. 190, 1990 Mich. Pub. Acts ____ (codified as amended at MICH. COMP. LAWS § 722.853 (1991)).

Under this act, surrogate parentage contracts will presumptively include a provision, whether or not express, that the birth mother will relinquish her parental or custodial rights to the child.

NEW HAMPSHIRE

Act approved April 10, 1990, No. 87, 1990 N.H. Laws 117 (codified at N.H. REV. STAT. ANN. §§ 168-B:1 to 168-B:32 (1991)).

This act requires surrogate arrangements to be judicially preauthorized and provides for the legitimacy of children of such arrangements. It also defines support responsibilities and gives the birth mother a 72-hour option after birth to keep the child.

The act forbids arranging surrogacy contracts for profit and generally limits the fees the birth mother may receive to expenses (including lost wages and attorney's fees) caused by the pregnancy.

Paternity Testing

NEW HAMPSHIRE

Act approved April 19, 1990, ch. 149, 1990 N.H. Laws 208 (codified as amended at N.H. REV. STAT. ANN. §§ 522:1 to 522:4-a (1991)).

This act authorizes courts in paternity suits to order the mother, child, and alleged father to submit to genetic marker tests, including DNA analysis.

SOUTH CAROLINA

Act approved June 7, 1990, No. 562, 1990 S.C. Acts 2426 (codified as amended at S.C. CODE ANN. § 20-7-954 (Law. Co-op. 1991)).

This act provides that genetic testing is not required in paternity actions where the court finds that a party has good cause to refuse such testing. "Good cause" may include (a) the potential violation of an overriding religious belief of either parent or (b) the potential for emotional or physical harm to the child, the custodial parent (if that harm reduces the parent's ability to care for the child), or the putative parent (if that harm outweighs the child's interest in a paternity determination).

DNA Identification of Sex Offenders

These acts require convicted sex offenders to submit to the withdrawal of blood and saliva samples from which DNA identification profiles will be determined. The profiles are to be

stored at a central agency and made available to criminal justice agencies.

INDIANA

Act approved March 27, 1990, P.L. 37-1990, § 34, 1990 Ind. Acts 1262, 1284 (codified at IND. CODE § 35-37-4-10 (1991)).

This act makes the results of forensic DNA analyses admissible as evidence in criminal proceedings without expert testimony on their reliability.

MICHIGAN

Act approved July 23, 1990, No. 191, 1990 Mich. Pub. Acts ____ (codified at MICH. COMP. LAWS § 750.520m (1991)).

This act provides for the taking of blood and saliva samples for law enforcement purposes in a medically approved manner by qualified persons.

DNA Identification Profiling System Act, No. 250, 1990 Mich. Pub. Acts ____ (codified at MICH. COMP. LAWS §§ 28.171 to 28.178 (1991)).

This act provides for the collection of blood and saliva samples from certain prisoners and convicted sex offenders for DNA testing purposes. These collections are to be done in such a way as to protect individual privacy interests. The act also provides for a committee to advise the legislature on various aspects of forensic DNA testing.

Act approved October 11, 1990, No 251, 1990 Mich. Pub. Acts ____ (codified at MICH. COMP. LAWS § 791.233d (1991)).

This act provides that prisoners convicted of sex-related crimes shall not be released on parole until they have provided blood and saliva samples for DNA identification purposes.

SOUTH DAKOTA

Act approved February 24, 1990, ch 173, 1990 S.D. Laws 218.

This act establishes a DNA identification system for sex offenders. Upon the arrest of such persons, law enforcement officers shall arrange for the collection of blood and saliva specimens for analysis. The authorized collector is not liable for damages if withdrawal of the specimen is administered with usual and ordinary care. DNA identification information is kept confidential.

VIRGINIA

Act approved April 9, 1990, ch. 669, 1990 Va. Acts 999 (codified at VA. CODE ANN. §§ 19.2-270.5, 19.2-310.2 to 19.2-310.7 and as amended at VA. CODE ANN. § 19.2-387 (1991)).

