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THE POLITICAL ECONOMY OF PATENT POLICY REFORM IN THE UNITED STATES

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1. Introduction

During the 1980s and 1990s, important legislative, judicial, and diplomatic initiatives emanated from the United States, strengthening patent and copyright enforcement systems both domestically and in the broader world economy. The political influences that led to these changes are interesting in their own right.[1] Even more interesting, however, is the fact that governmental emphasis on patent systems increased in the wake of impressive new findings from economic studies showing that patents played a surprisingly minor role in well-established corporations' decisions to invest in research, development, and technological innovation. The opposing movements of the political and behavioral science currents will be a principal theme of this article.

2. The Turbulent Early History

Governments' policies toward patents on inventions and copyright for artistic works have been marked by appreciable fluctuations over the course of history. At the dawn of the 17th century, patents and copyrights were components of the feudal system in Western Europe.[2] Sovereigns awarded exclusive

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1 . For a contribution with a similar focus and some similar conclusions, *see* WILLIAM M. LANDES & RICHARD A. POSNER, THE POLITICAL ECONOMY OF INTELLECTUAL PROPERTY LAW (2004), which is derived from LANDES & POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW (2003).

2 For authoritative histories, see Fritz Machlup and Edith Tilton Penrose, *The Patent Controversy in the Nineteenth Century*, 10 J. ECON. HISTORY 1 (1950); MACHLUP, AN ECONOMIC REVIEW OF THE PATENT SYSTEM, Study No. 15 of the Senate Judiciary Committee Subcommittee on Patents, Trademarks, and Copyrights (1958); and, putting

privileges to pursue a mechanical trade, publish books or music, and present theatrical performances to selected individuals -- usually but not always those with close connections to the noble courts and often favorites of the court. The privilege system was attacked under the banner of the Enlightenment, first during the reign of James I in England (1603-25) and then with the 1779 French Revolution and the eastward spread of anti-feudal policies under Napoleon. It was replaced by patents and copyrights made available to the middle classes through more transparent procedures, but limited in the time span over which they were applicable. In the New World, granting to authors and inventors exclusive rights to their writings and discoveries for limited times was enshrined in Article I, Section 8, of the U.S. Constitution.

The period between the 1770s and 1840s, when patent and copyright laws spread rapidly, was followed, at least in Europe (but less so in the United States), by an "anti-patent" movement. In England, reforms following publication of Charles Dickens' spoof, "A Poor Man's Tale of a Patent," simplified the processes by which patents were issued, imposed stricter examination of patent applications, and allowed abrogation of exclusive rights in cases of demonstrated abuse. The Swiss legislature repeatedly rejected proposals to enact patent laws, and in the Netherlands, existing patent laws were repealed in 1869, to be reenacted only in 1910.[3] The severe recession of 1873 triggered more favorable attitudes toward patents, and in 1887, even conservative Switzerland found it prudent to pass a patent law.

In the United States the patent system enjoyed widespread and persistent political support, among others, from Abraham Lincoln, who had personally patented an invention of his creation and who as an attorney in Illinois had litigated patent disputes. Inventors such as Thomas A. Edison and Alexander Graham Bell were idolized. Extensions over time of the Bell telephone monopoly and a cartel originally based upon the Edison electric lamp patents were sustained in a series of Supreme Court tests, reinforcing an earlier decision allowing a patent

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copyright privileges in a more democratic light, HANSJÖRG POHLMANN, DIE FRÜHGESCHICHTE DES MUSIKALISCHEN URHEBERRECHTS (1962).

3 *See* ERICH SCHIFF, INDUSTRIALIZATION WITHOUT NATIONAL PATENTS (1971).

holder unilaterally to stipulate the minimum prices at which its licensees could sell their products and ignoring evidence that the patent-holder had pursued numerous parallel actions that in effect cartelized the relevant industry.[4] During the 1960s the Department of Justice sought to overturn the still-binding precedent, but was unsuccessful.[5]

In most respects, however, the tide turned again during the Great Depression of the 1930s. Growing hostility toward monopoly was precipitated by the belief that downward price rigidities enforced by monopolistic sellers (as well as by cartels authorized under President Franklin D. Roosevelt's National Recovery Administration) inhibited recovery from the depression. Threats to national security posed by patent-based cartels in tungsten carbide machine tools and synthetic rubber raised questions about the abuse of patent grants. So also did the wide-ranging investigations of the Temporary National Economic Committee, which showed inter alia how industries such as glass container-making had been thoroughly regimented through collusive control of patents by the Hartford-Empire Company. At an American Economic Association symposium reviewing the TNEC's findings, later Nobel Laureate George Stigler found the Hartford-Empire story "an eloquent example of an evil demanding correction" and concluded flatly that "The case for limitation of restrictive [patent] licensing is surely irrefutable."[6]

Hartford-Empire was an early target of the reinvigorated antitrust enforcement paralleling the TNEC hearings. Its extensive patent agreements with other bottle-making technology providers and users were found to violate the antitrust laws. To remedy the situation, a federal district court judge ordered

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4 Bement & Son v. National Harrow Company, 186 U.S. 70 (1902), followed by U.S. v. General Electric Co., 272 U.S. 476 (1926). The rationale was that since holding a valid patent allowed the patent holder to exclude others and hence to monopolize sale of the relevant products, licensing restraints that preserved the patent holder's monopoly reward were acceptable.

5 *See e.g.* U.S. v. Huck Mfg. Co. et al., 382 U.S. 197 (1965), in which an attempt to overturn earlier *Bement* and *General Electric* precedents failed with a 4-4 division of Supreme Court justices.

6 George J. Stigler, *The Extent and Bases of Monopoly*, 32 AM. ECON. REV. Supplement 14 (1942). At the time, Stigler was teaching at the University of Minnesota.

inter alia that Hartford-Empire and companies with which it had joined forces be required to license all their bottle-making machinery patents -- after a Supreme Court intervention declaring royalty-free licensing to be confiscatory, at "reasonable" (i.e., modest) royalty rates.[7] After a subsequent Supreme Court decision stated that district court judges could exercise "judicial discretion" in formulating remedies for patent-based antitrust law violations, royalty-free licensing of General Electric's electric lamp patents was imposed.[8]

The Hartford-Empire and General Electric cases were followed by numerous antitrust settlements in which compulsory licensing of patents was ordered to remedy monopolistic situations where patents played a significant role. Between 1941 and the late 1950s, compulsory licensing decrees had been issued in settlement of more than 100 antitrust complaints, covering inter alia AT&T's transistor and other telecommunications apparatus patents, IBM's computer patents, and DuPont's nylon and other synthetic fiber patents. The cumulative number of patents affected is estimated to have been between 40,000 and 50,000.[9] Although the pace abated after 1960, additional decrees covered the roughly one thousand patents in Xerox's plain-paper copying machine portfolio[10] and several pharmaceutical products. Many European nations had until recently laws allowing compulsory licensing of patents, notably, in cases where an invention was not actually produced within the patent-issuing nation. However, the cumulative number of compulsory licensing orders has seldom exceeded a dozen in the typical large European nation -- a far cry from the tens of thousands of patents covered by U.S. antitrust decrees. Most of the U.S. compulsory licensing decrees were entered by mutual consent rather than as the result of fully contested litigation. Only the General Electric decree imposed royalty-free licensing

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7 U.S. v. Hartford-Empire Co. et al., 46 F. Supp. 541 (1942), 323 U.S. 386 (1944), 324 U.S. 570 (1944).

8 U.S. v. General Electric Co. et al., 115 F. Supp. 835, 844 (1953).

9 MARCUS A. HOLLABAUGH & ROBERT WRIGHT, COMPULSORY LICENSING UNDER ANTITRUST JUDGMENTS, staff report of the Subcommittee on Patents, Trademarks and Copyrights, Senate Committee on the Judiciary (1960) at 2-5.

10 In the Matter of Xerox Corporation, decision and order, 86 F.T.C. 364 (1975).

through a contested court order, but several others, including the AT&T order of 1956, entailed royalty-free licensing by mutual consent.[11]

3. Economic Impact Studies

The 1956 decree ordering the compulsory licensing of roughly 8,600 AT&T patents and the nearly simultaneous decree affecting IBM patents inspired particularly intense public scrutiny. The Wall Street Journal observed in an editorial:[12]

> So it may turn out that these are dangerous victories the Government boasts about. The settlements in these cases indicate a belief that everybody's patents should be everybody else's. But this is a philosophy that strikes at incentive; new ideas and new inventions may be lost. Such Government victories may turn out to be far more costly for the nation than for the companies.

Shortly thereafter eight colleagues and I formed a group to meet the requirement for a "topic report" in a Harvard Business School course taught by Georges F. Doriot, president of the first modern American high-technology venture capital group, the American Research and Development Corporation. We decided to study the incentive effects of compulsory licensing decrees. We read widely in the relevant literature (aided by studies commissioned under an ongoing Senate Judiciary Committee investigation); fanned out to interview 22 American corporations, many of whom had entered compulsory licensing decrees; received mail questionnaires from 69 companies holding 45,500 patents; and conducted an extensive statistical analysis of patenting trends. The results, privately-published in two book editions,[13] were profoundly surprising to us. We

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11 U.S. v. Western Electric, Inc., and the American Telephone and Telegraph Co., 1956 Trade Cases (CCH) Para. 68,246.

12 "Dangerous Victory," Jan. 27, 1956, p. 6.

13 F. M. SCHERER, S. E. HERZSTEIN, ALEX DREYFOOS, WILLIAM WHITNEY, OTTO BACHMANN, PAUL PESEK, CHARLES SCOTT, THOMAS KELLY, & JAMES J. GALVIN, PATENTS AND THE CORPORATION: A REPORT ON INDUSTRIAL TECHNOLOGY UNDER CHANGING PUBLIC POLICY (2nd ed.: 1959). The first edition was published in 1958.

discovered that with rare exceptions, whether or not well-established corporations could expect patent protection was typically unimportant in their decisions to invest in research and the development of new products and processes. "Of far greater everyday importance," we concluded, "are reward structures related to the necessity of retaining market positions, of attaining production more efficient than competitors', of securing the corporation through diversification against disastrous product obsolescence, and of gaining short-term advantages which can be exploited by advertising and well-developed sales channels."[14] To be sure, there were exceptions -- notably, situations in which firms were making risky investments into fields where they had little technical or marketing experience, and arguably (since our sample included few startup companies) for small new enterprises seeking a competitive foothold against well-entrenched rivals.[15] We found also from interviews, mail survey responses, and statistical analyses that prior compulsory licensing decrees had little or no unfavorable impact on research and development decisions, although they had led to less patenting of the inventions actually made and hence greater reliance on secrecy, especially on (concealable) process as distinguished from readily observed product inventions. This finding was supported in a later statistical study, conducted when company R&D spending data first became publicly available, which showed that the companies subjected to compulsory licensing decrees spent more on R&D relative to their sales on average than unimpacted companies of comparable size in the same fields of technology.[16]

Unaware of our study, economists at Cambridge and Oxford Universities undertook similar research on how the absence of patent protection would affect the R&D behavior of British companies. They found that across all industries covered, the weighted average reduction in R&D expenditures if no patent protection could be obtained -- a condition more drastic than

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14 *Id.* at 149.

15 The ambiguous situation of startup companies was characterized by the reaction of Professor Doriot when we told him about our contemplated research: "Hell, patents are simply instruments with which big companies bludgeon my startups."

16 F. M. SCHERER, THE ECONOMIC EFFECTS OF COMPULSORY PATENT LICENSING, New York University Monograph Series in Finance and Economics (1977), 67-75.

compulsory licensing with reasonable royalties -- would be eight percent.[17] However, in pharmaceuticals, a negative impact of 64 percent was predicted. Similar disparities between the incentive effect of patents in pharmaceuticals and other high-technology industries were revealed through particularly careful interviews with U.S. companies by Edwin Mansfield and colleagues.[18]

Many surveys have shown that the expectation of patent protection is much more important to investment in pharmaceutical R&D than in most industries. Drug R&D comes closest to what economists call the generation of knowledge as a pure public good. Most of the expenditure is directed toward finding molecules that might have interesting therapeutic action in human beings and then, through costly clinical trials, ascertaining that the target molecule is really effective and safe.[19] Absent patents, once that evidence has been amassed, it might be available for any and all would-be generic imitators to exploit. All that may be needed for the free-rider (or more accurately, cheap rider) is to spend a sum on process engineering tiny relative to the amounts spent on discovery and testing, whereupon a competing molecule can be marketed (if regulatory rules permit). However, further research added a caveat to this conclusion and clarified the role of what came to be known as "first mover" advantages as a barrier to rapid new product imitation and hence as a substitute for patent protection. Comparing side-by-side two pharmaceutical molecules, one unpatentable and one patented, Bond and Lean found that the erosion of the pioneer's price premium and market share was as slow for the unpatented product as for the patented product.[20] The reason, it became clear, was that being the first

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17 C. T. TAYLOR & Z. A. SILBERSTON, THE ECONOMIC IMPACT OF THE PATENT SYSTEM (1973) at 199.

18 Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGT. SCIENCE 173 (1986); and Mansfield et al., *Imitation Costs and Patents: An Empirical Study*, 91 ECON. JOUR. 908 (1981).

19 For a survey, see F. M. SCHERER, INDUSTRY STRUCTURE, STRATEGY, AND PUBLIC POLICY (1996), at 357-362.

20 RONALD S. BOND & DAVID LEAN, SALES, PROMOTION, AND PRODUCT DIFFERENTIATION IN TWO PRESCRIPTION DRUG MARKETS, Federal Trade

successfully to market a consumer product affixes in the mind of decision-makers an image of superiority and reliability that is hard for latecomers to surmount, whether the product is patented or not. However, it should be noted that the Bond and Lean study focused on products developed during the late 1950s, when regulatory strictures were more lax and the research and testing costs required to market a successful new drug entailed only about $1 million. By the late 1990s, the comparable costs had mounted to hundreds of millions of dollars, while the costs of engineering imitative generic products rose much less.

A major step toward confirming the role hoped-for patent protection plays in R&D decisions was taken by four prominent economists at Yale University.[21] They obtained elaborate survey responses from 650 U.S. R&D managers. One set of questions, emulating earlier inquiries for a smaller sample by Mansfield, asked how much R&D, measured relative to the first mover's R&D, would be needed to duplicate the first mover's innovation. For major patented new products, the average fraction was roughly 85 percent (weighting category ranges by response rates); for major unpatented products, 65 percent. Thus, patent protection raised imitation costs, but even without it, imitators could not simply "free-ride" on the innovator's work. The Yale group also asked respondents to rank on a scale of 1 ("not at all effective") to 7 ("very effective") the extent to which various instruments protected the competitive advantages from new and improved products and processes. The average scores across 130 industrial lines on the effectiveness of various means to reap the economic benefits of new and improved products were as follows:

Patents to prevent duplication	4.33
Patents to secure royalty income	3.75
Secrecy	3.57
Being first with an innovation	5.41
Moving quickly down learning curves	5.09

Commission Staff report (1977). *See also* William D. Robinson and Claes Fornell, *Sources of Market Pioneer Advantages in Consumer Goods Industries*," 22 JOUR. MKTG. RES. 305 (1985).

21 Richard C. Levin, Alvin Klevorick, Richard R. Nelson, & Sidney Winter, *Appropriating the Returns from Industrial Research and Development*, 1987 BRKGS. PAPERS ON ECON. ACTIVITY 783.

Superior sales or service efforts 5.59

Having patent protection was found on average to be relatively unimportant compared to three other ways of gaining first mover advantages. For new and improved processes, it was even less important on average, while, not surprisingly, secrecy was ranked more highly than either of the patent measures. There were, to be sure, exceptions. Among 77 industry groups with three or more responses, the pharmaceuticals industry ranked duplication-preventing patents as the most important means of holding off imitative competition, second in average score only to the agricultural chemicals field (with environmental effect test regulations similar to those imposed for pharmaceutical efficacy and safety).

Generally similar responses were obtained in an even larger Carnegie-Mellon University survey administered in 1994, to which more than a thousand industrial laboratory managers responded.[22] Using a different scale than the Yale survey, respondents were asked on what percentage of their product innovations various means of appropriating inventions' profit potential were effective. Patent protection had the second lowest average score of 34.83 percent, undercut only by "other legal" mechanisms. Lead time was viewed as the most important means, with an average score of 52.76 percent. Secrecy received much higher weight than in the Yale survey, with a 51 percent average, followed by complementary manufacturing capabilities (46 percent) and complementary sales and service efforts (43 percent). As in the Yale survey, patents received an unusually high score in pharmaceuticals, second only among 34 broad industry categories to medical equipment (ranging from catheters to imaging systems). Cohen et al. conclude that "patents are only one piece of a broader strategy to protect inventions," cautioning, as other studies did, that situations exist, even in industries according only modest weight to patent protection, in which at the margin patents are decisive in inducing R&D investments.[23]

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22 Wesley M. Cohen, Richard R. Nelson, and John Walsh, Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not), (May 2004) (revised working paper).

23 *See also* Ashish Arora, Marco Ceccagnoli, and Wesley M. Cohen, R&D and the Patent Premium (2006) (working paper).

Important lessons emerge from these queries addressed to real-world managers. First, alternative barriers to rapid imitation -- the substantial R&D costs imitators have to incur, lags in recognizing opportunities, image and cost advantages accruing to the first mover, and the like leave a substantial class of cases in which would-be innovators can anticipate revenue gains exceeding their innovation and production costs even when patent protection is totally absent. Second, given that non-patent stimuli to innovation exist, established firms are driven to undertake their own innovation efforts for fear of being overtaken by more aggressive rivals. This is the Schumpeterian "creative destruction" effect.[24] Third, patent protection does substantially enhance profit expectations in some industries -- e.g., much more so in industries with characteristics such as pharmaceuticals than in semiconductors or computers, with more complex, multifaceted products. Fourth, there may be feedback effects from patent protection to Schumpeterian creative destruction. Patent protection may help trigger an upstart firm's innovation that threatens established firms, but to the extent that it lessens the threat to established firms, it weakens their incentives to maintain a vigorous innovative pace.

These lessons appear to have trickled out at best slowly to the legal and policy-formulating communities. One might have expected the findings to have been especially relevant to legal scholars. However, a search of Social Sciences Citation Index for 1987 through May 2006 revealed that only 11 percent of the 496 citations received by the principal Levin et al. paper -- the most acclaimed of the various patent survey reports, and with an appropriately high citation count -- were in legal journals.

The diffusion to economists also left something to be desired. Beginning in the early 1980s, there was an explosion of theoretical work on the economics of the patent system.[25]

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24 JOSEPH A. SCHUMPETER, CAPITALISM, SOCIALISM, AND DEMOCRACY (1942), especially Chapter VII.

25 *See* my paper, Patents: What Do We Know; What Must We Learn? in the proceedings of a (1996) conference in Luxembourg on Appropriability and Patent Value: Econometric Aspects, which shows that the number of articles covered by the ECONLIT bibliography with "patent" or

However, nearly all of the theoretical contributions assumed -- contrary to the empirical evidence -- that patent protection was the only or principal barrier to rapid imitation of an invention or innovation. Clearly, economists were delinquent in providing an adequate theoretical basis for policy reforms.

4. The Impeti to Policy Change

During the 1970s, new initiatives for patent policy change began accelerating in the United States. One might ascribe the changes to the cyclical character of patent policy change observed in the historical past, or to the increased susceptibility of the U.S. government to interest group lobbying. On the latter we shall have more to say later. There was, however, another impetus on the macroeconomic front.

In 1969, productivity -- output per hour of labor input -- in the nonfarm business sector of the U.S. economy dropped and then entered a period of significantly diminished annual growth. By 1980, productivity was 15 percent less than it would have been had it continued the 2.5 percent annual growth rate it experienced from 1947 through 1969. By 1985, the shortfall was 20 percent. Also, company-financed R&D expenditures by U.S. industry, adjusted for general inflation, experienced the first break from a rising trend since the collection of statistics was initiated beginning with the year 1950. Further year-to-year declines occurred, and even in the good years growth was slower, so that by 1981, a 28 percent shortfall had accumulated.[26] Research by David Ravenscraft and myself tapping data from a small but unusually detailed sample of company business units revealed that the decline in R&D spending was probably attributable to a drop in the profitability of R&D investments, and when R&D was cut back, its profitability rose again, precipitating new growth.[27]

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some compound thereof in their titles rose from an average of four per year between 1969 and 1982 to 23 per year between 1984 and 1995.

26 *See* F. M. Scherer, *R&D and Declining Productivity Growth*, 73 AMER. ECON. REV. Supp. 215 (1983).

27 David J. Ravenscraft and F. M. Scherer, *The Lag Structure of Returns to R&D*, 14 APPLIED ECON. 603 (1982). For similar results with the pharmaceutical industry, *see* F. M. Scherer, *The*

Two seminal papers published simultaneously in 1967 showed that, contrary to conventional wisdom among economists, the United States could attribute much of its comparative advantage in international trade to superior technological innovation.[28] As the industrial nations of Western Europe and especially Japan recovered fully from the devastation of World War II, however, they began aggressively to challenge U.S. corporations for technological leadership.[29] In 1975, U.S. exports of high-technology goods exceeded imports by a ratio of 2.4 to 1. By 1980, the ratio had declined to 1.95 to 1 and by 1985 to 1.05 to 1.[30] The first reaction of U.S. industries to high-technology challenges from abroad was on average what the theory of arms races calls "submissive," i.e., a relative decline in R&D outlays. Some industries such as integrated steel, automobile tires, and television sets essentially gave up. But others such as the producers of integrated circuits, medical imaging apparatus, optical fiber cables, earth-moving equipment, and (less unambiguously) airliners responded aggressively and redoubled their R&D efforts to retain or regain their world market positions.

It was argued, among other fora in Congressional hearings, that patent policy reforms could help restore U.S. technological leadership. Perhaps, but the chains of causation were clearly more complex.[31] Reductions in corporate R&D spending were

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Link Between Gross Profitability and Pharmaceutical R&D Spending, 20 HEALTH AFFAIRS 216 (2001).

28 William Gruber, Dileep Mehta, and Raymond Vernon, *The R&D Factor in International Trade and International Investment of United States Industries*; and Donald B. Keesing, *The Impact of Research and Development on United States Trade*, 75 JOUR. POL. ECON. 20-48 (1967).

29 For statistical analyses and eleven case studies, see F. M. SCHERER, INTERNATIONAL HIGH-TECHNOLOGY COMPETITION (1992).

30 U.S. NATIONAL SCIENCE BOARD, SCIENCE & ENGINEERING INDICATORS: 1989 (1989) at 379. Later editions of the same report suggest a more modest decline because of a redefinition of what constituted high-technology industries.

31 For similar arguments, *see* Richard Posner, *The Insignificance of Macroeconomics in Patent Antitrust Law: A Comment on Millstein*, 9 CARDOZO L. REV. 1203 (1988). The paper on which Posner commented, by Ira Millstein, chief counsel at the time to the influential Business

precipitated by a fall in profitability. If stronger patent protection could restore profitability, it might facilitate a resurgence. And it was true that the most formidable new rival to U.S. technological leadership, Japan, maintained a much weaker patent system, among other things requiring the licensing of most patents and limiting through foreign exchange controls the royalties Japanese firms could pay U.S. patent holders.[32] But the exercise of patent rights within the United States did blunt some Japanese challenges, e.g., in optical fibers and integrated circuits.

Alternatively, however, the profits from innovation may have declined because the pool of attractive technological opportunities had been depleted following intensive "fishing" during the decades following World War II. In this sense, the productivity growth slump that began around 1969 was an extension of the so-called Kondratief cycles emphasized by Joseph A. Schumpeter in a 1939 classic.[33] Industrial research and development efforts were intensified in those industries that elected to fight back against tougher foreign competition.[34] But more importantly, growth was restored, sometimes with long lags, as a result of fundamental scientific and technological breakthroughs that underlay the information and biotechnology revolutions of the 1990s and the early 21st century -- notably, the invention of integrated circuits around 1959 and

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Roundtable, considered studies such as those by Levin et al. "inconclusive" and argued (fallaciously) that the effects of non-patent barriers "do not make the patent a less significant inducement."

32 *See* DANIEL OKOMOTO, BETWEEN MITI AND THE MARKET (1989) at 27-28; and Janusz Ordover, *A Patent System for Both Diffusion and Exclusion*, 5 JOUR. ECON. PERSPECTIVES 43 (1991).