This act deems DNA testing to be a reliable scientific technique and provides for the admission of such testing in criminal proceedings to prove identity. Those authorized to withdraw blood will face no civil liability as long as blood was withdrawn according to recognized medical procedures. The results of a blood analysis will be stored in a state data bank and made available to federal, state, and local law-enforcement officers for law enforcement purposes.

WASHINGTON

Act approved March 27, 1990, ch. 230, 1990 Wash. Laws 1270 (codified as amended at WASH REV. CODE §§ 43.43.754, 43.43.758 (1991)).

This act prohibits the use of DNA identification data for any purpose not related to a criminal investigation. It also requires blood samples to be obtained from sex offenders prior to release from confinement.

Biotechnology

FEDERAL

Biological Weapons Anti-Terrorism Act of 1989, Pub. L. No. 101-298, 104 Stat. 201 (1990) (codified at 18 U.S.C. §§ 175 to 178 (1991)).

This act was passed to protect the United States against the threat of biological terrorism. It criminalizes the development, production, and possession of any biological agent for use as a weapon. The assistance of a foreign state in using biological agents in this way is also made a crime. However, the act is not intended to restrict peaceful scientific research.

CALIFORNIA

Act approved July 13, 1990, ch. 252, 1990 Cal. Stat. ____ (codified as amended at CAL. FOOD & AGRIC CODE § 2272 (West 1991)).

This act requires county agricultural commissioners to report annually on the condition of the agricultural interests in the county, such as the control of pests. Information relating to biotechnology must be included in the annual report.

Act approved September 30, 1990, ch. 1642, 1990 Cal. Stat. ____ (codified as amended at CAL. FOOD & AGRIC CODE §§ 576 to 585 (West 1991)).

To strengthen pest prevention, control, and eradication efforts, this act creates an administrative structure within the University of California to advance pest research. The University of California Center for Pest Research is encouraged to give high priority to, among other things, improvements in technology designed to detect pests.

OKLAHOMA

Oklahoma Agriculture Biotechnology Act, ch. 226, 1990 Okla. Sess. Laws 755 (codified at OKLA. STAT tit. 2, §§ 2011 to 2018 (1991)).

The purpose of this act is to protect agriculture and public health from release of genetically engineered biological articles into the environment. It authorizes the State Board of Agriculture to promulgate rules and regulations needed for control of these articles. Persons must meet certain regulatory requirements before being able to maintain regulated articles.

Health Risks of Electric and Magnetic Fields

WASHINGTON

Act approved March 26, 1990, ch. 173, 1990 Wash. Laws 1078 (codified as amended at WASH. REV. CODE § 70.98.050 (1991)).

This act directs a state agency to collect and disseminate information relating to nonionizing radiation. It was passed out of concern about possible health effects resulting from exposure to electric and magnetic fields.

Using Animals for Research

COLORADO

Act approved April 16, 1990, ch. 264, 1990 Colo. Sess. Laws 1614 (codified at COLO. REV. STAT. § 35-42.5-101 (1991)).

This act requires pounds and shelters to make dogs and cats available for adoption for two weeks before allowing them to be used for experiments and to make reasonable efforts to contact the animal's owner. "Red tagging" (isolating dogs and cats suitable for adoption) is prohibited, and pounds or shelters that provide dogs and cats for experimentation must so inform an owner who is relinquishing one.

VIRGINIA

Act approved April 18, 1990, ch. 904, 1990 Va. Acts 1646 (codified at VA. CODE ANN. § 3.1-796.96:1 (1991)).

This acts provides that no animal bearing identification may be used for research without the owner's written consent.

Health Insurance Regulation

VIRGINIA

H.J. Res. 213, 1990 Va. Acts 2345.

This resolution directs a commission to develop standards for distinguishing state-of-the-art medical treatments from those which are experimental or investigative (and thus not covered by insurance).

Health Care Programs

FEDERAL

Breast and Cervical Cancer Mortality Prevention Act of 1990, Pub. L. No. 101-354, 104 Stat. 409 (codified at 42 U.S.C. §§ 1501 to 1509 (1991)).

This act establishes grants for states to perform breast and cervical cancer screening and provides quality standards for mammography programs and cytological screening procedures.