33 JOSEPH A. SCHUMPETER, BUSINESS CYCLES (1939). For the most persuasive empirical support, *see* ALFRED KLEINKNECHT, INNOVATION PATTERNS IN CRISIS: SCHUMPETER'S LONG CYCLE RECONSIDERED (1987). For an analysis from the 1970s and 1980s skeptical of the general depletion hypothesis, *see* MARTIN N. BAILY AND ALOK CHAKRABARTI, INNOVATION AND THE PRODUCTIVITY CRISIS (1988). For theoretical support rooted in the logic of highly skew payoff distributions, see William D. Nordhaus, *Comment*, 1989 BROOKINGS PAP. ON ECON. ACTIVITY: MICROECONOMICS 320 (1989).

34 INTERNATIONAL HIGH-TECHNOLOGY COMPETITION, *supra* note 29, Chapter 5.

microprocessors in the early 1970s and the steady cost declines that occurred through learning-by-doing and denser circuit-packing; the laser in the late 1950s and optical fiber data transmission during the 1970s; and gene splicing during the early 1970s. Patents played some role in all of these achievements, but given uncertainties, long lags, and the university origins of key breakthroughs, hardly a precipitating role. The Department of Defense insisted upon widespread licensing of integrated circuit patents, and several early developers of microprocessors cross-licensed their patents among one another and to other chip makers.[35] A small fortune was made through broad-based licensing of basic laser patents by the winner of a law suit claiming priority of invention, but only after litigation delays of more than two decades.[36] From a beginning in 1980, the Cohen-Boyer gene splicing patents were licensed at modest royalties to hundreds of entities by Stanford University and the University of California, yielding cumulative total royalties to the two universities of some $124 million by 1995.

5. How Patent Policy Was Changed

We turn now to our analysis of the principal changes in U.S. patent policy, focusing mainly on events of the late 1970s and early 1980s.

Copyright Law

Changes in copyright law may have been precursors to what happened on the patent front, so a brief look is warranted. As of 1962, the life of a copyright was limited to 28 years, with one 28-year renewal to 56 years allowed. Then, in the four

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35 Texas Instruments later collected an estimated $1 billion in royalties on its integrated circuit patents until it lost key lawsuits in Japan and the United States. "New Profits from Patents," FORTUNE, April 25, 1988, pp. 185-188; "When Copying Gets Costly," THE ECONOMIST, May 9, 1992, p. 95; "Chip Patent Suit by Texas Instruments," NEW YORK TIMES, June 30, 1992; and "Texas Instruments' Shares Fall on Ruling," NEW YORK TIMES, September 1, 1994.

36 "Now the Father of the Laser Can Get Back to Inventing," BUSINESS WEEK, February 17, 1986, p. 98; and "An Unexpectedly Bright Idea," THE ECONOMIST TECHNOLOGY QUARTERLY, June 11, 2005, at 25-29. Had Bell Laboratories won the lawsuit, it would have been required under its antitrust decree to license the patents non-exclusively.

decades that followed, Congress extended copyright lives eleven times, so that by the turn of the century, works were copyrighted for 70 years beyond the life span of the copyrighted work's creator.[37] In 1976, copyright extensions were made automatic, without the need to apply or register. According to Kevin Kelly, these changes occurred as an increasing number of creative works came to be owned not by individuals but by corporations able successfully to lobby Congress to prevent materials from returning to the public domain. Or as Lawrence Lessig concludes (p. 304), "The law speaks to ideals, but it is my view that our profession has become too attuned to the client. And in a world where the rich clients have one strong view, the unwillingness of the profession to question or counter that one strong view queers the law."

Patents from Government-Supported Research

World War II and its aftermath, including the cultivation of basic science through the National Science Foundation and the development of atomic energy, brought the U.S. federal government into extensive technological cooperation with private industry and universities. Who should have primary rights to patents resulting from government-financed R&D was a question settled in a diversity of inconsistent ways. Some clarity was brought through a policy statement issued by President John F. Kennedy in 1963,[38] but debate continued. In 1965 an inter-agency task force, the Committee on Government Patent Policy, operating under the auspices of the Federal Council for Science and Technology, undertook an ambitious empirical study of how the various patent policies were working. It hired a consulting firm, Harbridge House, to compile data on 2,024 patents made under government contracts and several hundred more originating in government laboratories, and to conduct a series of historical case studies on attempts to bring inventions conceived with government financial support into private-sector utilization. Harbridge House completed several interim volumes

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37 *See* LAWRENCE LESSIG, FREE CULTURE: HOW BIG MEDIA USES TECHNOLOGY AND THE LAW TO LOCK DOWN CULTURE AND CONTROL CREATIVITY (2005) at 134-135; and Kevin Kelly, "Scan This Book," NEW YORK TIMES MAGAZINE, May 14, 2006 at 48.

38 The Kennedy memorandum was published in 28 FEDERAL REGISTER 10943 (October 11, 1963).

and, in May 1968, a four-volume compendium of research findings.[39] The Committee on Government Patent Policy published its own report and patent policy recommendations in the fall of 1968[40] and presented them at a briefing conference before the Federal Bar Association in September 1969. The Committee's recommendations, which emphasized flexibility in allowing contractors to obtain exclusive patent rights mainly when there were prospects of commercial utilization or when granting exclusive rights broadened the government's potential contractor base, formed the basis for a new policy statement issued by President Nixon in August 1971.[41]

The Harbridge House research revealed that several variables affected the likelihood that government contract-originated inventions would be commercially utilized: (1) the intrinsic relevance of the technology to civilian needs; (2) whether the contractor had prior commercial experience in the relevant field; (3) how far the development had been carried under contract; (4) the magnitude of additional development outlays required in comparison to the market size and the risks attendant thereto; and (5) whether or not the contractor or another assignee had exclusive patent rights. For 1720 patents on which complete data were available, commercial utilization rates varied over two key variables as follows:[42]

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39 HARBRIDGE HOUSE, INC., GOVERNMENT PATENT POLICY STUDY, published in loose-leaf binder form, May 1968. The summary report is reproduced in U.S. H.R., Comm. on Science and Technology, BACKGROUND MATERIALS ON GOVERNMENT PATENT POLICIES, Vol. II (August 1976), at 69-140.

40 It is reproduced in BACKGROUND MATERIALS, *supra* note 39, vol. II at 143-182. I served as principal economic adviser to the Committee throughout the Harbridge House study period.

41 36 FED. REG. (August 1971). It is reproduced in volume I of BACKGROUND MATERIALS, *supra* note 39, at 11-23.

42 This analysis is drawn from Scherer, *supra* note 16, at 78-84.

	Contractor Had Prior Commercial Experience	Without Prior Commercial Experience
With exclusive rights	23.8%	6.6%
Without exclusive rights	13.3%	2.2%

Evidently, patent protection mattered, although the chain of causation remained ambiguous. In some cases, the qualitative studies showed, exclusive rights encouraged investments in commercial utilization; in others, contractors bargained more vigorously to obtain exclusive rights when commercial utilization was expected.

The pharmaceutical industry was found again to be an extreme case. One in-depth Harbridge House study revealed that, up to 1962, drug companies routinely screened new organic molecules synthesized under government grants by academic researchers.[43] However, when the Department of Health, Education, and Welfare imposed new reporting requirements that threatened the exclusivity of drug companies' rights to commercialize molecules found to be therapeutically interesting, such testing ceased abruptly. The moratorium ended in 1968 when HEW changed its policies to allow drug companies exclusive rights on grant-originated molecules they tested.

A particularly controversial question at the time was whether, when a government agency allowed its contractors to obtain exclusive patent rights, the government should retain "march-in" rights to require wider licensing of the patent if there was a failure to commercialize or there were monopolistic abuses in commercialization. Cases of clear abuse were found to be rare, in all but one questionable instance because adequate substitute products existed. Both the Committee on Government Patent Policy and the Nixon memorandum recommended retention of march-in rights, to be used flexibly and presumably rarely under an implicit rule of reason, or in cases of jeopardy to public health or safety.

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43 HARBRIDGE HOUSE INC., Report, EFFECTS OF GOVERNMENT PATENT POLICY ON DRUG RESEARCH AND NEW PRODUCT DEVELOPMENT (1967), Sections I and IV.

The U.S. Congress chose in due course to insert its own views into the debate. In 1965 S. 1809, embodying compromise policies, was approved by the Senate Judiciary Committee, but in 1967 its consideration by the full Senate was postponed indefinitely pending completion of the Harbridge House Study.[44] A draft bill was proposed to Congress by the White House in August 1976, supplanted by a bill drafted in the House of Representatives.[45] Hearings in 1976 before the House Committee on Science and Technology summoned as witnesses the executive secretary of the Committee on Government Patent Policy and others affiliated with it along with representatives of the principal government R&D contract-issuing agencies, industry, and an organization comprising university patent administrators. The Harbridge House report summary and related documents were published as background materials. No legislation ensued at first, but in subsequent sessions of Congress, further hearings were held by the House Science Committee as well as the Monopolies subcommittee of the House Judiciary Committee. The latter hearing, in December 1977, added substantive balance, inviting as witnesses inter alia outspoken Admiral Hyman Rickover (father of the Navy's nuclear submarine program), Walter Adams (an economist well-known for his anti-monopoly views), and the consumer activist chairman of the Federal Trade Commission.

After characteristic delays, two major bills emerged from the effort, the Bayh-Dole Act, signed into law in December 1980;[46] and the Stevenson-Wydler Act, passed in October 1980.[47] The floor debates were brief, and both bills sailed through Congress (controlled in both houses by Democrats) on voice votes. Bayh-Dole reversed the prevailing but flexible presumption that the government would retain title to inventions made under R&D contracts. It articulated a presumption that government contracts or grants to academic researchers or small

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44 Howard Forman, *Retrospection and Introspection Concerning Patents and Government Patent Protection*, 49 J. PAT. OFF. SOCIETY 687 (1967).

45 They are reproduced in FEDERAL COUNCIL FOR SCIENCE AND TECHNOLOGY, REPORT ON GOVERNMENT PATENT POLICY (1976) at 88-119.

46 P.L. 96-517, 94 Stat. 3019.

47 P.L. 96-480, 94 Stat. 2311.

businesses would normally permit patent rights to be retained by the contractors, subject to march-in under imprecisely articulated conditions. A 1987 executive order extended it to apply to all government R&D contract recipients, regardless of their size.[48] Stevenson-Wydler required the principal government agencies conducting R&D in-house to set up Research and Technology Applications offices. Since "the whole point of [the] bill [was] to stimulate the commercialization of industrial innovations," as one Congressional proponent observed in the final debate,[49] the offices were encouraged to negotiate exclusive patent licenses with industry for inventions resulting from agency research. In 1986, the Federal Technology Transfer Act extended Stevenson-Wydler to permit formation of cooperative research and development agreements (CRADAs) between government laboratories and industry, with the industrial partners retaining principal patent rights but paying royalties to cooperating agencies and their inventor employees.[50]

These legislative patent policy changes had important implications. Academic institutions in particular changed their behavior. Many which had not done so already created technology licensing offices to encourage patenting of relevant inventions by faculty researchers. University patenting rose sharply -- from an average of 332 patents received per year during the last three years of the 1970s to 952 per year in the last three years of the 1980s. At least part of the increase appears to have been caused by the imposition of lower standards on the patents sought. There was a marked decline in the number of subsequent citations received by the average university patent following the law change.[51] Links between university researchers and their industry counterparts increased in number and intensity, with an undoubted positive impact on the commercialization of academic

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48 3 C.F.R. 220 (1988).

49 126 CONG. REC.- HOUSE 24566 (Sept. 8, 1980).

50 P.L. 99-502, 100 Stat. 1785 (October 1986). No explicit provisions were included on march-in rights. Sec. 2(b)(3) is ambiguous on whether the waiver of federal rights exhausts the possibility of march-in for non-governmental uses.

51 *See* Rebecca Henderson, Adam Jaffe, and Manuel Trajtenberg, *Universities as Sources of Commercial Technology*, *in* JAFFE & TRAJTENBERG, PATENTS, CITATIONS & INNOVATIONS (2002) at 252-256.

research, especially in the field of biotechnology. Whether academic research as a result has been diverted at least marginally from basic to more applied goals and whether discoveries are disclosed more slowly so as not to jeopardize patentability is less than certain. To the extent that such consequences have followed, their desirability continues to be debated.[52]

Especially in academic circles, but also on inventions made cooperatively with government laboratories, serious questions have arisen over the resulting product prices. As we have seen, patents are of special importance to pharmaceutical (and related biopharma-ceutical) companies, in part because they provide strong protection from competitive imitation on products that often have relatively inelastic demands. This means that high prices can be commanded. AZT (azidothymidine), the first antiretroviral effective against AIDS, was synthesized by a medical institute researcher with federal research support.[53] After the unpatented molecule was offered to the National Institutes of Health by the private firm Burroughs-Wellcome, its therapeutic efficacy was demonstrated in clinical trials conducted initially at NIH and Duke University with significant support from federal government funds. Burroughs-Wellcome was able to obtain "method of use" patents covering AZT along with exclusive marketing rights reflecting AZT's early "orphan drug" status. It chose to sell AZT at annual costs per patient approximating $10,000 when production costs could not have been more than $2,000. This pricing strategy provoked outrage among AIDS advocates and members of Congress plus demands that the National Institutes of Health exercise their march-in rights to require the issue of non-exclusive patent licenses. That was not done, but Burroughs-Wellcome eventually implemented substantial price reductions in response to the public pressure. Several other drugs conceived or developed with federal government support have had similar high-price histories. What could have been the most egregious case was thwarted by a judicial finding of patent invalidity after the University of Rochester sought royalties it expected to reach $3 billion from

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52 *See e.g.* DEREK BOK, UNIVERSITIES IN THE MARKETPLACE (2003) at 10-12 and 140-143.

53 This discussion benefits from a case study, "AZT: A Favored Orphan?" written by Kris Thiessen at the John F. Kennedy School of Government, Harvard University, in 1998.

its work, supported by National Institutes of Health grants, underlying the development of Cox-2 inhibitors.[54]

The National Institutes of Health directorate has declined to exercise its Bayh-Dole march-in rights on patents covering drugs sold at particularly high prices. Indeed, as of 2005, the march-in provision had never been invoked by a government agency. There appear to be two main reasons. For one, the leadership of NIH claimed to an investigator that it had no experience determining what a reasonable price was and did not consider implementing price controls to be part of its mission.[55] Also, the law itself left ambiguities. The relevant march-in clause states in part that the granting agency has the right to compel issuance of non-exclusive licenses when:[56]

> (1) ... [T]he contractor or assignee has not taken ... within a reasonable time ... effective steps to achieve practical application of the subject invention... [or]
>
> (2) [A]ction is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignees, or their licenses.

Debate centers on the meaning of the reasonable satisfaction of needs provision. In response to a critical article in the Washington Post[57], the Bayh-Dole Act's co-sponsors insisted that the march-in rights are not contingent upon the pricing of a resulting product or the profitability of the commercializing

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54 *University's Patent for Celebrex Is Invalid*, N.Y. TIMES, February 14, 2004. *See* University of Rochester v. G.D. Searle Co. et al., 358 F. 3d 916 (2004). In November 2004 certiorari was declined by the Supreme Court. *See also Jury Rules Company Infringed Drug Patent*, HARVARD CRIMSON, May 5, 2006, reporting on a Federal District Court finding in favor of royalties for a fundamental biological pathways discovery by Harvard University researchers licensed to a biotech company. The case was Ariad Pharmaceuticals v. Eli Lilly Co. et al., Federal District court, Massachusetts.

55 Private communication from the investigator to the author. *Compare* David Korn and Stephen Heinig, *Recoupment Efforts Threaten Federal Research*, ISSUES IN SCIENCE & TECHNOLOGY (Summer 2004) at 24-29.

56 35 U.S.C. Sec. 303 (a) (1) and (2).

57 Peter Arno and Michael Davis, *Paying Twice for the Same Drugs*, WASHINGTON POST, March 27, 2002, p. A-21.

company, but they can be invoked only "when the private industry collaborator has not successfully commercialized the invention as a product."[58] This seems an unreasonable interpretation of subparagraph (2) above even if not (1),[59] but on such fuzzy constructs, reasonable people can disagree.

A Special Court for Patent Appeals

The status quo as the 1970s began was for patent case decisions at the Federal district court level to be appealed to any of the ten regional appellate courts, while appeals from decisions of the U.S. Patent and Trademark Office went to a special Court of Customs and Patent Appeals, sitting in Washington, D.C. There was considerable discontent over conditions in the appellate courts. Quite generally, an increased number of appeals with little expansion in the number of judges led to a perceived overload situation. Patent cases, which amounted to less than one percent of all decentralized appeals, were only a small part of the problem, although it was said (without clear quantitative evidence) that patent appeals were more complex than the average appeal. Patent advocates were unhappy over what they claimed to be wide differences in the outcomes of their appeals, allegedly because some appellate courts took a tougher line toward the validity of challenged patents, and on whether patents passing the validity screen were actually infringed, than others. This was said to have led to "forum shopping" -- patent owners sought venue in appellate courts friendly toward patent protection while alleged infringers sought more skeptical courts. Differences between courts in legal precedents were also an alleged problem, and inter-court differences were seldom carried to the Supreme Court for resolution. Patent advocates sought a unified appellate venue that would minimize forum-shopping and generate consistent precedents.

Appellate court reform questions were addressed repeatedly by diverse study groups. One of the most thorough was the so-called Hruska Commission, chaired by Senator Roman Hruska, which

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58 Birch Bayh and Bob Dole, *Our Law Helps Patients Get New Drugs Sooner*, WASHINGTON POST, April 11, 2002, p. A28.

59 For an extended discussion, *see* Peter S. Arno and Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls?* 75 TULANE L. REV. 631 (2001).

delivered its conclusions in 1975.[60] It favored creation of a new nationwide appellate court to which matters that posed important precedential questions (including patent cases) would be transferred at the behest of the normal appellate courts, which would retain jurisdiction over most patent appeals from federal district courts. Or alternatively, cases could be referred to the court by the Supreme Court when the high court was reluctant to hear an appeal itself. However, the proposal to create a separate court hearing all appeals on patents or other specialized subject matter was soundly rejected (a point largely neglected in subsequent Congressional reports and debate). The Commission warned that:[61]

> ... [T]he quality of decision-making would suffer as the specialized judges become subject to "tunnel vision," seeing the cases in a narrow perspective without the insights stemming from broad exposure to legal problems in a variety of fields.... Judges of a specialized court, given their continued exposure to and greater expertise in a single field of law, might impose their own views of policy even where the scope of review under the applicable law is supposed to be more limited.... [I]ndeed the court as a whole may be "captured" by special interest groups.

A consultant to the Commission found that among 90 identified conflicts on legal doctrines at the U.S. appellate court level, only three were in the patent field.[62]

The specific impetus for a unified court hearing patent appeals apparently coalesced when Attorney General Griffin Bell created within the Department of Justice an Office for Improvements in the Administration of Justice (OIAJ), headed by an assistant attorney general.[63] A proposal calling for a new

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60 Its report is reproduced as PROPOSED REVISION OF APPELLATE SYSTEM, 67 F.R.D. 195 (1975).

61 67 F.R.D. 195, 234-235 (1975). *See also* MARVER BERNSTEIN, REGULATING BUSINESS BY INDEPENDENT COMMISSION (1955) at 116-117.

62 67 F.R.D. 195, 196 (1975).

63 Daniel J. Meador, *Origin of the Federal Circuit: A Personal Account*, 41 AM. UNIV. L. REV. 581 (1992). Meador headed OIAJ.

centralized appellate court, merging the Court of Patent Appeals and the Court of Claims, was circulated in July 1978 to "every office, agency, organization, and individual likely to have any significant interest in the subject."[64] OIAJ's request for comments yielded 46 favoring the proposal, 29 opposed, and 15 that took no position.[65] Given this impetus, the U.S. Congress began considering bills (H.R. 3806, 2405, and S. 1477, and eventually H.R. 4482 and S. 1700) that would create a unified new Court of Appeals for the Federal Circuit with jurisdiction over all patent appeals as well as federal contract dispute claims, customs matters, and an array of other subject matter that was pruned back in Congressional committees. To advance their proposal, OIAJ staff made a concerted effort to co-opt Senator Edward Kennedy, chairman of the Senate Judiciary Committee, who was expected to challenge President Jimmy Carter in the 1980 election and might oppose a Carter-backed bill, but who introduced the OIAJ bill along with his own, adding amendments, in 1979.[66] Bills were passed in both houses of Congress but became bogged down through unrelated procedural complexities in late 1980. It was called up again in the 97th Congressional session beginning in January 1981 -- a Congress in which Republicans had gained a Senate majority while Democrats retained control of the House. New hearings were held. Two witnesses at the principal House Judiciary Committee hearing were judges from existing courts who would be automatically promoted to the new court, and another was a company patent attorney who would later be appointed to the new court. In addition to a former Commissioner of Patents, other witnesses represented the American Patent Law Association, the American Bar Association, the Industrial Research Institute (presumably reflecting the views of R&D-oriented corporations), and an independent committee opposing the new law, one member of which had testified in an earlier hearing on behalf of the American Bar Association.

The Bar Association was split. Some of its patent law members, and especially those who practiced in Washington, D.C.,

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64 *Id.* at 591.

65 *Id.* at 593.

66 *Id.* at 598-600 and 607. The original Senate bills were S. 677 and S. 678.

favored the bill. Others were against it. The ABA had created committees to consider the proposal for a centralized patent appeals court. At its plenary meeting in February 1980, a majority of the members present voted against it.[67] The ABA representative at hearings in April 1981 reported "very, very substantial division in views among patent lawyers;" said that the forum shopping claim was overblown; and testified that:[68]

> Uniformity, without more ... is quite plainly not a desirable objective. The legal system as a whole reaps the reward that various ideas are able, in the words of Mr. Justice Holmes, to "compete for acceptance in the marketplace" such that the law is refined and grows in a rational and just manner.

A House committee report following the hearings recommended creation of the new court by merging the existing federal Court of Customs and Patent Appeals with the Court of Claims, with jurisdiction mainly for the subject matter of those lower courts but handling patent appeals from all federal circuits. It observed that the responsible Subcommittee had inquired "deeply into technological innovation as an element of productivity in the American marketplace" and cited witness testimony arguing that the new court would be "one of the most far-reaching reforms that could be made to strengthen the United States patent system in such a way as to foster technological growth and industrial innovation."[69] There was no focused testimony on the causes of the productivity slump or on how changes in patent policy might be expected to remedy it.

During the most extended debate on the issues, Rep. Tom

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67 *See* the testimony of Benjamin L. Zelenko at the June 1980 hearings, reproduced as an appendix in U.S.H.R., Committee on the Judiciary, Subcommittee on Courts, Civil Liberties and the Administration of Justice, Hearings on H.R. 2405 (April 1981) at 422. *See also* Paul M. Janicke, *To Be or Not To Be: The Long Gestation of the U.S. Court of Appeals for the Federal Circuit (1887-1982),* 69 ANTITRUST L. JOUR. 645, 658 (2001).

68 Testimony of James W. Geriak in the Hearings on H.R. 2405, April 1981, supra note 67, p. 85.

69 House of Representatives, Committee on the Judiciary, Report together with Dissenting Views, COURT OF APPEALS FOR THE FEDERAL CIRCUIT ACT OF 1981, accompanying H.R. 4482 (November 4, 1981), at 20 and 27.

Railback (R-Ill.) submitted for the record a list indentifying selected individuals and organizations that had, usually through letters, supported passage of the bill.[70] Among 85 corporations favoring the bill, including two universities, 76 of the letters were signed by patent attorneys and only five by individuals whose titles suggested broader responsibilities. Among the 20 organizations cited for their support (none with responsible individuals identified), six were patent law groups, two federal bar associations, six business interest groups, and two were American Indian tribes. Since the call for comments in 1978 drew sharply divided opinions, mostly positive from corporate patent counsel and mostly negative from trial attorneys, one might ask why the letters listed in the 1981 debate were so overwhelmingly favorable. Selection bias could be one explanation, but another, according to OIAJ's head, is that "OIAJ staff had organized the corporate patent counsel into an effective support group for the Federal Circuit."[71]

One amendment made to the bill during its journey through Congress was a statement of the sense of Congress that the quality of the Federal judiciary is determined by the competence of its judges, and that the President should nominate as judges for the new court "from a broad range of qualified individuals" -- a counterfoil to the charge that the court's judges would be narrow specialists.[72]

In the definitive House of Representatives roll call vote on the bill November 18, 1981, 321 voted in favor and 76 against. Among Democratic congressmen, the vote in favor was 9.5 to 1; among Republicans (in the minority), 2.2 to 1. My regression analysis of the vote division introduced three explanatory variables:

DEM Dummy variable; 1 if Democrat, 0 if Republican.

RAND Industrial research and development expenditures

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70 127 CONG. REC.- HOUSE 27793-4 (Nov. 17, 1981).