CALIFORNIA

Act approved March 15, 1990, ch. 26, 1990 Cal. Stat. ____ (codified at CAL. HEALTH & SAFETY CODE§§ 156 to 156.3 (West 1991)).

This act modifies an existing state prenatal testing program. Specifically, it provides for the use of ultrasound, chorionic villus sampling, and blood testing for genetic and birth defects, as well as such other tests as may be developed; previously, only amniocentesis was authorized. The act also repeals the requirement that prenatal centers be acute care hospitals.

Anatomical Gifts

CALIFORNIA

Act approved September 29, 1990, ch. 1507, 1990 Cal. Stat. ____ (codified at CAL. HEALTH & SAFETY CODE§ 7160 (West 1991)).

This act requires a state agency to evaluate and to make recommendations to improve organ transplantation services for the general public and for minority and low-income communities. It was passed in response to the severe shortage of donated organs.

LOUISIANA

Act approved July 31, 1990, No. 1091, 1990 La. Acts 2856 (codified as amended at LA. CIV. CODE ANN. art. 2322.1; LAREV. STAT. ANN § 9:2797 (West 1991)).

This act declares that blood transfusions, organ transplants, and related acts are renditions of medical services and not sales. Thus, strict liability does not apply to such services.

TENNESSEE

Act approved April 5, 1990, ch. 775, 1990 Tenn. Pub. Acts 265 (codified at TENN. CODE ANN. § 4-3-2011 (1991)).

This act establishes a centralized database of organ and tissue donors to provide continuous information to donor service agencies.

Uniform Anatomical Gift Act

The following acts adopt the 1987 version of the Uniform Anatomical Gift Act, which was drafted to further encourage and facilitate organ donation. These acts generally allow certain close family members of a decedent to authorize donation of the decedent's anatomical parts, unless the decedent has previously objected to such a gift. Hospitals must set up a routine contact protocol to ensure that families of suitable donors are offered the opportunity to consider donation.

The donor and his estate are exempted from liability for injuries resulting from the use of an anatomical gift. Likewise, doctors who act in good faith to comply with the provisions of this law are exempted from criminal or civil liability for such acts.

The sale or purchase of body parts is expressly prohibited.

UTAH

Uniform Anatomical Gift Act, ch. 131, 1990 Utah Laws 451 (codified at UTAH CODE ANN. §§ 26-28-9 to 26-28-12 and as amended at UTAH CODE ANN. §§ 26-28-1 to 26-28-8 (1991)).

VERMONT

Act approved June 21, 1990, No. 273, 1990 Vt. Laws 440 (codified at VT. STAT. ANN tit. 18, §§ 5238 to 5247; tit. 9A, § 2-108 (1991)).

VIRGINIA

Act approved April 18, 1990, ch. 959, 1990 Va. Acts 1829 (codified at VA. CODE ANN. §§ 32.1-290.1, 32.1-292.2 and as amended at VA. CODE ANN. §§ 32.1-289 to 32.1-291 (1991)).

WISCONSIN

Act approved April 23, 1990, Act 298, 1989 Wis. Laws 1303 (codified as amended at WIS. STAT. §§ 146.025, 157.06, 343.14 to 343.17, 343.175, 343.50, 979.22 (1991)).

WYOMING

Act approved March 15, 1990, ch. 18, 1990 Wyo. Sess. Laws 38 (codified at WYO. STAT. §§ 35-5-113 to 35-5-117 and as amended at scattered sections of WYO. STAT. (1991)).

Prosthetics

The following acts help provide prosthetic devices to persons with developmental disabilities.

FEDERAL

Developmental Disabilities Assistance and Bill of Rights Act of 1990, Pub. L. No. 101-496, § 17, 104 Stat. 1191, 1200-03.

This act provides in part for grants to university affiliated programs to provide training to personnel to provide assistive technology services to persons with developmental disabilities.

CALIFORNIA

Act approved September 26, 1990, ch. 1381, 1990 Cal. Stat. ____ (codified as amended at CAL. WELF. & INST. CODE§ 14132.76 (West 1991)).