71 Meador, *supra* note 63, at 610. Professor Meador asserts at 619 that "had it not been for OIAJ there would be today no Federal Circuit," because other organized sources of potential support failled to exercise leadership.

72 Section 305 (1) and (2).

in 1981 (millions of dollars per million population), in a representative's home state.[73]

PROPAT The percent of cases in which patents were found to be both valid and infringed on appeal in the representatives' home appellate circuits between 1953 and 1977.[74]

The resulting regression equation in ordinary least squares[75] was as follows, with VOTE scaled as 1 for a "yes" vote and 0 for a "nay" vote, and with t-ratios in subscripted brackets:

$$\underset{}{\text{VOTE}} = \underset{}{0.706} + \underset{[5.83]}{0.222}\ \text{DEM} + \underset{[2.31]}{0.00033}\ \text{RAND} - \underset{[2.04]}{0.0035}\ \text{PROPAT}; \quad \underset{[10.75]}{}$$

$$R^2 = 0.112;\ N = 394.$$

The preponderance of Democratic support is verified, holding constant other variables. Representatives from states with relatively intensive R&D activity were more likely to support the bill, all else equal. Surprisingly, representatives from circuits with a high prior incidence of decisions in favor of patent holders were more likely to vote against the court's creation, all else equal.

The vote in the Republican-controlled Senate on December 8, 1981, was more one-sided, with 83 votes in favor and only six nays, three from each party. And so the new Court of Appeals for the Federal Circuit (CAFC) was created, commencing its work on October 1, 1982.

Its initial complement of judges was inherited from the prior Court of Customs and Patent Appeals and Court of Claims. As of early 1983, four of the eleven sitting judges had

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73 The source is NATIONAL SCIENCE FOUNDATION, RESEARCH AND DEVELOPMENT IN INDUSTRY: 1987 (NSF 89-323) at 55-56.

74 The data are from ADAM JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS (2005) at 100.

75 Logit regressions were quite similar; the coefficients in OLS regressions are more easily interpreted as the amount by which the vote fraction shifts with a unit change in an explanatory variable.

backgrounds in patent law; seven others were from alternative backgrounds. The enabling statute urged the President to make new nominations "from a broad range of qualified individuals." A committee appointed by President Reagan to explore the sources of declining productivity growth and identify improvements recommended to the contrary that the President appoint "experienced patent lawyers to vacancies that occur in the new Court of Appeals."[76] The recommendation does not appear to have had much impact. In May 2006, the court, whose membership had turned over completely, had five active judges with patent practice backgrounds and six without. However, the court heard a spectrum of cases broader than merely patent matters. Although assignment to panels was in principle random, the choice of the judge who would report the panel's decision, and hence with the opportunity to set at least a precedential tone, was far from random. A study by John Allison and Mark Lemley revealed that in 143 patent validity decisions rendered by the Court between 1989 and 1996, 63 percent of the decisions were written by judges with prior patent practice experience, even though the judges with a patent background comprised only 38 percent of the total number of judges participating in panels hearing validity arguments.[77] Similarly, in a panel discussion among CAFC judges televised by C-SPAN3 on May 19, 2006, chief judge Paul Michel observed that the court did not want judges without patent law experience hearing patent cases and noted the importance of "cohesion" among the CAFC members.

Senator Robert Dole was quoted in the floor debate as saying in Judiciary Committee deliberations preceding the passage of S- 1700 that "the bill will not substantively affect current law."[78] However, affect it did. The changes were immediate and dramatic, but also subtle. Most significantly, the new CAFC proved to be much more generous than the decentralized appellate courts in ruling that patents whose

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76 WHITE HOUSE CONFERENCE ON PRODUCTIVITY, PRODUCTIVITY GROWTH: A BETTER LIFE FOR AMERICA (April 1984) at 80.

77 Allison and Lemley, *How Federal Circuit Judges Vote in Patent Validity Cases*, 27 FLORIDA STATE U. L. REV. 752 (2000).

78 Statement of Senator Charles Grassley in CONG. REC. 29887 (Dec. 8, 1981). I was told the same thing about the bill's intent by a member of the Senate Judiciary Committee staff at the time.

validity was challenged on the basis of insufficient novelty or utility were in fact valid. The old courts rejected roughly two thirds of the patents on validity grounds; the new court accepted roughly two thirds.[79] This fed back to induce a higher acceptance rate at the district courts. With a validity ruling more likely, there were more attempts by patent holders to enforce patents, whose ultimate success depended then upon whether the courts ruled the relevant patents to have been infringed. The new appellate court's statistical record in infringement questions, on the other hand, was tougher on patent-holding claimants than in the previous decentralized courts.[80] In interpreting the so-called doctrine of equivalents, the CAFC tended to view the scope of litigated patents more narrowly than its predecessors.[81] But with a higher fraction of patents found to be valid, the percentage of tested patents found to be both valid and infringed rose during the first decade of the court's existence before declining, and the absolute number of patents found to be both valid and infringed per year more than doubled, with a generally rising trend.[82]

The new court also blazed a trail toward accepting new kinds of patents, e.g., on business methods and computer software, on which the difficulties of showing that prior art would preclude patenting were particularly great, and (with Supreme Court encouragement[83]) an expanded array of life form inventions -- much wider than European Community chose to protect.[84] It proved more amenable to accepting jury findings,

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79 *See* Jaffe and Lerner, *supra* note 74, at 100-106; John R. Allison and Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q. JOUR. 185 (1998); and Matthew D. Henry and John L. Turner, *The Court of Appeals for the Federal Circuit's Impact on Patent Litigation*, 35 J. LEG. STUDIES 85 (2006).

80 See Glynn S. Lunney Jr., *Patent Law, the Federal Circuit, and the Supreme Court: A Silent Revolution*, 11 SUP. CT. ECON. REV. 1 (2004), especially Figure 3.

81 *See* Henry and Turner, *supra* note 79; and Lunney, *supra* note 80. A key case was Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F. 3rd 558 (2000).

82 Lunney, *supra* note 80, at 80 (Appendix I).

83 Diamond v. Chakrabarty, 447 U.S. 303 (June 1980).

84 For a survey of 1,770 DNA sequence patents issued between September 1998 and June 2000,

despite evidence that juries were more likely to be awed by claims of technical novelty than judges. It was more willing than the decentralized courts to grant preliminary and final injunctions eliminating infringers from a field -- although on this, its exertions may be restrained by an important Supreme Court pronouncement in 2006 denying that there is a "general rule" supporting injunctions in patent infringement; instead, the traditional four-factor test (including considerations of equity) should be applied.[85] And very significantly, it revised the principles for assessing damages in cases of proven infringement, making it more likely that estimates of profits lost by the patent holder would err on the generous side, that the "profits lost" standard would normally be favored rather than the milder "reasonable royalty" standard, and awarding damages under both standards even though the later is logically subsumed within the former.[86] Under the new standards several damages awards running into the hundreds of millions of dollars were made.

These changes on balance strengthened patent protection, made it likely that companies found to be infringing valid patents would pay substantial damages, and hence raised the perceived benefits to companies (and universities) from building strong patent portfolios. Patent applications and patent issues soared in the years following the creation of the CAFC (marked by a dotted vertical line), as shown in Figure 1. A regression analysis shows a distinct and statistically significant break in the series at the year 1983,[87] with the growth rate of applications (less subject than patent issues to Patent Office backlog fluctuations) averaging 1.4 percent per year between

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see F. M. Scherer, *The Economics of Human Gene Patents*, 77 ACADEMIC MEDICINE at 1356-1359 (2002). *See also* Kyle Johnson and Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCIENCE 239 (October 14, 2005).

85 eBay Inc. v. MercExchange, 126 S.Ct. 1837 (May 15, 2006).

86 *See* Cecil D.Quillen, Jr., *Innovation and the Current U.S. Patent System*, forthcoming in VIRGINIA L. & BUS. REV. (2006).

87 The F-ratio in a test of differences is 8.54, which is highly significant statistically, with N = 20 and 81. The data, including only "utility" patents and not design or plant patents, were obtained from the Patent and Trademark Office web site. For a more detailed analysis, *see* Bronwyn Hall, *Exploring the Patent Explosion*, 30 J. TECHNOLOGY TRANSFER 35 (2005).

1955 (after postwar adjustments were accomplished) and 1982, and 5.97 percent per year between 1983 and 2004. With many more patents being sought, more patent attorneys had to be hired. The number of patent attorneys per billion dollars of price level-adjusted industrial R&D expenditures rose from approximately 50 in the 1970s to 75 in the mid-1990s.[88] With many more patents being issued, specific areas of technology became more congested, leading to a higher likelihood that one firm's proprietary technology would conflict with another firm's.[89] In an analogue of an arms race, companies strove all the more vigorously to expand their patent portfolios so they could use their patents in defensive counter-claims when accused of infringement. With many more patents and higher damages if one's technology were found to infringe another firm's patents, developing new products became like walking through a mine field, with dire consequences from a misstep.

While stronger patent protection per se should have increased the profitability of innovation and hence stimulated R&D expenditures, all else equal, the increased danger from infringing another firm's patents exerted an opposite negative influence. Figure 2 shows the long-run trend of U.S. industrial expenditures on research and development from 1953, the first year covered by systematic surveys, through 2000. Outlays are measured in constant 1996 dollars. As in Figure 1, the plot is logarithmic, so that a straight line indicates a constant rate of growth. Factors other than the legal regime in which patents were administered -- notably, macroeconomic shocks, the energy shocks of 1973-74, and the advent of wholly new technologies such as the Worldwide Web -- had an obvious impact. The most that can be said is that there is no noticeable acceleration of the growth rate in R&D following the creation of CAFC. In a statistical test comparing the periods 1956-82 and 1983-2000,

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88 John Barton, *Reforming the Patent System*, 287 SCIENCE 1933 (March 17, 2000).

89 *See e.g*. JAFFE & LERNER, *supra* note 74, especially Chapter 2; the review of Jaffe and Lerner by Rochelle Dreyfuss, *Pathological Patenting: The PTO As Cause or Cure*, 104 MICH. L. REV. 1559 (2006); Bronwyn Hall and Rosemarie Ziedonis, *The Patent Paradox Revisited: An Empirical Study of Patenting in the U.S. Semiconductor Industry*, 32 RAND JOUR. ECON. 101 (2001); and Ziedonis, When the Giants' Shoulders Are Crowded: Fragmented Rights and Incentives To Patent, working paper (March 2001).

the rates of growth are insignificantly different.[90]

I conclude that the CAFC did change patent policy when the legislators who supported it said it would not, that the record of debates on the enabling bill contains no solid evidence that the change would in fact stimulate R&D, and that there is no evidence of an acceleration in company-financed R&D between the 27 years before the bill was enacted and the 18 years thereafter.

Pharmaceutical Patent Reforms

As the 1980s dawned, pharmaceutical manufacturers had two major complaints, leading eventually to the Hatch-Waxman Act of 1984.[91]

For the makers of relatively new, typically patented, drugs, the key problem was declining effective patent life. Responding to the record of adverse side effects found with the tranquilizer Thalidomide, the Kefauver-Harris Act of 1962 increased the Food and Drug Administration's power to ensure that new drugs were safe. It also required proof from well-controlled clinical trials of a new drug's efficacy as well as its safety. Clinical trial periods and FDA decision-making lengthened appreciably as a result -- to an average of 7.5 years, with considerable variation, between the time when the FDA authorized testing in human beings to the date at which approval for marketing a new drug (a so-called NDA) was granted. Typically, drug companies filed for patent protection when animal tests demonstrated possible therapeutic effects, about a year before human tests began. With an average lag between patent application and patent issuance just short of two years and a patent life (since changed) of 17 years from issue to expiration, new drug marketers enjoyed on average only 10 to 11 years from the initiation of marketing to patent expiration, at which point, in principle, generic competition could begin. Both directly and through their trade association, the

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90 The F-ratio is only 1.33. Observations before 1956 are excluded because the National Science Foundation had not yet perfected its survey techniques. The source is NATIONAL SCIENCE FOUNDATION, SCIENCE AND ENGINEERING INDICATORS: 2004, vol. 2, at A4-5-6.

91 P.L. 98-417 (1984), 98 Stat. 1585.

Pharmaceutical Manufacturers' Association (PMA), the research-oriented drug companies sought relief from Congress in the form of patent life extension.

The generic drug manufacturers also had a problem. Because of restrictive FDA rules approved by the Supreme Court,[92] the obstacles to generic competition were substantial even after relevant patents expired. Generic producers were not able simply to "free ride" on the test results of the original drug producers, which, the pioneers claimed, generated data that were their exclusive property. Would-be generic producers were required to conduct their own clinical trials nearly as extensive as those of the pioneers. This barrier to imitation significantly discouraged generic entry.[93] Generic drug companies sought from Congress eased testing requirements taking advantage of an original drug's evident safety and efficacy, proved in both FDA-required tests and the marketplace.

Extensive hearings were conducted by several Congressional committees.[94] The hearings were a model of how proposed legislation should be considered. They included not only top officials of the principal interested parties -- the PMA, the Generic Pharmaceutical Industry Association, the Food and Drug Administration, and various drug companies -- but also the government's Office of Technology Assessment, which had made a study of the various proposals; a leading economic researcher on the economics of pharmaceutical innovation; a university-based physician who had done important research on drug testing; consumer advocate Ralph Nader; and a representative of the AARP, among others. The relevant issues were thoroughly aired.

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92 U.S. v. Generix Drug Corp. et al., 460 U.S. 453 (March 1983).

93 *See* E. W. Kitch, *The Patent System and the New Drug Application*, in R. L. LANDAU, ed., REGULATING NEW DRUGS (1973) at 81-108.

94 They include PATENT TERM RESTORATION ACT OF 1981, hearings on H.R. 1937, H.R. 6444, and S. 255, before a subcommittee of the House Judiciary Committee, July to November 1981; PATENT TERM EXTENSION AND PHARMACEUTICAL INNOVATION, hearings before the House Committee on Investigations and Oversight, February 1982; PATENT TERM RESTORATION ACT OF 1983, hearings before a subcommittee of the Senate Judiciary Committee on S. 1306 (June-August 1983); and DRUG LEGISLATION, hearings before the House Subcommittee on Health and the Environment on H.R. 1554 and H.R. 3605 (July-October 1983).

In the end, compromise language was negotiated by the two principal outside parties -- the PMA and the Generic Industry Association. It had two main parts. First, an extension on the life of one patent, chosen by the drug firm, would be allowed to compensate for regulation-mandated test and decision delays. The maximum extension, however, could not be more than five years or enough only to allow an effective patent life of 14 years from the time of FDA approval. Second, once patents expired, generic producers would be allowed to enter the market immediately on the basis of chemical analysis and abbreviated clinical tests -- typically involving 24 subjects -- showing that the generic version was chemically identical (i.e., bioequivalent) to, and was absorbed into a patient's bloodstream at approximately the same rate as, the original patented and FDA-approved drug. The most controversial part of the compromise, Section 202, the so-called Bolar amendment,[95] allowed generic drug makers to produce experimental quantities of a still-patented product "solely for uses reasonably related to ... the submission of information under a Federal law which regulates ... drugs" -- i.e., to conduct the trials demonstrating bioequivalence. In this way, the generic drug maker could submit its application to the FDA and, with luck, hit the ground running with its marketable product the day the original drug's blocking patent expired. The Bolar amendment established a new principle -- that experimental uses of a product might not be blocked by patent protection.[96]

The compromise was passed by overwhelming majorities in both houses of Congress. Within the pharmaceutical industry, however, controversy persisted. A cabal led by the Swiss-based company Hoffmann-LaRoche was displeased and saw to it that the president of the Pharmaceutical Manufacturers Association, Lewis Engman, who had played a key role in brokering the compromise that eventually reached Congress, was fired from his position.

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95 The name comes from a decision by the new Court of Appeals for the Federal Circuit in Roche Products Inc. v. Bolar Pharmaceutical Co., Inc., 733 F. 2d 858 (April 1984), preventing generic manufacturers from producing test quantities of a drug while the drug was still under patent.

96 For an extension reversing the CAFC's narrow reading of the Bolar amendment and allowing use in investigating novel drugs at preclinical stages as well as for generics, *see* Merck KGAA v. Integra LifeSciences, 125 S.Ct. 2372 (June 14, 2005).

The Hatch-Waxman Act had important effects. The share of all drug prescriptions dispensed in the United States and filled generically rose steadily from 19 percent in 1984, when the new law was passed, to 47 percent in 2000, with further increases expected.[97] Generic competition clearly became more vigorous.[98] Significant patent life extensions were also achieved, partly under the main terms of the Act and partly through strategic manipulation of provisions defining the various parties' rights in patent disputes.[99] The extension in patent lives should have increased industry profits, but more rapid and extensive generic competition worked in the opposite direction. Industry profitably did increase markedly after passage of the Act,[100] but the rising trend began three years earlier and had two other plausible causes -- the advent of so-called "rational drug design" in which scientific knowledge played a larger role, and the rapid spread of health insurance plans with drug expenditure reimbursement, which reduced the elasticity of demand and hence supported increased prices for patented drugs sold under monopolistic conditions.

A plausible argument can be advanced that the Act shaped an ideal compromise in terms of stimulating pharmaceutical innovation. Longer patent protection had at the margin its desired effect in increasing the profitability of a given efficacious new drug. Less widely recognized, but equally true, the acceleration of generic competition forced pharmaceutical makers to intensify their efforts to discover and test improved replacement products, for without them, the sales and profits

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97 PhRMA, PHARMACEUTICAL INDUSTRY PROFILE: 2003 at 62.

98 One consequence is little recognized. By reducing the front-end testing costs incurred for generic entry, the Act's provisions not only encourage early generic competition, but make it possible for more generic firms to squeeze into a given market, intensifying price competition. The existence of Hatch-Waxman plus the large size of the U.S. market explains why U.S. generic drug prices tend to be the lowest in the industrialized world.

99 Many of the manipulations were found to be illegal. *See* FEDERAL TRADE COMMISSION, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (July 2002); and *Generic Drugs: The Window Has Loopholes*," N.Y. TIMES, July 1, 2006, Business Section p. 1.

100 *See* Scherer, *The Link*, *supra* note 27.

from a patented drug can be expected to plummet shortly after patent expiration.[101] Thus, the Act provided both a carrot and a stick to encourage innovation.

Changes in Administration of the Patent-Antitrust Interface

There were other Congressional and judicial decisions altering patent policy in the 1980s and 1990. Here we note briefly one other line of development -- the presumptions applied by the U.S. antitrust agencies when the exploitation of patent positions was alleged to conflict with antitrust prohibitions.

During the 1970s the Antitrust Division of the Department of Justice articulated a list of nine so-called "no-no's," most of which delineated what a patent holder could do in licensing other firms before running afoul of the antitrust laws.[102] The approach in effect asked whether restrictions written into patent licenses were necessary and whether less restrictive measures could have achieved the same objectives. Agreements to set minimum prices at which licensees could sell licensed products and to restrict licensing of third parties, mandatory package licensing, and requirements that the licensee buy unpatented products from the licensor (i.e., ties) were viewed with special skepticism.

Partly because of Supreme Court decisions taking a more benign view of certain vertical restraints (such as exclusive franchising) and the installation of relatively pro-business Reagan appointees, a more tolerant view emerged on how patents and antitrust interacted. An early statement by an Antitrust Division official said that the nine no-no's "contain more error than accuracy" as statements of rational economic policy.[103] Five years later a deputy assistant attorney general criticized

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101 *See* the C-SPAN3 interview with Sidney Taurel, CEO of Eli Lilly Co., on May 8, 2006.

102 *See* SECTION OF ANTITRUST LAW, AM. BAR ASS'N., THE FEDERAL ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY, 2nd edition (2002) at 8-10. The document provides a comprehensive overview of the issues and reproduces Guidelines published by the antitrust agencies.

103 Remarks by Abbott B. Lipsky Jr. before the American Bar Association November 5, 1981, reproduced in CCH Trade Regulation Reporter, para. 13,129.

the "history of antagonism toward patent licensing" and urged that patent licensing could have numerous pro-competitive benefits.[104] On this he was clearly correct. Some deeper premises, however, were debatable. Ignoring the emerging literature on alternative first-mover advantages, he singled out patents as instruments for preventing free-riding on investments in technology, arguing that "patents create property rights without which technology would not exist -- or certainly not in its current abundance." As the work of Taylor and Silberston and Mansfield, already available at the time, made clear, this could be true for some new technologies, but by no means for all. The DoJ spokesman's further premise, therefore, is also questionable:

> Efforts to appropriate as much as possible of the surplus -- the social value in excess of marginal cost -- lying under the demand curve for the patented technology do not harm competition. Indeed, the potential for appropriating those rents is the engine [emphasis added] that drives the technology market.

In effect, the implication was that almost anything done unilaterally to increase an innovator's profits was beneficial for competition -- and given the way antitrust had come to be interpreted, beneficial for consumers. Such a view goes too far.

In 1995, after substantial interaction with the legal and scholarly communities, the Department of Justice and Federal Trade Commission jointly issued new Guidelines for the Licensing of Intellectual Property. In effect, the Guidelines stated that the antitrust agencies would analyze questionable patent - antitrust interactions on a "rule of reason" basis, asking whether a restraint "is reasonably necessary to achieve procompetitive benefits [e.g., superior or more extensive innovation] that outweigh ... anticompetitive effects." Given the complex repercussions of the practices addressed, a careful "rule of reason" approach seems eminently reasonable. One might hope, however, that antitrust agency staff charged with enforcing the guidelines and the courts interpreting them

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104 Remarks by Charles F. Rule before the World Trade Association and the Cincinnati Patent Law Association, October 21, 1986, reproduced in CCH Trade Regulation Reporter, para. 13,131.

possess a broad understanding of what economic analysis -- on both the theoretical and empirical sides -- reveals about the limited and conflicting roles patents play.

Extension of U.S. Patent Standards to Other Nations

Undoubtedly more important than reforms in domestic patent law were U.S. efforts to influence the patent laws of other nations, and especially less-developed nations. Piracy of copyrighted music, motion pictures, and computer programs -- matters not addressed in this paper -- was one provocation.[105] On patents, a key problem was the fact that the Paris Convention governing inter-national patent relations, inaugurated in 1883, allowed member nations to determine the coverage of their patent laws, requiring mainly that they not discriminate between domestic and foreign patent applicants. Many nations had patent systems providing much less protection for inventions than the United States did. Among 33 sizeable developing and high-income nations in 1990, for example, 14 offered no patent protection for pharmaceutical products, 15 none for food products, and 11 none for chemical products.[106] Eight of the 33, including Switzerland, home to three of the world's leading pharmaceutical companies, had joined the list of nations allowing patents for pharmaceutical products only between 1975 and 1989.

For pharmaceuticals, in which patents are accorded such importance, Italy was an early bete noire and focus of action. A patent law passed in 1939 and still applicable in the 1970s excluded pharmaceutical products from patentability. As a consequence, Italy became a world leader in producing and exporting generic pharmaceuticals to other nations -- before existing patents expired for the importing nations without product patent protection, otherwise as soon as national patent laws allowed. Among other things, during the late 1960s it was a major supplier of early "wonder drugs," broad-spectrum antibiotics, to the U.S. military purchasing authorities. This was stopped through an amendment to a foreign assistance bill, offered by a Congressman from Indianapolis on the floor of the

105 The term "piracy" was already used to denote cribbing of musical compositions in the 18th Century. *See* F. M. SCHERER, QUARTER NOTES AND BANK NOTES: THE ECONOMICS OF MUSIC COMPOSITION IN THE 18th and 19th CENTURIES (2005) at 167 and 176.

106 Edson K. Kondo, Patent Laws and Foreign Direct Investment: An Empirical Investigation, Ph.D. dissertation, Harvard University, May 1994 at 62.

House of Representatives in 1961 and passed by a vote of 87 to 65 (less than a quorum) after cursory debate.[107] A 1963 attempt to change the Italian law, led by large Italian pharmaceutical companies, was blocked in the Italian Parliament owing to small-firm opposition.[108] During the 1970s, a group of multinational pharmaceutical companies from the U.S.A., Germany, Japan, and Switzerland, joined by some larger Italian firms, challenged the constitutionality of Italy's law. In March 1978, Italy's Corte Constitutionale found the exclusion of pharmaceutical products to be unconstitutional and ordered the prompt acceptance of drug patent applications. In the decade that followed, pharmaceutical R&D and new product launches did not rise relative to world trends, while Italy's balance of trade in pharmaceuticals dropped from positive to negative.[109] India took Italy's place as the world's leading supplier of generic drugs to nations without product patents and, given its first-mover advantage, as an early generic supplier in the United States.