This act provides for a two year pilot program increasing the availability of prosthetic devices to participants in Medi-Cal, the state's medical assistance program for low-income residents. The goal of the pilot program is to facilitate Medi-Cal cost savings by encouraging increased use of prosthetic devices as an alternative to hospitalization. Under this program, no prior physician authorization is required to qualify for Medi-Cal reimbursement for

prosthetic devices which do not exceed $500 or for orthotic devices which do not exceed $250.

RHODE ISLAND

Act approved July 12, 1990, ch. 417, 1990 R.I. Pub. Laws ____ (codified at R.I. GEN. LAWS §§ 40-14.1-1 to 40-14.1-6 (1991)).

This act authorizes a program to provide assistive technology services to individuals with disabilities who are otherwise unable to afford such services. Such services are defined as including the acquiring of assistive technology devices, the designing and maintenance of such devices, and training in the use of such devices.

Telecommunications Relay Services for the Hearing or Speech Impaired

Except as otherwise noted, these acts establish telecommunications relay services for persons who are hearing or speech impaired. Such persons generally use teletypewriters and other equipment to conduct telephone communications. The telecommunications relay services provided for by these acts translate such communications between persons using such special equipment and persons using standard telephone equipment.

Most of these acts prohibit special user fees on the users of the relay services, requiring the cost to be apportioned among all local telephone users via surcharge. Also, because the relay services require third-party intermediaries who have access to the communications, some of these acts require that the relayed communications be kept confidential.

FEDERAL

Americans with Disabilities Act of 1990, Pub. L. 101-336, § 401, 104 Stat. 327, 366-69 (codified at 47 U.S.C. § 225 (1991)).

This act does not itself establish a relay service but rather requires all telecommunications common carriers to offer telecommunications relay services to its subscribers.

GEORGIA

Act approved April 11, 1990, S.B. 591, 1990 Ga. Laws 1118 (codified at GA. CODE ANN § 46-5-31 and as amended at GA. CODE ANN. § 46-5-30 (1991)).

MAINE

Act approved April 17, 1990, ch. 851, 1989 Me. Laws 1983 (codified at ME. REV. STAT. ANN. tit. 35-A, §§ 8701 to 8704 and as amended at ME REV. STAT. ANN. tit. 3, § 927-7; tit. 5, § 12004-I; tit 22, §§ 3601, 3602 (1991)).

This act establishes user fees to pay for the cost of the relay service rather than placing the cost on all local telephone users via surcharge.

MISSOURI

Act approved July 10, 1990, H.B. 1132, 1990 Mo. Laws 738 (codified at MO. ANN. STAT. §§ 209.251 to 209.259 (Vernon Supp. 1991).

This act makes no provision for maintaining the confidentiality of relayed transmissions.

RHODE ISLAND

Act approved July 3, 1990, ch. 135, 1990 R.I. Pub. Laws ____ (codified at R.I. GEN. LAWS § 39-23-5 (1991)).

This act adds a confidentiality requirement to previous legislation that had already established a statewide telephone relay service.

WASHINGTON

Act approved March 19, 1990, ch. 89, 1990 Wash. Laws 722, (codified as amended at WASH. REV. CODE §§ 43.20A.720, 43.20A.725, and 43.20A.730 (1991)).

The act makes no provision for maintaining the confidentiality of relayed transmissions.

Closed Captioned Television Transmissions

FEDERAL

Television Decoder Circuitry Act of 1990, Pub. L. No. 101-431, 104 Stat. 960 (codified as amended at 47 U.S.C. §§ 303, 330 (1991)).

This act requires that televisions with screens 13 inches or greater in size be designed to display closed captioned television transmissions without the use of external decoders. This requirement applies to all televisions either manufactured in the United States or imported for use within the United States. The Act also establishes performance and display standards of the required built-in decoder circuitry.

Americans with Disabilities Act of 1990, Pub. L. 101-336, § 402, 104 Stat. 327, 369 (codified at 47 U.S.C. § 225 (1991)).

This act requires that all television public service announcements produced or funded in whole or in part by the Federal Government include closed captioning of the verbal content of such announcement.