Beginning in the late 1970s a concerted effort began to bring the full array of laggard nations up to U.S. patent law standards. Among the prime movers were the U.S. pharmaceutical companies. Unlike the other legislative developments covered by this paper, the lobbying efforts that followed are richly documented.[110] Between 1981 and 1987, Edmund Pratt, CEO of Pfizer Inc., was chairman of the U.S. President's Advisory Committee on Trade and Negotiations (ACPTN). Its subcommittee on intellectual property was chaired by IBM CEO John Opel. In their role as advisors to the U.S. Trade Representative (USTR), coordinating international trade matters for the Executive Branch, and also in their communications with Congress, they pushed hard to bring patent and copyright issues to the

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107 107 CONG. REC.- HOUSE 16283-5 (August 18, 1961).

108 *Italian Sees Rise in Drug Research*, N.Y. TIMES, September 26, 1963, p. 47.

109 Sandy Weisburst, Strengthening Patent Protection in Italy, senior thesis, Harvard University, March 1995. The results are summarized in F. M. SCHERER, PATENTS: ECONOMICS, POLICY, AND MEASUREMENT (2005), Chapter 6.

110 *See especially* Michael Santoro, Pfizer: Global Protection of Intellectual Property, Harvard Business School case study 9-392-073 (1992); and MICHAEL P. RYAN, KNOWLEDGE DIPLOMACY: GLOBAL COMPETITION AND THE POLITICS OF INTELLECTUAL PROPERTY (1998). Much of what follows is drawn from those publications.

forefront of U.S. trade dealings with other nations and international agencies. At the time USTR had, with the exception of one overburdened staff member, virtually no independent economic analysis capability. Pratt and Opel reached out to organize lobbying efforts by other industry groups such as the Pharmaceutical Manufacturers Association, the Business Roundtable, and a panoply of organizations seeking copyright protection.

These lobbying efforts led initially to the passage of two amendments to Section 301 of the U.S. International Trade Act, which defines unfair trade practices against which the United States might retaliate. The first, in 1984, authorized the U.S. government to impose unilateral sanctions against nations that failed to provide adequate intellectual property protection. Section 301 was strengthened into what was called "Special 301" in 1988, requiring the USTR to prepare an annual report identifying foreign nations with the most objectionable patent and copyright policies, placing them on a priority list, and commencing an investigation to determine whether the subject nations' "IP" policies merited retaliatory measures. The USTR proceeded cautiously, establishing in 1989 only a "priority watch list" that included Brazil, India, Mexico, the Peoples Republic of China, South Korea, Saudi Arabia, and Thailand. In May 1989 the United States imposed 100 percent tariffs on $39 million of imports from Brazil as punishment for its deficient pharmaceutical patent policies. Threats were levied against Mexico, South Korea, China, and Thailand, among others. In 1991 the first actual priority list was issued, naming Thailand, India, and China as prime targets. Thailand's government had been dissolved in a no-confidence vote as a direct consequence of a patent bill introduced into the National Assembly in 1988 in response to early U.S. pressure.

The business advisors to the U.S. government and their industry allies also worked on a broader international front. Both directly and through U.S. representatives, they sought to have the Paris Convention modified to require uniformly high patent law standards for member nations. Efforts to reach this goal through the World Intellectual Property Organisation (WIPO), a branch of the United Nations, and at the Nairobi round of Paris Convention negotiations were a failure. Efforts with WIPO were "a disaster," a Pfizer executive said, because "WIPO works by majority, and simply put, there were more of them than

us."[111] Nairobi Round efforts during the late 1970s failed because United States, European, and Japanese delegates were unable to agree on a united front.[112] Absorbing the lessons from these failures, Pratt and Opel organized a combined lobbying effort by U.S. patent- and copyright-sensitive industries, who in turn recruited their counterparts in Europe, e.g., the Dolder Group of pharmaceutical companies,[113] and the Keidanren in Japan. All put pressure on their governments to make stronger intellectual property rights a priority issue in international trade deliberations.

The opportunity arose with the start of a new round of international trade policy negotiations -- the Uruguay Round -- in September 1986. The United States component of the effort was organized through an "Intellectual Property Committee" comprising the chief executives of 13 major companies.[114] Working with their counterparts from Europe and Japan, the IPC members distributed in June 1988 a 100-page "Basic Framework" setting goals for the inclusion of intellectual property issues in whatever treaty resulted from Uruguay Round negotiations. A key to the agreed-upon strategy was "linkage." Most less-developed nations opposed their inclusion, but United States negotiators, supported inter alia by individuals seconded to their team from the Patent and Trademark Office, made it clear that the United States would not ratify any treaty unless it included IP standards, and there would be no cherry-picking -- all provisions had to be accepted by a ratifying nation. If less-developed nations were eventually to secure relief from the Multi-Fibre Agreement, which limited the textile exports on which they had comparative advantage, and developed-nation barriers to agricultural product imports, they would have to go along with the intellectual property provisions. And perhaps

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111 Santoro, *supra* note 110, at 7, quoting Lou Clemente, Pfizer general counsel and chair of the intellectual property committee of the U.S. Council for International Business.

112 *See* Fenton Hay, *Canada's Role in International Negotiation Concerning the Patent Laws*, in JOHN PALMER, ed., 8 RES. IN LAW & ECON. (1986), pp. 239-263.

113 So-called because their chief executives met each year at the Dolder Grand Hotel in Zürich.

114 Pharmaceutical makers Pfizer, Merck, du Pont, Bristol-Myers, and Johnson & Johnson, plus General Electric, Warner Communications, Hewlett-Packard, FMC Corporation, General Motors, and Rockwell International.

even more important, having intellectual property questions covered by the ratified Uruguay Round Treaty removed most possibilities that the United States could brandish its Section 301 sword unilaterally. Tough bargaining yielded a compromise draft of what came to be called the "TRIPS" (Trade-Related Aspects of Intellectual Property Rights) agreement, which was included in the final draft treaty compiled by the GAAT Secretary-General and in the ultimate Treaty of Marrakech that replaced GAAT with the World Trade Organization.

U.S. advocates of TRIPS argued inter alia that less-developed nations should welcome strengthened patent laws because they would encourage domestic innovation, which among other things flourished in the early history of the United States, and because it would induce more inward technology transfer through foreign direct investment by multinational enterprises. There is an element of paradox in this argument, since most less-developed nations with weak patent policies were opposed to the changes, which suggests that the LDCs did not know what was good for them. The argument also overlooks the fact that during the first 47 years of its existence, the United States provided strong patent protection to domestic residents, but denied patents to foreigners, whereas LDCs were being asked under TRIPS to increase the scope of their patent protection to both domestics and foreigners. Economic theory provided at best ambiguous guidance on the alleged benefits to poor nations of strong and open patent systems.[115] Some econometric studies suggested that strong patent systems encouraged inward foreign direct investment, but the most positive early findings were based on subjective measures of patent system strength that could have reflected the evaluators' broader views on the desirability of nations for investing. The only early study using more objective measures reported negative or inconclusive results.[116]

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115 *See e.g.* Alan Deardorff, *Should Patent Protection Be Extended to All Developing Countries?* 13 THE WORLD ECON. 497 (1990); and *Welfare Effects of Global Patent Protection*, 59 ECONOMICA 35 (1992); and F. M. Scherer, *A Note on Global Welfare in Pharmaceutical Patenting*, 27 THE WORLD ECON. 1127 (2004).

116 *Compare* Richard Rapp and R. Rozek, *Benefits and Costs of Intellectual Property Protection in Developing Countries*, 24 J. WORLD TRADE 75 (1990); and Jeon-Yeon Lee and Edwin Mansfield, *Intellectual Property Protection and U.S. Foreign Direct Investment*, 78 REV.

The opposition of LDC negotiators to uniform U.S.-grade patent protection led to compromises in the TRIPS version ultimately accepted. For one, full implementation of TRIPS by nations categorized as least-developed could be delayed until 2005. Provision was made in Article 40 for non-exclusive compulsory licensing of patents in cases of monopolistic abuse and also, in Article 31:

> [Such] use may ... be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the rights holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in case of a national emergency or other circumstances of extreme urgency or in cases of public noncommercial use.

Curiously, most references to this provision in the U.S. press have stressed the "national emergency" part and ignored the language allowing compulsory licenses when negotiations have failed to converge on "reasonable commercial terms." How that misconception was propagated is unclear.

Article 31, subparagraph (f), also stipulated that compulsory licenses be authorized "predominantly for the supply of the domestic market of the Member authorizing such use." For most of the world's least-developed nations, this provision posed a special difficulty in such areas as pharmaceuticals, since those nations typically had neither the technical capabilities nor sufficient demand to support efficient domestic drug production under license. The problem was singled out as critical at the start of the Doha Round of trade negotiations in 2002, and in 2003, agreement was reached on amendments allowing waivers from subparagraph (f) for least-developed nations and for other nations showing that they lack the capacity to manufacturing particular pharmaceutical products.[117]

ECON. & STAT. 181 (1996); with Edson Kondo, *The Effect of Patent Protection on Foreign Direct Investment*, 29 J. WORLD TRADE 97 (1995), along with Kondo, *supra* note 106. *See also* KEITH E. MASKUS, INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY (2000), Chapter 5.

117 WTO document IP/C/W/405, 28 August 2003. At the December 2005 WTO Ministerial

To the best of the author's knowledge, the compulsory licensing provisions of the TRIPS agreement have been implemented sparingly, if at all. But their use has been threatened frequently to induce, especially from multinational pharmaceutical companies, substantial product price concessions or, e.g. in Brazil, voluntary licensing to domestic suppliers at modest royalties. Indeed, even the United States threatened compulsory licensing in 2001 to elicit substantial price reductions from Bayer AG of Germany on the drug Cipro when terrorist activity threatened an epidemic of otherwise untreatable anthrax.

6. Propaganda

In many contemporary discussions of patent policy, and even in this paper, the term "intellectual property" trips off the tongue as if it were implanted in the human brain's genetically inherited grammar. It is certainly a magical phrase. "Patents" and "copyrights" are words with little or no appeal to the moral sensibilities. But "intellectual property!" What right-thinking person could be against property? And who among the scribbling professions could not be all the more entranced when the property is intellectual?

What strikes a scholar who has been studying patent questions for more than a half century is that the phrase "intellectual property" was almost never heard during the 1950s and 1960s. None of the O'Mahoney Committee's 28 commissioned titles exploring the history, implementation, and economic consequences of the patent system during the late 1950s contains the term. A search of the two most comprehensively bibliographic of the O'Mahoney Committee studies and a later Joint Economic Committee study reveals very few titles, mostly ancient, using the term.[118] It repays effort therefore to investigate how the phrase achieved common currency.

Conference in Hong Kong, the compromise was adopted as a permanent amendment to the TRIPS agreement.

118 MACHLUP, *supra* note 2; JULIUS W. ALLEN, ECONOMIC ASPECTS OF PATENTS AND THE AMERICAN PATENT SYSTEM -- A BIBLIOGRAPHY, Study No. 14 of the committee; and S. C. GILFILLAN, INVENTION AND THE PATENT SYSTEM, Joint Economic Committee of the U.S. Congress (1964).

At first, "property" appears to have entered the literature without its "intellectual" modifier. Patent-like privileges were given out by sovereigns in the period of late feudalism, and in the revolutions against feudalism and royal fiat, some acceptable substitute for "privilege" had to be invented. The U.S. Constitution referred to "exclusive rights," but in Europe at the end of the 18th Century, it was de rigueur to refer to a creator's rights in inventions and artistic creations as "property." The usage was not without controversy. In their survey of French antecedents, Machlup and Penrose observe that "those who started using the word property in connection with invention had a very definite purpose in mind: they wanted to substitute a word with a respectable connotation, 'property,' for a word that had an unpleasant ring, 'privilege.' This was a very deliberate choice on the part of politicians working for the adoption of a patent law in the French Constitutional Assembly."[119] The property construction was rejected by America's first federal patent examiner, Thomas Jefferson, who wrote flatly that "Inventions cannot in nature be a subject of property."[120] Nevertheless, the property concept proved to be durable, and the first world-wide patent treaty, in 1883, was called the Paris Convention for the Protection of Industrial Property.

"Intellectual" was added to "property" much later. The earliest known printed use of the term is in an obscure Massachusetts federal circuit court ruling.[121] Polymath Lysander Spooner used the term in the title of a monograph left

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119 Fritz Machlup and Edith Penrose, *The Patent Controversy in the Nineteenth Century*, 10 J. EC. HIST. 1, 16 (1950). *See also* Machlup, *supra* note 2, at 22.

120 JOHN P. FOLEY, ed., THE JEFFERSONIAN CYCLOPEDIA (1900) at 728 (letter to Isaac McPherson in 1813). A consistent but more extended discussion is found in what appears to have been an earlier letter to McPherson reproduced at 433.

121 Davoll et al. v. Brown, cited in Woodury & Minot, CCD Mass. 7 F. Cas. 197 (1845). Following his mention of the term, Judge Woodbury cites a Supreme Court decision, Grant v. Raymond, 31 U.S. 218 (1832), but nowhere in that decision is the phrase "intellectual property" found. At 18 in INTELLECTUAL PROPERTY RIGHTS: A CRITICAL HISTORY (2006), CHRISTOPHER MAY & SUSAN SELL cite a Harvard Law School web-based paper (no longer available) identifying a single federal court use of the term during the 19th century and escalating use beginning in the 1930s.

incomplete and unpublished around 1855.[122] The term appears four times in French and German titles from the 1860s cited in Machlup's bibliography, mostly addressed to the attack on patent systems being waged in Europe at the time.[123] Its next recorded appearance in American literature titles, gleaned from a search of three major research library catalogs, was in a collection of essays by N.S. Shale in 1878.[124] It then reappears, according to the compendium by Julius Allen,[125] in the titles of three articles published between 1944 and 1952 in the house organ of the U.S. Patent Office, J. OF THE PATENT OFFICE SOC. A published lecture by Sir Arnold Plant titled *The New Commerce in Ideas and Intellectual Property* followed in 1953.[126]

The phrase's takeoff into widespread use may have been associated with the creation of the Geneva-based World Intellectual Property Association (WIPO) in 1966 and its predecessor, United International Bureaux for the Protection of Intellectual Property, founded in 1963. Few intervening references could be found in bibliographies and library catalogs. A seminal role in establishing those organizations was played by Arpad Bogsch, who before their formation was a legal counselor at the U.S. Copyright Office. Obituaries at the time of his death in 2004 called him "the founding father of modern intellectual property" and "the creator of the modern intellectual property system."[127] None of the six books, all on

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122 CHARLES SHIVELY, THE COLLECTED WORKS OF LYSANDER SPOONER (1971), Chapter VII.

123 Machlup, *supra* note 2, at 85-86 (citing works by Molinari, Paillotet, Rentzsch, and Vermeire). The University of Pennsylvania library catalog lists an additional 1859 book by Frederic Passy.

124 THOUGHTS ON THE NATURE OF INTELLECTUAL PROPERTY AND ITS IMPORTANCE TO THE STATE (1878).

125 *Supra* note 118 at pp. 15 and 29.

126 Plant's earlier and more famous work, *The Economic Theory Concerning Patents for Inventions*, new series 1 ECONOMICA 30 (1934), does not use the phrase. It contains a remarkably prescient view of first mover advantages as a substitute for patenting.

127 Obituaries published on the worldwide web by the International Association for the Protection of Intellectual Property and the International Confederation of Societies of Authors

copyright, written by Bogsch before 1966 and listed in the Harvard University catalog, included the words "intellectual property" in their title, but he appears to have been an important contributor to their acceptance in popular discourse. He plainly did not create the modern system of granting exclusive rights in inventions and other creative works.

Other organizations followed suit during the period when the U.S. patent policy reform movement was at its peak. The American Patent Law Association changed its name to American Intellectual Property Law Association and made a corresponding change in the name of its journal (now AIPLA Q. JOUR.) in 1983 or 1984. The relevant section of the American Bar Association was still named the Section of Patent, Trademark & Copyright Law in 1987, but it then changed its name to Section on Intellectual Property Law and in 1993 renamed its quarterly newsletter the IPL NEWSLETTER in place of PTC[128] NEWSLETTER. It sponsored a conference on "Industrial and Intellectual Property: The Antitrust Interface," in October 1984. The INTELLECTUAL PROPERTY JOUR. was initiated in 1984. During the early 1980s the office of the U.S. President's Special Trade Representative created a new position, Assistant USTR for International Investment and Intellectual Property.[129] The industry lobbying group formed in 1986 to influence deliberations under the Uruguay Round was called the Intellectual Property Committee. In 1989 a revived subcommittee of the U.S. House of Representatives Committee on the Judiciary was named the Subcommittee on Courts, Intellectual Property, and the Administration of Justice. In 1994 the U.S. Senate still had a Subcommittee on Patents, Copyrights, and Trademarks. It was dissolved in 1995 and reborn in 2005 as the Intellectual Property Subcommittee.

Semantics are not policy. But they undoubtedly influence policy-making as well as being influenced by it. The growing use of the term "intellectual property" to describe patent and trademark matters probably contributed to the emergence of a favorable mind set that in turn set the stage for the patent policy reforms of the 1980s.

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and Composers. *See also* Ryan, *supra* note 110, at 126.

128 I.e., Patent, Trademark, and Copyright.

129 Santoro, *supra* note 110, at 9.

7. Conclusion

U.S. patent policy was altered in significant ways during the 1970s and 1980s through legislative, administrative, and judicial actions. Some of the legislative changes were well-grounded in objective analyses of the problems at hand and what could be accomplished; others, and in particular the centralization of patent appeals in a Court of Appeals for the Federal Circuit, were not. In most cases, the parties with the strongest vested interest in new legislation got what they wanted -- most generally, with the exception of the generic drug provisions in the Hatch-Waxman Act, a strengthening of the role patents play in American industrial life. The patent law profession in particular thrived. But the changes brought negative consequences along with the positive. In particular, by encouraging the proliferation of patents covering inventions of dubious novelty and increasing the statistical probability that knowing or inadvertent infringement of patents leads to dire consequences, it increased the risks as well as the rewards from inventive activity. It is far from clear that the positive effects outweigh the negatives. Fortunately, as economic studies have shown repeatedly, patents do not play a particularly important role in most fields of industrial innovation, and equally fortunately, those who advise industrial leaders in their journeys through the patent minefield are adept at negotiating solutions that in most instances avoid serious impediments to the pace of technological progress. It is nevertheless useful to assess the negatives and attempt to correct them through legislative or judicial action. In this, we would be emulating the example of one of the world's most famous inventors, James Watt, who observed "I have been trying experiments on the reciprocating engine, and have made some alterations for the better and some for the worse, which latter must return to their former form."[130]

On the assumption that the Appellate Court for the Federal Circuit will not be disbanded, which is probable but not inevitable, the key to improvement is seating judges with a broad perspective on how technological progress is actually

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130 Letter of James Watt to Dr. William Small, January 28, 1769, reproduced in J.P. MUIRHEAD, THE ORIGIN AND PROGRESS OF THE MECHANICAL INVENTIONS OF JAMES WATT (1854).

induced. Over the long run, this can be achieved if the President and Senate, in exercising their powers of appointment and consent, insist that nominees be persons of broad experience and wisdom and shun nominees representing a narrow interest group -- e.g., the patent bar. In practice, to be sure, judges with the capabilities of an Oliver Wendell Holmes or a Learned Hand are rare and best-suited for higher responsibilities. At minimum, therefore, nominees to the court should be subjected to a searching examination on their knowledge about how innovation takes place in the real world. Appropriate prepatory readings can be suggested.[131] Effecting a transformation in the composition of the Court is likely, however, to take at least a decade. In the interim, it would be desirable for the highest judicial authorities to encourage attendance of ACFC judges at broad-ranging seminars on the science, sociology, and economics of technological innovation. These should be quite different from the outings organized at posh spas by special interest groups. They should be planned and operated by a reputable university faculty and staffed by scholars with a diverse range of interests and biases.

With the Bayh-Dole Act, the key open challenge is balancing the interest in exclusive rights against the broader public interest in securing maximum public benefit from the government's investments in basic science. As a general principle recognized by the law's drafters, exclusivity helps to stimulate investment in development and commercialization. But there was recognition, at least at the time the law was enacted, that abuses might occasionally require the exercise of the law's

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131 E.g., in addition to the standard legal texts: in law, Robert Merges and Richard Nelson, *On the Complex Economics of Patent Scope*, 90 COLUMBIA L. REV. 839 (1990); Michael Heller and Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (May 1, 1998); and ROCHELLE DREYFUSS, DIANE ZIMMERMAN, & HARRY FIRST, eds., EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY (2001). In sociology, BERNARD BARBER & WALTER HIRSH, eds., THE SOCIOLOGY OF SCIENCE (1972). In economics: BURTON KLEIN, DYNAMIC ECONOMICS (1977); WILLIAM J. BAUMOL, THE FREE-MARKET INNOVATION MACHINE: ANALYZING THE GROWTH MIRACLE OF CAPITALISM (2003); NATHAN ROSENBERG, INSIDE THE BLACK BOX: TECHNOLOGY AND ECONOMICS (1982); Edwin Mansfield et al., *supra* note 18; Levin et al., *supra* note 21; and LEWIS BRANSCOMB & PHILIP AUERSWALD, eds., TAKING TECHNICAL RISKS (2001).

march-in rights. Congress should reiterate that it intended a balance to be struck. It should create a special panel with the difficult task of determining when exclusive rights on government-supported inventions have been abused and the extent of licensing required to set matters right.

The Hatch-Waxman Act was in many respects an ideal compromise, trading longer periods of patent protection to compensate for regulatory lags with speedier entry of generic drugs into production once blocking patents have expired. The threat of generic entry in turn spurs pharmaceutical firms to redouble their R&D efforts in order to replenish their new product pipelines. The main problem with Hatch-Waxman is that drug developers have exhibited great ingenuity in finding ways to extend their periods of patent protection by accumulating patents on minor variants of the originally proven molecule and paying the first-moving generic entrant not to enter, using a loophole in the law to block the entry of other would-be generic producers. Congress should clarify the law, remaining faithful to the Constitutional requisite that exclusive rights be "for limited Times" (emphasis added) and insisting that drug production be opened up for generic competition once basic patents have expired, leaving however the right to produce validly patented improvement molecules exclusively in the hands of the original drug developer (or any other firm that patents and tests improved variants).

For the federal antitrust agencies, the extension of patent monopolies in time through profuse improvement patenting and their extension in scope through restrictive cross-licensing agreements pose important enforcement problems. Here too, the problem is in part one of education. Those who manage the antitrust agencies need to learn that there are important barriers to rapid imitation, enhancing incentives for innovation, other than the patent system, so maximization of monopoly rewards associated with patent holdings is unlikely to maximize economic welfare. They need to learn that extension of patent monopolies over time and in scope is more likely to suppress than stimulate innovation.[132] They need to learn, as my

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132 *See* Merges and Nelson, *supra* note 131; and, for seven case studies, F. M. Scherer, *Technological Innovation and Monopolization*," in WAYNE DALE COLLINS, ed., ISSUES IN COMPETITION LAW AND POLICY, forthcoming from the American Bar Association.

colleagues and I did a half century ago, that compulsory licensing of patents is not likely to decimate firms' incentives for investment in innovation. Knowing this, they may come to appreciate that carefully considered intervention in cases of protracted and abusive monopoly through patenting can on balance be beneficial. The emphasis, to be sure, is on careful consideration, clear precedents, and appropriate timing.

Without doubt the most important of the issues addressed in this paper is the extension of first-world patent standards to third-world nations under the Treaty of Marrakech. At their present stage of development, having to confer patents on first-world products is likely to reduce, not enhance, the welfare of hard-pressed low-income nations. The United States and other rich nations should not undertake retaliatory measures against third world nations that exercise their clear right under the Treaty to order compulsory licensing, import patented drugs from other low-price nations, or limit the scope of patent protection on borderline products. Even when they allow patent rights to be exercised, their demand and the monopoly profits that can be derived from it are unlikely to be sufficient to stimulate greatly increased inventive activity in the first world.[133] Among other things, their demand is too weak to stimulate much development of new drugs targeted toward tropical diseases, i.e., those prevalent only in the third world. But it is at least arguable, even if not universally accepted, that the rich nations have an obligation to help their fellow humans in this regard. This means that in rich nations, public and philanthropic funds should be generously allocated to foster the development and distribution of drugs and vaccines whose main use will be to lessen the burden of disease in the third world. This will be a step back from the Machiavellian logic that underlay negotiation of the Marrakech Treaty, but it will be a step forward for humanity.

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133 See Scherer, *supra* note 115.